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**Anatomy of a Public Health Scare:
Fear and Accountability in the Creation of Vaccine Courts**

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Introduction

Vaccination has been a major issue in public health discourse since the invention of the first smallpox vaccine in the 18th century. Up to the beginning of the 20th century, infectious diseases were the leading causes of death globally, with influenza and tuberculosis topping the list for adults.¹ Vaccines fundamentally changed how society approached disease. As vaccine formulations became more sophisticated and health departments gained power, the goal changed from surviving epidemics to preventing them. By the 1930s, heart disease and cancer replaced infectious diseases as the leading causes of death in the United States.² Though this was also due to industrialization and advances in sanitation, vaccination succeeded in easing the burden of disease on the population. As a result, medicine and public health in the late 1900s focused largely on addressing non-communicable diseases like heart disease, cancer, and diabetes. The 1980s also saw the beginning of the HIV/AIDS epidemic, which required a major shift in healthcare resources.³ The landscape of medicine and healthcare in the United States changed dramatically in the 20th century, and infectious diseases were no longer a priority.

In the 1970s, two notable events occurred in the infectious disease field: the smallpox vaccine was removed from the recommended vaccination list and the United States recorded its last case of wild polio. As a preventative intervention, vaccines are often named “victims of their own success”: the more effective they are, the less visible those effects are to the public. Smallpox and polio, seasonal diseases that killed or crippled hundreds of thousands every year, became lessons in medical textbooks and stories from parents. When the reason for a vaccine

¹ Centers for Disease Control and Prevention, “Leading Causes of Death, 1900-1998,” https://www.cdc.gov/nchs/data/dvs/lead1900_98.pdf.

² *Ibid.*

³ Centers for Disease Control and Prevention, “CDC Timeline 1980s,” May 12, 2015, <https://www.cdc.gov/museum/timeline/1980.html>.

disappears from the population, it becomes difficult to understand why the vaccine should be required. Public concern moved from the diseases to the vaccines, and anti-vaccination movements grew.

Anti-vaccination movements were created when vaccines were invented. Most groups formed in the 19th century protested government oversight or distrusted the intentions of medical professionals. People in these movements who opposed vaccination believed that vaccines infringed on freedom of choice or that physicians were lying about their purpose.⁴ These movements were less successful simply because the general public had different priorities: personal choice was less important than surviving the next smallpox outbreak. However, the motivations behind anti-vaccination groups changed dramatically when disease prevalence decreased. Focus shifted from an overbearing government to the ingredients in vaccines and what kinds of reactions they may cause. When the public is no longer fearful of epidemics, people have the privilege of redirecting their attention to smaller risks.

As with any medication, there is a risk that individuals will react negatively to the ingredients. In most cases, soreness or redness at the site of injection is the worst anyone will experience from a vaccine. There is a possibility that more serious reactions can occur; for people with specific allergies or compromised immune systems, the risk of seizures, brain swelling, and death are higher. For people without certain comorbidities or allergies, the chances of experiencing an adverse reaction to a vaccine are incredibly low, especially when compared to the risks associated with contracting the disease. Taking the MMR vaccine (measles, mumps, and rubella) as an example, about 1 in 1 million doses of this vaccine will result in a condition

⁴ Sara Novak, "The Long History of America's Anti-Vaccination Movement," *Discover Magazine*, Nov 26, 2018, <https://www.discovermagazine.com/health/the-long-history-of-americas-anti-vaccination-movement>.

that causes brain and spinal cord inflammation.⁵ In comparison, about 3 in 1000 children who contract measles will die from respiratory or neurologic conditions.⁶ The difference in these numbers is clear: contracting measles is much more dangerous than getting the vaccine. There is no such thing as a “no risk” solution, and though it may sound cold, a 1 in 1 million chance is what many in the medical field would call an acceptable and necessary risk to save as many lives as possible. However, when people have lived their entire lives without seeing a case of measles, it is difficult to keep these numbers in perspective. For some, the risk from vaccines is more prominent than the theoretical risk from a disease.

Against a backdrop of non-communicable disease and panic over HIV/AIDS, fears around the DPT vaccine in the United States seemed to come out of nowhere. The DPT vaccine, which protected against diphtheria, pertussis (whooping cough), and tetanus, was a triple shot recommended to children from the 1940s to the 1990s. Early in the 1970s in England, reports about the dangers of the DPT vaccine began to trickle into the medical world. In 1973, pediatric neurologist John Wilson stood in front of the crowd at the Royal Society of Medicine in London and told stories of suffering and death: “Wilson reported one child who had transient blindness and mental deterioration. Another had vomited for four days, become blind, and died six months later during an uncontrolled seizure.” British media exploded after Dr. Wilson’s speech, and vaccination rates plummeted to 31 percent the following year.⁷

⁵ World Health Organization, “Information Sheet: Observed Rate of Vaccine Reactions, Measles, Mumps and Rubella Vaccines,” May 2014,

https://www.who.int/vaccine_safety/initiative/tools/MMR_vaccine_rates_information_sheet.pdf.

⁶ Centers for Disease Control and Prevention, “Measles (Rubeola) Complications, Jun 13, 2019,

<https://www.cdc.gov/measles/symptoms/complications.html>.

⁷ Paul A. Offit, *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (New York: Basic Books, 2015), 13.

Concerned about increasing reports of whooping cough outbreaks, British officials hired Dr. David Miller to conduct a largescale study on the DPT vaccine. His study found a statistically significant association between neurological complications and the DPT vaccine. According to Dr. Miller, one in one hundred thousand children would experience permanent brain damage after three doses of the vaccine. This study was the first of its kind to use credible and rigorous research methods to study the DPT vaccine, and physicians believed the results.⁸ However, an important component of research is the ability to replicate results. After Dr. Miller's study was published, the next fifteen years were dedicated to replicating his findings—no one could. Studies throughout the 1980s confirmed that the adverse reactions reported in Dr. Miller's study were not caused by the DPT vaccine. In fact, it was biologically impossible that the vaccine could have caused complications like brain damage and epilepsy. The pertussis component of the vaccine was made with whole, dead pertussis bacteria; this method of production was considered “crude,” but since the pertussis bacteria was so complex, this was the only way a vaccine could be made. The vaccine was still considered safe, but the crude pertussis component made the shot slightly more reactive than other immunizations.⁹ Despite this increased reactivity, the nature of the dead bacteria used in the solution meant that there was no ingredient in the vaccine that could cause brain damage in children.¹⁰

Studies were published and medical experts spoke to the press, but as panic about the DPT vaccine continued to spread around the world, one thing was clear: this issue was not about the science. This was the most evident in the way news of the DPT vaccine reached the American public, not through a news report or a medical journal, but through a primetime

⁸ Offit, *Deadly Choices*, 18.

⁹ *Ibid.*, 26.

¹⁰ *Ibid.*, 29.

television program. In 1982, *DPT: Vaccine Roulette* aired on NBC. Hosted and produced by a reporter named Lea Thompson, *DPT: Vaccine Roulette* claimed to unveil the dangers of the DPT vaccine that the government had been hiding from the public.¹¹ The documentary was sensationalistic and cited false information, but it had the same effect on the United States as Dr. Wilson's speech had on England. Through extensive news coverage, fear of the DPT vaccine spread through the country, and no amount of reassurance from medical professionals or the government could stop it. This fear led to massive lawsuits against vaccine manufacturers and supply shortages of the DPT vaccine throughout the country. From 1982 to 1986, panic over the diphtheria-pertussis-tetanus vaccine in the United States started in the media and ended on the Congressional floor. In 1986, after years of confusion and debate about the DPT vaccine, the structure of the American court system changed with the National Childhood Vaccine Injury Act. The science was irrelevant in these debates; from scared parents to bankrupt vaccine manufacturers, the effect of fear during this time was more significant than any research study.

This paper will analyze the anatomy of a public health scare in the United States. It will explore questions about the power of the media, the relationship between private and public industry, and how public perception can drive changes in the judicial system. Newspaper reports and Congressional documents reveal the story of how the DPT vaccine changed how the government addresses adverse reactions. The three chapters of this thesis will move chronologically through the 1980s, examining and analyzing (1) how information about vaccines was introduced and spread through the public (2) questions about responsibility and the role of industry in accountability for vaccine injuries (3) what role the government played in addressing

¹¹ *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson (1982; Washington D.C.; WRC-TV, aired on NBC), Found on YouTube. <https://www.youtube.com/watch?v=qpUsg4bDH5w>.

the public health emergency and responding to public panic. What happened with the DPT vaccine in the United States was not about the science; it was about perception. The question was not, “Will the DPT vaccine harm my child?” The question was, “Do I think the DPT vaccine will harm my child?” The perceived risk of the pertussis component in the vaccine drove panic in the United States, and more significantly, the panic caused a fundamental shift in how the government addresses vaccine injuries through the creation of a no-fault compensation system.

Chapter One **The Power of the Press and the Beginning of the DPT Scare**

On April 19, 1982, families across the United States settled in their living rooms, switched on their television sets, and flipped to a documentary that would spark controversy across the country. *DPT: Vaccine Roulette*, which aired on NBC three times, was an hour-long film about the dangers of the DPT vaccine. The vaccine protected against diphtheria, pertussis, and tetanus, and infants and children were required to receive five doses before entering school.¹² Starting in the 1960s and 1970s, several papers were published in Great Britain that hypothesized a correlation between the DPT vaccine and several neurological complications. The results of these studies were publicized around Europe and Japan, eventually leading to a drop in vaccination rates and, in Japan, a temporary ban on administering the shot.¹³ These events were the basis of *Vaccine Roulette*, bringing the same fear and panic from around the world into the living rooms of the U.S. public.

DPT: Vaccine Roulette was a prime example of the role the media plays in public health reporting in the United States. The film was covered extensively in newspapers, magazines, scientific journals, and news channels. Families stepped forward with heartbreaking stories about the harm the vaccine caused, and any attempt at rebuttal from the government or the medical community fell on deaf ears. The public was convinced—the DPT vaccine was dangerous and the country’s leaders had been complicit in hurting America’s children. This chapter will explore the role of the media as the catalyst for the movement against the DPT vaccine in the United States. Parent groups like Dissatisfied Parents Together were created in the wake of *Vaccine*

¹² “Vaccine Information Statement,” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, April 5, 2019, <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html>.

