

“There are unanswered questions about vaccine safety. . . .
No one should be threatened by the pursuit of this knowledge.”

—Bernadine Healy, M.D., former director, National Institutes of Health (NIH),
and current health editor, *U.S. News & World Report*

VACCINE EPIDEMIC



**How Corporate Greed, Biased Science, and
Coercive Government Threaten Our Human
Rights, Our Health, and Our Children**

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Vaccine Epidemic

*How Corporate Greed, Biased Science, and Coercive Government
Threaten Our Human Rights, Our Health, and Our Children*

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Mary Holland

Center for Personal Rights, Inc., is a nonprofit organization founded to protect and advance personal rights, including the right to vaccination choice. Its cofounders and board of directors are Louise Kuo Habakus, Mary Holland, and Kim Mack Rosenberg. Mack Rosenberg and Ginger Taylor are contributing editors of this book.

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**To all who are asking the questions
and all who are demanding the answers.**

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On résiste à l'invasion des armées; on ne résiste pas à l'invasion des idées. "Greater than the tread of mighty armies is an idea whose time has come."

—*Victor-Marie Hugo, 1852, Histoire d'un Crime French novelist, statesman, human rights activist*

FOREWORD

Louise Kuo Habakus, MA, and Mary Holland, JD

Vaccination evokes strong opinions and emotions. Some are grateful and relieved to get vaccines. Others are angry and resentful about vaccination mandates. Many are caught in the middle—afraid, confused, and looking for the straight scoop. If you want to understand the real issues in the vaccination debate, read this book. Whether you are a parent, student, employee, soldier, or anyone else, you have a stake in this debate. No matter who you are, sooner or later you will wonder,

Should I get a vaccine?

Do I have a choice?

Who decides?

The vaccination debate has two distinct viewpoints, one “pro-vaccine” and the other “pro-choice.” The camps usually hurl the same insults at one another, characterizing the other side as irresponsible, dangerous, denialist, corrupt, and antiscience. Although this book favors vaccination choice and explains why, we attempt to objectively outline each basic view by setting derogatory labels aside.

THE PRO-VACCINE CAMP

The pro-vaccine camp strongly supports U.S. vaccination policy. Two new books published in early 2011 advance this position: Paul Offit's *Deadly Choices* and Seth Mnookin's *The Panic Virus*. These books join Arthur Allen's *Vaccine*, Susan Jacoby's *The Age of American Unreason*, and Michael Specter's *Denialism* in their critique of those who question vaccine safety. Here are their key arguments:

1. **Government officials are best qualified to make vaccination decisions.** Only government can ensure that a sufficiently high percentage of people vaccinate to preserve societal herd immunity.
2. **Vaccines are overwhelmingly safe and effective,** and the benefits vastly outweigh the risks. Adverse events are vanishingly rare.
3. **Science proves the benefit of vaccines beyond a reasonable doubt.** The science is in—vaccines are not responsible for any increase in common childhood health problems, including autism. They're safe and effective.
4. **Vaccine refusers are dangerous and selfish.** People who elect not to vaccinate are parasites. They are selfish, irrational, and threaten others with deadly disease.
5. **Only "false prophets" suggest that vaccines may cause disorders like autism.** Quack healthcare practitioners concoct unfounded treatments for autism and prey on vulnerable parents desperate for help. People should disdain and shun them.
6. **Vaccine exemptions should be abolished.** Dr. Offit and others suggest that states should abolish philosophical and religious exemptions. People abuse them and put others at risk. Because vaccines have been proven safe and effective, people have a social responsibility to vaccinate.

THE PRO-CHOICE CAMP

This book details the pro-vaccination choice perspective in law, religion, science, ethics, philosophy, and personal experience. Here are its key points:

1. **Vaccination choice is a human right.** Because vaccination poses a risk to life, liberty, and security of person, only an individual or guardian may decide how, when, and whether to vaccinate.
2. **Society as a whole benefits from the cumulative impact of free and informed individual healthcare choices.** The theory of herd immunity is not an adequate rationale for state compulsion to vaccinate.
3. **Vaccine safety science is flawed and incomplete.** The Institute of Medicine as well as informed scientists, doctors, and officials have repeatedly acknowledged that fundamental questions about vaccine safety remain unanswered.
4. **The U.S. vaccine program is rife with conflicts of interest.** Vaccines are big business and all of their promoters—pharma, government, medicine, and science—get their cut. The vaccine program does not put children’s safety first.
5. **Biomedical interventions are valid.** Considerable science and anecdotal evidence support biomedical interventions for autism spectrum disorders and other chronic conditions. These interventions include diet, vitamin and mineral supplementation, chelation, and gastrointestinal treatment. Individuals are entitled to the practitioners and remedies of their choosing.
6. **Vaccination exemption rights must expand, not contract.** Individuals have the right to free and informed consent for all medical interventions, including vaccination. In practice, not just in theory, individuals must have the right to make their own decisions.



As polarized as these camps are, we do share common ground. Both sides want a healthy, vibrant society. Both sides want responsible health policy grounded in ethics and science. Both sides see the vaccination issue as hugely important and seek to sway the public. Both sides are doing the work to understand each other’s analysis and arguments. Progress will not come from shadowboxing in our respective corners. It is now time for engagement and dialogue.

So, we invite the leaders of the pro-vaccine camp—in government, industry, and the professional medical associations—to publicly debate our different views. And, we invite the reader to read on.

Introduction

THE CASE FOR VACCINATION CHOICE

Louise Kuo Habakus, MA, and Mary Holland, JD

VACCINATION CHOICE IS A HUMAN RIGHT

Vaccine Epidemic addresses an issue of serious public concern for parents and all Americans. It builds the case that it is your right—not the government's—to decide whether to vaccinate yourself or your children. Only you, with your healthcare practitioner, can make the appropriate risk-benefit trade-off, and only you can be fully accountable for your choice, as with any other medical intervention.

All medical interventions, including vaccination, require free and informed consent. To abridge that right is to violate the essential human rights to life, liberty, and bodily integrity. By denying truly free and informed consent to vaccination, U.S. vaccine policy violates fundamental rights. This book brings together for the first time in-depth discussion of the ethical, legal, and scientific dimensions of the vaccination debate from the perspectives of those who insist on the right to decide.

VACCINES ARE EPIDEMIC

Starting on the day of birth, nearly all American children receive vaccines. The Centers for Disease Control and Prevention (CDC) recommends seventy doses of sixteen different vaccines between birth and age eighteen. The federal government recommends vaccines for adults too. It is the states, however, and increasingly private employers, that compel them. All fifty states mandate from thirty to forty-five doses of about a dozen different vaccines for admission to day care and school.

Public health officials proclaim that vaccines are safe and effective, but the truth is far more complicated. Vaccination is a serious medical intervention for healthy individuals against a disease that *might* occur. The decision whether to vaccinate has important, potentially life-altering ramifications. While vaccines protect some, they unquestionably harm and cause death to others. For government to compel a potentially life-threatening product sets vaccination apart from other medical procedures. Public health officials tell us that those who suffer adverse reactions are exceedingly few. The basis for such an optimistic claim is doubtful.

Science on vaccine safety is inadequate. There are no randomized controlled studies comparing the total health outcomes of the vaccinated versus the unvaccinated. Scientists do not know the cumulative impact of the childhood vaccination schedule. Vaccines are approved and licensed individually, yet the CDC recommends that doctors give multiple vaccines at once. Furthermore, the CDC recommends vaccines to populations for which there are no safety data, such as flu shots for pregnant women. Research confirms that fewer than 10 percent of doctors report adverse vaccine events. Even so, the Vaccine Injury Compensation Program has paid over \$2 billion in damages to more than 2,500 families since 1988.

Vaccines are *epidemic*—they have spread rapidly and extensively to almost all children and to many adults in the United States and around the world. In the 1800s and early 1900s, vaccines were a medical intervention of last resort during infectious disease outbreaks. In the last fifty years, however, governments have imposed multiple preventive vaccines on all children and some adults for the “greater good.” Today, vaccines and their advertisements are everywhere—from the doctor’s office to the Internet to the corner drugstore. The primary definition of an epidemic is a contagious disease that spreads rapidly. The Center for Personal Rights (CPR) does not suggest that vaccines are equivalent to disease. But it does suggest that vaccines are a widespread popular development. The book describes a modern *epidemic* of vaccines—recent, prevalent, and unprecedented in human history.

THE NO-CHOICE CHOICE

Governments, schools, employers, doctors, and officials concede that Americans have a choice about vaccination—but, in practice, they make that choice nearly impossible to exercise. There is pressure to begin vaccinating children literally from the moment of birth. Formally, all states honor medical exemptions from vaccination as the law requires. Further, forty-eight states recognize religious exemptions, twenty recognize philosophical exemptions, and some recognize exemptions for documented immunity (blood tests showing sufficient antibodies). Choice is honored in the breach, however. States punish doctors who grant “too many” medical exemptions, schools don’t inform parents that exemptions exist, and states impose vaccination on the unwilling through school exclusion and child removal.

Compulsory vaccination for schoolchildren, soldiers, and healthcare workers heightens the pressure to vaccinate all people for whom vaccines are recommended. It also reinforces the stigma for those who do not comply. Government and the medical profession exercise potent financial, legal, and social levers to ensure that people make the “right choice.” Should you wish to make the “wrong choice”—no day care, no public school, often no private school, often no access to your doctor. You even risk possible charges of child neglect and the threat of child removal. While in theory the country acknowledges the virtue of vaccination choice, in practice, it indulges the vice of coercive medicine. Renowned human rights scholar Louis Henkin understood: “hypocrisy is the homage that vice pays to virtue.” The U.S. vaccine program hypocritically gives lip service to choice while violating the fundamental principle of free and informed consent to medical intervention.

BASIC QUESTIONS ABOUT VACCINATION CHOICE

This book is for people who want to explore the basic question: Do I have a choice? From this simple question cascades a torrent of more difficult ones:

- Is it ethical for the government to compel individuals to accept medical procedures that could cause injury and death without free and informed consent?
- May the government legally withhold essential rights and privileges, such as a public school education, to induce vaccination compliance?
- What is the science for vaccine safety and efficacy?
- Are mandates ethical if people do not know they have choices?
- Is there a legal duty to protect those most at risk for vaccine injury?
- What ethical and legal responsibilities does society bear to compensate those injured?
- Should doctors and vaccine makers be shielded, as they are, from legal liability?

These are some of the challenging questions that this book addresses through the contributions of twenty-five authors—credentialed professionals and mainstream parents—who share their specialized expertise and personal experiences.

PART I: THE CASE FOR VACCINATION CHOICE

In Part I, we outline the essential components of the claim that all people are entitled to vaccination choice. The right is well-founded in human rights, civil rights, religious law, science, history, ethics, and philosophy. Mary Holland, lawyer and CPR cofounder, explains why vaccination choice necessarily implicates the rights to life, liberty, and security of the person. Sookyung Song places vaccination choice in the context of contemporary international human rights norms supporting free and informed consent for all medical interventions. Louise Kuo Habakus, CPR director and cofounder, assesses U.S. vaccine policy from a health and human rights perspective, finding that it comes up short.

Jim Turner, lawyer and health advocate, explores the civil rights dimension of the national vaccine program through the lens of the U.S. Constitution and the due process required to impose the death penalty. Holland and Robert Krakow, lawyer and disability rights advocate, address what happens when vaccines cause injury. They outline the remarkable liability protections the pharmaceutical industry and medical profession lobbied for and won in the 1986 National Childhood Vaccine Injury Act. They explain how, as a result of the act, the vaccine-injured and their families face unprecedented hurdles to obtain compensation. William Wagner, a law professor, considers vaccination choice as a parental right under the Constitution and religious law.

Carol Stott, an epidemiologist, and Andrew Wakefield, doctor and scientist, address the science—what we know, what we don't know, and what we appear not to want to know. Based on peer-reviewed science, they argue that the case for a link between vaccines and autism and other childhood health problems is robust and cries out for further research. They provide a primer on epidemiology and important guidance about the use of epidemiology to answer questions of causation.

Historian Robert Johnston writes about the critical role of dissent in a democracy. There is a long tradition of dissent from orthodox healthcare in the United States, including the advocacy movement that sprang up against coercive vaccine programs as early as 1721. Human rights advocate Vera Sharav illuminates what we know from painful historical experience: that any digression from humanitarian medicine with its commitment to “first, do no harm” is fraught with danger. She shows us examples not only from the Nazi past but also from contemporary U.S. medicine of doctors who caused grave harm for financial enrichment under the banner of “the greater good.” Sharav makes clear that current U.S. practice fails to honor human rights obligations. Only free and informed consent to vaccination, as to all medical interventions, fulfills medicine's Hippocratic oath.

Allen Tate discusses the utilitarian ethic that underlies all vaccine mandates. When we speak of the greater good, we invoke a higher moral authority claiming that we will benefit more people and save more lives. Nevertheless, there is an uncomfortable underside to the argument. Can we sacrifice one to save ten? Five to save six?

PART II: URSULA LE GUIN’S “OMELAS” AND ITS ECHOES

Ursula Le Guin’s award-winning parable, “The Ones Who Walk Away from Omelas,” asks the hard questions: What society do we want? What price for paradise? Faced with the bargain that is struck, would we walk away or stay? Linking to Tate’s discussion of utilitarianism, this fictional account forces us to choose.

Then we break the silence of vaccine injury to hear the echoes of Omelas. These personal accounts are by turns painful, heartbreaking, courageous, and hopeful. We hear from Gay Tate, Judy Converse, and Sonja Hintz, mothers who watched in agony as their babies suffered severe vaccine reactions. They have fought mightily, guided by professional and parental dedication, to heal their children and help others.

Tate and Converse express alarm at what is happening to children. How can there be no outcry against rising infant mortality and skyrocketing childhood diagnoses for attention deficit disorder, autism, learning disabilities, and asthma? How can it be that patients who go to doctors with vaccine injuries—Hintz, Tate, Pingel, Smith, Rovet, Converse—meet with denial and accusations that they are “faking it”? The people of Omelas owe their happiness to the child in the basement and they are profoundly grateful. In contrast, the U.S. government tells its citizens that they have an obligation to protect herd immunity while it denies the existence of vaccine injury. Instead of receiving gratitude, the vaccine-injured are scorned and called liars. What does this say about us?

Sonja and Alex Hintz describe Alex’s remarkable recovery from autism. Through biomedical interventions to address his medical conditions, Alex is now a neurotypical teenager. His recovery is cause for celebration and enormous optimism for the hundreds of thousands of young people with autism today. Alex is not alone—thousands of children on the autism spectrum have benefited from effective biomedical interventions. Yet conventional medicine rejects the efficacy of such approaches and challenges those medical practitioners who use them. The profession today is ostracizing and punishing practitioners, like Dr. Wakefield, who have pursued inconvenient truths and treatments, just as the establishment persecuted other revolutionary thinkers in their day.

Expanded vaccination recommendations and mandates increasingly place older children and adults at risk too. Amy Pingel recounts her teenage daughter’s devastating neurological damage after receiving the Gardasil vaccine against human papillomavirus. Lisa Marks Smith, a forty-eight-year-old mother, tells how she almost died after a routine flu shot from a local pharmacy. Richard Rovet, retired medic, nurse, and U.S. Air Force captain, who cared for hundreds of victims of the military’s experimental anthrax vaccine program, speaks out. His commanding officer, Colonel Felix M. Grieder, responds with a powerful afterword to Captain Rovet’s chapter. These deeply personal stories depict the extraordinary burdens vaccines have placed on some.

PART III: THE TOPICS IN DEBATE

Part III explores the exceptionally contentious terrain of the vaccination debate from the perspective of those who adamantly support choice. Michael Belkin, prominent investment analyst and parent of a newborn who died from a vaccine, explains how a corrupt market economy has shaped vaccine policy. Read about the “blowback” that is sure to follow today’s vaccine rage. All investment bubbles burst in time, and the vaccine bubble is no exception.

Ginger Taylor, contributing editor, examines government statements on vaccines and autism and the media’s failure to investigate them. When the government and media mislead the citizenry, true democracy no longer exists. Even though government and medicine would like to slam the book shut on this controversy, it is not going away.

Boyd Haley, former chair of the Department of Chemistry at the University of Kentucky, argues that thimerosal, the mercury-containing preservative, has played a key role in the autism epidemic.

Kim Mack Rosenberg, CPR cofounder and contributing editor, argues that child protective services sometimes label the choice not to vaccinate as “medical neglect” and seek child removal. She explains the rights families have.

Twila Brase, nurse and health freedom advocate, shows us that the specter of coercive medicine extends beyond vaccination. While it is possible that the pervasive genetic information gathered from infants may be used for good, it is equally possible that it may be used for ill. Only laws that protect and enforce medical ethics can guard against abuse.

In medicine, Sherri Tenpenny provides a doctor’s view of public health and challenges the belief that health must come through a needle. Annemarie Colbin, noted healthcare lecturer and author, assesses vaccines from a holistic health perspective. Children today are sicker than ever before, with chronic disabilities and nutritional disorders, yet few in mainstream medicine dare ask whether there might be a vaccine link. Habakus provides resources for the critical question, “What should parents do?” She summarizes the government’s position and eight books by leading physicians who span the spectrum of medical advice and offer recommendations about vaccination and the options that parents have. The chapter highlights the wide and conflicting range of medical views, further underscoring the need for choice.

We close Part III with an examination of the sound and fury behind the story of Dr. Andrew Wakefield. Holland examines the charges against him and concludes that medical regulators and the media made Wakefield a scapegoat. He dared to dissent from medical orthodoxy by suggesting that parents have a choice; the establishment retaliated. Wakefield discusses the suppression of vaccine safety science from the unique vantage point of one who has lost his career, his medical license, and his home country simply because he sought to pursue possible links between vaccines and autism.

TOOLS FOR VACCINATION CHOICE

CPR shares “tools of the trade” for those who support an individual’s right to choose or refuse vaccination. It contains scientific abstracts, supporting documentation, Harris Interactive poll data, and CPR’s principles and calls for action. We provide a website link to CPR’s top 30 slides on vaccination choice and a list of frequently asked questions including responses about the return of deadly diseases, vaccine safety, and vaccination ethics.



Vaccination, like all medical interventions, involves a risk-benefit assessment that only individuals, in conjunction with their healthcare practitioners, are qualified to make. Government coerces no other one-size-fits-all medical program; its justification for this one is unconvincing. A growing body of scientific literature points towards the contribution of vaccines to rising childhood immune and neurological disorders. Using the precautionary principle as a guide, people must be able to choose.

For those who do choose vaccines, the burden to prove safety must be on the government—not on those injured to prove that vaccines caused damage. Today, the government has a lightweight burden to show safety and efficacy, and those injured have a heavyweight burden to prove harm. These burdens must shift, and the government must fund impartial science to study the unintended, as well as the intended, effects of vaccination.

SURVIVING BETRAYAL

Taken together, the authors make a reasoned case for vaccination choice. Although the book seeks discourse on a thoughtful plane, neither the book nor the debate is about reason alone. They are also about powerful human emotions—parents’ love for their children, a soldier’s dedication to fellow soldiers, and the righteous anger of people betrayed by those in whom they placed sacred trust. Parents trust their doctors, soldiers trust their superior officers, and citizens trust their governments to ensure medical safety. When people reluctantly reach the conclusion that their trust was betrayed, they have a fierce and courageous anger. Vaccines needlessly harmed the lives of many of the authors and their children and numerous others. By raising legitimate questions about vaccination, CPR seeks to make these voices heard.

TOWARDS A REASONED MAINSTREAM DIALOGUE

Americans are rightfully concerned. There are no safe vaccines but only difficult choices to weigh and make. Americans want and deserve a more accurate, measured, and responsible national dialogue concerning vaccination. To dismiss as “anti-vaccine” those who advocate for choice, safety, transparency, and restraint harms us all. The legitimate battlegrounds in the vaccine debate are between compulsion and choice, transparency and nondisclosure, caution and recklessness, and accountability and impunity. Debasing an important and vast subject into a pro-vaccine versus anti-vaccine shouting match serves no one.

