

Chapter 2

History of Vaccine Concerns

Abstract Vaccine concerns date back to the eighteenth century during a time of smallpox epidemics in colonial America. Despite increased survival rates among those who were inoculated by variolation, opposition to this procedure was strong. Modern day vaccine fears were fueled by the Cutter Incident when incompletely inactivated polio vaccine was inadvertently administered to children resulting in significant morbidity and mortality. This incident was followed in the 1980s by the release of “*DPT: Vaccine Roulette*,” a television documentary that engendered fears about the DTP vaccine and galvanized the formation of a well-known anti-vaccine group, National Vaccine Information Center. Parental vaccine safety concerns were fueled by this group and further strengthened with the publication of a controversial paper by Dr. Andrew Wakefield in which he suggested that the MMR vaccine was linked to autism. Despite the retraction of this paper and the discovery that many of its findings were fraudulent, others joined the anti-vaccine movement, including actress Jenny McCarthy and Dr. Bob Sears. These outspoken individuals have influenced many parents by suggesting that parents choose non-scientifically based alternative vaccination schedules that delay or omit vaccines.

Keywords Anti-vaccine · Dr. Bob · Jenny McCarthy · Barbara Loe Fisher · Andrew Wakefield · Edward Jenner · Cutter Incident · Vaccines

2.1 The Birth of the Anti-Vaccine Movement

Concerns surrounding vaccines date back to the eighteenth century during a time when colonial America experienced epidemics of smallpox. When smallpox entered a colonial port city as many as 60% of residents became ill and an estimated 25% died (National Humanities Center 2009). During one of these outbreaks in 1721, Dr. Zabdiel Boylston inoculated 280 people by rubbing material from a smallpox sore to a small wound (Boylston 1726). This procedure was known as variolation. Boylston was met with strong resistance and soon there were two distinct groups—the “pro-inoculators” and the “anti-inoculators.” The pro-inoculators group included Boylston and two clergy—Cotton Mather and Benjamin Colmon. The anti-inoculators were led by Dr. William Douglass, founder of the New England Currant, and James Franklin, the older brother of Benjamin Franklin. The

Table 2.1 Fatality of natural and inoculated smallpox (Boylston and Williams 2008)

	Boston ^a		England ^b	
	Died	Survived	Died	Survived
Natural smallpox	844	4915	2848	19,303
Inoculated smallpox	6	276	13	611 ^c

^a Relative risk natural vs. inoculated smallpox: 6.9 (range 3.2–15) $p < .0011$

^b Relative risk natural vs. inoculated smallpox: 8.0 (range 4.7–13.6) $p < .0011$

^c Relative risk inoculated in Boston vs. England: 1.02 (range 0.4–2.6) $p > 0.9$

two groups publically shared heated exchanges in the Boston newspapers (National Humanities Center 2009).

In 1724, Boylston traveled to London where he published his findings on his work with smallpox inoculation (Boylston and Williams 2008). The findings were remarkable (Table 2.1). Boylston demonstrated that those in Boston who were not inoculated against smallpox had nearly 7 times the risk of dying from the disease and those in England who were not inoculated had 8 times the risk of death from smallpox (Boylston and Williams 2008).

Concerns about inoculations continued in England when Edward Jenner demonstrated that infecting a person with material from a cowpox blister could protect them from smallpox. His ideas were also met with strong opposition. At the time many people found the theory that intentional disease exposure could make a person healthier counterintuitive. Many believed it to be a violation of God's will because it changed the course of natural events. There were also fears that the vaccine itself would cause the disease and potentially death. Lastly, some opposed the idea of vaccination because of the belief that it violated their personal liberties. This opposition only increased as the British government implemented mandatory vaccination policies (Hammond et al. 2013).