¹³ Institute of Medicine (US) Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, “Pertussis and Rubella Vaccines: A Brief Chronology,” National Center for Biotechnology Information, January 1, 1991, <https://www.ncbi.nlm.nih.gov/books/NBK234365/>.

Roulette and grew rapidly. The movement was bolstered with book publications about the risks of the DPT vaccine, including one from the co-founder of Dissatisfied Parents Together that was widely popular. Through the media, the public first became aware of the inherent risks in vaccines, but this gave a voice and a platform to an anti-vaccine movement that encouraged parents not to vaccinate their children against deadly illnesses.

Pertussis, more commonly known as whooping cough, used to be a common childhood illness in the U.S., causing weeks of uncontrollable coughing, vomiting, and exhaustion; the disease was characterized by the telltale “whoop” that often followed a coughing fit as the infant struggled to get breath back into the lungs. Whooping cough can cause severe complications, particularly in babies under one year old who have not been vaccinated. Pneumonia, convulsions, apnea (irregular or stopped breathing), encephalopathy (brain disease), and death are among the worst effects, and though these are rare, the coughing and other milder symptoms can last for months after the initial infection and forces the child to live in misery.¹⁴

None of that information about pertussis was provided in *DPT: Vaccine Roulette*. Instead, the documentary focused on “uncovering” the risks the medical establishment and the government had been hiding about the vaccine. Lea Thompson, the host and producer, portrayed herself as a crusader for the families and children who believed they had been affected by the DPT shot. According to an article published in the *Washington Post* shortly after the film aired, “eleven minutes of the film were devoted to the crippled children and their families, and less than two minutes to a description of a little girl with whooping cough.”¹⁵ Thompson opened the

¹⁴ “Pertussis (Whooping Cough) Signs & Symptoms,” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, August 7, 2017, <https://www.cdc.gov/pertussis/about/signs-symptoms.html>.

¹⁵ Donna Hilts, “TV Report On Vaccine Stirs Bitter Controversy,” *Washington Post*, April 28, 1982, <https://www.washingtonpost.com/archive/local/1982/04/28/tv-report-on-vaccine-stirs-bittercontroversy/80d1fc8a-1012-4732-a517-7976c86ab52d/>.

film by declaring that there was a “general void of information” about the DPT vaccine in the United States that she intended to remedy, but instead succeeded in sparking an anti-vaccination movement that still exists today.¹⁶

DPT: Vaccine Roulette was structured like a battleground. On one side, the side Thompson wanted the viewer to root for, were the people who believed the DPT vaccine was dangerous; Lea Thompson portrayed herself as a warrior fighting alongside families who wanted justice for their children. The other side, the ones responsible for stealing the lives of these children, was the United States government and the medical community. Alternating between awkward interviews with medical and government officials and heart-wrenching accounts from parents of “vaccine-damaged children,” the film was designed to illicit fear and anger from its viewers. The families Thompson interviewed were strategically chosen: Six families with six children at varying ages. Four boys and two girls living in normal homes with loving parents and more toys than they knew what to do with. These families would have been perfect if not for the awkward jerky movements and vacant stares from the children whose brains never developed properly, or the stress lines and dark circles on the faces of the parents. The loud and ominous heartbeat thumping in the background before rolling the interview footage warned viewers of another heartbreaking story about how the DPT vaccine destroyed a family.

Take Abra Yankovich, a two-year old girl with severe brain damage from seizures her parents believe were caused by the vaccine. With the heartbeat soundtrack playing in the background, the frame froze on Abra’s drool-covered face while text scrolled across the screen like a typewriter:

¹⁶ *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson, Time stamp: 0:50-0:57.

Abra Yankovich
Age: 2
Reaction: Stopped breathing, seizures
SEVERELY DISABLED AND RETARDED¹⁷

Abra's parents, Emily and Conley, sat in their living room with Abra as they described her reaction after receiving the DPT shot:

When she was four months old, on the same day she had her vaccination, she had her first seizure. She was shaking and she was turning blue and she appeared to have breathing problems... We told the doctor that she had had her vaccination that day, and could there be a link there? He said, 'no she was probably just choking; just take her home and she'll be fine.' But two weeks later she went into a grand mal seizure; she was very near dying.¹⁸

The Yankovichs said they knew the vaccine was what hurt their daughter, but they had to search across the country to find a pediatrician who believed them. Mr. Yankovich told Thompson that Dr. Gordon Millichap, a pediatrician in Chicago, said he "wouldn't even give [the shot] to his dog."¹⁹ Throughout this interview, the camera would zoom in on Abra laying on her stomach on the floor, throwing toys around. Her blonde hair was in pigtails high on her head and her light blue eyes occasionally stared vacantly past the camera. At the end of the interview, Mrs. Yankovich said in a measured and detached voice that, "we've been told she will probably never walk on her own and she probably will never talk."²⁰

The Yankovichs had no trust in the medical community, and from their perspective, rightfully so. Emily and Conley were forced to travel from Wisconsin to Chicago with their small child, subjecting her to tests and evaluations from dozens of medical centers along the way, to find one physician who believed their daughter's disabilities were caused by the DPT

¹⁷ *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson, Time stamp: 22:28-22:50.

¹⁸ *Ibid.*, Time stamp: 22:55-23:15.

¹⁹ *Ibid.*, Time stamp: 23:19-23:45.

²⁰ *Ibid.*, Time stamp: 24:05-24:18.

vaccine. In this interview, the medical community was established as an uncaring entity, where doctors refused to believe parents despite the evidence that seemed to stare them in the face.

This sweet, blonde-haired, blue-eyed little girl was reduced to crawling on the floor and flinging her arms out to catch herself as she tried to play. The message was sent loud and clear through the television screen: this could happen to your child, too.

The government and medical professionals Lea Thompson interviewed in *Vaccine Roulette* were portrayed as suspicious and incompetent. They sat in plain rooms with no color and nothing to focus on but the sense of discomfort projecting from the officials. In one interview with Dr. John Robbins from the United States Food and Drug Administration (FDA), Thompson pressed him for information about a study on the DPT vaccine conducted at the University of California, Los Angeles (UCLA) that had run out of funding. Thompson asked, “This was the only study that the government was doing on the DPT shot in forty years and you’re saying you don’t have enough money to go back and check on those children who had reactions?” Dr. Robbins replied, defensively and with a shrug of his shoulders, “The funds for contractual agreements, there are just no funds for that in the FDA now.”²¹

These interviews were conducted with no background music and no sound effects, cutting back and forth between stationary shots of Thompson and the unfortunate person being interviewed. In this interview with Dr. Robbins, Thompson sat with her hands folded on the table, leaning into each question. Meanwhile, Dr. Robbins fidgeted with his hands and seemed caught off-guard with each question that was fired at him. Thompson asked pointed and leading questions in each interaction she had, whether it was to parents, government officials, or straight to the audience at home. She was not unbiased, and she unapologetically steered interviews in

²¹ *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson, Time stamp: 17:50-18:13.

the direction she wanted them to go. With each new revelation about the DPT vaccine, the viewer was sucked deeper into the narrative Thompson created.

In the final minutes of the film, Lea Thompson reported on the findings of her self-proclaimed investigation into the DPT vaccine:

Thousands of children get the ‘P’ part of the DPT shot and apparently suffer few consequences. However, some children have suffered learning disabilities and severe brain damage as a direct result of the shot. There is no way of knowing how many DPT victims there are in the United States, but there certainly are far more than the medical community or the government would like to admit.²²

Thompson emphasized the failure of the government to conduct adequate research on the pertussis component of the vaccine and blamed physicians for “blindly following the lead of the government in making this shot mandatory.”²³ She left parents with the sense that whooping cough was not a severe illness, and they would be taking a greater risk by attempting to vaccinate their children. Finally, the last scene in the documentary opened to a doctor’s office with a small toddler and his father. The little boy cried as the doctor gave him a shot, and his father can be heard saying, “It’s one those things little boys have to have. See, it’s all gone already.” The frame froze, and the same heartbeat soundtrack from the family interviews played in the background.²⁴ Viewers were left with the sinking feeling that they were witnessing another potential DPT victim as the screen faded to black.

The response to *DPT: Vaccine Roulette* was almost instantaneous. News coverage across the country and an inundation of calls to physician and government offices from panicked parents placed the DPT controversy at the forefront of the public awareness. Articles from a wide range of publications centered on the controversy, from *The New York Times* and *The*

²² *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson, Time stamp: 47:38-48:02.

²³ *Ibid.*, Time stamp: 48:50-49:09.

²⁴ *Ibid.*, Time stamp: 50:38-50:51.

Washington Post to small magazines like *Better Homes and Gardens* and public health journals. Article titles such as, “The Whooping Cough Vaccine: Protector or Killer?” and “Documentary Stirs Vaccine Controversy” failed to assure the public of the safety of the vaccine; rather, they presented the topic as an open debate that pushed parents to fear for their children getting the shot. The day after *DPT: Vaccine Roulette* aired, clips were played on NBC’s *Today Show* and Thompson was interviewed.²⁵ Those who did not get the chance to watch the documentary the previous night could have woken up the next morning and watched Thompson herself speak about the film’s accuracy. As the media took advantage of the public’s focus on the DPT vaccine, inconsistent and often alarmist messages were communicated, which reached audiences across the country and encouraged the anti-vaccine movement to grow.

Lea Thompson claimed that the purpose of *DPT: Vaccine Roulette* was to provide parents with enough information to make informed decisions about whether to give their children the vaccine. The information she presented was simple: a child with whooping cough would surely recover, while a child with a reaction to the DPT vaccine would live with lifelong, crippling disabilities. Though the information presented in the documentary seemed well-researched and convincing, Thompson misled the public on some of the biggest issues surrounding the DPT vaccine.