Our current vaccination schedule is in many ways a grand experiment—we do not know whether widespread, mandatory vaccination will ultimately prove beneficial or harmful. Beyond the science, however, is the question of individual rights. Does any country, and in particular a democracy, have the right to impose vaccination on unwilling individuals, especially in the absence of disease epidemics and adequate safety science? Foremost in the minds of the country’s founders was the imperative to protect citizens’ inalienable rights. Government today apparently does not trust individuals to serve their own best interests.

The mainstream media portray concerns about compulsory vaccination as an antivaccine agenda. This is grossly inaccurate. The reality is that a majority of American parents support vaccination choice. According to an online Harris Interactive poll sponsored by CPR in May 2010, 52 percent of American parents believe that parents should have the right to decide which vaccines their children receive without regard to government mandates. In this landmark study, Harris reached a representative sample of 1,114 parents with children up to age seventeen. Through this poll, CPR also learned that over half of American parents are concerned that pharmaceutical firms have undue influence over vaccine mandates. Moreover, a majority believe that the federal government should fund an independent scientific study of fully vaccinated versus unvaccinated individuals to assess long-term health outcomes. With only modest variations by education, socioeconomic status, and other criteria, these concerns span the gamut of American parents.

Those deeply concerned about vaccination choice, parental rights, vaccine safety, and undue corporate influence are the majority. Vaccination choice is a broad-based American movement.

Vaccination choice is not a partisan issue—and it is not even just about vaccines. It is about ethics, human rights, science, freedom, dignity, and democracy. It is about the common ideals that Americans hold dear. It is about who we are and what we stand for. And it is literally about the biological integrity of the next generation and those that succeed it.

Part I

THE CASE FOR VACCINATION CHOICE

HUMAN, CIVIL, AND RELIGIOUS RIGHTS, SCIENCE, HISTORY, ETHICS, AND PHILOSOPHY

Since Jacobson v. Massachusetts in 1905, the world has embraced human rights in many forms—women’s suffrage, the Nuremberg Code, free and informed consent, medical autonomy, the human rights revolution, and public health revolutions in sanitation, hygiene, and antibiotics. A thorough reconsideration of compulsory vaccination mandates is long overdue, based on the language of the Jacobson decision, which calls on courts to end vaccination mandates that are oppressive and unreasonable.

—Mary Holland, JD

The U.S. government’s mandatory vaccination policies do not appear to comply with international human rights standards. The government has limited the exercise and enjoyment of specific rights—including children’s right to obtain a free, public education—based on vaccination status.

—Louise Kuo Habakus, MA

A country that requires all children to receive a product—no matter how beneficial—knowing that some children will die and others’ lives will be destroyed by the use of that product, risks losing all moral authority.

—James Turner, JD

Science lies at the heart of the vaccination controversy, and there can be no substitute for it. The ethical practice of medicine requires full and informed consent. It is not possible to have the informed part of informed consent without the science. That vaccine safety science has been and remains inadequate is not in dispute.

—Carol Stott, PhD, MSc, CSci, CPsychol, and
Andrew Wakefield, MB, BS, FRCS, FRCPath

Chapter One

VACCINATION CHOICE IS A FUNDAMENTAL HUMAN RIGHT

Mary Holland, JD

Consider the meaning of the phrase “*fundamental human right*.” “*Fundamental*” means essential, basic, and inalienable. “*Human*” means what we have simply by virtue of the fact that we are human beings. We are born human; we need not be of a particular age, nationality, gender, or class. A “right” is a claim that we may enforce against governments and other people. Thus we assert that we have inalienable claims we can make within society, simply because we are human beings. The decision of when and whether we vaccinate ourselves and our children is a fundamental human right.

Vaccination choice is a fundamental right because it implicates our most precious rights—to life, liberty, and security of person. Basic laws—such as religious laws, the Universal Declaration of Human Rights, the U.S. Constitution, and international laws that all countries must obey—exist to protect inherent human dignity and the equal and inalienable rights of all members of the human race. Having witnessed the war crimes, genocide, and crimes against humanity committed during World War II, nations of the world explicitly embraced human rights in the United Nations Charter.¹ They recognized that it would be impossible to secure a peaceful, just world without the Universal Declaration of Human Rights that proclaims a “common standard of achievement for all peoples and all nations.”² In the aftermath of World War II, the world embraced the human rights principles of the Nuremberg Code, a set of ethical principles that forbids experimentation on human subjects without free and informed consent.³

Today’s human rights laws reject many institutions of the past—slavery, genocide, piracy, torture, inhuman treatment, and systematic discrimination based on race or gender. Some of these laws—such as the prohibition against slavery—have become international norms that apply regardless of whether a particular country has signed a treaty or law to that effect. Today, nations also reject medical experimentation on human subjects without informed consent. Increasingly, nations are recognizing that all healthcare interventions must be based on free and informed consent.⁴

It is an undisputed, scientific fact that vaccines in their current state of development injure and cause death to certain vulnerable people. U.S. law considers vaccines to be “unavoidably unsafe.”⁵ Vaccination mandates today seek to protect the majority while sacrificing the

unknowable, and unknowing, genetically vulnerable few. This utilitarian practice can only be justified if it is based on free and informed consent.

With a complete understanding of the risks and benefits of vaccines, individuals, parents, or guardians may elect to undergo the risks of vaccination to protect against possible disease. They are free to engage in a risk-benefit calculus with their healthcare practitioners and to accept the consequences of their choices. It is unjustifiable, however, for the state to deprive individuals of accurate information and then to coerce them to accept potentially life-threatening medical interventions. Compulsory state vaccination policies violate the rights to liberty and security of person, and when vaccinations result in death, such policies violate the right to life. Even in circumstances of epidemic disease, compulsory vaccination policies would be suspect without consideration of less invasive alternatives, such as self-quarantine and even coercive quarantine.

In the United States, several vulnerable groups—such as children, military personnel, and immigrants—do not have a choice whether to receive vaccinations. Children cannot attend school and adults cannot keep some jobs without fulfilling vaccination mandates. The Vaccine Information Statements that healthcare workers are required by law to give with each federally recommended vaccination are grossly incomplete and often not given at all.⁶ Unlike manufacturers of almost all other products, vaccine manufacturers in the United States are legally free from ordinary tort liability for their “unavoidably unsafe” products.⁷ The absence of free choice whether or not to use dangerous products, particularly when the manufacturers have exceedingly little liability for them, violates our fundamental rights.

States’ rights to compel vaccination in this country stem from a 1905 U.S. Supreme Court decision, *Jacobson v. Massachusetts*.⁸ In that case, the Supreme Court upheld Massachusetts’ right to require adults to be vaccinated during a smallpox epidemic. If the adults failed to comply, the state required them to pay a \$5 fine. The Supreme Court found Massachusetts’ regulation reasonable for protecting the public’s health, but it also pointed out that its decision would not justify “regulations so arbitrary and oppressive” that they would be “cruel and inhuman in the last degree.” Based on *Jacobson*, every state now offers at least the formal right to medical exemption from vaccination.

Overall, *Jacobson* has been interpreted expansively. *Jacobson*, justifying reasonable use of a state’s police power, is now the basis for condoning mandates for up to forty-five doses of about one dozen vaccinations for children—in the absence of epidemics, at the cost of public school attendance, based on inadequate and incomplete science, and with significant evidence of undue corporate influence. One may argue today that state vaccination mandates—including compulsory vaccinations for sexually transmitted diseases, such as hepatitis B, and noncontagious diseases, such as tetanus—are oppressive, unreasonable, and disproportionate to the public’s health needs. *Jacobson* does not justify today’s compulsory vaccination program.

Since *Jacobson* in 1905, the world has embraced human rights in many forms—women’s suffrage, the Nuremberg Code, free and informed consent, medical autonomy, the human rights revolution, and public health revolutions in sanitation, hygiene, and antibiotics. A thorough reconsideration of compulsory vaccination mandates is long overdue—based on the language of the *Jacobson* decision, which calls on courts to end vaccination mandates that are oppressive and unreasonable. Even in the context of a military draft, which the *Jacobson* Supreme Court decision refers to by analogy, U.S. citizens have the right to conscientious objection. We must demand the right to philosophical exemption from vaccination mandates in every state as a first

step towards truly free and informed vaccination choice.

On many occasions, Martin Luther King, Jr. quoted an abolitionist minister from the 1850s, Theodore Parker, saying, “The arc of the moral universe is long, but it bends toward justice.”⁹ Ending compulsory vaccination is its own human rights struggle. It is time to bend the arc of the moral universe toward the justice of vaccination choice.¹⁰

Chapter Two

THE INTERNATIONAL HUMAN RIGHTS STANDARD

Sookyung Song

International law asserts the fundamental human rights to life, liberty, and security of person. National governments must protect and uphold these fundamental rights according to universal standards. International human rights law plays an increasingly important role in all countries, including the United States. Almost all countries have signed basic international human rights conventions, holding them to common goals and standards, and have strived to live up to them.

International law has long recognized that prohibitions against abusive human experimentation are necessary. On numerous occasions, from experiments by Nazi doctors to the U.S. Tuskegee Syphilis Study to the recent Pfizer trovafloxacin experiments in Nigeria,¹ the modern world has observed the dangerous tendency to exact individual sacrifice in medical experiments for the alleged benefit of humankind. The interests of individual participants are not necessarily in line with those of the scientists and broader society, which may attach more value than the human subjects do to scientific progress and the so-called common good. Balancing these conflicting interests, international law has for decades incorporated the critical norm to protect human subjects from experimentation without free and informed consent.

The international community first set down fundamental human rights after World War II. Having witnessed unspeakable human rights violations and having suffered the worst war in human memory, world leaders codified fundamental human rights in the Universal Declaration of Human Rights under Eleanor Roosevelt's leadership. Later, building on this declaration, countries adopted the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. Together, the international community refers to these documents as the International Bill of Human Rights.

The modern international human right to bodily integrity affords the individual a right to make informed choices about vaccination and all medical interventions. The underlying idea is that those who undergo the risk of experimentation must make the final decision about their own participation after they are informed of the purpose, risks, and benefits of the experiment. While this right to choice in international law sprang from the Nuremberg Code, the international right to informed consent now encompasses the right to free and informed consent for *all* medical decision making.

This chapter provides a brief overview of the development of the human rights to bodily

integrity and free and informed consent and shows why these rights apply to vaccination.

POST–WORLD WAR II HUMAN RIGHTS NORMS

Modern bioethics began in 1947 at the criminal trial of Nazi doctors. These practitioners had carried out medical experiments on human subjects in which they intentionally injured and killed individuals for the purpose of scientific discovery. The judges in these trials established ten principles, later called the Nuremberg Code, on ethical standards for medical research.² The foremost principle in the Nuremberg Code is that “the voluntary consent of the human subject is absolutely essential.” The Nuremberg Code elaborated that the subject’s consent must be competent, informed, and free from coercion or inducement.

One year later, in 1948, the United Nations National Assembly adopted the Universal Declaration of Human Rights (UDHR)³ out of a global effort to represent the expression of rights to which all human beings are entitled. Although the after effects of the Nuremberg trials were still felt, the UDHR did not expressly address human experimentation but simply prohibited any “cruel, inhuman or degrading treatment,”⁴ with the belief that this language was broad enough to cover experimentation on human subjects.

The International Covenant on Civil and Political Rights (ICCPR)⁵ subsequently laid out specifics on the rights proclaimed in the UDHR and directly picked up the issue of human experimentation. In Article 7, the ICCPR clearly dictates that “no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.” Article 7 articulates that medical experimentation without free consent may at times amount to torture or inhumane treatment. Unlike the UDHR, however, the ICCPR drafters did not stop there. In addition to the prohibition against certain kinds of treatment, Article 7 affirmatively creates an individual right to informed consent for medical research. The structure of this provision, with the second sentence complementing the first, reflects an effort to address medical conduct that may not rise to the level of torture but nonetheless infringes on the right to bodily integrity. The drafting history of Article 7 illuminates how seriously the drafters considered the consent principle:

Early in the drafting process, government representatives discussed whether this sentence should be included at all. Those in opposition to the addition of the second sentence believed that it was not necessary, since it aimed to prohibit that which was already covered by the first sentence . . . What is notable about this aspect of the development of Article 7 is that those who objected to the second sentence opposed it not because they felt it was irrelevant but because they believed it was already covered by the prohibition on “torture or cruel, inhuman or degrading treatment or punishment.” The drafters finally agreed that the matter was so important as to require a special provision, even at the risk of repetition.⁶

THE COUNCIL OF EUROPE'S 1997 CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

In part because of the pace of medical innovation, the international community has returned to these core principles on several occasions to further elaborate them. The European community was at the forefront of this movement. In 1997, the Council of Europe adopted the Convention on Human Rights and Biomedicine (the Oviedo Convention).⁷ While this document is binding only in European countries that signed it, the Oviedo Convention represents the most up-to-date development of biomedical law. The Oviedo Convention reflects the ethical requirements in a society where the research community has become more aggressive in pursuing scientific knowledge, the boundary between science and medicine has become blurred, medicine has become more complex and difficult for patients to comprehend, and medical research is no longer confined to national or jurisdictional boundaries.

In response to these social changes, the Oviedo Convention provides greater protection of individual rights by guaranteeing free and informed consent to *all* medical interventions. Unlike the UDHR and ICCPR, this recent convention is not limited to human experimentation—it abolishes the distinction between research and therapy and addresses the need for individuals to have adequate information about all medical interventions. The Oviedo Convention requires consent for any medical intervention, including prevention, diagnosis, treatment, rehabilitation, and research.⁸ It even recognizes that a medical intervention may be psychological as well as physical.⁹ This comprehensive approach is necessary today because medical treatment and research are rapidly converging and no longer have static, distinct meanings. To maintain adequate protection, individuals must have the right to free and informed consent regardless of the historical distinction between therapy and research.

THE 2005 UNESCO DECLARATION

In 2005, the global community followed suit and adopted many of the expansive principles of the Oviedo Convention. The United Nations Education, Scientific, and Cultural Organization (UNESCO), a specialized United Nations agency, adopted the Universal Declaration on Bioethics and Human Rights in the UNESCO Declaration.¹⁰ The UNESCO Declaration made it clear that the interests of individuals cannot give way to the “sole interest of science or society.”¹¹ Article 6 states that individuals must give “prior, free and informed consent” to “any preventive, diagnostic and therapeutic medical intervention” and “scientific research.” Moreover, requirements for informed consent for participation in scientific research on human subjects include even higher procedural safeguards than requirements for consent to treatment.

Taken together, the message is clear: International bioethics norms are moving away from distinctions between research and treatment and now require free and informed consent to all medical interventions.

THE CONTEMPORARY INTERNATIONAL STANDARD IS FREE AND INFORMED CONSENT FOR ALL MEDICAL INTERVENTION

While neither the Oviedo Convention nor the UNESCO Declaration has binding legal effect in the United States, they both carry unique persuasive power in that they highlight the global trend in an area where the traditional legal system has not kept pace with rapid social and scientific change.

One hundred ninety-three countries are members of UNESCO. While the UNESCO Declaration does not establish enforceable rights, it is persuasive about what the global standard for informed consent should be. Drafters of the UNESCO Declaration strategically chose to write a declaration rather than a treaty for the same reasons that UDHR drafters chose to write a declaration more than fifty years earlier. In both instances, legislators perceived an urgent need to reform the existing law but viewed the treaty process as too slow and arduous—it would require much more time for negotiation and consultation, and less than the majority of states would be willing to sign it. However, the UNESCO Declaration’s declaratory form does not undercut its legitimacy or potential legacy. The UDHR, though nonbinding, not only has become a foundational document for many subsequent human rights treaties and for customary international laws that all countries must obey but also has influenced many national constitutions and laws.

In the same vein, we should see the declaratory form of the UNESCO Declaration as an intermediate step for further legal development. We should understand the UNESCO Declaration’s principles, which are largely built on the Oviedo Convention, as precursors to international human rights norms of the near future.

There is a growing global trend toward higher standards for informed consent for all medical interventions, and growing impatience with medical paternalism. This trend logically applies to vaccination, an invasive medical procedure that carries both known and unknown risks and benefits. The case is even stronger for vaccination than other medical interventions because historical justifications to waive the right to free and informed consent do not necessarily hold true. The medical community plays only a marginal role in determining the effectiveness and safety of vaccines. Instead, the vaccine industry, the very party that has a financial stake in the outcome, primarily drives safety verification, creating a huge conflict of interest. Depriving society’s most vulnerable citizens—infants and young children—and their guardians of informed consent is particularly egregious under the developing international law norms providing free and informed consent for all medical interventions.

Thus medical practitioners must first inform individuals receiving vaccines of the purpose and nature of the intervention, as well as the risks and benefits associated with the vaccination, and then must obtain consent. Emerging international law norms and a faithful reading of the Nuremberg Code require no less.

Chapter Three

A HUMAN RIGHTS ASSESSMENT

Louise Kuo Habakus, MA

Mandatory vaccination represents a limitation on human rights. Any limitation of fundamental rights, such as the rights to liberty and security of person, is serious, regardless of the supposed public good involved. The distinguished health and human rights professor Jonathan M. Mann, MD assumed that a government must justify any restriction on human rights in the name of public health. He wrote,

Unfortunately, public health decisions to restrict human rights have frequently been made in an uncritical, unsystematic, and unscientific manner. Therefore, the prevailing assumption that public health . . . is an unalloyed public good that does not require consideration of human rights norms must be challenged. For the present, it may be useful to adopt the maxim that health policies and programs should be considered discriminatory and burdensome on human rights until proven otherwise.¹

The discipline of human rights offers a powerful set of widely accepted norms and principles with which to assess public health policies. Human rights scholars have developed assessment tools to evaluate public health policies based on the core international human rights documents. Mann further states,

The specific rights that form the corpus of human rights law are listed in several key documents. Foremost is the Universal Declaration of Human Rights (UDHR), which, along with the United Nations Charter (UN Charter), the International Covenant on Civil and Political Rights (ICCPR)—and its Optional Protocols—and the International Covenant on Economic, Social and Cultural Rights (ICESCR), constitute what is often called the “International Bill of Human Rights.” The UDHR was drawn up to give more specific definition to the rights and freedoms referred to in the UN Charter. The ICCPR and the ICESCR further elaborate the content set out in the UDHR, as well as set out the conditions in which states can permissibly restrict rights.²

When we apply a state-of-the-art human rights framework to U.S. mandatory vaccination policies, will the policies pass muster?

THE PUBLIC HEALTH–HUMAN RIGHTS IMPACT ASSESSMENT INSTRUMENT

Scholars at the Harvard School of Public Health developed a Public Health–Human Rights Impact Assessment Instrument³ to evaluate possible human rights violations that occur when governments take actions in the name of public health that limit individual rights. They argue that such actions must be taken as a last resort and must only occur when they meet the following specific, stringent human rights conditions:

1. The goal of limiting rights may not be contrary to purposes and principles of the United Nations Charter.
2. The limitation must be justified by protection of a legitimate goal such as national security, public safety, and protection of public health or public order.
3. Limitations may be allowed only in a democratic society that presumes a participatory decision process and capacity for redress.
4. A right may be restricted only if the limitation is provided for by law.
5. The limitation of rights must be strictly necessary in order to achieve the public good, which must be carefully assessed on a case-by-case basis.
6. The limitation of individual rights must be proportional to the public interest and its objective (the so-called proportionality test).
7. The limitation must be the least intrusive and least restrictive measure available, which will accomplish the public health goal.
8. The limitation of rights must not be applied in a discriminatory manner.

What follows is a discussion of each of these eight core human rights principles as they apply to mandatory vaccination policies in the United States.

1. The goal of limiting rights may not be contrary to purposes and principles of the United Nations Charter.

The UN Charter calls for the maintenance of peace and international security and respect for human rights. The preamble states,

We the peoples of the United Nations determined: to save succeeding generations from the scourge of war, which twice in our lifetime has brought untold sorrow to mankind, and to reaffirm faith in fundamental human rights, in the dignity and worth of the human person . . .⁴

The Charter recognizes the central role of human rights protection. Every human being possesses dignity and worth. Since mandatory vaccination represents a restriction of rights, the UN Charter would require a careful and thorough evaluation of any public health policy's appropriateness.

2. The limitation must be justified by protection of a legitimate goal, such as national security, public safety, and protection of public health or public order.