In 1853, the British government passed a bill requiring all children to be vaccinated against smallpox by 6 months of age. Parents who failed to comply faced heavy fines or imprisonment. As a result, the first anti-vaccination movement was born. Richard, George, and John Gibbs founded the Anti-Compulsory Vaccination League in 1866 and the movement grew quickly with more than 200 anti-vaccination leagues formed in the following 30 years. The anti-vaccination movement in England was organized, strong, and sometimes violent. As a result of this movement, the British government passed a conscientious objection law in 1898. Soon after, immunization coverage rates drastically decreased as more than 200,000 certificates of conscientious objections were issued. Interestingly, however, Ireland and Scotland did not experience similar resistance, and subsequently saw a drastic reduction in smallpox, whereas England continued to experience high morbidity and mortality from the disease (Offit 2011).

2.2 The Cutter Incident

One concern about vaccines that has persisted throughout history is the perceived lack of safety. Unfortunately, the idea that vaccines could be unsafe was highlighted during the manufacturing of the polio vaccine. On the heels of one of the most significant public health achievements came one of the worst biological tragedies in the USA—the Cutter Incident. Cutter Laboratories was a small, family-owned pharmaceutical company in Berkeley, California that was licensed to produce Jonas Salk’s polio vaccine. After years of scientific effort, Dr. Salk developed an inactivated polio vaccine. During the rush to mass produce the vaccine, Cutter laboratories released for administration several lots of vaccine in which the poliovirus was not fully inactivated but rather contained live, active poliovirus. 120,000 children were subsequently exposed to live, active poliovirus upon vaccination. Of those who received the vaccine, 70,000 suffered mild polio, 200 were permanently paralyzed, and 10 died. The company’s error resulted in one of the worst pharmacologic disasters in US history and laid the groundwork for distrust in the pharmaceutical industry (Offit 2005, 2011).

2.3 The Twentieth Century Anti-Vaccine Movement

On April 19th, 1982, a NBC affiliate in Washington D.C. aired “*DPT: Vaccine Roulette*,” a one-hour documentary featuring the stories of children whose parents believed had been harmed by the DPT vaccine. DPT, also known as DTP, was a vaccine that protected against diphtheria, tetanus, and pertussis. Lea Thompson wrote, produced, and starred in the documentary which focused on the pertussis component of the vaccine. “*DPT: Vaccine Roulette*” featured vivid images of children with mental retardation, seizures, and other intellectual and physical disabilities. It also shared opinions from physicians who supported the belief that the DPT vaccine was unsafe and harmful. One physician, Dr. Robert Mendelsohn, stated “It’s probably the poorest and most dangerous vaccine that we have now, [and] the dangers are far greater than any doctors have been willing to admit” (Offit 2011).

“*DPT Vaccine Roulette*” continued to make waves across the USA. It aired twice more in Washington D.C. as well as on NBC’s *The Today Show*. Stories from the film were featured in magazines and newspapers across the country. One of the viewers was Barbara Loe Fisher. Fisher believed that her son had been irreparably harmed after receiving his fourth dose of DTP. Soon after the airing of “*DPT: Vaccine Roulette*,” Fisher and others formed “Dissatisfied Parents Together (DPT).” “Dissatisfied Parents Together” later became the well-known anti-vaccine group, the National Vaccine Information Center (NVIC), which remains a major source of vaccine misinformation in the USA. Fisher has been a fierce and unrelenting advocate and spokesperson for parents with vaccine concerns. Since the formation of

DPT and NVIC, she has voiced her concerns as the author of “*A Shot in the Dark: Why the P in the DTP Vaccination May Be Hazardous to Your Child’s Health.*” Due to her influence in print and television media, she shaped many parents’ beliefs about vaccines and raised nationwide interest in vaccine safety. In the years following the airing of “*DPT: Vaccine Roulette*” and the publication of “*A Shot in the Dark,*” thousands of parents refused receipt of DPT. Moreover, vaccine manufacturers were suddenly flooded with personal injury lawsuits, which forced many companies to stop producing vaccines and led Congress to pass the National Childhood Vaccine Injury Act. This Act provided protection for vaccine manufacturers against litigation for vaccine injury and ensured the stability of the US national vaccination program (Offit 2011). An example of an early interview with Ms. Fisher on ABC’s *The Morning Show with Regis Philbin* can be found at the following link (<http://www.youtube.com/watch?v=-2b0-hMGm-o>).