One of Thompson’s most glaring mistakes was the lack of emphasis on the dangers of whooping cough for infants and children. The film was supposed to cover a balanced mixture of DPT supporters and opposers, but it failed to do this when only one child with whooping cough

²⁵ Donna Hilts, “The Whooping-Cough Vaccine: A Protector or a Killer?” *The Washington Post*, (Washington, D.C.), April 28, 1982.
<http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/147436304?accountid=10226>;
 Randi Henderson, “Documentary Stirs Vaccine Controversy,” *The Sun*. (Baltimore, MD), May 6, 1982.
<http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/538015311?accountid=10226>.

was shown, while six alleged vaccine-damaged children were covered in-depth. Thompson interviewed a British doctor named Gordon Stewart who, referencing whooping cough, claimed, “a completely well child does not die from the cough.”²⁶ In reality, about 1 out of 100 infants under one-year old will die even if they received hospital care.²⁷ *Vaccine Roulette* also misled viewers about the prevalence of negative reactions to the DPT vaccine. All vaccines carry inherent risk; a small percentage of every population will experience a reaction, from fever and swelling to the possibility of more severe allergic reactions.²⁸ However, the film portrayed adverse reactions from the DPT vaccine as a hidden epidemic, and the government had been hiding the prevalence of negative effects from the shot. While it was true that the pertussis component of the vaccine was more reactive than other vaccines, the statistic was still relatively mild with 1 out of 100,000 children having adverse reactions; 1 out of 10,000 children with pertussis suffer permanent brain damage.²⁹ Overall, *Vaccine Roulette* was an alarmist film that claimed neutrality, but encouraged parents to reject vaccinations with false and exaggerated information.

In 2011, physician and author Paul Offit wrote the book *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*. He also claimed that Thompson and the producers of the documentary communicated inaccurate and biased views for the sake of scaring parents into choosing not to vaccinate their children. For two chapters, forty pages, Offit picked through *Vaccine Roulette* and systematically discredited nearly every claim Lea Thompson made. Offit

²⁶ *DPT: Vaccine Roulette*, Directed and hosted by Lea Thompson, Time stamp: 9:06-9:20.

²⁷ “Pertussis,” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, August 7, 2017, <https://www.cdc.gov/pertussis/about/complications.html>.

²⁸ “Vaccines: Vac-Gen/Side Effects,” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, August 15, 2019, <https://www.cdc.gov/vaccines/vac-gen/side-effects.htm>.

²⁹ Donna Hilts, “TV Report On Vaccine Stirs Bitter Controversy,” *Washington Post*, April 28, 1982, <https://www.washingtonpost.com/archive/local/1982/04/28/tv-report-on-vaccine-stirs-bittercontroversy/80d1fc8a-1012-4732-a517-7976c86ab52d/>.

credited the DPT scare, and *Vaccine Roulette*, with spawning the modern-day anti-vaccination movement in the United States. He allowed his disdain for Thompson to shine through in his writing, harshly criticizing her for her lack of remorse, despite overwhelming scientific evidence that the DPT vaccine did not cause many of the disabilities it was blamed for. Offit quoted a statement from her in 1997 where she said, “*DPT [Vaccine Roulette]* was important to me personally because it spawned a movement.” This was followed by Offit’s quick and bitter input about Thompson as the cause of a misinformed and dangerous movement.³⁰ Though biased in his own right, Offit eloquently and, most importantly, accurately presented a viewpoint shared by the medical community and the United States government. In 2011, the heat of the moment for *Vaccine Roulette* had passed, but Offit echoed the hundreds of physicians and officials who stepped forward in the 1980s to undo the damage Thompson managed to inflict on their credibility.

Physicians and organizations on both sides of the issue were given the opportunity to step forward on May 7, 1982 when the Senate convened a meeting to hear testimonies from stakeholders in the DPT vaccine debate. Less than a month after *DPT: Vaccine Roulette* aired, representatives from the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics, parent groups such as Dissatisfied Parents Together, and many others contributed to questions on the vaccine’s safety while Congressmen listened with concern.

On the side supporting the DPT vaccine were government and medical organizations. Their testimonies centered on dispelling the myths about the disabilities caused by the shot, as well as discrediting *Vaccine Roulette* as a source of reliable information. Dr. William Foege, the director of the CDC in Atlanta, Georgia, criticized the film for its biased lens, stating, “we

³⁰ Offit, *Deadly Choices*, 54.

consider the program to have been distorted, verging on the irresponsible. Unfortunately, it has been heavily promoted by the local TV station and it appears that attempts are being made to provoke a major controversy where one does not currently exist.”³¹ Dr. Vincent Fulginiti, director of infectious diseases in the American Academy of Pediatrics, supported Dr. Foege’s statement with descriptions of the response from parents after the documentary aired. Dr. Fulginiti told the committee that “many parents are refusing immunization, with pertussis vaccine and with all vaccines,” emphasizing that *Vaccine Roulette* did not just affect vaccination rate for the DPT shot, but for all immunizations.³² These testimonies demonstrated the frustration and concern in the medical community about the ramifications of the documentary and its continued news coverage.

On the other side of the debate were parents and parent groups who believed the vaccine was too dangerous to give to their children. Isabella Gelletich testified that her son was severely disabled from the DPT vaccine. With her emotional testimony, Gelletich described the callousness of the medical establishment when she tried to tell her doctors that her son was injured from the vaccine:

Now, after the fact, the medical community will try to tell you and me that my son is a statistic. They will say that Michael is one in 70,000 or one in 70 million. They will tell you that this is an acceptable risk to protect the masses from disease [...] The medical profession’s credibility has been seriously and effectively challenged by the Lea Thompson Report on Vaccine Roulette.³³

Testimonies like these were ones that were not only stated in the Congressional Hearing, but in newspapers and interviews across the country. The parent group Dissatisfied Parents Together

³¹ U.S. Congress, Senate, Committee on Labor and Human Resources, To Examine Adverse Drug Reactions From Immunization, Efforts In Preventative Medicine, and Characteristics of Certain Diseases, 97th Congress, 2nd session, May 7, 1982, 26.

³² U.S. Congress, Senate, Committee on Labor and Human Resources, To Examine Adverse Drug Reactions From Immunization, 105.

³³ *Ibid.*, 135.

(DPT) was established by a group of individuals who had watched *Vaccine Roulette* and realized or confirmed that the DPT shot had caused their children's disabilities. Barbara Loe Fisher, who went on to co-author a book on the issue, Jeffrey Schwartz, and Kathi Williams founded Dissatisfied Parents Together to advocate for the development of a safer DPT vaccine and a national vaccine injury reporting system and compensation program.

Kathi Williams testified on behalf of the organization in the Congressional Hearing and shared how it had been created. She told the panel, "Generally, we found out that most parents did not know the pertussis vaccine had severe side effects. Most parents said they had not reported their child's reactions to the DPT shots because their doctors had not told them to watch for severe reactions."³⁴ Dissatisfied Parents Together was not originally intended to be an anti-vaccination group, though the focus shifted over time; the organization began as a group of parents pushing back against the idea that adverse vaccine reactions were statistics. Mothers like Isabella Gelletich and Kathi Williams argued against the public health belief that the population takes precedence over the individual. Following this hearing, Dissatisfied Parents Together created the slogan, "When it happens to your child, the risks are 100 percent."³⁵

The stories of the members of Dissatisfied Parents Together were not limited to testimonies in hearings; the organization was mentioned frequently in news articles about the risks of the DPT vaccine. In 1985, Jeffrey Schwartz's daughter, Julie, died from a seizure disorder she developed shortly after receiving her DPT shot two years earlier. Two months later, the *Chicago Tribune* published an emotional story about the circumstances around Julie's death, and Jeffrey spoke to the reporters about his reasons for founding Dissatisfied Parents Together.

³⁴ U.S. Congress, Senate, Committee on Labor and Human Resources, To Examine Adverse Drug Reactions From Immunization, 79.

³⁵ Stephen Engelberg, "Vaccine: Assessing Risks and Benefits," *The New York Times* (New York, NY), Dec. 19, 1984, <https://www.nytimes.com/1984/12/19/garden/vaccine-assessing-risks-and-benefits.html>.

The article was sympathetic to the Schwartz family and to the organization, going so far as to paint vaccine manufacturers and pediatricians as uncaring about the deaths of children like Julie: “There are pediatricians who think that groups such as Dissatisfied Parents Together are overreacting. But it’s hard to tell that to someone whose child has died the way that Julie Schwartz died.”³⁶ With heartbreaking stories and relatable characters, organizations like the one Schwartz co-founded had an advantage when addressing the public for support.

The weakness of the government and medical establishment response to *Vaccine Roulette* was in where representatives chose to express their views. Research on the DPT vaccine and reactions to the documentary were most often published in medical journals and expressed in official meetings like the House Congressional Hearing. The average individual did not have a subscription to *The American Journal of Medicine* or access to physician board meetings. The sources with the most accurate information on the vaccine with the most reliable opinions from professionals were inaccessible to the general public. Groups like Dissatisfied Parents Together were given free reign over the press to spread their version of the truth about vaccines. Physicians and government officials remained insular while parents and anti-DPT groups used the media to target the general public, resulting in an imbalanced flow of information responsible for the growth of the anti-vaccine movement. In this way, the media was used as a tool to spread the sympathetic stories of parent groups over the research of credible sources.

Much of the attention on Dissatisfied Parents Together in the mid-1980s can be credited to the publication of *DPT: A Shot in the Dark* in February 1985. Barbara Loe Fisher, one of the co-founders of the organization, co-authored the book. Alternating between a biased history of the DPT vaccine and profiles of parents with injured children, *A Shot in the Dark* was an

³⁶ Bob Greene, “Child Dies Despite Best of Intentions,” *Chicago Tribune* (Chicago, IL), July 21, 1985, <https://www.chicagotribune.com/news/ct-xpm-1985-07-21-8502170507-story.html>.

expanded version of Lea Thompson's *DPT: Vaccine Roulette*. The book contained the same emotional appeal as Thompson's film, presenting readers with seemingly undeniable evidence of the danger of the DPT shot and the callousness of physicians and government officials.

In a chapter titled "For the Love of a Son," Maryl and Bill (no last name provided) spoke about what happened to their son Sam after he received the third dose of his DPT series. After years of unexplained seizures and periods of paralysis, Sam's development regressed and then stalled; he could not breathe on his own, walk, speak, or swallow, but despite all this, his brain scans continued to come back with normal results.³⁷ After years of intensive therapy, at sixteen years old, Sam had limited mobility and could speak simple phrases. Maryl and Bill stated that they only realized the DPT vaccine had caused Sam's disabilities after watching *DPT: Vaccine Roulette*:

The television documentary also had a tremendous impact on Maryl. 'What affected me most about the program was that parents continue to bring wonderfully healthy, strong babies to be vaccinated, and some of them end up severely handicapped with futures that cannot even be imagined. I would do anything to help prevent that from happening to other children,' Maryl said.³⁸

Sam's story was one of eight in *DPT: A Shot in the Dark*, each driving home a different point about the risks of the DPT vaccine or the incompetency of medical professionals. The book ended with a plug for Dissatisfied Parents Together, promoting the organization's efforts to uncover the government's efforts to hide the damaging effects of the DPT vaccine. Fisher and Coulter portrayed Dissatisfied Parents Together as an organization advocating for awareness and education rather than anti-vaccination, but the tone of the book could easily be interpreted in that way. On the last page, a quote from a mother read:

³⁷ Harris L. Coulter and Barbara Loe Fisher, *DPT: A Shot in the Dark* (San Diego: Harcourt Brace Jovanovich, 1985), 180.