The 1905 U.S. Supreme Court decision, *Jacobson v. Massachusetts*, is the United States' legal foundation for vaccination mandates and determines that mandates are necessary for public health or safety. Although *Jacobson* upheld a vaccination mandate for smallpox, it warned against potential governmental abuse of public health regulations. The decision noted that the smallpox mandate was justified because there was an imminent health hazard that "imperiled the entire population."⁵ The Supreme Court warned, though, that such mandates must not be arbitrary, oppressive, unreasonable, or "go far beyond what was reasonably required for the safety of the public."⁶ While the protection of society from infectious disease is a legitimate goal, there are important questions about whether the current measures adopted by federal and state governments are excessive.

3. Limitations may be allowed only in a democratic society, which presumes a participatory decision process and capacity for redress.

On the surface, vaccination mandates appear to meet this criterion. The United States is a democratic country, and states impose vaccination mandates through the legislative process. The reality of the decision-making process, however, is less democratic than it appears. Vaccine manufacturers have many opportunities to influence legislation through lobbying and private financing of political campaigns. Recent changes to campaign finance laws have made large corporations even more influential in electoral politics. Many advisers on governmental advisory committees have deep professional and financial stakes in vaccination policy. Truly public participation in such committees is extremely limited. Voting members frequently have conflicts of interest,⁷ including stocks, patents, grants, and honoraria from industry. Public health officials often benefit from a lucrative “revolving door” that may convert their public service into a private sector sinecure. Congressional interventions, including the 1986 National Childhood Vaccine Injury Act, have severely restricted the capacity for redress from a vaccine-induced injury. The net result is that public health decisions regarding vaccination policy may not be as truly democratic as they appear.

4. A right may be restricted only if the limitation is provided by law.

State governments rely on the Supreme Court precedent of *Jacobson v. Massachusetts* to uphold the constitutionality of vaccination mandates. There are reasons, though, that a decision mandating the vaccination of adults in 1905 does not apply to childhood vaccination mandates today. *Jacobson* upheld Cambridge's regulation, imposing a smallpox vaccination mandate during an epidemic. The town assessed a relatively small fine to adults who decided not to comply, and the regulation contained an exemption for children. Some argue that states' reliance on the *Jacobson* decision today is misplaced.⁸ Much has changed since 1905—there are no infectious disease epidemics in the United States, and state governments impose vaccination mandates *only* on children.

5. The limitation of rights must be strictly necessary in order to achieve the public good, which must be carefully assessed on a case-by-case basis.

We must challenge the assumption that vaccination mandates are strictly necessary for the public good. These mandates have not been studied empirically. Infectious disease mortality had a precipitous and sustained decline during the entire twentieth century. Before the advent of federal vaccination policy, health officials attributed these gains to the significant investments the country made in modern sanitation and hygiene infrastructure.

The last century brought forth dramatic developments that revolutionized public health in households and communities.⁹ These included hand washing, flush toilets, good plumbing, covered cesspools, and sewage treatment. The country implemented new medical procedures, such as the sterilization of surgical equipment. Refrigeration brought about important food safety changes. Modern roads and railways helped to deliver fresh produce to the cities. Housing improvements and decreased crowding led to a reduction in deaths from airborne diseases. Moreover, as specific, effective antibiotics were developed and perfected, the number of fatalities due to infectious diseases plummeted. All of these changes occurred before vaccine use became widespread.

Pediatrics, the journal of the American Academy of Pediatrics, admitted in 2000 that “vaccination does not account for the impressive declines in mortality seen in the first half of the century.”¹⁰ Infectious diseases were on their way out before vaccination became commonplace. Some diseases for which vaccines were never developed or routinely administered—such as typhoid fever, scarlet fever, and the bubonic plague—have almost completely disappeared. Public health officials simply do not know what would have happened in the absence of widespread vaccination. They cannot assert with certainty that vaccines are responsible for disease eradication or that vaccines are required to maintain herd immunity.

The second portion of the condition specifies that the limitation of rights must be assessed on a case-by-case basis. This means assessing the public health restriction as well as the individual facing the restriction. There are three important reasons why a case-by-case approach is a critical, unmet condition for vaccination mandates in the United States today.

First, not all mandates that exist today are “strictly necessary.” Many state vaccination mandates are for diseases from which American children do not typically die. Some diseases, such as chickenpox and rotavirus, have never caused a significant number of deaths in children. Other diseases, such as pertussis, have become less virulent and more easily treated with modern medical technology and antibiotics. Tetanus is not contagious and maybe treated with antibiotics and tetanus immune globulin (TIG).¹¹

Furthermore, young children are required to receive vaccines for diseases that do not routinely afflict them. Such mandates are not “strictly necessary.” State mandates exist for vaccination against hepatitis B and human papillomavirus, diseases that spread primarily through intravenous drug use and sexual contact. Similarly, the vaccine for rubella, a mild disease in children, is administered to toddlers primarily to protect the unborn fetuses of pregnant women. Immunity following vaccination is not lifelong, and the administration of the rubella vaccine at an early age has the potential to render older individuals susceptible at a time when the disease may pose a

greater health risk.¹²

Second, an individualized assessment is appropriate because some states have more burdensome mandates than other states do, imposing substantially greater vaccine-related risks on the children who reside in those states. New Jersey, for example, mandates the most vaccinations for day care and school admission. In 2008, it became the only state in the country to mandate children to receive annual flu shots. Twenty states offer philosophical exemptions from mandatory immunization—allowing parents the right to opt out of required vaccinations for their children because of moral or philosophical beliefs—and forty-eight states allow religious exemptions, but two states, West Virginia and Mississippi, only offer medical exemptions.¹³ The variation in state requirements highlights the need for case-by-case inquiry in order to protect fundamental human rights.

Last, without screening mechanisms to identify children most at risk for a vaccine-related injury, mandates may do more harm than good. A case-by-case approach is critical to be able to screen for those whom vaccines are mostly likely to harm. Medical professionals acknowledge that some people—including infants, those with severe allergies to vaccine ingredients, and those with immunodeficiencies—are unable to receive certain or all vaccines. Doctors do not know how children at risk will respond to a specific antigen or to the cumulative impact of multiple, simultaneous vaccines. Since adequate vaccine safety research has not been done, it is impossible to identify with greater precision those who should use alternative vaccination schedules or avoid vaccines altogether. Case-by-case analysis would allow for consideration of individual vulnerabilities.

6. The limitation of individual rights must be proportional to the public interest and its objective (the so-called proportionality test).

Proportionality is the quality of being in proportion, balance, or appropriate in size or magnitude relative to other items. In the United States today, no widespread infectious epidemic of any single disease exists, and yet, state governments impose vaccination mandates for a dozen diseases or more. The burden of diseases is not proportional to the number of vaccination mandates. To date, public health officials have not demanded randomized, controlled trials to evaluate the long-term health outcomes of vaccinated versus unvaccinated individuals. Additionally, the government has not commissioned research to prove that outbreaks will occur if childhood vaccination mandates stop. In the absence of science, the government cannot prove the proportionality of childhood vaccination mandates.

7. The limitation must be the least intrusive and least restrictive measure available that will accomplish the public health goal.

In the absence of a public health emergency and compelling science, vaccination mandates for young children are unduly intrusive and restrictive. Most families cannot choose whether or not to comply because they cannot do without day care and public education. While the government does not literally force vaccination, its coercive means are restrictive and intrusive.

Moreover, there does not appear to be an ongoing assessment of the public's health needs. Since the implementation of vaccination mandates for school admission, state governments only add vaccines to the schedule; mandates are almost never removed.

8. The limitation of rights must not be applied in a discriminatory manner.

Current compulsory childhood vaccination policies discriminate against children. If the theory of herd immunity is correct, then vaccination and revaccination of the adult population must be necessary to achieve the high, designated threshold levels deemed protective. There would need to be repeated boosters for adults, since vaccine-induced immunity fails in some percentage of the population and wanes over time regardless. Applying vaccination mandates only to children is discriminatory and contradicts the theory of herd immunity, which underlies the necessity of childhood vaccination mandates.

Mandatory vaccination policies do not appear to comply with international human rights standards. The government has limited the exercise and enjoyment of specific rights—including children's right to obtain a free, public education—based on vaccination status. According to this human rights assessment framework, we must consider reforming the vaccination program because specific and stringent conditions have not been fulfilled. Existing mandates are discriminatory and disproportionate to the public health goal.

A WORD ABOUT HERD IMMUNITY

The validity of herd immunity undergirds all compulsory vaccination policies. The theory of herd immunity posits that there is resistance to the spread of an infectious disease when a sufficiently high percentage of people in a community are immune to that disease. Herd immunity is achieved when the vaccinated portion of the population acts as a protective cordon that prevents a resurgence of the disease and, as a result, protects vulnerable individuals who are unable to receive vaccines (or whose vaccinations failed). Public health officials invoke the legitimacy of herd immunity to justify mandatory vaccinations. By definition, a high number of people must receive vaccines to attain herd immunity.

Herd immunity is a questionable theory. Researchers may point to epidemiological studies and anecdotes that appear to support it, but its validity remains in doubt. Public health historian James Colgrove writes¹⁴ that target immunization levels of 70 to 80 percent, the “magic numbers,” are accepted on faith but not proven. He quotes a county health commissioner who conceded, “We must perforce accept . . . [assumptions about herd immunity] until some future controlled study gives us a definite answer.”¹⁵

What is most salient and troubling about the theory of herd immunity is that the original basis for its validity has nothing to do with vaccines. People observed a protective effect in the community when a sufficiently high number of individuals contracted the wild form of a disease and secured lifelong immunity. This enduring, cumulative protection from the natural acquisition and resolution of disease is what public health officials called “herd immunity.” In the 1930s and 1940s, health officials began using “techniques of mass persuasion”¹⁶ and “aggressive salesmanship”¹⁷ to increase the public’s compliance in receiving vaccines. They reviewed the scant literature and limited empirical data and enlisted epidemiological theory to help endorse vaccinations and achieve target rates.¹⁸ Since vaccine-induced immunity appeared to afford protection similar to natural immunity, officials presumed that vaccines could also create herd immunity. Vaccine-induced immunity, however, is not the same as natural immunity. A person who contracts measles in early childhood will never get the disease again; a person with vaccine-induced immunity will need to receive boosters or assess his or her antibody levels periodically. Vaccine-induced immunity is qualitatively different. Vaccines do not always work, and even when they do, their protection weakens over time.

There are many examples that throw the validity of herd immunity into question. Outbreaks of diseases such as measles, mumps, and chickenpox, among others,¹⁹ routinely occur in fully vaccinated communities. Pertussis, or whooping cough, is another case in point. Federal vaccination guidelines recommend five doses of the pertussis vaccine, in the combination of diphtheria, pertussis, and tetanus, for children by age six and a sixth dose of each at age eleven. Despite repeated boosters and high compliance rates,²⁰ public health officials are now discussing the need for additional boosters because of sporadic pertussis outbreaks²¹ among the vaccinated and unvaccinated. The disease is most dangerous in early infancy, and babies typically contract it from their parents—not schoolchildren.²² While vaccine promoters see another booster as the best answer, perhaps a superior approach would be to reconsider the effectiveness of vaccines and the validity of herd immunity.



In conclusion, vaccination mandates are public health measures intended to fulfill a legitimate goal that restricts and intrudes on fundamental human rights. There is significant value in

applying a human rights framework to vaccination mandates. The necessity for childhood vaccination mandates today cannot be justified on human rights principles. Therefore, until public health policies can pass muster under a serious human rights examination, all citizens should have vaccination choice.

Chapter Four

DUE PROCESS AND THE AMERICAN CONSTITUTION

James Turner, JD

Over the past two decades the United States government has paid over \$2 billion to families of children who died or have been permanently harmed by vaccinations.¹ A government that requires individuals—particularly children—to be vaccinated, knowing that some will die and others will be permanently disabled as a result, risks losing all moral authority.

VACCINES ARE LESS THAN PERFECT

If our national, state, and local governments—including schools, hospitals, prisons, and other government-funded enterprises—are to maintain their moral authority, we must adopt important new procedures and answer troubling questions regarding vaccines. I first began looking carefully at this public policy issue in 1970. What I found deeply troubled me.

John Gardner, President Lyndon Johnson's secretary of Health, Education, and Welfare (HEW) from 1965 to 1968, called me in the summer of 1970. He said that after leaving office, he had learned that unfortunate, indeed dangerous activities involving vaccines had been going on while he was secretary. He asked if I would be willing to look into them.

At the time, I was working with Ralph Nader, and we had just published my book, *The Chemical Feast*. We had accomplished some visible successes: the U.S. Food and Drug Administration (FDA) had removed cyclamate sweeteners from the market until they could be proven safe, the food industry had voluntarily removed monosodium glutamate (MSG) from baby food, and the president had ordered a review of all food chemicals said to be generally recognized as safe by the FDA.

Secretary Gardner wanted to know if the same kinds of lapses we had discovered for food were also occurring in vaccine regulation, as he had been told. In 1970, the National Institutes of Health (NIH) Division of Biologics Standards, not the FDA, regulated vaccines. This agency, charged with ensuring vaccines' availability rather than their safety and efficacy, acted more as an NIH research group than a national drug regulator.

Secretary Gardner introduced me to J. Anthony Morris, PhD, a microbiologist who, at the time, was a senior vaccine regulatory researcher and a control officer for influenza vaccines at the NIH. He, in turn, introduced me to the officials in charge of the other vaccines, who were some of the most dedicated and conscientious government officials I have ever met. Each spelled out story after story of problems. The diphtheria-pertussis-tetanus (DPT) vaccine control officer called the DPT shot then in use the "dirtiest material put into humans." The cholera vaccine reviewer said, "A glass of proper mineral water would work better than the shot," which masked symptoms and might even spread the disease. The quality control officer worried about the amount of mercury in vaccines—in 1971! Dr. Morris gathered years of research, casting doubt on the safety and efficacy of flu vaccines.

Others outside the agency added their stories. The scientist who won the Nobel Prize for discovering "slow viruses" worried that these agents—related to problems such as mad cow disease—might be contaminating certain vaccines, such as the yellow fever vaccine. The key scientific advocate for the creation of the Centers for Disease Control and Prevention (CDC) said he had been fired in the early 1960s for refusing to make the annual announcement urging Americans to get the flu shot. The attorney general found that NIH vaccine regulators were illegally exempting vaccines from drug regulation.

We communicated these facts to the Government Research Subcommittee of the Government Operations Committee of the United States Senate chaired by Abraham Ribicoff of Connecticut, also a former HEW secretary. He held hearings where the HEW secretary at the time, Elliot Richardson, announced that because of these concerns, vaccine regulation would be transferred from the NIH to the FDA. The former NIH regulatory body became the FDA's Center for Biologics Evaluation and Research (CBER).²

Dr. Morris began his professional career with the elite vaccine group at Walter Reed Army Medical Center in Washington DC during World War II. A large number of the world's leading vaccine researchers and advocates began their careers in this group, which, under the leadership of the renowned Dr. Joseph E. Smadel,³ became the Walter Reed Army Institute of Research in 1953.

In 1956, Dr. Smadel left Walter Reed to join the NIH as an associate director. He took this job to help clean up the vaccine regulation that had allowed the Salk vaccine to paralyze nearly two hundred people and kill ten. NIH scientists who had discovered paralysis as a possible side effect of the Salk vaccine before market launch were ignored. Scientists with connections to Salk and the vaccine's manufacturer overruled their lessconflicted colleagues who wanted to stop the program until they had eliminated its potential for harm. Once people died, it only took thirty days to find the problem.

Shortly after arriving at the NIH, Dr. Smadel arranged for his colleague Dr. Morris to move from Walter Reed to join him. Drs. Morris and Smadel were particularly concerned about data that raised questions about the safety and efficacy of flu vaccines. They knew, for example, of armed forces data that suggested a connection between an increase in Guillain-Barré syndrome (GBS) and flu vaccine inoculation.

In 1963, Dr. Smadel became chief of the Laboratory of Virology and Rickettsiology at the NIH in order to more closely study vaccine safety and efficacy. He took this step because he had discovered that polio vaccines grown in live monkey's kidney cell culture contained simian virus 40 (SV-40), a cancer-causing agent. At the NIH, he did bench science alongside Dr. Morris and other vaccine researchers. While a demotion, this position allowed him greater access to vaccine regulatory activity.

Unfortunately, Dr. Smadel died later that same year, leaving Dr. Morris to carry on a review of vaccine safety alone. For the next few years, Dr. Morris worked mostly on respiratory vaccines and viruses, primarily the many varieties of flu. This was the work he was doing when John Gardner introduced us in 1970. At that time, his superiors were trying to fire him for continuously raising embarrassing questions about vaccine safety and efficacy. As the vaccine regulation battle unfolded, Dr. Morris was not fired, but several of his superiors were. Once vaccine regulation moved to the FDA, the battle continued. Dr. Morris turned down an opportunity to become part of the senior elite that ran the agency, in favor of bench research and continuing his critique of the ongoing, faulty vaccine process. His critique cost him his job. He was fired in 1980, though he was able to preserve his retirement rights.

Dr. Morris's final battle inside the government occurred during the buildup, collapse, and aftermath of the ill-conceived 1976 effort to inoculate all Americans against swine flu. Congress balked at funding the program until the outbreak in Philadelphia of what became known as Legionnaires' disease. The CDC refused to rule out swine flu as the cause of this event until the day after Congress approved funds for the program to vaccinate all Americans against swine flu. That day, the CDC announced that Legionnaires' disease was not swine flu. The government terminated the swine flu program when the vaccine caused injury and death to some. The vaccine only reached about 25 percent of the two hundred million people intended to receive it.

MONEY FOR VICTIMS ENTERS THE DEBATE

The 1976 swine flu debacle set off another round of anger and lawsuits, which ended in 1986 when Congress passed the National Childhood Vaccine Injury Act. Dr. Morris vigorously fought against this legislation. He believed that the government's use of cash payments to escape its legal responsibility to provide safe and effective vaccines would end any possibility of ensuring no harm from vaccines, which was his goal. Time has proven him right.

Barbara Loe Fisher, the tireless founder of the National Vaccine Information Center, testified before the California State Senate Committee on Health and Human Services in 2002:

I worked with Congress in the early 1980s on that [vaccine compensation] law and have watched it be turned into a cruel joke as 2 out of 3 vaccine injured children are denied federal compensation for their often catastrophic vaccine injuries because HHS [Department of Health and Human Services] and the Department of Justice officials fight every claim, viewing every award to a vaccine injured child as admission that vaccines can and do cause harm.⁴

Barbara Loe Fisher's story about the development and neutering of the 1986 National Childhood Vaccine Injury Act ("1986 Act") is a truly distressing object lesson in do-good legislation. The vaccine industry promoted the legislation ensuring compensation because it provided protection to them against mounting lawsuits. At the insistence of the parents of dead and injured children, the compensation law design was broadened to include vaccine safety provisions as well as financial assistance to families of vaccine-injured children. But time has shown that those added provisions lacked teeth.

The 1986 Act required doctors to give parents information on vaccination benefits and risks. It required doctors to record the vaccine manufacturer's name and vaccine lot number in the child's permanent medical record and to document and report hospitalizations, injuries, and deaths following vaccination to a centralized federal Vaccine Adverse Events Reporting System. Today this set of procedures works minimally, if at all.

The 1986 Act also called on the Institute of Medicine at the National Academy of Sciences to review the medical literature for evidence that vaccines can cause immune and brain dysfunction. It seemed designed to help reduce, if not eliminate, unnecessary vaccine-induced injuries and deaths, but in fact, the bill's momentum for passage came from its shift of liability from manufacturers to taxpayers for vaccine-induced disabilities and deaths.

The 1986 Act intended that parents of vaccine-injured children would receive federal compensation on an expedited, no-fault, fair basis as an alternative to lawsuits. The act promised vaccine manufacturers that they were no longer liable for the vast majority of vaccine-induced injuries and deaths. The act included a table of Compensable Events that listed clinical symptoms of adverse reactions to vaccines. A child having symptoms on this table would receive compensation unless the government could present compelling evidence that proved the vaccine had not caused the symptoms. The Department of Health and Human Services and the Department of Justice opposed the bill to the end. Yet, through rule-making authority, they were ultimately given the power to change almost everything once the law was passed.