2.3.1 Andrew Wakefield

In 1998, Andrew Wakefield and colleagues at the Royal Free Hospital and School of Medicine in London published a case report of twelve children with ileal-lymphoid-nodular hyperplasia, non-specific colitis, and regressive developmental delay. This publication proposed that the MMR vaccine caused a series of events that included intestinal inflammation, loss of intestinal barrier function, entrance of encephalopathic proteins into the bloodstream, and subsequent development of autism. The intestinal biopsy findings in the twelve children supported his hypothesis (Wakefield et al. 1998). This paper was the nidus for a substantial increase in parental vaccine concerns, especially surrounding the MMR vaccine. Rates of MMR vaccine uptake decreased precipitously in England and measles outbreaks subsequently occurred throughout the United Kingdom.

Wakefield’s paper triggered a flood of research that evaluated the theory that the MMR vaccine caused developmental delays, primarily autism. Following Wakefield’s publication, numerous studies were conducted that compared groups of children who did and did not receive the MMR vaccine; no differences between the groups were identified (Taylor et al. 1999, 2002; Peltola et al. 1998; Dales et al. 2001; Farrington et al. 2001; Kaye et al. 2001; Madsen et al. 2002). In addition, in 2004, the Institute of Medicine reviewed the body of literature and found that the “evidence favors rejection of a causal relationship between the MMR vaccine and autism” (National Research Council 2014).

Wakefield’s findings were later discovered to be fraudulent. In 2011, the investigative journalist Brian Deer summarized his inquiry into Wakefield’s study in a series of articles published in the *British Medical Journal*. Through extensive interviews and research, Deer was able to uncover many concerning aspects of Wakefield’s work. Deer’s findings included the following: (1) the researchers failed to obtain institutional review board approval for the study; (2) study participants were recruited by an anti-vaccine group; (3) all of the children’s medical histories were

found to be misreported or altered; and (4) 8 months prior to the paper's publication Wakefield submitted a patent for a measles vaccine. Deer also discovered that Wakefield was retained by a personal injury lawyer representing several families who believed the MMR vaccine caused their child's autism and were suing pharmaceutical companies. The study was funded by the personal injury lawyer who referred his clients to Wakefield for participation with the intention of creating a case against the vaccine manufacturers. Soon after this information was released, ten of the thirteen authors withdrew their names from the paper (Offit 2011; Deer 2011).

In 2010, the *Lancet* formally retracted Wakefield's paper. Moreover, England's General Medical Council, the organization responsible for the licensure and registration of medical practitioners in the United Kingdom, found Andrew Wakefield guilty of multiple counts of dishonesty and stated that he had acted with "callous disregard" when he caused children to undergo clinically unnecessary invasive medical procedures. Wakefield was struck off the medical register in England and is no longer able to practice medicine there (Offit 2011; Deer 2011).

Soon after the MMR-autism association was debunked, anti-vaccine advocates turned their attention to vaccine ingredients, primarily thimerosal. Thimerosal is an ethylmercury preservative used in vaccines and other medications that is known to not cross the blood-brain barrier. Even though no scientific evidence has shown it to be harmful, as a precautionary measure in 1999, the US Public Health Service, American Academy of Pediatrics (AAP), and vaccine manufacturers agreed to remove thimerosal from most vaccines (AAP 1999). Today, the only vaccine containing thimerosal is the multi-dose influenza vaccine. However, anti-vaccine groups continue to perpetuate the belief that thimerosal in vaccines caused autism or was harmful. As a result, numerous peer-reviewed studies were conducted that examined whether receipt of a thimerosal-containing vaccine caused autism and no link was found (Stehr-Green et al. 2003; Madson et al. 2003; Fombonne et al. 2006; Hviid et al. 2003; Verstraeten et al. 2003; Heron and Golding 2004; Andrews et al. 2004). Also, in 2004, the Institute of Medicine reviewed the body of literature and found that the "evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism" (National Research Council 2014).