³⁸ *Ibid.*, 181.

What makes me so mad is that it could have been avoided. I thought I was being a good parent to give [my son] that shot. If I had known about the risks, if I had been given an option, I might have taken my chances with the natural disease. I don't know. But I do know that God gave me a perfect child...God gave me a perfect child and man, with his own ways, damaged God's perfect work.³⁹

This mother was lamenting about the pain that could have been avoided if she had chosen not to get her son vaccinated. She considered vaccines a product of man that “damaged God's perfect work,” despite the millions of lives saved from infectious diseases. Based on this quote alone, the reader was left with the sense that vaccines could only do harm.

Coulter and Fisher's book had some of the same issues that were in Thompson's documentary. In *A Shot in the Dark*, Coulter and Fisher made little effort to communicate the severity of whooping cough. Going so far as to include an interview with a mother whose child survived whooping cough, the authors aimed to emphasize that modern medical treatments have reduced the disease to a scary, but relatively mild inconvenience compared to the risks of getting the DPT shot. Coulter and Fisher also tended to overemphasize the prevalence of adverse reactions to the DPT vaccine. By only presenting cases and statistics related to negative reactions and deaths alleged to be from the pertussis component of the shot, the authors magnified the problem and created the impression that every child was at significant risk if they got vaccinated. From a credibility standpoint, *A Shot in the Dark* was not cited properly. The chapters with interviews of parents and families never mentioned last names, and they were not cited in the lengthy, unorganized bibliography crammed at the end. There was no way to confirm whether any of these children's disabilities were caused by the DPT vaccine or whether the families interviewed were real people.

³⁹ Coulter and Fisher, *A Shot in the Dark*, 408.

Despite this lack of research rigor, *DPT: A Shot in the Dark* was covered with sympathy in some media sources. A *Washington Post* article titled, “Two Parents Groups Speak Out Against Multiple DPT Vaccine: Side Effects Blamed for Brain Damage,” commended the book and the work of Dissatisfied Parents Together as a call-to-action for a safer vaccine and stricter regulations.⁴⁰ However, some sources such as *The New York Times* article “Shots or Not?” pointed out the lack of reliable citations and criticized the book and the anti-DPT movement for jeopardizing the future supply of vaccines, which will be discussed in the next chapter.⁴¹

The beginning of the DPT vaccine hysteria in the United States would not have occurred without media in all its forms— films, news broadcasts, newspapers, books. In many cases, the desire for a good story outweighed the responsibility to report facts. *DPT: Vaccine Roulette* swept through the nation seemingly overnight, informing viewers about adverse reactions to the DPT vaccine using inaccurate and exaggerated information. Press coverage on parent stories and anti-DPT organizations throughout the 1980s allowed the misinformation to spread unchecked, while medical community and government messages often never reached the public. For the first time, the public became aware of the risks inherent in vaccines. Unfortunately, this occurred not under the careful guidance of medical professionals, but from explosive and sensationalistic coverage from the press. In the following years, the DPT hysteria set the stage for a much more dangerous problem— as lawsuits against vaccine manufacturers increased, rises in vaccine prices and drops in vaccine production threatened the immunity of the entire country.

⁴⁰ Sandra Sugawara, “Two Parents Groups Speak Out Against Multiple DPT Vaccine: Side Effects Blamed for Brain Damage,” *The Washington Post*, (Washington D.C.), Feb. 8, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/138751373?accountid=10226>.

⁴¹ Harry Schwartz, “Shots or Not?: DPT A Shot in the Dark. By Harris L. Coulter and Barbara Loe Fisher,” *New York Times* (New York, NY), Feb. 3, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/111220243?accountid=10226>.

Chapter Two **Changing the Discussion Around DPT**

Throughout the 1980s, the American public responded to the fear around the DPT vaccine by lashing out straight at the source: the vaccine manufacturers. At the start of the decade, just three laboratories supplied the millions of doses needed to vaccinate the country's children against three deadly illnesses. Wyeth Laboratories of Philadelphia, Connaught Laboratories in Swiftwater, Pennsylvania, and Lederle Laboratories in Pearl River, New York were placed under immense financial strain following hundreds of lawsuits. In June 1984, both Wyeth and Connaught Laboratories stopped distribution of the DPT vaccine, leaving Lederle Laboratories as the sole provider. By December of that same year, the nation was facing an unprecedented shortage of the vaccine.

The public needed someone to blame for what was perceived as a failure of the public health system, and families in the United States leveraged the court system to grant justice. Without a response strategy, the vaccine industry was critically destabilized, and it was no longer economically or politically beneficial for manufacturers to be in the vaccine business. Courts found fault in the manufacturers for supplying a product that carried inherent risk, and this presented a significant shift in the questions surrounding the DPT debate. Should companies have been held responsible for the one in 310,000 children who reacted negatively to a vaccine? What about one in 1 million? The American people targeted manufacturers, but the federal government was responsible for addressing the DPT crisis, and the government was unprepared to respond.

The aftermath of *DPT: Vaccine Roulette* played a significant role in the increased number of lawsuits against DPT vaccine manufacturers. In an interview with *The Sun*, Lea Thompson was proud of the effect her documentary had, stating, "If anything, the lawsuits are bringing

home the realization that there are far more kids out there [with damage] than anyone dreamed.”⁴² In *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*, author Paul Offit noted the nearly immediate effect that Lea Thompson’s *DPT: Vaccine Roulette* had on public action:

[Personal-injury lawyers] urged parents of vaccine-damaged children to come forward, to get the justice and compensation they deserved. In 1981, one year before *Vaccine Roulette*, 3 lawsuits were filed against vaccine makers. By the end of 1982, lawyers had filed 17 suits; during each of the next four years, they filed 41, 73, 219, and 255.⁴³

With *Vaccine Roulette* and advertisements from lawyers, families who believed their children were injured from the DPT vaccine were provided with both motivation and means to sue. The documentary, and the media storm that followed it, instigated hundreds of lawsuits against Wyeth, Connaught, and Lederle, and Thompson’s comments implied that this response was exactly what she had intended.

More often than not, juries sided with the families, costing the vaccine manufacturers millions of dollars in settlements. Michelle Graham was a few months old in 1980 when she received her first DPT shot at a clinic run by the Missouri Department of Health. Shortly after, she developed a severe neurological condition called encephalopathy, which causes irreversible damage to the brain.⁴⁴ Michelle’s parents sued Wyeth Laboratories, which had supplied the DPT vaccine to the clinic, for two wrongdoings: Wyeth had failed to produce a safer vaccine, and they neglected to accurately report the risks of the vaccine. According to the Grahams’ lawyer, “Wyeth has the technical know-how to develop (or design) a safer, yet equally

⁴² Kathy Lally, “Whooping cough vaccine dwindles: Supply falls, price soars,” *The Sun* (Baltimore, Maryland), Jul 22, 1984,

<http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/536615683?accountid=10226>.

⁴³ Offit, *Deadly Choices*, 18.

⁴⁴ *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1987); “Encephalopathy,” Healthline, <https://www.healthline.com/health/hepatic-encephalopathy>.

efficacious...pertussis vaccine, but has refused to do so due to the increased manufacturing costs.” In addition, the Grahams claimed that Wyeth was aware that “the incidence of adverse reactions was actually much greater” than what was reported.⁴⁵ The jury agreed, and ruled that Wyeth owed the Graham family 15 million dollars in compensation. As the judicial system continued siding against the manufacturers, families sued for more money; by 1984, plaintiffs were requesting up to 1.3 billion dollars.⁴⁶

By seeking justice in the court system, families introduced subtle, but important changes in the discussion around the DPT vaccine. In Lea Thompson’s documentary and even in Fisher and Coulter’s book, *DPT: A Shot in the Dark*, the goal was to induce fear in the viewer or the reader. To achieve that, Thompson, Fisher, and Coulter had to convince people that the DPT vaccine was injuring their children. The core questions they were answering were about the science of vaccines; parents were forced to ask themselves whether their child’s disability was caused by the DPT vaccine. In court rooms, however, the goal was to win compensation. In Michelle Graham’s case, a doctor was never called to confirm whether the DPT vaccine caused her brain damage. Instead, the record reflected that, “for the purposes of this motion, the court will assume the plaintiff’s condition was caused by the pertussis vaccine.”⁴⁷ For Wyeth, or any manufacturer, to be at fault for failing to produce a safer vaccine or neglecting to communicate the risks, the plaintiffs’ lawyers would have needed to establish beforehand that the current vaccine was dangerous. When the DPT crisis transitioned from people’s living rooms to court rooms, the questions about the vaccine also changed. People were no longer asking about

⁴⁵ Graham v. Wyeth Laboratories (D. Kan. 1987).

⁴⁶ Offit, *Deadly Choices*, 19.

⁴⁷ Graham v. Wyeth Laboratories (D. Kan. 1987).

whether the DPT vaccine harmed children, but about how the private sector would compensate its victims.