In 1999, Ms. Fisher summarized a decade's worth of experience for parents trying to use the

compensation system:

Today, the bitter truth is that, although more than \$1 billion has been paid out to some 1,000 families whose loved ones have been harmed by vaccines, three out of four vaccine victims are turned away. Although parents pay a surcharge on each vaccine their child gets and the money from that surcharge is put into the vaccine injury trust fund, there is more than \$1 billion languishing in the trust fund because HHS and Justice pay expert witnesses and lawyers to fight every vaccine injury claim. And to make it easier for compensation to be denied to vaccine injured children, under rule making authority these federal agencies gutted the Table of Compensable Events in 1995 and arbitrarily rewrote the definition of encephalopathy (brain dysfunction) that had been used by medicine [for] decades.⁵

Today the government surrenders its moral authority by requiring children to receive vaccines it knows will cause death or permanent damage to some. Vaccines may have value for those who can use them safely. However, as the government continues to defend vaccine-caused deaths and disabilities and coerce families to put their children at risk, confidence in vaccines will decline, resistance to their use will grow, and what value they might have will be lost. In short, the way we are conducting mandatory vaccination now is not only causing the death and disability in children, it is undermining the very programs for which advocates claim great benefits. At a minimum, routine vaccination mandates must end. We must create a sound system for identifying all vaccine-induced injuries, and for giving proper care to all children, both before and after vaccination and vaccine-induced injuries.

IS MANDATORY VACCINATION CONSTITUTIONAL? AN APPROACH TO MINIMIZE VACCINE-INDUCED INJURIES AND PUBLIC OUTRAGE

The state of Arkansas requires that vaccination “shall not apply if the parents or legal guardians of that child object thereto on the grounds that immunization conflicts with the religious or philosophical beliefs of the parent or guardian.”⁶ To obtain an exemption, parents must sign a notarized statement requesting a religious, medical, or philosophical exemption from the Arkansas Department of Health (DOH). The parents must then complete an educational component prepared by the DOH, sign a statement of informed consent with a refusal to vaccinate, and provide a signed statement of understanding that the unvaccinated child may be removed from school during a disease outbreak. For the pertussis vaccine, the rule says that if a child’s sibling or half sibling had an adverse reaction, the child is exempt. The Arkansas law contains a “philosophical” exemption, which defeats mandatory vaccination. Currently philosophical exemptions exist in twenty states and should be the law in every state.⁷

The campaign that led to the Arkansas philosophical exception culminated in the law authorizing exemption signed on April 1, 2003. It began when a federal judge threw out the previous religious exemption law because it required a “statement . . . from a pastor or church official that the parents or guardians are members or adherents of a recognized church or religious denomination whose tenets are opposed to immunization.” The court found that an individual could have a religious belief precluding vaccination without belonging to a recognized church. The families of 123 children who had religious exemptions appealed the law, and while the appeal was pending, the state legislature passed the “philosophical” exemption law.

One constitutional argument presented to the appeals court specifically urged the court to find mandatory vaccination unconstitutional. The case called into question the constitutionality of current mandatory childhood immunization programs required of children to attend school. All five-year-olds must have received approximately sixteen viral or bacterial agents, even though health authorities acknowledge that a random and significant number of children will die or be disabled each year by the required shots. This acknowledgement of vaccine-induced injury is underscored by the federal government’s payout of over \$2 billion to families of dead and disabled children since 1986.

The Fifth Amendment of the U.S. Constitution says, “No person shall . . . be deprived of life, liberty or property without due process of law.” The Fourteenth Amendment extends this protection to persons in the states, saying, “No State shall make or enforce any law which shall . . . deprive any person of life, liberty, or property, without due process of law.” Mandatory vaccination programs, as conducted, fail to provide due process to individuals.

The case law justifying mandatory vaccination programs contains limitations on the state power to compel vaccination. It refers to the need for an emergency (e.g., a threatened or actual epidemic), it gives vaccine-endangered individuals the choice to opt out, and it recognizes conscientious objection. While current programs formally recognize these elements, in practice, their procedures fail to meet the due process requirements necessary to protect life.

THE DEATH PENALTY ANALOGY

The stark contrast between the process required to obtain compensation after a vaccine-induced tragedy—including documentation, hearings, counsel, and appeals—and the process before compulsory immunization underscores the procedural paucity of mandatory vaccination programs (see chapter 5: The Right to Legal Redress). Capital punishment’s procedural history offers insight into the constitutional problems of mandatory immunization. A 2002 New York district court decision found federal capital punishment unconstitutional because of lack of due process. At the same time that the Arkansas vaccination case was pending before the appeals court, two federal district courts—one in New York and one in Connecticut—declared capital punishment unconstitutional. They based their decisions on the fact that over two hundred individuals nationwide had been released from death rows across the country after their convictions were overturned. The courts found that these innocent individuals had not received due process.

Appellate courts overturned these cases saying that, even though the juries that convicted them had made clear factual mistakes, the existence of a jury trial met the requirements of due process. Still, the capital punishment victims received more due process than any child receiving mandatory vaccines, who receive no due process at all. The argument that the U.S. Constitution requires due process for vaccine recipients, including informed consent and the right to opt out, is straightforward. Because a small, predictable, but individually somewhat unforeseeable number of children will die or be permanently disabled by mandatory vaccines, an increasing number of parents are seeking ways to avoid vaccination.

The Arkansas federal court declared the Arkansas vaccine exemption unconstitutional because it applied only to members of established churches. The court held that individuals could have a religious belief that justified a vaccine exemption even if they belonged to no established mainstream church. The language of the court could be read to suggest that unconstitutionality might be best corrected by expanding the exemption to a broader number of religions. Left unaddressed was the broader question of when, if at all, the state may mandate behavior that subjects a minority of citizens to the certitude of death or permanent disability.

The vaccination exemption argument continues. Mandatory vaccine regulation today is comparable to that of capital punishment in 1972, when the U.S. Supreme Court decided *Furman v. Georgia*.⁸ That is, state procedures used to implement the policy of moral and medical exemptions are so lacking in effectiveness that they lead to the unconstitutional taking of life. *Furman* led to a four-year-long moratorium on capital punishment until states adopted procedures for implementing the death penalty that satisfied the Supreme Court’s reading of due process.

Current mandatory immunization programs have major procedural failings. These failings include a lack of clarity about exemption standards and a bias against informing families of their exemption rights. It also leaves life-and-death decisions about medical exemptions and the assessment of the risk-benefit ratio solely in the hands of government bureaucrats. Bureaucrats decide the fate of children without the substantive input of the families most likely to be affected. In this procedural framework, as with recipients of capital punishment sentences before *Furman*, children who become disabled or die from vaccinations have not received the due process the Fifth and Fourteenth Amendments require.

In this situation, the proper course is to suspend the mandatory nature of the immunization program until and unless states adopt procedures to protect against the unnecessary death and disability of children required to receive vaccines. A rational procedure for effective immunization should include a right to opt out of vaccination.

PROCEDURES TO MEET DUE PROCESS REQUIREMENTS

First and foremost, every state must adopt the right to philosophical exemption.⁹ There ought to be several procedural steps that states must take before mandating vaccination. The government must prove that those who are vaccinated will be harmed by those who are not vaccinated. There must be an open public procedure to evaluate how likely an epidemic threat is and how effective the respective vaccine is against that threat compared to how dangerous the vaccine is to individuals. In such a proceeding, the government must prove that the benefits for the subject vaccine in the prevailing conditions outweigh the harms. Interested families who may be harmed by state mandates must have input into the decision-making process. States must establish procedures to balance fairly the benefits and risks and to create appropriate opt-out rights. Without these and related procedural reforms, the mandatory vaccine program cannot withstand constitutional scrutiny.

Under the Due Process Clause of the Fourteenth Amendment, no state may “deprive a person of life, liberty or property without due process of law.” Courts have decided that the Fourteenth Amendment protection encompasses a constitutionally protected right to refuse unwanted medical interventions, including the “principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment.”¹⁰ In the case of a minor, courts have consistently held that the parents have the capacity to act in the child’s best interest, which includes making decisions regarding appropriate healthcare. A child is not “the mere creature of the State.”¹¹

An Arkansas case concerned the right to refuse unwanted medical treatment, namely, state-mandated medical vaccinations, which courts have determined cause death and serious bodily injury.¹² The issue of who is or is not susceptible to vaccine-induced injury is in constant flux. The number of mandated immunizations per individual child has increased from four in the 1950s to approximately thirty to forty-five for most children today. HHS has reduced the number of compensable injuries since the 1986 Act took effect. As a result, there are more exposures to possible harm and fewer officially recognized injuries. The government has provided no effective procedural framework with public participation to adjust the compensation scheme to cover today’s expanded vaccination mandates.

By contrast, when families suspect a vaccine-induced death or injury and seek compensation, the 1986 Act’s detailed and meticulous procedures come into play. The Act pays for an attorney to represent the family of the dead or injured child. The attorney must submit a petition for compensation to the Vaccine Injury Compensation Program of the Court of Federal Claims. If the Department of Justice contests the petition, there is a hearing process and an administrative judge, or special master, decides whether to provide compensation. The family may also remove its claim from this program to civil court.¹³ The government’s decisions on which vaccinations to compel include no analogous procedural safeguards despite the knowledge that a predictable number of children will die or become disabled.

LEGAL PRECEDENTS FAVOR PROCEDURAL SAFEGUARDS

Jacobson v. Massachusetts is the seminal U.S. Supreme Court case addressing the state's authority to mandate vaccination.¹⁴ Recent Arkansas federal district court decisions on exemptions cited *Jacobson* with very little discussion, as the basis for Arkansas's authority to mandate vaccinations.¹⁵ It is unfortunate that the Arkansas courts failed to thoroughly review *Jacobson*, because the Supreme Court emphasized that it was upholding the Massachusetts statute under the "necessities of the case," namely, that an epidemic was prevalent and increasing. In fact, Massachusetts did not force vaccination on any adults—it merely required them to pay a relatively small fine for noncompliance if they elected not to receive vaccination.

The Supreme Court "observed that the legislature of Massachusetts required the inhabitants of a city or town to be vaccinated *only when*, in the opinion of the Board of Health, that was *necessary for the public health or the public safety.*"¹⁶ Recognizing the public health emergency, the Supreme Court was careful nonetheless to warn that even during an epidemic, the police power of the state "might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons." The Supreme Court apparently did not contemplate that compulsory vaccination would be imposed outside of a clear public health emergency.¹⁷

Similarly, shortly after the *Jacobson* decision was made, Arkansas cases upheld a board-of-health regulation enforcing a smallpox vaccination mandate, only after determining that there was a public health emergency.¹⁸ Since there was no smallpox in the schools at issue or in the surrounding community, the courts looked to the statewide threat to find a basis for upholding the regulation as reasonable and necessary. One court noted that it was "commonly known at the time smallpox was prevalent in the State and that unless preventive measures were adopted a smallpox epidemic might result."¹⁹ It was only under these expanded parameters that the court was able to find that the rule was not "unreasonable or unnecessary."²⁰ Other cases have similarly held that state-mandated vaccination of children requires exigent circumstances, such as an epidemic or outbreak of a contagious disease, in order to be reasonable and necessary.²¹ Courts in the early twentieth century invalidated vaccination mandates when there was no imminent danger from a disease.²²

In spite of legal authority requiring emergencies for mandatory vaccination and in spite of the fact that some children will die and some will be permanently disabled, states have made mandatory immunization a routine requirement for attending school. They have done so bureaucratically, without implementing any procedure for members of the community to participate in the decision for mandatory immunization. As a result of the vaccination program, lives are harmed and lost without even the pretense of due process.

VACCINATION MANDATE STAKES ARE HIGH

In 2002, District Judge Jed S. Rakoff found the Federal Death Penalty Act unconstitutional because it created too great a risk that innocent people would be executed.²³ This opinion and order reaffirmed and incorporated Judge Rakoff's original decision of April 25, 2002, in the same case that new science had rendered capital punishment unconstitutional because it established as irrefutable that innocent people were on death row.²⁴

Judge Rakoff's capital punishment opinion underscored the consternation of judicial authorities that innocent people might be executed. He wrote,

It is therefore fully foreseeable that in enforcing the death penalty a meaningful number of innocent people will be executed who otherwise would eventually be able to prove their innocence. It follows that implementation of the Federal Death Penalty Act not only deprives innocent people of a significant opportunity to prove their innocence, and thereby violates procedural due process, but also creates an undue risk of executing innocent people, and thereby violates substantive due process.²⁵

The potential execution of an individual for a crime he or she did not commit, even after a fair trial and posttrial scrutiny, created a sense of failure that led Judge Rakoff to declare the Federal Death Penalty Act unconstitutional:

If, instead, we sanction execution, with full recognition that the probable result will be the state-sponsored death of a meaningful number of innocent people, have we not thereby deprived these people of the process that is their due? Unless we accept—as seemingly a majority of the Supreme Court in *Herrera* was unwilling to accept—that considerations of deterrence and retribution can constitutionally justify the knowing execution of innocent persons, the answer must be that the federal death penalty statute is unconstitutional.²⁶

Obvious distinctions exist between the state's action in seeking the death penalty and the state's action in ordering mandatory immunization. However, the distinctions seem to make the death and disability that follow mandatory vaccination more, rather than less, shocking to the conscience. In the case of mandatory immunization, innocent children die or are disabled with no opportunity to be represented in fighting for their lives and without proving that the state interest in advancing public health requires such an outcome. Such deprivation of life in the absence of due process violates substantive due process and shocks the conscience. The fact that the federal appeals court overturned Judge Rakoff because the death row victims received jury trials underscores the due process failure for those who are required to receive vaccines.²⁷ The dead and disabled children had no hearing at all.

Justice Sandra Day O'Connor said of capital punishment:

I cannot disagree with the fundamental legal principle that executing the innocent is inconsistent with the Constitution. Regardless of the verbal formula employed

—“contrary to contemporary standards of decency,” “shocking to the conscience,” or offensive to a “principle of justice so rooted in the traditions and conscience of our people as to be ranked as fundamental”—the execution of a legally and factually innocent person would be a constitutionally intolerable event.²⁸

The death of an innocent child in the service of mandatory immunization is shocking. It is contrary to contemporary standards of decency and it violates a principle of justice deeply rooted in tradition—that affected parties must be allowed to participate in decisions that affect their lives, liberty, and property. Parents and the public must participate in the decisions regarding vaccination risk-benefit tradeoffs. They must decide which, if any, vaccines to mandate, at what age the vaccines should be administered, how many doses should be administered, and reasons for exemptions. Just like the execution of an innocent inmate, the death of an innocent child from a mandatory immunization program violates the U.S. Constitution.

CONCLUSION

Based on my life experience and my awareness of vaccination regulatory failure for the past forty years, this I know to be true: In a moral society, there can be no mandated vaccinations. In a moral society, citizens must be allowed to choose which vaccines they and their children receive and when. Without vaccination choice, society places both public and individual health at risk. Vaccination choice is a fundamental human right.

Today, Dr. J. Anthony Morris, with whom I began my vaccination policy sojourn, is ninety-two years old and living in the same house he has occupied since he began working for the U.S. government during World War II. Tony continues his sharp critique of vaccination policy that uses slovenly science to create unnecessary risks for the lives and well-being of the people, especially children, it intends to help. But a long life is the best revenge. When I asked Tony what message he would give to the American people, he said, "Tell them I do not take the flu shot."

Chapter Five

THE RIGHT TO LEGAL REDRESS

Mary Holland, JD, and Robert Krakow, JD

Vaccines, like all prescription medicines, carry risks—the law considers them to be “unavoidably unsafe.”¹ Because the government and medical community want to ensure high vaccination rates, they do not publicize this legal fact. To the contrary, they tell the public that “vaccines are safe and effective.”² The public is lulled into believing that vaccines are almost perfectly risk free. That, however, is public relations.

Congress passed the 1986 National Childhood Vaccine Injury Act (“the Act”) in part to compensate families for “vaccine-related injury or death.”³ The Act includes a Vaccine Injury Table listing brain damage, paralytic disorders, anaphylaxis, seizures, and death, which are the basis for compensation if they occurred within specific time periods after vaccination.⁴ The Act establishes a National Vaccine Injury Compensation Program (VICP) to compensate injured children for specified “on-table” injuries and for “off-table” injuries where the petitioners can prove causation.

In the name of protecting children’s health, the Act changed the legal landscape fundamentally. Instead of keeping doctors and the vaccine industry directly liable for adverse reactions to vaccines, the Act created a taxpayer-financed compensation program for injuries. Unprecedented at that time, the Act was, in effect, a corporate bailout for the pharmaceutical industry, forcing the public—rather than the industry—to pay for damage from “unavoidably unsafe” products. Thus the Act deprived children of two of the most significant legal protections they had to ensure safety and remedial compensation: informed consent and the right to sue manufacturers directly.

The U.S. Department of Justice (DOJ) represents the Department of Health and Human Services (HHS) in claims of vaccine-induced injury or death before the U.S. Court of Federal Claims. Neither the vaccine industry nor doctors are defendants in the VICP. So far, HHS has compensated about 2,500 claims of vaccine-induced injury and has committed over \$2 billion in compensation and legal fees.⁵

The idea behind the compensation program is simple—if children are injured in the “war on disease,” society has an ethical duty to care for them, just as society has a duty to care for soldiers injured while serving in the military. Congress gave bipartisan support to the Act and intended for compensation to be quick, easy, certain, and generous. In principle, there was

congressional and public consensus that caring for vaccine-injured children was the right thing to do.⁶

The reality has not lived up to the principle. The message that “vaccines are safe and effective” does not reflect the reality that vaccines injure and cause death. Due to this tension, perhaps, the government goes to great lengths to compensate as few cases as possible, maintaining the fallacy that vaccine-induced injury occurs in a vanishingly rare number of cases.

If a parent or guardian asserts that vaccines caused his or her child’s injury,

they [the DOJ] will deny your reality. They’ll deny your word. They’ll say you’re lying. They’ll say you made it up. They’ll say you’re mistaken. They’ll say you’re very well-educated so you know how to game the system. And then you’ll come up against the full weight of their authority—expert witnesses with unlimited funds who will say that your child’s injury is genetic, genetic, genetic. You’ll find obstruction in the Department of Justice. You’ll find resistance. And you’ll find scorn.⁷

The VICP has been a dismal failure. Almost four out of five claimants lose in what was meant to be a petitioner-friendly administrative forum.⁸ The tenor of VICP proceedings is exceptionally hostile and adversarial—the exact opposite of what Congress intended. Petitioners must litigate almost every case—almost no injuries are “on-table” administrative claims anymore. Though Congress intended cases to resolve within a year, cases now take many years to litigate.

There is a long list of things that are wrong with the VICP. First and foremost, while it is referred to as a court, it simply is not a court. There is no judge, no jury, no right to require the adversary to provide information, and no formal rules of evidence and civil procedure. It is an administrative tribunal meant to handle simple injury cases based on certain presumptions. In a completely inappropriate way, the VICP is being used today as a forum for exceedingly complex health litigation, such as the Omnibus Autism Proceeding.⁹ The VICP is woefully inadequate for handling such litigation.

The following list outlines some of the major problems with the VICP.

1. THE LACK OF JUDICIAL INDEPENDENCE.

In lieu of judges, the U.S. Court of Federal Claims appoints “Special Masters” to decide questions of fact and law and oversee VICP proceedings. The U.S. Court of Federal Claims and the U.S. Court of Appeals for the Federal Circuit only review legal decisions for abuse of discretion and factual mistakes. Special Masters do not have the kind of judicial independence they need to decide these extremely controversial and serious cases. They are appointed to four-year terms, they have no specialized training in medicine, they primarily come from governmental law jobs, and they sometimes appear to defer to the DOJ and HHS.¹⁰ Decisions in cases like the Omnibus Autism Proceeding potentially affect national vaccination policy. Special Masters, lacking the life tenure of judges or even long-term appointments, are not suited to make decisions that might affect federal policy.

2. THE LACK OF EQUALITY BETWEEN THE GOVERNMENT AND PETITIONERS.

There are gross financial inequalities between the DOJ and petitioners in these cases. The DOJ has a virtually unlimited budget and can unilaterally retain and pay for expert witnesses. The VICP pays the petitioners' experts' and lawyers' fees, but there's a catch: The VICP often compensates petitioners' lawyers years after a case has started. Moreover, the DOJ and the U.S. Court of Federal Claims have the opportunity to review and cut petitioners' legal fees. There is no reciprocal right for petitioners' lawyers to review and approve or disapprove the DOJ's fees. In other words, the VICP, the DOJ, and HHS have strong financial levers used to exert control over petitioners' lawyers and experts. The financial playing field steeply tilts in the government's favor.