2.3.2 *Jenny McCarthy*

Over the last decade, anti-vaccine sentiment has become a cultural phenomenon. While Barbara Loe Fisher initiated the parent-led movement in the 1980s, it wasn't until 2007 that it became mainstream with the arrival of actress Jenny McCarthy as a celebrity spokesperson.

Soon after her son Evan was diagnosed with autism, McCarthy became convinced that vaccines were the cause. In 2007, during an appearance on *Oprah*, Jenny McCarthy shared the story of her son's descent into autism and publically blamed vaccines. McCarthy stated, "Right before my son got the MMR shot I said to the doctor, 'I have a very bad feeling about this shot. This is the autism shot, isn't

it?’ And he said, ‘No! That is ridiculous. It is a mother’s desperate attempt to blame something on autism.’ And he swore at me. And then the nurse gave him that shot. And I remember going, ‘Oh, God, no!’ And soon thereafter I noticed a change. The soul was gone from his eyes” (Bratton 2011). Oprah followed with a response from the Centers for Disease Control and Prevention (CDC), which stated there was no science to support the connection between vaccines and autism. Jenny defiantly responded, “My science is Evan, and he’s at home” (Bratton 2011).

McCarthy subsequently appeared on *Larry King Live*, *Good Morning America*, and several other television shows during which she repeatedly shared her son’s story, criticized the public health and medical community, and lobbied against vaccines. Gradually McCarthy’s message shifted from blaming the MMR vaccine to criticizing all vaccines, claiming that they contained toxins and that the recommended vaccination schedule called for too many vaccines too soon in a child’s life. In 2008, McCarthy and then-partner, Jim Carrey, led a march and rally in Washington D.C. calling on medical and public health authorities to “green our vaccines” (Offit 2011). McCarthy’s high-profile campaign against vaccines generated a significant amount of doubt and distrust among parents towards vaccines, the effects of which are still being felt today.

2.3.3 Dr. Bob Sears

At the same time that Jenny McCarthy was rallying against vaccines across the USA, a pediatrician from southern California wrote a best-selling book that gave credence to many myths about vaccines and offered vaccine-concerned parents alternative approaches to vaccination. Bob Sears, MD, is the son of Robert and Martha Sears, creators of the *Sears Parenting Library*, who for decades have dispensed advice on pregnancy, labor and delivery, breastfeeding, and parenting (Offit 2011). Dr. Bob, as he prefers to be called, has become the medical spokesperson for the anti-vaccine movement. Sears states that he is trying to find middle ground between parents with vaccine concerns and a medical community that continues to adamantly emphasize the safety of vaccines and the importance of timely vaccination. Sears’ book, “*The Vaccine Book: Making the Right Decision for Your Child*,” is a collection of erroneous statements about vaccines, vaccine safety and efficacy, and vaccine-preventable diseases. Throughout his book, Sears minimizes the severity of vaccine-preventable diseases as well the susceptibility of under or unvaccinated children to these diseases. Moreover, he reinforces the practice of delaying or refusing vaccines so much so that he puts forth two vaccine schedules—Dr. Bob’s alternative vaccination schedule and Dr. Bob’s selective vaccination schedule. Both schedules modify the US recommended vaccination schedule; the alternative schedule delays specific vaccines until later ages whereas the selective schedule excludes the administration of some vaccines entirely (Sears 2011). The safety and effectiveness of these

alternative vaccination schedules has not been studied by Sears or any other investigator. As Paul Offit, MD, so eloquently states, “It’s...amazing when one considers that Robert Sears has never published a paper on vaccine science; never reviewed a vaccine license application; never participated in the creation, testing, or monitoring of a vaccine; and never developed an expertise in any field that intersects with vaccines—specifically, virology, immunology, epidemiology, toxicology, microbiology, molecular biology, or statistics. Yet he believes he can sit down at his desk and come up with a better schedule” (Offit 2011).



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