In June 1984, Wyeth Laboratories made an announcement that shook the vaccine industry and sent a message about how serious the DPT controversy was becoming. A *Washington Post* article reported:

A Wyeth spokesman estimated that the company held at least 25 percent of the United States market. Wyeth notified its customers that as of June 13 it had ceased production⁷ of the pertussis portion of the vaccine after 30 years because of “dramatic increase in the cost of participating in this market.”⁴⁸

The cost of the lawsuits had overtaken the company, and Wyeth had decided to stop manufacturing the DPT vaccine. Connaught Laboratories followed with an announcement of its own shortly after, stating that the loss of their private insurance made the financial burden too great to continue fighting lawsuits and distributing the vaccine.⁴⁹ In the space of one summer, two-thirds of the country’s suppliers pulled out of the DPT market, leaving Lederle Laboratories to bear the cost of distributing the vaccine and assume liability for its effects. However, Wyeth and Connaught had not abandoned the market completely; both companies agreed to fulfill their existing production contracts to avoid shortages. In addition, Wyeth arranged to continue manufacturing the DPT vaccine with Lederle as its distributor, but only until Lederle completed a planned expansion of its production capacity.⁵⁰

Despite the efforts from vaccine manufacturers to provide for the country’s supply needs, the market could not compensate for the loss. Soon after Wyeth and Connaught stopped

⁴⁸ Cristine Russell, “Firm Ceases Making Vaccine,” *Washington Post* (Washington D.C.), Jun 19, 1984, <https://search.proquest.com/docview/138259896/abstract/E36603B7B85A4DFFPQ/13>.

⁴⁹ Associated Press, “Drug Firms Seek Exemption: DPT Vaccine Supply Tied to Shelter From Liability,” *The Washington Post* (Washington D.C.), Dec 20, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/138138599?accountid=10226>.

⁵⁰ Walter Orenstein, “More whooping cough vaccine slated.” *The Sun* (Baltimore, Maryland), Dec 16, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/535739374?accountid=10226>.

distribution of the DPT vaccine, newspapers began reporting on spot shortages. *The Los Angeles Times* reported in September that “doctors in Nebraska began running short of DPT last month, and state health officials there said they were worried. Local officials expressed similar concerns in Georgia” and the Academy of Pediatrics in Pennsylvania began running out of supplies six weeks prior.⁵¹ *The Wall Street Journal* interviewed a Texas health official who emphasized the severity of the shortage, stating that Texas only had enough DPT vaccine to last until early August, which would pose a dangerous dilemma for children who need complete immunization records to attend school.⁵²

By December, it was clear that the nation was facing a potential whooping cough epidemic if the DPT vaccine supply continued to fall. The CDC released an official statement about the shortages and provided healthcare workers with recommendations about how to prolong their supplies of the shot. The announcement provided a brief, neutrally worded background on what caused the shortages, skipping over the increased number of lawsuits against manufacturers, and instead stating that “major changes have occurred in the pattern of manufacture and distribution of diphtheria-tetanus-pertussis (DTP) vaccine in the United States.” This was followed shortly by a warning for the medical community that the shortage would get worse; several batches of Lederle’s vaccine failed to meet requirements for distribution, meaning that no new vaccines would be available until February of the following year.⁵³ Three months without new batches meant an additional burden would be placed on stores that were already running low in many places around the country, so the CDC recommended that physicians take

⁵¹ Eric Malnic, “Threat Seen in Shortage of Baby Vaccine,” *Los Angeles Times* (Los Angeles, California), Sep 18, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/153967806?accountid=10226>.

⁵² Johnnie L. Roberts, “Shortage of Vaccine for Whooping Cough Seen in Some States,” *The Wall Street Journal* (New York, New York), Jun 27, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/134886065?accountid=10226>.

⁵³ Centers for Disease Control, “Diphtheria-Tetanus-Pertussis Vaccine Shortage – United States,” *Morbidity and Mortality Weekly Report*, Dec 14, 1984, <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000452.htm>.

unconventional action: ration their vaccines. Before this announcement, children were required to receive five doses of the DPT vaccine at two, four, six, and eighteen months, and between four and six years old. The agency determined that physicians should delay the doses typically given at eighteen months and four to six years, which would “achieve substantial savings in the rate of DTP vaccine use, while still protecting those at greatest risk of these diseases.”⁵⁴

Physicians were hesitant about the CDC’s recommendation. Dr. Martin Smith, a pediatrician and the vice president of the American Academy of Pediatrics, was confident that delaying the last two doses of the DPT vaccine would not have any ill effects on the children, but he expressed concern about whether the measure would succeed in prolonging supplies: “Our biggest concern is the fact that we’ve got to have a supply for children at 2, 4, and 6 months.”⁵⁵ Other physicians were concerned about the effect of the shortage on the rest of the population. One researcher told *The New York Times* that “the presence of a group of children who had not been fully immunized would increase the amount of whooping cough bacteria circulating in the United States,” which could infect adults in the population “whose immunity against the disease has waned.” A physician from the American Academy of Pediatrics also explained the risk presented to infants younger than two months who were not old enough to receive their first dose: “It isn’t so much the health of the kids who miss their shots that we worry about. The problem is whether they bring it home to younger siblings.”⁵⁶ Despite the CDC’s confidence that delaying the last two doses of the DPT series would preserve the supply, the medical community

⁵⁴ Centers for Disease Control, “Diphtheria-Tetanus-Pertussis Vaccine Shortage.”

⁵⁵ Associated Press, “CDC Warns of Vaccine Shortage,” *The Washington Post* (Washington D.C.), Dec 14, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/138124372?accountid=10226>.

⁵⁶ Stephen Engelberg, “Shortage of Whooping Cough is Seen,” *The New York Times* (New York, New York), Dec 14, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/122445295?accountid=10226>.

shifted its attention to the unintended, and equally dangerous, consequences of such a drastic action.

In addition to an unstable vaccine supply, several newspapers raised flags about Lederle's motivation for continuing to distribute the vaccine. In one article, reporters gave Lederle "great credit" for continuing to provide the shot despite the financial burden, "but it also invites the question whether it is not using this product, in which it now has a monopoly, to subsidize the development of other products in more competitive markets."⁵⁷ The public's trust in vaccine manufacturers was plummeting, and though the nation needed Lederle to continue producing the vaccine, people were uneasy about the company's power. Though it was never verified whether Lederle was raising prices on the vaccine to fund other projects, the cost of the vaccine was an unquestionable burden on doctors, hospitals, and public health agencies. In 1982, one dose of DPT vaccine was ten to twelve cents. In 1984, one dose of DPT vaccine was \$2.80.⁵⁸ This exponential price increase, along with growing concerns about the vaccine shortage, finally prompted Congress to respond.

On December 19, 1984, the House of Representatives convened to hear from everyone involved in the DPT crisis. Henry Waxman (D-CA), chairman of the committee, opened with a polarizing statement:

The supply of DTP is too important for so much confusion. The public needs to know whether it can rely on public health officials and drug manufacturers to assure an adequate supply of vaccine. If there is a shortage, what brought it about? Did the Federal Government know about it in time and is it prepared to cope with the

⁵⁷ "A Shortage of Vaccine," *The Washington Post* (Washington D.C.), Dec 20, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/138129879?accountid=10226>.

⁵⁸ Earl Lane, "Policy DPT: Problems Threaten Supply of Whooping Cough Vaccine," *Newsday* (Long Island, NY), Feb 5, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/1469975495?accountid=10226>.

situation? What can be done to prevent this from happening again? If there is no real shortage, how did the false alarm this week come about?⁵⁹

From his opening remarks, Representative Waxman revealed that the government was uninformed about the DPT shortage, and he subtly questioned the competency of the CDC and the vaccine manufacturers. The first part of the hearing proceeded in similarly accusatory language, as the chairman pressed representatives from the CDC and several other federal agencies about their knowledge of the vaccine shortage. The tone and language of the transcript implied an underlying frustration from the committee towards these representatives, and the start of the meeting appeared more like a trial than a fact-finding endeavor.

Taking the brunt of the questioning was Dr. James Mason, who was the director of the CDC. The logistics of the communication between Wyeth, Lederle, and Connaught were discussed at length, and the chairman spent a considerable amount of time grilling Dr. Mason about how they were tracking the manufacturing roles of each company. From Dr. Mason's testimony, the narrative the media was reporting was correct. Wyeth Laboratories pulled out of distributing the vaccine in June 1984, followed shortly by Connaught because of complications with private insurance contracts. At the time of the hearing, Lederle Laboratories was the only distributor of DPT; however, the point of confusion for the committee was the partnership between Wyeth and Lederle. Since the CDC was not aware of the partnership from the beginning, Representative Waxman interpreted the gap in knowledge as an example of the agency's failure: "You have a responsibility to assure we have a sufficient supply to immunize all the children in the country. There are only three companies we are talking about."⁶⁰ This

⁵⁹ U.S. Congress, House of Representatives, Committee on Energy and Commerce, A Bill to Amend the Public Health Service Act to Provide for the Compensation of Children and Others Who Have Sustained Vaccine-Related Injury, and for Other Purposes, 98th Congress, 2nd session, Dec 19, 1984, 263-264.

⁶⁰ U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 270.

comment could have been condescending or matter-of-fact depending on the Congressman's tone, but based on the line of repeated questioning, Representative Waxman was making a point about the committee's disappointment and frustration in the CDC's actions. From their perspective, the responsibility for ensuring a stable supply of vaccines fell on public health agencies and in this case, they failed.

The next portion of the hearing focused on why the country was running out of the DPT vaccine. According to the chairman, the DPT shortage came down to a lack of proper stockpiling, which led to another line of accusatory questioning from Representative Waxman. The committee was also discussing other important childhood vaccines, specifically the MMR (measles, mumps, rubella) and polio vaccines, and the chairman was concerned about their supply as well. He asked Dr. Mason, "If there is a fire tomorrow in the plant where the polio vaccine is manufactured, what would happen?" Dr. Mason succinctly replied that the country would have a shortage. The chairman followed with, "Are we going to then start putting money into iron lungs for polio victims? Shouldn't we now be thinking about how to get these children immunized and have enough supply so we won't be vulnerable to such a not completely unheard of possibility of fire and destruction to the supply?"⁶¹ The Congressman's passion and concern for ensuring an adequate supply of vaccines was clear throughout this hearing, and perhaps that passion partially explained outbursts like this one; however, with questions like "Are we going to then start putting money into iron lungs for polio victims," Representative Waxman revealed a combative side that spoke to his frustration with how the CDC had been handling the vaccine supply.

⁶¹ U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 279.