3. THE LACK OF ADEQUATE ACCESS TO EXISTING SCIENCE.

The most important information about vaccine safety is the taxpayer-funded Vaccine Safety Datalink, the government repository of epidemiological data on the vaccine program.¹¹ In the Omnibus Autism Proceeding, which aggregated over five thousand claims, petitioners were not granted adequate access to the Vaccine Safety Datalink information about early thimerosal studies while the DOJ presumably had access.¹² Without this data, petitioners' lawyers were at a severe disadvantage in making their argument for a thimerosal-autism link. In a normal court, a judge would have compelled access to such critical information as part of the civil discovery process, in which the parties are forced to share relevant information about causation. Because the VICP was not set up as a court to deal with complex questions of causation—it was set up to review recovery for presumptive injuries—it failed to address the heart of the vaccine-autism question.

4. THE ABSENCE OF ESSENTIAL SCIENCE.

In order to prevail in the VICP on a claim of vaccine-induced injury, a petitioner must present a plausible scientific theory, a logical sequence of cause and effect, and a connection in timing between the vaccination and the injury.¹³ The burden of proving a vaccine-induced injury is on the petitioner. There are many universally acknowledged gaps in vaccine safety science, which leave petitioners without the ability to definitively prove their cases and therefore, without compensation, even when there is no credible explanation for what happened to the child except vaccine-induced injury.

5. THE LACK OF TRANSPARENCY AND THE PERCEPTION OF ARBITRARINESS.

To protect families' privacy, medical records in the VICP are generally sealed and unavailable. The DOJ may settle cases rather than litigate them and may enter in to stipulations to keep information confidential, as happens in most kinds of civil litigation. The discrepancy between settled cases and dismissed cases leads to an appearance of arbitrariness, with the inability to compare and contrast VICP and DOJ decisions on full, factual records.

For instance, the DOJ appropriately agreed to compensate one child diagnosed with an autism spectrum disorder in the Omnibus Autism Proceeding, based on an individualized expert report.¹⁴ The child's family appears to have received a significant amount of compensation that will cover the enormous cost of caring for the child, who was severely injured.¹⁵ The expert report is sealed. This outcome for the family diametrically contrasts with the case of another child in the Omnibus Autism Proceeding, for which the government produced another individualized expert report from the same expert.¹⁶ The two expert reports appear to have been completely different in the two cases. In the compensated case, the expert's report led to compensation for encephalopathy leading to regressive autism. In the uncompensated case, the expert's report led to a denial of compensation for encephalopathy leading to regressive autism. The lack of transparency in the decision-making process creates an appearance of capriciousness and injustice. It is inexplicable to families with claims and to the public why HHS conceded one case of vaccine-induced autism while aggressively opposing five thousand markedly similar cases of vaccine-induced autism.

6. THE LACK OF DISCOVERY.

Although discovery—a civil court’s ability to require the parties to produce documents, answer questions, and make witnesses available for questioning under oath—is theoretically possible in the VICP, the court is not obligated to make it available. The ability to subpoena documents or witnesses absent a court order is rarely granted. Unlike in normal courts, where civil litigants win and lose on discovery, discovery and subpoena powers are all but absent in the VICP.

7. THE LACK OF ADEQUATE PROCEDURAL SAFEGUARDS.

The VICP does not have normal rules of evidence or civil procedure. While Congress created this informality for the petitioners' benefit, the lack of rules now severely hampers petitioners. For example, in the Omnibus Autism Proceeding, the DOJ was able to introduce expert reports without producing the underlying data¹⁷ and information that almost certainly would have been deemed irrelevant and excluded in a normal court proceeding.¹⁸ The VICP's lack of formal rules for civil procedure and evidence harms petitioners. Despite the lack of evidentiary rules, the VICP has begun to impose standards of admissibility applied in normal courts,¹⁹ such as the *Daubert* rule, which governs the admissibility of scientific evidence. Thus, the full burden of producing proof subject to evidentiary rules is being imposed on petitioners who have neither the resources nor the legal mechanisms through discovery to meet these formidable challenges.

8. THE GOVERNMENT’S LACK OF BURDEN TO PROVE CAUSATION.

The Court of Federal Claims assumes that once the FDA and the CDC have approved vaccines, they are safe. Therefore the government is not required to prove the safety of a vaccine—and the petitioner must demonstrate the harmfulness of a vaccine, even though the U.S. Court of Appeals for the Federal Circuit acknowledges this scientific area is “bereft of complete and direct proof of how vaccines affect the human body.”²⁰ Only when the petitioner has made a very strong case that suggests compensation is necessary does the government have to provide an alternate theory of causation. This burden of proof does not correspond with Congress’s intention to afford parents the presumption of recovery. Congress never intended that parents would litigate every case; on the contrary, they expected that the Vaccine Injury Table would afford families’ presumptions of recovery that would streamline the entire legal process. Congress expected that certain injuries from specific vaccines within certain time frames would lead to almost automatic compensation.

9. THE LACK OF A JURY OF PEERS.

The VICP permits no juries. Most families who have had the misfortune of bringing a claim to the VICP believe that more citizen participation would ensure more fairness. While courts have upheld the constitutionality of the VICP to date, many petitioners who have gone before it consider it to be fundamentally unfair. As one parent with a claim on behalf of her child in the Omnibus Autism Proceeding said, “The deck is stacked against families in Vaccine Court. Government attorneys defend a government program, using government-funded science, before government judges.”²¹

10. THE INAPPROPRIATELY SHORT STATUTE OF LIMITATIONS.

Petitioners have only three years from the time a vaccine-induced injury occurs to file a claim. The Vaccine Injury Table was set up in a time when it was thought that all vaccine-induced injuries happened immediately. This concept of vaccine-induced injury does not reflect many of the disabilities petitioners allege today—autism, seizure disorders, learning disabilities, arthritis—which are conditions that may appear years after vaccination and that have gradual and indistinct onsets. Furthermore, many doctors are unfamiliar with the emerging scientific evidence linking certain disabilities to vaccines.²² While many lawmakers have proposed a longer statute of limitations, the three-year window remains—and excludes many families who think their children’s injuries were due to vaccines. Even if a claimant is not in a position to know that a vaccine may have caused an injury, the three-year limitation will strictly apply.



The U.S. Supreme Court heard *Bruesewitz v. Wyeth*, an important vaccine-related case, in October 2010. This case will decide whether petitioners, after they have filed in the VICP, may then file a claim in a normal court if they suspect a vaccine had a design defect. The petitioner, Hannah Bruesewitz, sued in the VICP with the intention of receiving compensation for permanent injuries caused by a diphtheria-pertussis-tetanus (DPT) vaccine. She developed a severe seizure disorder as an infant immediately after receiving a DPT shot. After litigating and losing in the VICP, she sued in a Pennsylvania civil court, arguing that the DPT vaccine’s design was defective and unreasonably dangerous. A Pennsylvania federal district court and the Third Circuit Court of Appeals decided that Bruesewitz had no right to bring the claim to civil court. In their view, the Act preempted or precluded her claim. The Supreme Court will have to decide whether Bruesewitz has this right.

The Supreme Court’s decision could have a major impact on vaccine law and safety. This decision may determine whether there are effective judicial checks on defectively designed vaccines. If vaccine-injured individuals have no recourse in civil courts, then what protection does the public have against defectively designed vaccines? As Supreme Court Justice Sotomayor asked during the *Bruesewitz* hearing, “What is the inducement for them [the vaccine industry] to do it [fix defective vaccine designs] voluntarily?”²³

Congress should radically reform the VICP or abolish it. The Act has failed to achieve its primary goals—to compensate for vaccine-induced injuries and to make vaccines safer. The VICP has achieved only its third goal—to insulate industry and medical professionals from liability for vaccine-induced injuries. In that area, the Act has succeeded, at the grave expense of vaccine-injured children.

Chapter Six

GOD, GOVERNMENT, AND PARENTAL RIGHTS

William Wagner, JD

In 1653, an Englishman built a church and on it placed the following inscription:

In the year when all things sacred were throughout the nation either demolished or profaned, a man founded this place, whose singular praise it is to have done the best things in the worst of times . . .

Like the English church builder, parents find themselves placed on this earth at a time when all things sacred—including the unalienable truth that parents are best equipped to make decisions in the best interest of their children—face destruction or irreverent mocking.

The sacred and legal underpinnings of American parents' unalienable right to direct the upbringing of their children are embedded in deeply rooted divine, natural, and common law traditions. These timeless truths articulate an inviolable objective standard or reference point: Parents, not the state, have responsibility for and authority over decisions concerning the raising of their children—including vaccination choices.

DIVINE, NATURAL, AND COMMON LAW TRADITIONS

Long before the United States was a nation, the ancient *Holy Bible* articulated the authority and responsibility of parents to direct the upbringing of their children.¹ Thus, as a matter of religious conscience, parents made, and today continue to make, medical and other decisions in the best interest of their children. Indeed they view such decisions as a sacred parental responsibility of the highest order. For example, under divine law, God designates parents, not the state, as his agent to direct and control the upbringing of children. Since ancient times, parents exercised this responsibility as a matter of religious conscience. In doing so, they have, either quietly or boldly, declared the ancient sacred tenet: “As for me and my house, we will serve the Lord.”²

Many of the natural law writings that influenced America’s founders reflect those parental rights revealed first in divine law.³ Moreover, the English philosopher John Locke, in his *Second Treatise of Civil Government*, recognized an important distinction between a parent’s right to govern the upbringing of his or her child, a state’s political power to govern for the security of society, and a dictator’s despotic power to take for self-enrichment. Locke warned of the threat to liberty from the state usurping parental authority.⁴ Looking back, his caution seems no less than prophetic.

English jurist Sir William Blackstone’s writing convincingly shows that our nation’s common law traditions also reflect the principles from natural and divine laws that the authority and responsibility to direct the upbringing of children rest with parents.⁵ This unalienable liberty, and the idea that government exists to preserve it, became part of the American tradition.

AMERICAN TRADITIONS: THE DECLARATION OF INDEPENDENCE, THE U.S. CONSTITUTION, AND THE U.S. SUPREME COURT

America's founders enshrined the liberty recognized in sacred divine, natural, and common law traditions in the Declaration of Independence and then in the U.S. Constitution. Drawing upon these traditions, our founders, in 1776, boldly stated,

We hold these truths to be self-evident, that all . . . are endowed by their Creator with certain unalienable rights, that among these are life, liberty, and the pursuit of happiness. That to secure these rights, Governments are instituted . . . deriving their just powers from the consent of the governed . . .

We see the Declaration's promise in the Constitution's structure and language. We, the people, delegated power to the government to secure our freedom, while expressly limiting the government's ability to deprive individual liberty.

Thus it is not surprising that the Supreme Court traditionally afforded parents a fundamental constitutional right to direct decisions concerning the upbringing of their children—both as the right to the free exercise of religious conscience under the First Amendment and as the implied right to liberty protected by the Fourteenth Amendment. For example, in a 1925 Supreme Court decision, *Pierce v. Society of Sisters*,⁶ the Supreme Court stated, “The child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations.” Almost fifty years later, in *Wisconsin v. Yoder*,⁷ the Supreme Court upheld that “the primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition.”

In formulating laws related to parents and their children, lawmakers often looked to this objective standard as a benchmark, which was reflected in statutory law. Where lawmakers failed, Supreme Court majorities regularly upheld the fundamental liberty, invalidating state action that violated constitutional parental rights and freedom of religious conscience.

We might pause for a moment to note the incongruity of parents looking to a Supreme Court opinion for the authority to raise their children—an authority they already possess, naturally and divinely. For many American parents, it is a self-evident truth that God endows them with the unalienable right to protect and direct the upbringing of their children.⁸

The government, however, increasingly substitutes itself for God, as the source of our liberty. The paradigm shifts under this evolving legal philosophy. To evaluate state action that has an impact on parental decisions, the state replaces self-evident, unalienable standards with its own morally relative, utilitarian assessments. Thus the freedom of conscience and the sanctity behind parents directing the upbringing of their children no longer serve as moral benchmarks against which to measure whether government vaccination laws are right or wrong, good or bad, just or unjust. Instead, parents are told that questions regarding vaccination laws are public policy matters for the government to decide. Moreover, parents should not bother asking to participate in the debate if our view of the world is informed by religious principles since we are told we must only adopt public policy informed by secular dogma—without regard to any sacred,

conscientious, or moral considerations.

Beware. When the government eliminates a self-evident moral element from the law, it removes any moral reference point with which to measure whether laws are right or wrong, good or bad, just or unjust.

In this situation, the government inevitably institutes its own brand of utilitarianbased policies at the expense of individual liberty and the freedom of conscience.⁹ With nothing to limit those in power from imposing rules that they deemed to be in the best interest of the public, bad things happened—forced sterilization of healthy women, scientific experimentation on African Americans without their consent, and the institution of slavery are just a few examples—when the American government refused to recognize self-evident, unalienable liberty as a limit on its utilitarian policy making. Likewise, all around the globe, the freedom of conscience and parents’ unalienable right to raise their children no longer serve as a reliable limit on governmental action. Thus parents increasingly encounter government action—merely for expressing sincerely held religious tenets or otherwise exercising freedom of conscience.

Freedom of conscience is a fragile thing. I have held in my hands the ashes of faithful parents and children who died because of their consciences. As a diplomat in Africa, I also worshiped in a church where hundreds of men, women, and children were slaughtered as they sought sanctuary. In addition, I can tell you about an African member of my team who was brutally tortured for standing up for freedom of conscience and good governance under the rule of law.

After these experiences, I vowed never to remain silent. Therefore I tell you that despite the deeply rooted traditions recognizing parental rights, a profound threat to your sacred liberty to protect your children exists. Indeed, this threat is one of the most perilous ever to work its way through our nation’s political and judicial institutions.

Looming ominously is a growing body of evidence that lower courts and even a majority of the current Supreme Court may no longer recognize parental rights as a fundamental liberty protected by the Constitution. In this regard, contemporary definitions of a person’s fundamental rights and liberties frequently vary, depending on a judge’s interpretation of the Constitution.

A CHALLENGE

Replacing the sacred parental right to responsibly determine a child's medical treatment with dictatorial government mandates inevitably erodes a country's essential foundations. Those who came before us built our constitutional, democratic republic upon the foundations of faith, family, and freedom. That foundation is under attack by those who seek to transform our pluralistic nation (where everyone may freely participate in public policy development) to a secular nation (where everyone, except those who are religious, may participate). Although structural institutions of a free government may stand for a while, the principles for which they stand can eventually cease to exist.

Proponents of state-mandated vaccinations for children attack a sacred standard. The self-evident, inviolable standard that parents are best equipped to make decisions in the best interest of their children should not be subject to the morally relative, utilitarian whims of a shifting governmental regime. The government is supposed to protect parents' freedoms, not seize them.

Like the English church builder in 1623, this book has the potential to build faith, family, and freedom—to do the best things, even in the worst of times—so that parents may carry out their sacred duty. May each one of us rise to the occasion.

Chapter Seven

AN URGENT CALL FOR MORE RESEARCH

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Note: The authors would like to thank Louise Kuo Habakus for her contributions to this chapter.

THE NEED FOR SCIENCE

Science lies at the heart of the vaccine controversy, and there can be no substitute for it. The ethical practice of medicine requires full and informed consent. It is not possible to have the *informed* part of informed consent without the science. That vaccine safety science has been and remains inadequate is not in dispute.

The National Academy of Sciences chartered the Institute of Medicine (IOM) in 1970 to serve as an adviser to the federal government on issues affecting public health and to act independently on issues of medical care, research, and education¹ through the analysis and evaluation of evidence-based information. The IOM has played an important role in guiding vaccine policy over the past several decades. Excerpts from a succession of IOM reports over a fifteen-year period illustrate the continued lack of progress in addressing the paucity of research on vaccine safety.

Institute of Medicine Reports on Vaccine Safety

In 1991:

In the course of its review, the committee encountered many *gaps and limitations in knowledge* bearing directly and indirectly on the safety of vaccines. These include *inadequate understanding* of the biologic mechanisms underlying adverse events following natural infection or immunization, *insufficient or inconsistent information* from case reports and case series, *inadequate size or length of follow-up* of many population-based epidemiologic studies, and *limited capacity of existing surveillance systems* of vaccine injury to provide persuasive evidence of causation. The committee found *few experimental studies* published in relation to the number of epidemiologic [*sic*] studies published. Clearly, *if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped.*² (emphasis added)

In 1994:

Committee members were struck by the *lack of evidence*. . . . For about two-thirds of the relations evaluated, the committees found either that there was *no evidence* bearing on the question of causality or that the available evidence was *insufficient or inadequate* to make a determination about causality.³

Clinical trials for evaluating vaccine efficacy generally *do not include sufficient sample sizes* to permit adequate evaluations of the risk of adverse reactions. Participants expressed dismay that post-marketing studies of vaccines are generally *not randomized controlled trials*. The role of clinical trials for assessing adverse reactions is *limited*.⁴

Discussion arose about the issue of the *lack of unvaccinated controls* in the studies under consideration. Some participants felt that *a true control group* in a study of vaccines and adverse events would consist of never-vaccinated children (whereas now, control groups often consist of children who had not been vaccinated *recently [sic]*). *It would then be possible* to look at the frequencies of adverse events and disease in these children in comparison with the frequencies in those who had been vaccinated. This *might be particularly relevant* in studying adverse events with long latencies from the time of vaccination.⁵ (emphasis added)

In 1997:

A number of factors make it *difficult to detect adverse events* associated with the administration of a vaccine: (1) the *need to study* multiple exposures and multiple outcomes, (2) the lack of unique vaccine-associated syndromes, making it *difficult to establish causality*, (3) the *need for large sample sizes and lack of large*

computerized immunization databases with individual level data including vaccine lot number, (4) brief exposure periods for each individual, (5) high vaccination coverage makes unvaccinated individuals highly selected.⁶

More research could be done on potential long-term adverse events from vaccines as well as the potential of vaccines to induce or worsen immune disorders. *Research also could usefully address* such questions as whether age is a factor in the adverse events experienced following vaccination and whether some groups of individuals are more prone to such adverse effects than others.⁷ (emphasis added)

In 2001:

Little is known about ethylmercury (the active component in thimerosal) compared to methylmercury.⁸

There are *no data* that elucidate how much, if any, mercury exposure from all sources contributes to the prevalence of autism, ADHD, or speech or language delay.⁹

As noted in previous IOM reports (IOM, 1994 a, b, 2001), a positive ecological correlation constitutes only *weak evidence* of causality, and *additional research would be needed* to establish a causal association.¹⁰

The available case reports are *uninformative* with respect to causality. There are *no published epidemiological studies* examining the potential association between thimerosal-containing vaccines and neurodevelopmental disorders. The *unpublished and limited* epidemiological studies provide *weak and inconclusive* evidence. . . .¹¹

The committee has found *inadequate* evidence to accept or reject a causal relationship between thimerosal-containing vaccines and neurodevelopmental disorders. Although the available evidence is *indirect and incomplete*, and the relationship is not established, it is biologically plausible. Because thimerosal was used in millions of vaccine doses over several decades, it is *important that additional research be done* to understand the nature of the risk, if any, from this exposure to thimerosal.¹² (emphasis added)

In 2002:

The committee concludes that the epidemiological and clinical *evidence is inadequate* to accept or reject a causal relationship between multiple immunizations and an increased risk of allergic disease, particularly asthma.¹³

The committee was *unable to address* the concern of some that repeated exposure of a susceptible or fragile child to multiple vaccines over the developmental period may also produce atypical or nonspecific immune or nervous system injury that could lead to severe disability or death. Such adverse

health outcomes may not be “classical” diseases but variants of diseases . . . there are *no epidemiological studies that address this*, either in terms of exposure or outcome. That is, there is *no study that compares an unvaccinated control group with children exposed to the complete immunization schedule, nor are there any studies* that looked at health outcomes other than those classically defined, such as infections, allergy or diabetes. Thus, *the committee recognizes with some discomfort that this report addresses only part of the overall set of concerns* of some who are most wary about the safety of childhood vaccines.¹⁴

Research on the developing human immune system, especially in relation to vaccines, is *limited*.¹⁵ (emphasis added)

As the immunization schedule expanded, the IOM acknowledged a concomitant “dramatic increase in the complexity of immunization safety issues.”¹⁶ Although the IOM identified this complexity and these inadequacies and recommended more research over a fifteen-year period, critical questions about vaccine safety remain unanswered.