When the representatives of the three vaccine manufacturers gave their opening statements, the same narrative was repeated, but each company also revealed their priorities. Robert Johnson, president of Lederle, spoke primarily about why the company had to raise the price of the vaccine. He told the committee that “increased production costs combined with the escalating litigation resulted in a price increase of the vaccine.”⁶² Dr. Daniel Shaw, vice president of Medical Affairs at Wyeth, explained the partnership between Wyeth and Lederle, emphasizing that Wyeth was achieving a higher level of vaccine production now than before the partnership, attempting to escape blame for the country’s shortage. David Williams, vice president of Connaught, had the shortest statement of the three men. He notified the committee that Connaught had not resolved the insurance conflict, which was preventing the company from distributing any of their supply. Mr. Williams also pitched a unique solution to the committee: Congress should indemnify Connaught so they could release the 3 million doses they had in storage, temporarily relieving the shortage.⁶³

The representatives’ statements were followed by another lengthy questioning session led by Representative Waxman, who was determined to understand every detail of liability insurance for vaccine manufacturers. Alternating between the three men, the chairman slowly gathered information about which types of insurance the companies held, how long they were insured, why Connaught could not secure insurance, and the logistics of insurance between Wyeth and Lederle. Overall, the questioning was straightforward and professional, unlike the small outbursts during the CDC’s testimony. Making subtle reference to a bill that he had recently introduced to Congress, Representative Waxman’s last question to the panel asked whether the manufacturers would lower the price of the DPT vaccine if they were relieved of the liability

⁶² U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 283.

⁶³ *Ibid.*, 296.

costs. In response, Mr. Williams from Connaught confirmed, “I think I can say that if the Government took on that responsibility, there would be a significant reduction in the current cost of DTP vaccine.”⁶⁴ In the coming months, intense debate around who should be liable for adverse reactions to vaccines would determine whether this was true.

When news of the Congressional hearing reached the media, the consensus was a sense of confusion. Reporters focused on the manufacturers, painting them as uncooperative and secretive with their information. One article was skeptical about whether litigation was the true reason companies were ceasing distribution and raising prices, stating that many of the lawsuits “have been settled out of court, with the judges usually ordering – at the request of manufacturers – that the size of the settle be kept secret.” One aide to the House Committee said on record that “the companies have not exactly been forthcoming.”⁶⁵ The public was confused, and the hearing ended with more questions than answers. Congress had not decided on whether Connaught would be indemnified for their DPT vaccines, and there was no discussion about long-term solutions to stabilizing the DPT supply. The tension between the committee and the health agencies and the growing animosity between the public and the drug companies revealed the need for definitive action, but the role each of these stakeholders would play in the solution was still to be determined.

In the testimony provided by the American Academy of Pediatrics during the Congressional hearing, the president provided a particularly apt explanation of the DPT crisis:

It is an unfortunate fact of life that as vaccines have been developed for many of our childhood diseases and as their use has become universal with almost complete disappearance of those diseases, the public concern for these once dreaded childhood diseases tends to wane while concern for the rare reactions to the

⁶⁴ U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 306.

⁶⁵ Earl Lane, “Policy DPT: Problems Threaten Supply of Whooping Cough Vaccine,” *Newsday* (Long Island, NY), Feb 5, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/1469975495?accountid=10226>.

vaccines begins to mount. These diseases are now so uncommon that the rare reactions are now a source of intolerable proportion.⁶⁶

Vaccines have always carried an inherent risk, and the sensationalistic way the public was made aware of that fact contributed heavily to the fear surrounding the DPT vaccine. The inundation of lawsuits against vaccine manufacturers and subsequent threat of a vaccine shortage revealed the need for a better compensation system. Should manufacturers be held responsible for providing a product that saves millions and condemns a few? An interview with a physician in the American Medical Association explained, "It is a scientifically established fact that vaccines will cause a certain predictable incidence of adverse reactions...even where there is absolutely no negligence in the manufacture and administration of the vaccine."⁶⁷ However, from the perspective of the few who had these reactions, their suffering deserved to be acknowledged. From the tension within the government and the reluctance from companies to share information, progress was stalled on how to help these families while maintaining a stable vaccine supply. In the coming months, Representative Waxman from the Congressional hearing would play an increasingly important role in addressing these unanswered questions.

⁶⁶ U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 312.

⁶⁷ Associated Press, "Drug Firms Seek Exemption: DPT Vaccine Supply Tied to Shelter From Liability," *The Washington Post* (Washington D.C.), Dec 20, 1984, <http://ezproxy.cul.columbia.edu/login?url=https://search.proquest.com/docview/138138599?accountid=10226>.

Chapter Three **The Solution to the DPT Crisis?**

In a House Committee hearing on December 1984, the Vice President of Lederle Laboratories cut straight to the heart of the DPT vaccine shortage problem by stating, “I think I can say that if the Government took on that responsibility, there would be a significant reduction in the current cost of DTP vaccine.”⁶⁸ “That responsibility” he referred to was the liability for adverse reactions to vaccines. Up to this point, DPT vaccine manufacturers were drowning in lawsuits, forced to claim responsibility for injuries caused by an inherent risk in their product. The 1984 hearing left the government struggling with how to solve a complicated problem. Lawsuits left the country with an unreliable and quickly diminishing supply of vaccines, pertussis rates were increasing, and the public was growing more fearful about the risks of vaccination.

Against this uncertain and urgent backdrop, the National Childhood Vaccine Injury Act of 1986 (NCVIA) was born. The Act was the culmination of years of unexpected and unprecedented cooperation between groups of clashing stakeholders, including Congressmen, parent groups, medical associations, and vaccine manufacturers. The government has a responsibility to operate fairly between citizens and corporations, and the passing of the NCVIA demonstrated the complexities and hardships involved in striking this balance. The NCVIA was an example of cooperation that created a hopeful precedent for approaching future polarizing issues; however, the vaccine compensation program that resulted from this bill was imperfect. Though it could be argued that the government succeeded in addressing the DPT vaccine

⁶⁸ U.S. Congress, House of Representatives, A Bill to Amend the Public Health Service Act, 306.

problem, the lingering question of who should be responsible for vaccine injuries was deftly avoided.

In December 1984, the U.S. Centers for Disease Control and Prevention (CDC) announced a nationwide shortage of the DPT vaccine and recommended that physicians begin rationing their doses. Physicians raised alarms about this recommendation, fearing that under-vaccinated children would pose a risk to themselves and vulnerable members of the population. These fears proved to be warranted when outbreaks of pertussis (whooping cough) began increasing the next year. In 1985, the CDC reported over 3,500 cases of pertussis, compared to 2,200 cases in 1984.⁶⁹ For 1984 and 1985 combined, 70 percent of the reported cases were not properly vaccinated against pertussis.⁷⁰ In November 1985, newspapers began reporting on whooping cough outbreaks throughout the country. *The Chicago Tribune* described the outbreaks as “near-epidemic levels,” with the incidence rate “almost double that in 1982.” The article attempted to convince readers that the risks of damage from pertussis outweighed those of the vaccine, but also acknowledged the difficult choice many parents faced: “Even if the odds favor immunization by at least 10 to 1, even if the chances are remote that any given youngster will suffer permanent damage from the vaccine, that’s not assurance enough.”⁷¹ Calls for a safer DPT vaccine were becoming more urgent in the media, but with the slow pace of vaccine research and lack of funding, the country needed a more immediate solution.

⁶⁹ Centers for Disease Control and Prevention, “Pertussis (Whooping Cough),” August 7, 2017, <https://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html>.

⁷⁰ Centers for Disease Control and Prevention, “Epidemiologic Notes and Reports Pertussis Surveillance – United States, 1984 and 1985,” *Morbidity and Mortality Weekly Report*, March 12, 1987, <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000893.htm>.

⁷¹ Joan Beck, “Whooping cough strikes again,” *Chicago Tribune* (Chicago, IL), Nov 14, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/170722934?accountid=10226>.

On the vaccine manufacturer side, some positive changes took place. Connaught Laboratories, which was forced to stop distributing the DPT vaccine due to insurance complications, announced its return to the market. In April 1985, the company restarted widespread distribution of the vaccine, joining Lederle Laboratories and easing the nation's shortage.⁷² This should have been an upward swing in the battle to stabilize the vaccine supply, but Connaught's return did not stop the stream of litigation filed against the manufacturers. By 1986, both Lederle and Connaught were in danger of once again losing their private insurance. The president of Lederle announced that the company would lose its coverage in the summer, and to prepare for the possibility of self-insurance, they planned to drastically increase the price of their DPT vaccine. Lederle was the main supplier for physicians and private practices, which meant that the price patients paid at the doctor's office would increase as well. Government officials predicted that Connaught, the main government supplier, would soon follow Lederle in hiking up their vaccine prices.⁷³ With the threat of DPT vaccines becoming inaccessible and rising rates of pertussis, there was more pressure than ever to find a solution to the DPT problem.

Amidst outbreaks and looming shortages, key players from the government emerged to address the DPT problem. Representative Henry Waxman (D-CA), Senator Paula Hawkins (R-FL), and Senator Orrin Hatch (R-UT) contributed significantly to the ultimate passage of the NCVIA. Representative Waxman and Senator Hawkins, though they served opposing parties, were both passionately involved in solving the DPT issue early on. As the Chairman of the House Committee on Energy and Commerce, Representative Waxman led the hearing in

⁷² Jay Siwek, "Colicky 2-Month-Old, PMS, Herpes and Newborns," *The Washington Post* (Washington D.C.), May 15, 1985, <http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/138695584?accountid=10226>.

⁷³ Cristine Russell, "Firm Will Early Triple Price of DPT Vaccine: Lederle Blames Liability Problems," *The Washington Post* (Washington D.C.), May 21, 1986, <http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/139026083?accountid=10226>.

December 1984 that investigated the reasons for the vaccine shortage. In addition, both Congressmen drafted bills that year that proposed solutions to the shortage and issues of compensating victims, which served as the framework for the final version of the NCVIA. Senator Hatch did most of the legwork and networking necessary to get the bill through Congress. He was also the Chairman of the Senate Committee on Labor and Human Resources, which reviewed Senator Hawkins' bill in a Congressional hearing. As part of a strategy to get the Act past President Ronald Reagan, Representative Waxman, Senator Hatch, and two other Congressmen combined their legislation into what was eventually named the State Comprehensive Mental Health Services Plan Act. Through bipartisan cooperation and stubborn determination, these three Congressmen played vital roles in creating the vaccine court.

Getting the bill on President Reagan's desk was a matter of teamwork and a great deal of compromise. In *Lawyers, Lawsuits, and Legal Rights: The Battle Over Litigation in American Society*, Thomas Burke provided a broad and comprehensive overview of the series of proposals and bills that eventually became the NCVIA. As soon as it became clear that there would be DPT shortages in 1984, Representative Waxman and Senator Hawkins became two of the most vocal Congressmen about stabilizing the supply. The first relevant piece of legislation from this pair introduced in April 1985 was coined the "Hawkins-Waxman Bill." Hawkins introduced this bill to the Senate as S. 827 National Childhood Vaccine Improvement Act of 1986.⁷⁴ This gave plaintiffs a choice between the no-fault vaccine court and the normal tort system. The no-fault system would be funded by taxes placed on vaccines and once plaintiffs chose a path, they were locked into the system. Burke pointed out that vaccine makers were "unimpressed" with the bill and criticized the preservation of the tort option. In addition, the bill created a lose-lose situation

⁷⁴ Thomas F. Burke, *Lawyers, lawsuits, and legal rights: the battle over litigation in American society* (Berkeley: University of California Press, 2002), 150.

for the manufacturers: “they would be paying a surtax to support the compensation program, but they would still be faced with the threat of unpredictable tort verdicts as well.”⁷⁵ Later on, three new bills were submitted to the House of Representatives, one of which was from Representative Waxman. H.R. 5184 National Childhood Vaccine Injury Act of 1986 differed significantly from other proposals because it favored the demands of the vaccine manufacturers. The bill “required parents to file first with the no-fault compensation system” and they “could commence a tort lawsuits only after receiving a final judgement in the no-fault system.”⁷⁶ In this version, Waxman succeeded in getting vaccine manufacturers on board, but parent groups were strongly opposed to the protections granted to the industry. The desires of these stakeholder groups were on opposite sides of the spectrum, and it was clear through the subsequent Congressional hearings that major compromises would need to be made to appease everyone involved.

On July 18, 1985, the Senate Committee on Labor and Human Resources held a hearing to review S. 827 or the Hawkins-Waxman Bill. Through collaboration between parent groups and the American Academy of Pediatrics (AAP), S. 827 favored plaintiffs’ ability to choose and maneuver between a no-fault compensation system and typical tort litigation. Senator Hatch facilitated the testimonies as the committee Chairman, and Senator Hawkins was present on the committee as well. They heard testimonies from several important stakeholders regarding the bill proposal, including representatives from Dissatisfied Parents Together (DPT), Lederle Laboratories, Connaught Laboratories, the American Academy of Pediatrics (AAP), and the Department of Justice. Senator Hatch opened the hearing by encouraging an attitude of openness and collaboration. He emphasized the need for communication between parties and spoke highly of each organization present at the meeting. This may have been the Senator’s way of appealing

⁷⁵ Burke, *Lawyers, lawsuits, and legal rights*, 151.

⁷⁶ *Ibid.*, 153.

to each group's good graces, but nevertheless he seemed to be successful in easing some tensions. The Chairman began:

The question of assuring an adequate supply of safe and effective vaccines has to be dealt with. In part, this is going to mean dealing with the issue of unpredictable liability claims against manufacturers. I believe we will hear more than one solution to this particular problem proposed this morning. All approaches must be considered and judged on their own merits.⁷⁷

In his opening remarks, Chairman Hatch established that the hearing was investigative in nature. At this point, several solutions had been proposed in addition to S. 827, and the goal was to weigh these options and hear from some of the most vocal groups involved in the vaccine supply issue. S. 827 did not pass the Senate, but this hearing allowed these groups to clearly state their positions on what should be done about the DPT vaccine.

The parents from the group DPT came into the hearing with a tactical advantage: each brought a tragic and emotional story to tell the committee. Throughout the vaccine crisis, their most effective tool for gaining supporters was to overemphasize adverse reactions. This hearing was no different, and with devastating stories of loss, DPT communicated their goals for a federal compensation program. Denise Judd, head of the Utah branch of DPT, summarized the organization's opinions with this statement:

All we want is justice. We want you to do something to help us make our baby's death, and the death and vaccine injuries of so many other children, mean something. Don't pass a bad compensation bill that takes away a parent's freedom to go to court or that unjustly limits compensation in the court system. That is not justice.⁷⁸

S. 827 was co-authored by Dissatisfied Parents Together, and the strength of their emotional appeal earned the support of many Congressmen sitting in the room that day. Mrs. Judd's son

⁷⁷ U.S. Congress, Senate, Committee on Labor and Human Resources, S. 827 To Amend the Public Health Service Act to Provide for the Compensation of Children and Others Who Have Sustained Vaccine-Related Injury, and for Other Purposes, 99th Congress, 1st session, Jul 18, 1985, 3.

⁷⁸ *Ibid.*, 30.

died after receiving his first dose of DPT vaccine, and her story made it extremely difficult to argue against granting parents like her the freedom to seek justice for their children.

The vaccine manufacturers did not have emotional appeal in their testimonies, but they commanded attention because they held the DPT vaccine supply in their hands. Robert Johnson, president of Lederle, threw the company's support behind a bill that was introduced in the House of Representatives. Johnson supported this alternative proposal because it provided the greatest amount of security for vaccine makers. In his statement, Johnson emphasized that the alternative bill established a "ceiling on the awards that can be granted to persons who claim to have been injured by vaccines, a limit that is high enough to care for even acutely injured persons, but also gives reasonable predictability for manufacturers and health care providers."⁷⁹ David Williams, vice president of Connaught, stepped forward next to discuss Connaught's position. Williams, like Johnson, prioritized the predictability of a vaccine compensation system. However, Connaught was not in support of either S. 827 or the bill Lederle backed. Williams testified that "the current pending legislation...while a step in the right direction, do not go far enough to permit an indefinite, continued supply of vaccines at a reasonable price, isasmuch as both pieces of legislation provide for an alternative remedies under the tort system."⁸⁰ In this hearing, Connaught took the most extreme stance of the vaccine manufacturers by insisting that tort litigation should not be an option for plaintiffs. The main concern for vaccine makers was security, and neither company believed that Hawkins' S. 827 bill was the right solution.

The AAP's testimony was perhaps the most surprising of the Senate hearing. As an association of physicians, the AAP was aware of the precariousness of the vaccine supply. Their practices and hospitals would have been the first affected by price changes and vaccine

⁷⁹ U.S. Congress, Senate, Committee on Labor and Human Resources, S. 827, 240.

⁸⁰ *Ibid.*, 265.

shortages. It would have been in their and their patients' best interest to follow Lederle and Connaught's lead during this hearing. However, the AAP went in the opposite direction. Dr. Martin Smith, vice president of the Academy, stated these priorities:

The academy has tried to judge these proposals according to two criteria: First, does it provide a better and more prompt form of justice for children than is presently available. This is the first and the most important criterion. Second, does it create an improved environment that will allow continual production of vaccine...⁸¹

The Academy's first and most important priority was to ensure that individuals with adverse reactions could receive compensation, placing them squarely on the side of parent groups in this hearing. This went directly against much of the messaging that the medical community was using, which was to emphasize that adverse reactions only occurred in a small fraction of the population and the country's health was more important than individual health. Their biggest concern at the height of the DPT vaccine shortage was the effect that under-vaccinating children would have on the country's immunity. By advocating for parent groups like DPT, which had encouraged people not to vaccinate their children, the AAP effectively opposed the medical community's message. In this case, the Academy chose to prioritize individuals over the health of the population.

On July 25, 1986, Representative Henry Waxman's Committee convened to discuss House proposals to solve the DPT problem. Waxman's H.R. 5184 was among the options, and in his opening statement, he revealed his strategy for creating a vaccine court:

I recognize that the bill I have introduced is probably not the first choice of most parties to this controversy. Manufacturers would undoubtedly prefer greater insulation from liability. Parents of injured children would certainly prefer larger compensation and fewer restrictions on court activity. The Reagan administration would, I am sure, prefer legislation that spends no money. But this bill is an attempt

⁸¹ U.S. Congress, Senate, Committee on Labor and Human Resources, S. 827, 323.

to craft the best possible compromise among these positions, one that will care for injured children and maintain an adequate supply of vaccine.⁸²

H.R. 5184 did not make it past the Senate floor, but Representative Waxman's emphasis on compromise carried through to the final version of the NCVIA. He succinctly and accurately identified the priorities of all the stakeholders and drafted a bill that he hoped would be "everybody's second choice."⁸³

The final version of the NCVIA was the result of months of Representative Waxman's "shuttle diplomacy" among vaccine manufacturers, physicians, and parent groups. Broadly, the bill created a no-fault compensation system that plaintiffs were required to enter first before considering tort litigation. The bill granted protection measures to vaccine makers in tort lawsuits and made them immune to liability if their vaccines complied with federal standards. However, plaintiffs were allowed to enter tort litigation early if they could prove that manufacturers "failed to exercise due care."⁸⁴ Several amendments and compromises had to be made by all parties, but in the end, all agreed on Representative Waxman's proposal. The final hurdle was getting the bill through President Reagan.

Staunchly against the mere idea of a no-fault system, President Reagan stated that there was "no compelling evidence that the existing method of compensating victims through the tort system was inadequate" and criticized the program for being too generous to the plaintiffs.⁸⁵ Knowing this, Representative Waxman formed a coalition with the other three ranking leaders of health-related committees in the House and the Senate. The four Congressmen decided to

⁸² U.S. Congress, House of Representatives, Committee on Energy and Commerce, H.R. 1780, H.R. 4777, and H.R. 5184 Bills to Amend the Public Health Service Act to Establish a National Vaccine Program for the Development of New Vaccines, the Improvement of Existing Vaccine Compensation to the Victims of Vaccine-Related Injuries and Deaths, to Ensure the Supply of Childhood Vaccines, and for Other Purposes, 99th Congress, 2nd session, Jul 25, 1986, 2.

⁸³ Burke, *Lawyers, lawsuits, and legal rights*, 152.

⁸⁴ *Ibid.*, 154.

⁸⁵ *Ibid.*, 151.

package the vaccine compensation bill with four other provisions, creating a piece of legislation that everyone could support. The final bill was S. 1744 State Comprehensive Mental Health Services Plan Act of 1986. The Act included a bill that allowed domestic pharmaceutical manufacturers to sell drugs internationally, which the Reagan administration strongly supported. Another provision was a new Alzheimer's disease initiative, as well as a bill that made it easier to report physicians' medical malpractice lawsuits. The final act was a repeal of a federal health planning law, which Reagan and Senate Republicans had been targeting.⁸⁶ S. 1744 was a brilliant move that reduced much of the opposition to the vaccine program, but Senator Hatch lobbied tirelessly on the day of the Senate vote to gather the last of the necessary support. On October 18, 1986, S. 1744 passed the Senate and landed on President Reagan's desk.