In addition, funding for vaccine safety has been and remains insufficient, despite urgent, unanswered questions. In 1995, Dr. Robert Chen, chief of Vaccine Safety and Development at the CDC, said,

The only line item for vaccine safety research is, I think, on the order of a little less than \$2 million per year. That basically covers operation of VAERS (Vaccine Adverse Events Reporting System) period, and nothing else.¹⁷

In 2008, almost fifteen years later, Dr. Louis Cooper, vaccine inventor and a former president of the American Academy of Pediatrics, wrote that the total vaccine safety science research budget was \$20 million or 0.5 percent of the \$4 billion total vaccine budget for purchase, promotion, and delivery of vaccines.¹⁸ Despite insufficient scientific knowledge and funding for safety research, the compulsory vaccination program continues to expand.

Epidemiology and the Vaccine Safety Discourse

Frequently, those who have expressed concerns about the validity of studies claiming “no association” between vaccines and autism have claimed that, because the majority of these studies are “epidemiological,” they cannot be used to establish or refute causality. This is misleading and needs clarification.

Epidemiology is the study of the distribution and determinants of disease in the human population; it is the basic science and fundamental practice of public health.¹⁹ As such, it is a discipline that has a much wider scope and range of methods than is generally acknowledged, certainly with respect to vaccine safety discourse.

Epidemiological studies may be descriptive or analytical, and analytical studies include not only case-control and cohort designs (see the section Epidemiological Primer below) but also randomized clinical trials and animal experimentation. All these types of study fall within the scope of “epidemiology.” This is more than a semantic point. Referring to epidemiology as though it were an inappropriate method to evaluate the possible association between vaccines and autism has, at best, meant that many arguments against the validity of the literature have been confused. At worst, it has meant a failure to articulate what has and has not been demonstrated by the data so far. Ultimately, it has resulted in a failure to identify the real gaps in our knowledge.

Epidemiological data can be used (1) to describe the characteristics and distribution of a disease, (2) to describe its possible association with various factors at the population level, (3) to generate hypotheses about the causal nature of observed associations, (4) to test the validity of these hypotheses in observational or experimental studies, (5) to describe the clinical and biological characteristics of an identified disease, (6) to evaluate proposed treatment regimens, and (7) to directly test the effect of exposures in experimental designs.

The studies that are frequently referred to as indicating “no association between vaccines and autism” have, for the most part, been population-based, analytic, observational studies; almost all of them have reported “no association” and almost all of them are flawed. The reason they are flawed, however, is not that they are epidemiological. It is not that epidemiology is a “blunt tool, incapable of testing causal hypotheses,” and it is not that there are so few people affected that “epidemiology couldn’t be expected to pick them up.” To the contrary, the studies are flawed either because they have been badly designed or because they have not been designed with the right hypothesis in mind in the first place. Their aims, design, analytic procedures, and conclusions, singly or together, have been consistently inappropriate and in some instances, plain wrong. If these studies had been designed, conducted, analyzed, and interpreted properly, they would almost certainly have furthered our understanding of the issue and helped to confirm or refute the role of vaccines in causality.

Epidemiology Primer

It will be helpful at this stage to go back to the books—a basic epidemiological text will suffice.²⁰ Epidemiological studies may be descriptive or analytical. Descriptive epidemiology aims to describe the general characteristics of disease distribution in relation to person, place, and time. Descriptive studies are valuable. They provide information to healthcare providers and those responsible for resource allocation, and they may also be used to generate hypotheses about disease causality, but their design precludes them from being used to test hypotheses.

Descriptive epidemiological studies include the following:

- Ecological (or correlational) studies, in which characteristics of entire populations are used to describe a disease in relation to a factor or exposure; no data are evaluated at the individual-patient level.
- Case reports or case series, which describe the experience of a single patient or a group of patients.
- Cross-sectional surveys, in which diseases and exposures are assessed simultaneously in a well-defined population. These may be considered analytical in one circumstance: when the factor or exposure is static, unchangeable, and consistent over time (e.g., birth weight).

Analytical epidemiology involves using comparative studies to test hypotheses about associations between an exposure and a disease. Analytical studies can be observational or experimental. Observational analytic studies include:

- Prospective cohort studies, in which an exposed group and an unexposed group are followed over time to determine how many people in each group develop the disease of interest.
- Retrospective cohort studies, in which records from exposed and unexposed individuals are examined for evidence of the disorder of interest.
- Case-control studies, in which a group of cases (the “diseased” group) is compared with a group of controls (the “nondiseased” group) in terms of the exposure of interest.

Experimental epidemiological studies include:

- Clinical trials, in which human subjects are allocated to separate groups with different treatment regimens.
- Experimental animal models.

Experimental studies actively manipulate exposures in the studies’ designs. Manipulation of potentially harmful exposures has obvious ethical implications and is most often carried out in experimental animal models. It has been argued that these experimental studies must not be done because the manipulation of a

vaccine's exposure is unethical—the vaccination would, by necessity, be withheld from one of the groups. However, it's also possible to argue that such a design is unethical because one group would be exposed to an insufficiently tested vaccine—though 80 percent to 95 percent of the population in developed countries is currently exposed to such vaccines. Experimental studies of vaccine safety on humans have been dismissed as not feasible for many reasons.

Given the urgent need to address questions of causation using higher standards of scientific inquiry, more scrutiny and resources to this important question are required. Other designs such as experimental studies using animal models or analytic studies of human populations, in which vaccinated and unvaccinated groups are examined, are appropriate and ethical, but they need to be done well.

2004 IOM Immunization Safety Review Committee Report on Thimerosal and Autism

In view of the challenges of epidemiological research generally and the paucity and poor design construction of the epidemiological research examining the relationship between vaccines and developmental injury specifically, it came as a surprise to many when the eighth and final report of the IOM's Immunization Safety Review Committee was released in May 2004. In drawing its conclusions on the vaccine-autism connection, the IOM chose to rely upon the research at a level that was not supported by the science. Despite severe limitations of the research that the IOM itself had identified, the IOM announced,²¹

The committee concludes that the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism. The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism. The committee further finds that potential biological mechanisms for vaccine-induced autism that have been generated to date are theoretical only. (Note: when the IOM uses the term "epidemiological" above, it means "population-based.")

This 2004 IOM study is the basis upon which the government made its decisions to *not* recommend

1. a policy review of the current vaccination schedule,
2. a policy review for administration of the MMR vaccine or of thimerosal-containing vaccines, and
3. further funding for vaccine-related autism research.

A Fear of What the Research Might Show?

Evidence-based medicine²² (EBM) is the highest standard of medicine. It uses peer-reviewed published scientific research to maximize accurate prediction of outcomes in medical treatment. EBM categorizes different types of clinical evidence and grades them according to the integrity of their results, as defined by minimization of bias and error. While a cornerstone of EBM is the randomized, controlled trial (RCT),²³ the RCT model doesn't lend itself easily to addressing the vaccine-autism issue for reasons given earlier. The challenges do not mean, however, that we have reached the limits of scientific inquiry. To the contrary, there is critical evidence-based research that can and must be done.

In the case of vaccine safety, the evidence base should come from adequate assessment of total health outcomes using designs that are appropriate to address the issue of causality, with clearly and appropriately defined case versus control groups (in case-control designs) or exposed versus unexposed groups (in cohort designs). The problems with the majority of studies aiming to address the issue of causality include the failure to define appropriate case groups and the failure to include potential cases as controls. For cohort studies, poorly defined exposure events, with little consideration of the timing of exposures or the cumulative effect of several exposures over time, have contributed to design flaws. Other problems include poor understanding of the actual hypotheses and retrospective analysis of data gathered in studies not originally designed to address the issue.

The absence of an adequately designed vaccinated versus unvaccinated study, which many have argued to be the ideal for assessing causality, led to a bill in Congress which sought to remedy this situation. Congresswoman Carolyn Maloney (D-NY) introduced H.R. 2832, the Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act of 2007. It never became law. She reintroduced the bill in 2009.²⁴ To date, the forces of political influence have not prevailed to support the passage of this proposed legislation.

As parent advocate and author Mark Blaxill wrote,

So the obvious research project of comparing the total health outcomes in vaccinated vs. unvaccinated individuals has been rejected not merely as too expensive, [now] it simply must not be done. In the Orwellian logic of the CDC, such studies in humans would be “prospectively unethical” and “retrospectively impossible.” Let's be frank here. This is an epistemological obscenity: It's not just that we don't know some very basic things about the safety of the sacred program, we also cannot know and should not seek to know. This stance should offend even the most skeptical scientists.²⁵

This is where misunderstandings about what epidemiological studies can and can't do become crucial. The accepted position, promoted by the CDC, is that a study of vaccinated versus unvaccinated individuals can't happen because it would need to be an RCT. Of course, it wouldn't. What is needed is a well-designed prospective cohort study; there are no negative ethical implications of this type of study whatsoever. This does not preclude the importance of clinical studies, which are also of crucial importance, but this study should analyze well-

designed population studies that isolate well-defined groups and compare their clinical and biomedical presentations with relation to vaccine exposure. No exposure manipulation is required, so there are no ethical issues to address in that regard. So why are these studies not being carried out?

Dr. Bernadine Healy, a former chief of the National Institutes of Health and current member of the IOM, offers some insight. In May 2008, Dr. Healy said to CBS reporter Sharyl Attkisson:

There is a completely expressed concern that they don't want to pursue a hypothesis because that hypothesis could be damaging to the public health community at large by scaring people. First of all, I think the public's smarter than that. The public values vaccines. But more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show.

I think that the public health officials have been too quick to dismiss the [vaccine-autism] hypothesis as irrational. ²⁶

In response to the claim that there is no vaccine-autism link, Healy responded, "You can't say that." As a member of the IOM, she would know. The IOM's 2001 review of the MMR vaccine and autism stated, "While the committee did not exclude the possibility that MMR vaccine could contribute to ASD 'in a small number of children,' it felt comfortable concluding that the evidence 'favors rejection of a causal relationship at the population level between MMR vaccine and ASD.'" ²⁷ Further, it did not recommend a policy review of the licensure of the MMR vaccine or of the current schedule and recommendation for administration of the MMR vaccine. ²⁸ Again, in 2004, the IOM concluded, "The evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." ²⁹

Parents are not convinced. A recent report estimated that one in four parents believe vaccines cause autism ³⁰ and another estimated that 89 percent choose vaccine safety as their top priority for medical research in children's health. ³¹ Remarkably, government today remains unable to answer these basic questions about vaccine safety:

- Do vaccines cause autism?
- How do the total health outcomes of those who are vaccinated compare with those who are unvaccinated?
- Is the CDC's recommended vaccination schedule safe?

In the absence of evidence-based research, U.S. vaccine policy rests on a theory, not on empirical evidence.

Most extraordinarily, in the absence of adequate science, doctors are blaming parents. The American Academy of Pediatrics (AAP), the professional association of U.S. pediatricians, issued a press release in the fall of 2010 stating, "Deadly diseases are making a comeback," and parents who choose to vaccinate their children are "at the heart of all these outbreaks." ³² The AAP is promoting the message of drug industry representatives and vaccine inventors, that "the antivaccine movement threatens America's children."

Vaccines Can Cause Harm

The government and the IOM clearly state that vaccines can cause harm. The IOM states, “No vaccine is perfectly safe or effective, and vaccines may lead to serious adverse effects in some instances.”³³ Its committee concluded that the evidence either favors or establishes causation between vaccines and adverse events (see table).³⁴ The government’s Vaccine Injury Table codifies this information.

Vaccines	Adverse Events
DPT vaccine	Encephalopathy, shock, and anaphylaxis
Rubella vaccine	Chronic and acute arthritis
DT vaccine	Guillain-Barré syndrome and brachial neuritis
Measles vaccine	Anaphylaxis and death from a vaccine-strain viral infection
Oral polio vaccine	Guillain-Barré syndrome, polio, and death from a vaccine-strain viral infection
Hib vaccine	Susceptibility to Hib disease
MMR vaccine	Thrombocytopenia, anaphylaxis
Hepatitis B vaccine	Anaphylaxis

The Vaccine Injury Table³⁵ lists the injuries and conditions that are presumed to be caused by certain vaccines along with the time periods in which the first symptoms must occur after vaccination, and these criteria must be met in order to receive compensation. It further indicates that an acute complication or sequela of any of the listed injuries, including death, is compensable. The government acknowledges that other vaccine-induced injuries may occur, but the onus is then on the vaccinee to prove that the vaccine caused the condition.

Science That Supports Previously Unrecognized Vaccine Risk and Injury

There is emerging scientific evidence that vaccination may be causing more widespread harm than is generally recognized by the medical community. Recent peer-reviewed studies, published within the past three years, suggest the possibility that vaccines are causing a greater degree of neurodevelopmental and immune disorders than is generally appreciated (see appendix to this chapter). Peer review is the process by which manuscripts submitted for publication or abstracts submitted for presentation at scientific meetings are judged for scientific and technical merit by other scientists in the same field.³⁶ As such, the peer-review process confers acceptability from peers and is assumed to be the arbiter of fairness and objectivity. Despite its peer-reviewed status, this information tends to be ignored by those promoting vaccines.

1. Primate studies evaluating the impact of a vaccination schedule based on the complete 1994 to 1999 U.S. vaccination schedule

As Kennedy et al.³⁷ discuss, studies that evaluate the safety of vaccines in the human population should use the species most closely related to humans. While the great apes (chimpanzees, orangutans, gorillas, and gibbons) represent our closest “relatives,” they are now endangered species. The Old World monkeys (macaques, baboons, mandrills, and mangabeys) are now frequently used in preclinical primate research. By studying primate outcomes, researchers are able to infer human exposure risks.

Recently, Hewitson and colleagues reported on a pilot study in which male infant rhesus macaque monkeys who received the complete 1994 to 1999 U.S. vaccination schedule were compared to an unexposed control group on a number of measures. A series of analyses were undertaken as part of the study and these have generated two reports to date.

In the first report, “Delayed acquisition of neonatal reflexes in newborn primates receiving a thimerosal-containing hepatitis B vaccine: Influence of gestational age and birth weight,”³⁸ the authors report on data collected after a single birth dose of the hepatitis B vaccine, containing the mercury-based preservative thimerosal. Thirteen vaccinated animals received a weight-adjusted amount of thimerosal containing 2 micrograms of ethylmercury (the dose human infants receive contains 12.5 micrograms). Seven unexposed animals received either a saline placebo injection or no shot at all. Compared to the controlled animals, the exposed animals exhibited significant delays in the development of major survival reflexes—root, snout, and suck. The exposed animals took more than twice as long as the control group to acquire these reflexes, which are typically used to measure infants’ brain development and are vital to primate infants’ survival in the wild.

The study did not attempt to separate out the effects of the vaccine as a whole, of thimerosal specifically, or of a combination of the two. However, the researchers established that primate infants of lower birth weight and gestational age were at a greater risk. These findings, when combined with the findings of the hepatitis B study by Gallagher and Goodman (see below), raise serious questions about the wisdom of neonatal vaccination and demand an urgent call for more research.

The second paper, “Influence of pediatric vaccines on amygdala growth and opioid ligand binding in rhesus macaque infants: A pilot study,”³⁹ reports that, after controlling in the statistical analysis for the volume of the left amygdala, and after correcting for multiple comparisons in the longitudinal design, specific opioid-antagonist [11C] diprenorphine (DPN) binding in animals recently exposed to the MMR vaccine remained diprenorphine (DPN) binding in animals recently exposed to the MMR vaccine remained relatively constant following exposure; however, a statistically significant decrease in [11C] DPN binding in unexposed animals occurred at that time. There was also evidence of a greater total brain volume in the exposed animals following earlier exposure to various other vaccines.

The results, which require confirmation in a larger design, suggest that maturational changes in amygdala volume and the binding capacity of [11C] DPN in the amygdala were significantly altered in infant macaques receiving the vaccination schedule, and therefore, exposed animals did not follow the same neurotypical trajectory as controlled (unvaccinated) animals whose

amygdala volumes decreased over time.

2. Hepatitis B vaccine and developmental disability

In a 2008 study, “Hepatitis B triple series vaccine and developmental disability in U.S. children aged 1-9 years,”⁴⁰ Gallagher and Goodman found evidence to suggest that boys in the United States who were vaccinated with the thimerosal-containing triple series hepatitis B vaccine were more susceptible to developmental disabilities than unvaccinated boys. (No increased risk was identified in girls.) The fully vaccinated boys’ odds of requiring special education services were more than twice as high as the unvaccinated boys’ odds. After adjusting the findings for confounding variables, the vaccinated boys’ odds of receiving special education services were 8.63 times greater than the unvaccinated boys’ odds.

The authors analyzed 1,824 children between ages one and nine who participated in the National Health and Nutrition Examination Survey (NHANES) in 1999 to 2000. They asked if the children received the triple series hepatitis B vaccine and if the children received special education or early intervention services. While the birth dosage was not specifically queried, the CDC’s birth dose recommendation was in place during the entire study period.

The same authors have since published their evaluation of the association between the hepatitis B vaccination (HBV) of male neonates and parental reports of autism diagnosis among boys aged three to seventeen who were born before 1999.⁴¹ They found that “HBV in U.S. male neonates born before 1999 was positively associated with almost 3-fold greater odds for autism.”

3. DPT vaccine and asthma

In an epidemiological cohort study sponsored by the Canadian Institutes of Health, “Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma,”⁴² McDonald et al. applied a retrospective longitudinal design using vaccinated versus unvaccinated children to assess the impact of different time schedules for vaccinations and their associations with asthma. A cohort of nearly 14,000 children born in Manitoba, Canada, in 1995, for whom complete vaccination and healthcare records were available, was identified and evaluated. Among the 11,531 children who received at least four doses of DPT, the risk of asthma at age seven was reduced by 50 percent in children whose first DPT immunizations were delayed by more than two months. The risk was further reduced if the first three doses of DPT were delayed.

According to the authors, the study generates some interesting hypotheses for the biological mechanisms behind early childhood vaccinations and the development of asthma. They caution that it is premature to make recommendations until these findings can be confirmed with the newer DTaP combination vaccine, which contains the acellular pertussis vaccine. DPT vaccines containing the whole-cell pertussis vaccine are no longer used in many countries because the DTaP vaccine has a lower incidence of adverse events. However, the incidence of asthma in Canada, as elsewhere, continues to rise, suggesting the introduction of the DTaP has no mitigating effect.⁴³

The study points out that vaccination schedules vary by country. Scientists may glean potential insights from varying disease prevalence in different countries. For example, Japan recommends three doses of the DTaP vaccine six to nine months after birth, but the first dose can be given no earlier than three months after birth. Between 1975 and 1988, Japan did not vaccinate children under two years of age. In 1982, Japan’s asthma prevalence rate in children was about 3.2 percent and by 2002 it was 6.5 percent. While Japan’s asthma rate doubled over twenty years, the rate is significantly lower than the rates in North America. The authors also noted that children who received the pertussis vaccine after age two had higher rates of pertussis than children who received the vaccine when they were younger.

4. Meta-Analyses

A number of reviews also suggest that vaccines possibly fill a role in explaining the increased numbers of people diagnosed with autism.