The nation and the media were split on whether Reagan should sign S. 1744. One article in *The Wall Street Journal* was against the bill, arguing that a state-by-state approach instead of federal action was "a more sensible approach to the problem."⁸⁷ *The New York Times* took the opposing stance, commending the "Waxman Bill" for benefitting all stakeholders and pointing out that the legislation was supported by both vaccine manufacturers and parent groups, two parties continuously at odds with each other.⁸⁸

Despite the controversy, under pressure from parent groups, physicians, and vaccine makers, President Reagan signed S. 1744 into law on November 14, 1986. Regarding the vaccine compensation provision, President Reagan made this statement:

I do have serious reservations about title III of S. 1744, which creates the framework for a vaccine injury compensation program and a national vaccine

⁸⁶ Burke, *Lawyers, lawsuits, and legal rights*, 155.

⁸⁷ "Vaccine Bill is Bad Medicine," *Wall Street Journal* (New York, New York), Oct 24, 1986, <http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/135235186?accountid=10226>.

⁸⁸ "Help for Vaccine Victims and Makers," *The New York Times* (New York, New York), Oct 2, 1986, <http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/110979194?accountid=10226>.

program. Title III would establish a court-administered program to compensate persons who suffer an injury as a result of receiving a childhood vaccination. Although the goal of compensating those persons is a worthy one, the program that would be established by title III has serious deficiencies.⁸⁹

President Reagan was hesitant about the structure and funding of a no-fault vaccine compensation program, and many of his concerns were valid. The Act passed with no funding provision, and Representative Waxman would not be able to secure funding until two years later. However, the work that went into creating the NCVIA demonstrated a rare occurrence of collaboration between parties that held opposite beliefs, and the vaccine court program that resulted from this Act succeeded in its mission to stabilize the vaccine market.

In a recent email exchange with Representative Waxman, he explained briefly why he was so passionate about passing the NCVIA: “My biggest motivation for the National Childhood Vaccine Injury Act was to give confidence to the vaccine manufacturers that they would not be bombarded with lawsuits they would have to defend, when on very rare occurrences, a child was injured by a vaccine.”⁹⁰ The vaccine compensation program did stabilize the DPT vaccine supply, but parent groups remained unsatisfied. In 2008, president of Dissatisfied Parents Together Barbara Loe Fisher made this statement regarding the compensation program:

[...] Many parents I have spoken with maintain that the Vaccine Injury Compensation System is a failed experiment in tort reform that should be repealed. They believe the vaccine injured should be able to return to the courts, where discovery is allowed, to sue vaccine manufacturers for design defect and failure to warn and sue pediatricians who carelessly implement one-size-fits-all vaccine policies rather than adhere to the precautionary principle to “First, do no harm.”⁹¹

⁸⁹ Ronald W. Reagan, “Statement on Signing the State Comprehensive Mental Health Plan Bill, Nov 14, 1986, <https://www.reaganlibrary.gov/research/speeches/111486e>.

⁹⁰ Henry A. Waxman, e-mail message to author, March 3, 2020.

⁹¹ Barbara Loe Fisher, “The Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform?” Nov 18, 2008, <https://www.nvic.org/injury-compensation/vaccineinjury.aspx>.

Over two decades after the Act's passage, the conflict still raged over who should be held responsible for vaccine injuries. The no-fault solution left parents with no one to blame, and plaintiffs were frustrated by a system that protected the people they believed were responsible for their children's injuries.

Though the government aimed to balance between public and private interests, in the end, choices had to be made. Was it more important to secure the vaccine supply for the country or get justice for the tragedies of individuals? Ultimately, the government was, and continues to be, responsible for the lives of millions. In its implementation, vaccine court was a solution designed to appease manufacturers, not necessarily the plaintiffs. At the end of the battle, there was no satisfying answer to the question of who was responsible for adverse reactions to the DPT vaccine. According to the government's no-fault court, the answer was: no one.

Conclusion

After President Reagan signed the National Childhood Vaccine Injury Act in 1986, nothing happened. It took two years for Congressman Waxman and his supporters to secure enough funding to establish the new court system described in the bill. Officially established in 1988, the Vaccine Injury Compensation Program (VICP) operates under the U.S. Department of Health and Human Services. The VICP, also known as vaccine court, provides compensation to individuals who have experienced certain adverse reactions from specific vaccines within a particular timeframe. In other words, the court uses a document called the Vaccine Injury Table to guide decisions about which plaintiffs qualify for compensation, as well as how much they can receive from the tax-funded trust fund.⁹² When the VICP was first established, adverse reactions to the DPT, MMR, and polio vaccines listed in the Vaccine Injury Table encompassed a generously wide range of permanent disabilities and causes of death. As a result, the first few years of the VICP were characterized by hundreds of families receiving compensation with little to no adversity.⁹³

As research caught up with policy in the United States, government officials began to realize that the piece of legislation that created vaccine courts did not plan for an easy way to make changes to the Vaccine Injury Table. In her book about the legal basis for vaccine courts, Anna Kirkland wrote, “The vaccine court was cobbled together to solve an immediately pressing problem without much consideration of its long-term operation.”⁹⁴ A years-long battle ensued to make adjustments to the Vaccine Injury Table and the procedures of the court. In 1995, after

⁹² Health Resources & Services Administration. “Vaccine Injury Compensation Program,” Jan. 2020, <https://www.hrsa.gov/vaccine-compensation/index.html>.

⁹³ Anna Kirkland, *Vaccine Court: The Law of Politics and Injury* (New York: New York University Press Scholarship Online, 2017), 73.

⁹⁴ *Ibid.*, 76.

overwhelming evidence was collected from research studies, the Vaccine Injury Table was revised to exclude seizure disorders from the list of possible adverse reactions to the pertussis component of the DPT vaccine.⁹⁵

One of the main arguments in this thesis was that the DPT crisis in the United States was not about science, but about the perception of risk. Regardless of the scientific evidence, people were convinced that the pertussis component of the DPT vaccine would harm their children. The people driving the misinformation campaign about the DPT vaccine were not villains or outcasts—they were parents. They feared for their children’s lives and did everything in their power to spread what they thought was the truth. Were parents and advocacy groups wrong about the risks of the DPT vaccine? Yes, the DPT vaccine did not cause the neurological damage or seizure disorders that many anecdotes claimed. These groups created panic and fear that reached up to the levels of industry and government; they took advantage of the justice system to bankrupt vaccine manufacturers and created a national shortage. The federal government, under the direction of a few individual Congressmen, needed to step in to address a public health emergency that was created from public panic, but the solution they implemented also succeeded in validating misinformed beliefs. It took seven years from the establishment of vaccine courts in 1988 to the removal of seizure disorders from the Vaccine Injury Table for those beliefs to be disproven.

The story of the DPT crisis and the creation of vaccine courts in the 1980s was about fear and responsibility, but also about the role of science in healthcare policy. Vaccine court legislation was passed and implemented long before the science was available to support it. This

⁹⁵ Offit, *Deadly Choices*, 31.

was in response to a misinformed, but overwhelming call-to-action from the American public to the federal government. Facing a public health emergency, a national vaccine shortage, government officials needed to make compromises and act quickly to address the problem. Vaccine courts were not the perfect solution to the DPT crisis, leaving unanswered questions about responsibility and accountability for vaccine injuries. Congressman Waxman wrote this as a response: “The bill is no one’s first choice...but almost everyone agrees that the compensation bill is better than the current situation. No one wants to return to the terrors of epidemics of crippling and killing disease.”⁹⁶

Over three decades later, the world is facing an epidemic of crippling and killing disease: COVID-19. Writing about misinformation and the perception of risk during this pandemic certainly hits home. In an environment where fear was the primary emotion and thousands were dying every day around the world, many state governments made the decision to place their citizens under lockdown and cease daily life. While this decision was made based on informed experiences from other countries and lessons from past pandemics, very little was known about COVID-19 itself. Progress in infectious disease research is usually measured in years, not months or weeks; new research about how the virus is spread, what effect it has on the body, and who is at risk seems to be published every day. With many facing unemployment and lack of access to food and necessities, it can be difficult to understand why governors have implemented such drastic measures, and discussions about the need to “open the country up” appear often.

⁹⁶ Henry A. Waxman, “When a Vaccine Injures a Child: A no-fault way to compensate,” *The Washington Post*, (Washington D.C.), Oct. 9, 1986.
<http://ezproxy.cul.columbia.edu/login?url=https://search-proquest-com.ezproxy.cul.columbia.edu/docview/138780218?accountid=10226>.

Amidst an overwhelmed health system and public demands for a return to normal life, news networks, drug companies, and politicians have fixated on one solution: a COVID-19 vaccine. In early April, the World Health Organization reported research on 62 potential vaccines in varying stages of research.⁹⁷ Articles and reporters discuss the progress towards a vaccine every day, and it seems like the world is holding its collective breath for the moment someone has a breakthrough. In a BBC article titled, “Coronavirus vaccine: when will we have one?” a COVID-19 vaccine was portrayed as the key to resuming normal life: “A vaccine would provide some protection by training people’s immune systems to fight the virus so they should not become sick. This would allow lockdowns to be lifted more safely, and social distancing to be relaxed.”⁹⁸

The situation today is the opposite of a vaccine controversy. The biggest concern is about implementing social distancing measures and developing a treatment or vaccine that will protect the population— thoughts about individual risk have been pushed aside. However, the DPT crisis demonstrated that just because a vaccine exists does not mean the problem has been solved. Once focus can shift back to the individual, the world may see the emergence of the same misinformation campaigns and public protest that have occurred with almost every vaccine invented. If public health and government officials do not remain vigilant, a COVID-19 vaccine may not be the solution to this pandemic, but the start of a larger problem.

⁹⁷ World Health Organization, “DRAFT landscape of COVID-19 candidate vaccines,” April 4, 2020, https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf?ua=1.

⁹⁸ James Gallagher, “Coronavirus vaccine: When will we have one?” *BBC News*, April 23, 2020, <https://www.bbc.com/news/health-51665497>.

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