In a recently published paper, “Sorting out the spinning of autism: heavy metals and the question of incidence,”⁴⁴ DeSoto and Hitlan reviewed empirical research and carried out a meta-analysis to address autism incidence and its possible association with an exposure to environmental toxins. They conclude that the weight of relevant research has strongly shifted, and “convergent evidence” now supports a link between exposure to environmental toxins and a serious increase in the population-frequency of autism, which is occurring in numerous countries. Their analysis concludes that:

- Independent labs have found that autism rates in school districts are predicted by the distance from and exposure to toxic emissions within states.⁴⁵
- Exposure to toxins during pregnancy or early infancy is a factor used to predict later ASD symptoms.⁴⁶
- Detectable levels of mercury in blood, present in 8 percent of American women, are demonstrated to cause specific damage to developing brain cells.⁴⁷
- Levels of mercury and other heavy metals in the blood of a human fetus may be up to 70 percent higher than the mother’s levels.⁴⁸

A PubMed search of “autism AND heavy metals OR autism AND mercury” yielded 163 articles; 58 were research articles with empirical data relevant to the hypothesis of a link between autism and one or more toxic, heavy metals. Of these articles, fifteen were offered as evidence against a link between exposure to heavy metals and autism, and forty-three were offered as evidence supporting a link between exposure to heavy metals and autism.

The authors review the acknowledged errors in studies that were previously used to refute this hypothesis; these errors included lacking an objective confirmation of diagnosis (i.e., relying upon clinical judgment), treating a continuous variable as dichotomous, defining nonzero numbers as zero, and employing methods that resulted in having 95 percent of samples returned by the lab because they were too low to detect. In their reanalysis, DeSoto and Hitlan found that the data “support the contention that those with autism had higher levels of heavy metals.” They urge professionals to refer to the original studies in order to clearly understand the methods and results before weighing the evidence.

In a paper titled, “Timing of increased autistic disorder cumulative incidence,” McDonald and Paul investigate the timing of the increased incidence of autism.⁴⁹ The authors, who work for the U.S. Environmental Protection Agency, suggest that pinpointing the “changepoint” year would help to narrow the focus in the search for possibly causal environmental factors, within and among countries. They examined the cumulative incidence (sum of all cases for a specific birth cohort up to a given age) of autistic disorder (AD) based on published data from different locations around the world. Three studies met the criteria: one each from Japan, Denmark, and the United States (California). The changepoint years for each country were consistent and “surprising.” The data strongly suggest a major causal environmental change that affected children born in those locations in the late 1980s. The authors point out that the changepoint data are also consistent with data on AD incidence in children born after 1987 in Minnesota, in

children born in the mid- to late-1980s in Sweden, and in children born between 1987 and 1992 across the United States. The findings are clearly indicative of a major and relatively circumscribed causal environmental change affecting children born in the late 1980s.⁵⁰

Vaccinations represent both novel and increasing exposures that occur while children are still in utero (i.e., they are given to pregnant women) and then are directly administered to children starting on the day of birth. In debating the role of vaccines in these autism trends, the following events are notable:

- Denmark introduced the MMR vaccine in 1987.
- Japan introduced the MMR vaccine in 1989.
- MMR vaccination recommendations in the United States changed in the 1980s: those who received the vaccine at twelve months or younger were revaccinated at fifteen months; a second vaccination, to be administered by the age of four, was introduced in 1991; and the current recommendation to vaccinate at twelve months was introduced.
- In 1990, vaccine manufacturer Merck quadrupled the amount of the mumps virus included in the U.S. MMR vaccine; it was increased from 5,000 to 20,000 units. The viruses contained in the MMR vaccine interfere with each other and may increase the risk of adverse reactions. The U.S. birth cohort of 1989 was the first to receive this new vaccine.
- Among many changes and additions to the vaccination schedule, the hepatitis B vaccine, containing the mercury-based preservative thimerosal, became part of the recommended schedule in 1991.

Due to the significant economic and societal costs of autism, McDonald and Paul stress the importance of determining whether a preventable exposure to an environmental factor may be associated with the increase in AD incidence. Such environmental factors would need to disrupt early human neural development. The authors conclude that future studies should focus on novel or increasing exposures, occurring from in utero to at least three years of age in the birth cohorts of 1988 and 1989. Vaccines surely cannot be ruled out. This study raises important questions and emphasizes the need for more science, including vaccine science.

These studies do not prove a causal association between vaccines and autism, any more than those cited by the IOM and CDC prove that there is no causal association between them. What they do indicate is that the true status of vaccine safety science has been systematically misrepresented by those whose priority is not vaccine safety. They also suggest the possibility that vaccines fill a substantial, causal role in the autism epidemic. One might rationally think that these hypotheses would drive substantial funding into vaccine-autism research. Yet the opposite appears to be the case (see above).

Statistical Manipulation in Whose Interest?

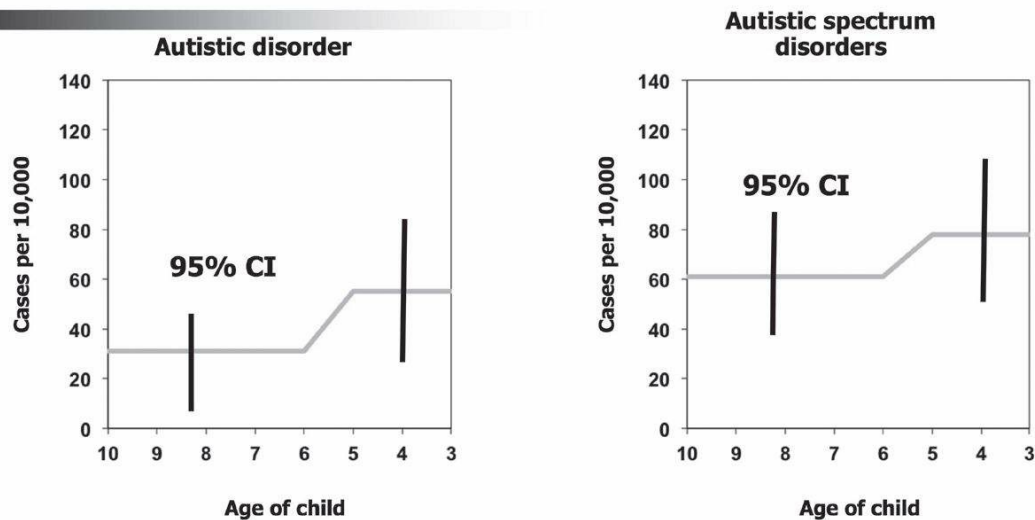
The lengths to which epidemic denialists are prepared to go to disguise the facts are astonishing. Due to concerns about a possible autism cluster in Brick Township, New Jersey, in 1997, the CDC investigated the cases and possible environmental causes, and determined that there was “no cluster” and no increasing trend of autism rates in Brick.⁵¹

After finding all of the autism cases in Brick, the CDC scientists separated them into two groups. Age-specific rates of autism and autistic spectrum disorder were calculated for preschool children (aged three to five) and elementary school children (aged six to ten). When the rates for each group were compared, the confidence intervals overlapped, indicating that the numbers were not significantly different between age groups, and that there was no evidence of an increasing rate (see figure). In addition, no environmental factors had been identified that could account for the apparent autism cluster in Brick. Yet, the CDC failed to identify any concerns and instead chose to conclude its investigation.

Perplexed by the reported findings, parent researchers Mark Blaxill and Sallie Bernard obtained and reanalyzed the original data that the CDC collected regarding cases of full-syndrome autism. Instead of dividing the cases into two unequal and arbitrary groups, they plotted the data for autism prevalence by year of birth. The findings were dramatically different (see figure 2). The CDC’s average rate for preschool children was determined by a range that included zero cases in the oldest children to almost one in one hundred cases in children born only three years later! The CDC’s average rate for school-age children was determined by a range in which the highest number approached one in one hundred, and low numbers were for three-year-olds, who were not yet diagnosed and therefore should not have been included in the analysis.

Figure 1

“It Remains Unclear” if Real Autism Rates Are Rising: Brick Township, New Jersey Time Trends

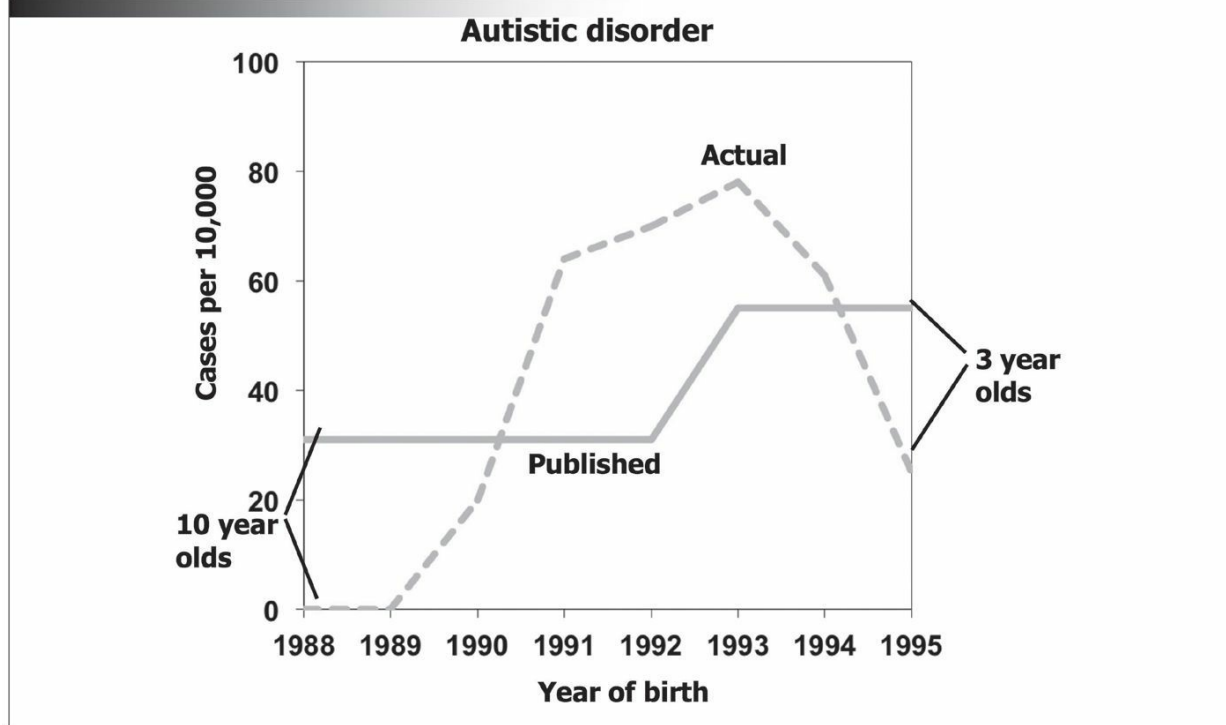


“Age specific rates were calculated for pre-school (3-5 year old) and school aged (6-10 year old) children... Confidence intervals for the two groups overlapped, indicating that prevalence rates for the two groups were not different.”
—Bertrand et al, 2001

Source: Adapted from data reported in J. Bertrand et al., “Prevalence of Autism in a United States Population: The Brick Township, New Jersey investigation,” *Pediatrics* (2001) 108:1155-61; and from data provided by the authors to Sallie Bernard of SafeMinds.

Figure 2

Comparing Reported and Actual Time Trends for Autistic Disorder in Brick Township, New Jersey



Source: Adapted from data reported in J. Bertrand et al., "Prevalence of Autism in a United States Population: The Brick Township, New Jersey Investigation," *Pediatrics* (2001) 108:1155-61; and from data provided by the authors to Sallie Bernard of SafeMinds.

The simple fact is that Brick Township's autism rates went from zero to nearly one in one hundred in a few short years, with a highly significant increasing trend. The CDC's actions can only be interpreted as a deliberate effort to obfuscate this fact. Had they presented an honest analysis of the data, the source of the autism epidemic might have been identified and dealt with by now.

The mainstream press routinely draws conclusions about vaccine safety in the absence of sufficient evidence. For example, we are told that:

1. The removal of thimerosal from pediatric vaccines did not result in a reduction in the population frequency of autism. Therefore thimerosal-containing vaccines do not cause autism.
2. Ten infants died in a pertussis outbreak in California.⁵² A CNN article quotes a health official who says that pertussis is vaccine-preventable and criticizes parents for choosing not to vaccinate their children. The health official concludes that everyone who comes into contact with diseases needs to be vaccinated to protect newborns.

In both of these cases, there is simply not enough information to support the conclusions.

Regarding the first example, at the same time that thimerosal was removed from most pediatric vaccines, the number of vaccines given to pregnant mothers and children—some containing thimerosal—dramatically increased. Thus the cumulative burden of these vaccines' other exposures, such as the aluminum salts used as vaccine adjuvants, increased as thimerosal exposures declined. We cannot separate out the impacts of these other, potentially “confounding” factors.

Regarding the second example, it is not appropriate to tie disease outbreaks to reduced vaccination rates based on ecological data (an earlier section of this chapter, “Epidemiology Primer,” explains why ecological studies can't be used to address causality). There is no publicly-available evidence that these children did, in fact, have pertussis. The willingness of public health authorities, on one hand, to freely bandy such numbers about and, on the other hand, to dismiss possible adverse reactions to vaccines as “coincidence,” is lamentable. Within a large population that may be experiencing a change in vaccination compliance, we cannot assume that the deaths were actually related to pertussis; and even if they were, we cannot assume that the cases were all caused by unvaccinated and infected individuals. Ecological data cannot be used to indicate causality because it is not evaluated at the level of individual exposures and outcomes and is, therefore, subject to misinterpretation (this is known as the ecological fallacy). This is an error of inference, in which an association observed at the population level is assumed to exist among individuals. A hypothetical example of this fallacy would be the assertion that drunk driving is safe because fewer road accidents occur in areas where alcohol consumption is high.

CONCLUSION

This chapter highlights the well-recognized gaps in vaccine safety that the Institute of Medicine has acknowledged for over fifteen years. But it also points to the growing body of peer-reviewed science that suggests previously unrecognized vaccine risks and injuries. The Hewitson primate studies, the Goodman and Gallagher hepatitis B studies, the DeSoto meta-analysis on mercury and autism, and the EPA “change point” year in autism prevalence study all support the great need for more research.

Center for Personal Rights (CPR) strongly supports urgent funding for evidence-based vaccine safety science. These studies should be funded by the government but conducted by independent researchers who have no stake in a particular outcome. The studies cannot be conducted by agencies that promote vaccination and have a mission to ensure public confidence in vaccines.

The government’s failure to fund the basic scientific studies of these medical products while simultaneously recommending or mandating them raises profound ethical questions. CPR believes this underscores the imperative for vaccination choice.

Chapter Eight

A LONG AMERICAN TRADITION

Robert Johnston, PhD

In this chapter, I hope to offer some important highlights of American history that connect to what is happening right now. Above all, I want to argue that the current movement for vaccine safety and liberty is deeply connected to powerful movements in America's past that have been fueled with intense skepticism about coercive vaccination mandates. Vaccine safety advocates have contributed forcefully and meaningfully to our country's many vigorous debates about personal liberty, medical expertise, and the political roles of ordinary citizens in a healthy democracy.¹

Citizens who question the established vaccination laws are frequently labeled dangerous and deluded. This, unfortunately, is a long American tradition. Another American tradition, however, is an outpouring of activism from those who have questioned the wisdom of mandating vaccinations.

The story begins as early as 1721, when working class and lower middle class Bostonians protested against the scientific and religious elite's introduction of smallpox inoculation to their city.²

Controversies over vaccination went on to animate much of the nineteenth century. Some of the most vulnerable communities in the country took the lead in protesting vaccination mandates. Free blacks, who were profoundly connected to the lack of bodily autonomy that they or their relatives had experienced as slaves, consistently resisted vaccination. Indeed, one of our most important American heroes, Frederick Douglass, declared himself an implacable opponent of compulsory vaccination.³

Other opponents included immigrants who had recently arrived in America from tyrannical countries in Europe and Asia. When German, Polish, or Chinese people came to the United States, they expected personal liberty. When the vaccinators came to their doorsteps, they sometimes quietly resisted, and sometimes noisily rebelled. Compulsory vaccination inspired a major riot in Milwaukee, for example, as immigrants poured out into the streets to fight off coercive and paternalistic public health authorities. They stopped their rebellion only when they had won major concessions from medical officials.⁴

However, it was not just the poor and most oppressed who resisted compulsory vaccination.

Increasingly in the late nineteenth and early twentieth centuries, middleclass citizens also made claims for full medical freedom. Some were concerned about the dangers of vaccination, others were insistent on the wisdom of parents in medical matters, others believed in natural healing, and all refused to believe that, in the land of liberty, the government should have the power to compel a controversial and potentially dangerous medical intervention.⁵

All this should sound quite familiar as these themes continue to play out more than a century later.

The result of all this activism of ordinary citizens is that by the 1930s, only nine states (plus the District of Columbia) had laws on the books that mandated vaccination. Moreover, several states that at one time had mandated vaccination, such as California, Washington, and Arizona, actually repealed their laws as the result of popular opposition.

We can now see that such citizen activists were not only remarkably successful but they were also remarkably insightful. For example, they had quite legitimate concerns about the safety of smallpox vaccination—the main vaccination of that era. A century ago, public health officials would not give these safety concerns the time of day. However, as the result of Dick Cheney’s post–September 11 attempt to launch a massive antibioteerrorism smallpox vaccination campaign, even mainstream newspapers, public health officials, and millions of medical workers came to recognize the significant dangers of the quite crude smallpox vaccine.

There were other important ways that vaccine skeptics of a century ago were correct. Today, more parents and citizens are advocating for personal rights. Again, we should take inspiration from activists of long ago—in this case from my favorite vaccine skeptic, Lora C. Little. After losing her son Kenneth to what she believed to be the side effects of vaccination, Little became a tireless—and quite colorful—worker against the vaccine establishment.

Little’s most heroic moment came in 1913, when she got a referendum on the ballot in Oregon. This referendum was designed to overturn a law the legislature had just passed, mandating compulsory eugenic sterilization for, among other things, “habitual criminals, moral degenerates and sexual perverts.” Little was able to get the majority of Oregonians to support her in her crusade against the evils of eugenics—the idea of breeding a better “race” that was disturbingly popular in early twentieth-century America and that ultimately helped inspire the Nazis.⁶

This proud history of activism continued throughout the twentieth century, although often in a more subdued way. Many organizations have come and gone, including Little’s American Medical Liberty League, based in Chicago during the 1910s and 1920s.

After a period of relative slumbering, popular skepticism about vaccinations reignited in the 1970s and 1980s, inspired by, among others, Chicago pediatrician and self-professed “medical heretic” Robert Mendelsohn, *Mothering* magazine, and the 1982 formation of Dissatisfied Parents Together (DPT). This is a history about which we should be equally proud.⁷

In the end, activists, citizens, and parents should recognize that they are part of a grand American tradition. That tradition transcends left and right, embracing all who care about personal liberty. That tradition shows that Americans have long refused to forget their concerns about democracy, even when it comes to scientific matters, such as medicine, that “the experts” wish to control. And that tradition shows that dissidents are often the wise ones who use their activism to force our scientific and political leaders to recognize their blind spots as well as their

need for humility when it comes to doing the will of the people.

Chapter Nine

MEDICAL ETHICS AND CONTEMPORARY MEDICINE

Vera Hassner Sharav, MLS

The cornerstone of medical ethics is the physician's ancient Hippocratic oath: "I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone." Often stated as "first, do no harm," this personal and professional commitment to adhere to the precautionary principle of medicine, which puts the patient's interest first, is the basis for our trust in medical doctors.

History has demonstrated that any movement to transform medical ethics from the humanitarian Hippocratic tradition to collective, population-based, utilitarian ethics—which justify compromising the interest of the individual for the so-called "greater good of society"—is the first step down a slippery slope whereby civilized medicine has all too often been derailed, by engaging in unconscionable practices that we, or any community, should never be willing to accept. As Leo Alexander, MD, chief U.S. medical consultant at the Nuremberg Trials who helped formulate the Nuremberg Code, warned in 1949, "From small beginnings the values of an entire society may be subverted and led to the horrors of (active) euthanasia, gruesome and unscientific medical experimentation, and ultimately, death in government clinics, and later—in concentration camps."¹

Dr. Alexander pointed out that well before the Nazis came to power in Germany, a cultural change under the Weimar government "had already paved the way for the adoption of a utilitarian, Hegelian point of view, with sterilization and euthanasia of persons with chronic mental illnesses being discussed by Bavarian psychiatrists as early as 1931 and extermination of the physically or socially unfit openly accepted and discussed in official German medical journals by 1936."² Years before genocide was an official policy, prominent German doctors became willing collaborators in the subversion of medicine from a healing profession to a mechanism of murder, by rationalizing that their actions were for the "good of German society" and to improve "the health of the German nation."

As early as 1920, two prominent German scholars, Karl Binding (a lawyer) and Alfred Hoche (a psychiatrist), co-wrote an influential book, *Permission for the Destruction of Life Unworthy of Life*. The authors reinforced the ideology of social Darwinism and eugenics—which called for population control to prevent the "degeneration" of white racial stock. The book provided the rationale for medical killing that the Nazis later used to justify their "systematic secret

execution” of the disabled. The authors dismissed the Hippocratic oath as a vestige of “ancient times” and, following the eugenics hierarchy of human categories, they deemed persons with terminal illnesses and mental disabilities as “unworthy” of life and therefore unworthy of scarce medical and fiscal resources. They discarded medicine’s moral commitment to “do no harm,” to preserve life, and to prescribe treatments for the good of the individual patient. Instead, they encouraged physicians, who must weigh benefits and risks, to protect “higher values” over the needs of the individual patient. The health of the state, they insisted, is of “a higher civil morality.”³

INFANTICIDE: THE FIRST LEGAL KILLINGS

The first victims of utilitarian medicine—whose lives were deemed “unworthy of life”—were disabled German infants and children under the age of three, who were murdered by doctors in the service of the state. The murder of these infants required the willing cooperation of doctors and midwives who reported every birth of a child with disabilities to the authorities.⁴ A directive issued by Hitler in late October 1939, and designated as a state secret, was to begin the T-4 euthanasia program;⁵ the three-year age limit for medical murder was soon broadened to include children (ages three to seventeen) whose behavior was deemed abnormal or antisocial, and eventually, to include mentally ill adults. The killing took place at hospitals that were converted to killing centers, where victims were gassed when they entered the “showers.” An estimated 275,000 to 350,000 mentally disabled children and adults were murdered⁶ with Zylcon B, the gas later used to systematically exterminate six million Jews, the principal target of Nazi hate propaganda.

As Leo Kass, MD, a prominent American ethicist, stated, “It is moral myopia to think that all values must yield to the goals of better health and desirable traits. A cost of such yielding can be the reduction of human beings to the status of just another man-made thing.”⁷ American medicine has its own dark history of morally indefensible public health policies, ostensibly adopted “for the greater good.”

STERILIZED IN THE NAME OF PUBLIC HEALTH

Compulsory surgical sterilization, now recognized as a crime against humanity,⁸ was a cornerstone of American eugenics—a sociopolitical racist movement with scientific pretention that was dubbed the “science of improvement.” It included state-mandated sterilization of persons deemed to be carriers of (presumed) defective genetic traits, whose reproduction was viewed by the elite establishment as posing “a menace for society.” Eugenacists asserted that human beings should be selectively bred, just like plants and animals: The goal was to “weed out defective persons from society just as a farmer would clear a field.”⁹ Eugenics appealed to American ethos and optimism about scientific and technological progress and its ready-made “scientific” solutions. Eugenics provided theoretical, pseudoscientific underpinnings that medicalized social problems—by offering biological interventions for the prevention of naturally occurring diseases—as well as complex human and societal problems. Eugenacists promoted compulsory sterilization as a prophylactic medical measure—a form of genetic engineering. Their stated purpose was to “protect the public health” by preventing the “unfit” from reproducing. Eugenacists applied veterinarian methods for improving the genetics of animal populations to human beings; they were seeking to “improve the human race . . . through better breeding.”¹⁰

The United States was the first country to carry out eugenics-driven compulsory sterilization programs under state statutes. Indiana enacted the first law in 1907 and the last forced sterilization was performed in Oregon in 1981. Adherents of compulsory sterilization policies were the elite of American society—including prominent academic leaders, “progressive” healthcare professionals, public health officials, and major industrialists. The Model Eugenic Sterilization Law published in 1914 served as the template for most state statutes and included an indemnification clause to protect physicians who performed surgical sterilizations from legal action—the clause is similar to the legal immunity currently provided for physicians who perform government-recommended and state-mandated vaccinations. The first individuals to undergo mandatory sterilization were mentally ill patients in state institutions. By the 1920s, sterilization laws were applied to people with mental and physical disabilities, as well as immigrants, orphans, Native Americans, Mexican Americans, and African Americans—all of whom were deemed to be “feebleminded” and “unfit.”¹¹

In 1926, the U.S. Supreme Court upheld the legality of Virginia’s compulsory eugenic sterilization policy in an eight-to-one decision, *Buck v. Bell*,¹² accepting the dubious argument that sterilization on behalf of the collective health of the citizenry was constitutional. The Supreme Court explicitly based this decision on the *Jacobson* vaccination decision. The majority wrote, “The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough.”¹³ This infamous decision greatly accelerated the pace of forced sterilizations and led additional states to enact sterilization laws. It provided an important precedent that prompted state courts to uphold a state’s right to control a person’s right to procreate when adequate hereditary evidence showed that their procreating threatened the welfare of society. The decision has never been overruled.

By 1944, thirty states had sterilization laws, and more than forty thousand sterilizations had been performed.¹⁴ What’s more, state-sponsored compulsory sterilizations in the United States continued long after their suspension in Germany following the Nazi trials and long after eugenics theories and policies had been discredited after the revelation of the Nazi sterilization

policies that had devolved into genocide.

A review by two Yale University physicians¹⁵ comparing the eugenic sterilization programs in the United States and Germany from 1930 to 1945 found that before World War II, physicians in both countries participated in state-authorized eugenic sterilization programs:

A comparison of U.S. and German histories reveals similarities that argue against easy dismissal of a Nazi analogy. On the basis of a review of editorials in *The New England Journal of Medicine* and *Journal of the American Medical Association* from 1930 to 1945, it is difficult to accept the suggestion that the alliance between the medical profession and the eugenics movement in the United States was short-lived. Comparison of the histories of the eugenic sterilization campaigns in the United States and Nazi Germany reveals important similarities of motivation, intent, and strategy.¹⁶

Indeed, in 1933, the Nazis enacted a compulsory sterilization law modeled after the American Model Eugenical Sterilization Law. The Nazis sterilized four hundred thousand people. In the United States, thirty-three states had compulsory sterilization statutes, and an estimated sixty thousand poor and working-class Americans were involuntarily surgically sterilized between the 1920s and the mid-1970s.¹⁷ Both governments justified compulsory sterilization in the name of public health.

“Other people had beautiful babies . . . We felt like we had been robbed in that particular category.” These are the words of Kenneth Newman who was forcibly sterilized at Fairview Training Center in Oregon, as was his wife, when they were teenagers. They and thousands like them were declared “unfit to reproduce” by medical experts and public health officials of the day. Only seven states have apologized for forced sterilizations. Only five states have apologized for slavery.¹⁸

America’s litany of abusive—even lethal—experimental medical travesties was conducted by prominent academic physicians, who were often sponsored by public health agencies. The following list provides only a few examples.

- 1932–1972: The notorious Tuskegee syphilis experiment, sponsored by the U.S. Public Health Service, was conducted, in which physicians denied lifesaving medicine to African American men.
- 1946–1948: The U.S. Public Health Service and the National Institutes of Health sponsored a vaccination experiment that intentionally infected nearly seven hundred institutionalized Guatemalans with sexually transmitted diseases. The principal researcher was the same doctor who conducted the Tuskegee experiment. The Guatemalan experiment was concealed for sixty-four years. The public only learned about it when the U.S. government apologized on October 1, 2010, calling it “clearly unethical.”¹⁹
- 1941: The “refrigeration experiments” conducted at Longview State Hospital of the University of Cincinnati²⁰ and at McLean Hospital of Harvard University²¹—like those conducted at Dachau by Nazi doctors—exposed mentally disabled patients to freezing temperatures of thirty degrees Fahrenheit for 80 to 120 hours.
- 1942: U.S. Army and Navy doctors infected four hundred prisoners in Chicago with malaria in experiments designed to obtain “a profile of the disease and develop a treatment for it.”

The Nazi doctors on trial at Nuremberg cited this experiment in their own defense.²²

- 1956–1972: Doctors deliberately infected “mentally retarded” children at the Willowbrook State School in New York with hepatitis in an experiment aimed at tracking the development of this viral infection, in pursuit of developing a hepatitis vaccine. Parents were coerced into agreeing to the experiment because participation in the study was a condition for admission to the institution. The researchers defended the study, claiming hepatitis was rampant at the institution and the children would have been infected regardless.²³

These, and hundreds of other examples, demonstrate the reality of medical travesties that occur when doctors stray from Hippocratic medical ethics to serve “the greater good.”

INTERNATIONAL CODES OF MEDICAL ETHICS

The revelations at the Nuremberg Doctors' Trial, which took place from 1946 to 1947, that documented medical atrocities of unprecedented scope and magnitude committed by Nazi doctors, shocked the world. How could highly educated physicians—whose professional oath required them to promote health, alleviate suffering, and protect life—become active instruments of torture and death? In his opening statement, Telford Taylor, the chief prosecutor at Nuremberg, pointed out that this was “no mere murder trial” because the twenty-three defendants were physicians who had sworn to “do no harm” and to abide by the Hippocratic oath. He told the judges that the people of the world needed to know “with conspicuous clarity” the ideas and motives that moved these doctors. He asked, “How could physicians actively and enthusiastically treat other human beings as less than beasts?”²⁴

In their verdict, American judges issued the Nuremberg Code (1947) whose first precept is “the voluntary, informed consent to medical research is absolutely essential.” The Nuremberg Code, which is deeply rooted in Hippocratic ethics, is the most authoritative document for the protection of human subjects. The Nuremberg Code serves as the cornerstone for all subsequent medical ethics codes, including the Belmont Report, which is the foundational U.S. document for human subject research codified in U.S. federal regulations.²⁵

By valuing the liberty and welfare of research subjects above the promise of medical progress, the Nuremberg judges sought to place the interests of individual humans above the interests of society in medical progress. The Doctors' Trial demonstrated in harrowing detail the need to hold physicians to universal standards they might otherwise violate. Legal codes of medical ethics are necessary to guarantee every human being inalienable human rights—especially the right to “life, liberty and security of the person,” guaranteed by the Universal Declaration of Human Rights written in 1948. They are also necessary to guarantee the opportunity to give or refuse informed consent to medical intervention.

Children do not have the capacity to exercise their human rights and must rely on surrogates to make medical judgments on their behalves. Because surrogates have not always acted in their best interest, however, children require added legal protections.

In the 1970s, after the hepatitis experiments at Willowbrook were brought to the public's attention, the issue was hotly debated by prominent medical ethicists, such as Paul Ramsey of Princeton University, who argued for the children's best interest. Children should not be exposed to drugs “insufficiently tested on human beings” unless they may “further the patient's own recovery.”²⁶ Father Richard McCormick of the Kennedy Institute of Bioethics at Georgetown University argued from the utilitarian perspective, claiming that parents may consent to their children's participation in non-therapeutic experiments because, if they could, children would (or ought to) consent as long as there were “no discernible risks, no notable pain, no notable inconvenience . . . almost no cost to the child.”²⁷

In 2001, the Maryland Court of Appeals affirmed, in a strongly worded landmark decision, the rights of children to be protected from any risks of harm caused by nontherapeutic research.²⁸ The case, *Grimes v. Kennedy Krieger Institute* (KKI), involved the exposure of Baltimorean toddlers to a contaminated environment in a government-sponsored lead abatement experiment, conducted between 1993 and 1995. The experiment sought to determine a cost-effective lead abatement level. It came to light when two families sued KKI, claiming that their children had

suffered brain damage from exposure to lead poison. The researchers, who knew that lead paint posed a risk of mental retardation in children, recruited poor families with young children to live in a lead-infested environment. The young children were expected to ingest lead-laced paint dust. During the experiment, the children's blood lead levels were measured over time and those levels rose significantly, but parents, who consented to the research without being fully informed about the risks of exposure, were not informed that the increased levels posed an increased risk of harm. The Environmental Protection Agency sponsored the experiment and Johns Hopkins University's ethics review board approved it. The Maryland court rejected the argument that the research met an important public health need, which unequivocally affirmed the preeminence of an individual child's best interest:

We have long stressed that the "best interests of the child" is the overriding concern of this Court in matters relating to children . . . Whatever the interests of a parent, and whatever the interests of the general public in fostering research that might, according to a researcher's hypothesis, be for the good of all children, this Court's concern for the particular child and particular case, over-arches all other interests. It is, simply, and we hope, succinctly put, not in the best interest of any healthy child to be intentionally put in a non-therapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children.

The panel of judges likened this unconscionable lead abatement experiment to Nazi medical atrocities, admonishing the researchers for conducting the experiment and rebuking Johns Hopkins's review board for approving an experiment in which children served as mere measuring tools—or "canaries in the mines."

Although federal regulations were finally adopted in 1983 that restricted the use of children in research that offers a potential benefit to them,²⁹ the regulations lacked effective checks and balances, and abuses continued. From 1986 to 2000, thousands of children in foster care—wards of the state in at least seven states—were used as human subjects in HIV/AIDS drug and vaccine trials³⁰ sponsored by corporations and the government. The children, mostly poor minorities ranging from infants to late teens, suffered severe discomfort and some even died. These high-risk phase I trials were conducted without parental consent or the approval of an independent advocate and in violation of federal regulations.

In 1997, bowing to corporate and special-interest pressures, Congress eroded its interpretation of existing federal regulations restricting the use of children as experimental subjects by enacting the FDA Modernization Act (FDAMA). The FDAMA encourages the use of children to test patented drugs and even provides manufacturers huge financial incentives, including six additional months of marketing exclusivity, for testing drugs in children. Children, who had no voice in the adoption of this legislation and are legally precluded to exercise the right to refuse, were forced to bear the burden of drug testing so that drug companies could qualify for a highly lucrative six-month patent extension. Those financial incentives, and the lifting of restrictions on the use of vulnerable children in experiments, also had a major impact on other biomedical research players—such as academic and governmental research institutions, professional associations, and scientific journals—who benefited from the opportunity the FDAMA provided for expanding pediatric drug trials.³¹ Thus all research stakeholders have profited financially

from a policy that renders children as commodities for commercial exploitation.

In 1997, the FDA's chief of the gastrointestinal drug division acknowledged that "at least" three children in clinical trials had died after being given the heartburn drug Propulsid. The FDA informed Janssen Pharmaceuticals that Propulsid was "not approvable" for use in children, but babies continued to be recruited to test the drug—even as the drug's deadly side effects were known. Janssen Pharmaceuticals used one hundred children and babies in Propulsid drug trials at one hospital alone. The babies had been born with gastroesophageal reflux, which is not a life-threatening condition: It is characterized by "recurrent spitting and vomiting, which occurs in about four out of ten healthy children, and doesn't always require treatment. Propping up the baby after feeding and correctly positioning the baby for sleep usually eliminates the condition. Experts agree that most babies outgrow the condition by their first birthday."³²

In 1999, Propulsid's sales reached \$950 million while the number of deaths reached eighty adults and children. That same year, nine-month-old Gage Stevens was recruited for a controlled, FDA-approved clinical trial and was given Propulsid and Tagamet for four months. He died of cardiac arrhythmia—just as six-month-old Chase Brown had the year before. By the time it was taken off the market, nineteen children who had been given Propulsid had died. After his death, Gage Stevens' parents said, "Little did we know that Gage was basically a guinea pig, and they never told us that [Propulsid] causes dangerous side effects, or [that] there had been deaths."³³ A public policy that puts the well-being of a child at risk—for the good of others or, more likely, for commercial reasons—violates fundamental moral principles and devalues the child as a human being.

MANDATORY VACCINATION POLICIES

Mandatory vaccination policies are a violation of medical ethics and human rights. Mandatory vaccination policies violate fundamental moral principles, and they have a profound and deleterious effect on medical practice and the relationship between patient and physician. When a physician is administering a state-mandated vaccine, that physician is serving as an agent of the state. However, doctors who administer medical interventions without ascertaining that they are for “the good of [the] patient” and “will not do harm” violate the physicians’ responsibility under the Hippocratic oath. Doctors who adapt their practice to conform to population-based utilitarian ethics are betraying patients’ trust by putting the interests of society above the interest of the individual patient who may be harmed as a result.

Mandatory vaccination policy is predicated on two problematic rationales. The first rationale in support of mandatory vaccination is that vaccines are “safe.” Unlike other medical interventions, vaccines are given to healthy children and adults, and they are known to cause severe adverse effects—some of which are endemic to the disease against which they are intended to protect. Indeed, legally, vaccines are classified as “unavoidably unsafe,”³⁴ an indication that they pose an inherent risk. Vaccines have not been subjected to scientifically rigorous, placebo-controlled safety trials before they have been approved for use in children. Instead, they are tested by exposing healthy human beings to one of two vaccines—each of which poses risks of harm—so the true magnitude of risk is masked. Most of the data, including government-gathered data, are undisclosed and inaccessible for independent scientific scrutiny. This raises serious concerns about the integrity of publicly disseminated claims about vaccine safety.

The second rationale given for mandatory vaccination is the necessity to “protect the herd,” that is, for “the greater good of society.” The Nazi doctors at Nuremberg used the very same rationale—and it was rejected.

Mass vaccination of healthy children whose lives are put at risk “to protect the herd” is tantamount to a massive, involuntary human experiment in violation of the “absolutely essential” human right to “voluntary, informed consent” under the Nuremberg Code. Mandatory vaccination policies for children have provoked an extremely contentious battle. How can anyone justify a public policy that forces vulnerable infants and young children to bear the burden of risk and suffering—including neurological damage, seizures, permanent disability, and death—for “herd immunity”?

By age eighteen, children in the United States receive seventy doses of sixteen vaccines. Infants, whose immune systems are undeveloped, are exposed to more than thirty-three doses of over one dozen vaccines by fifteen months of age, including hepatitis B, diphtheria, tetanus, pertussis, polio, rubella, measles, mumps, chickenpox, pneumococcal infections, *haemophilus influenzae* type b, and influenza. Moreover, infants are being vaccinated not only against childhood diseases, but also against diseases to which they are unlikely to be exposed for the express purpose to protect adults. For example, why are newborn infants on the day of birth being vaccinated against hepatitis B, a disease contracted by having unprotected sex or sharing needles? Furthermore, why are two-month-old infants vaccinated against tetanus, which is extremely rare, occurs primarily in older populations, is effectively treatable after exposure, and is uncontagious?

To gain even a cursory appreciation of the level of risk to which infants and children are exposed, one should examine *The Merck Manual*. It acknowledges that vaccines contain toxoids, weakened bacteria that can cause severe, debilitating symptoms—including life-threatening conditions, such as encephalitis.³⁵

If vaccines have greatly improved the health of America's children, then it is fair to ask why the United States' ranking among world nations in infant mortality has plummeted from twelfth in 1960 to twenty-ninth in 1990, down to forty-sixth in 2010. The U.S. Centers for Disease Control and Prevention (CDC) acknowledges, "The U.S. infant mortality rate is higher than those in most other developed countries, and the gap between the U.S. infant mortality rate and the rates for the countries with the lowest infant mortality appears to be widening."³⁶

While the infant mortality rate in European and Asian countries has decreased, to 2 to 3 deaths per 1,000 live births, more than 6 infants per 1,000 under one year of age will die, and 7.8 children per 1,000 under five years of age will die this year in the United States.³⁷ The United States lags behind nearly every developed country and even poor countries such as Cuba, whose healthcare expenditure is \$230 per capita, whereas the United States' is \$6,096 per capita. "Infant mortality and our comparison with the rest of the world continue to be an embarrassment to the United States," said Grace-Marie Turner, president of the Galen Institute, a conservative research organization.³⁸

U.S. medicine is dominated by corporate interests—physicians, academic institutions, and government agencies—whose financial interests are intertwined with drug and vaccine manufacturers. Physicians, professional associations, medical institutions, and government agencies are collaborating partners in the business of medicine. The practice of medicine, medical research, and medical information dissemination channels are imbued with the utilitarian business ethics calculus. Thus individuals and communities are viewed as the means by which to increase profits. Neither individuals nor the citizenry are well served when the integrity of medicine is debased, its scientific method is tainted, and its humanitarian and moral principles are violated with impunity.

Conflicts of interest compromise our current vetting system for medical research. The system is designed to bring new products to the market with little regard for their lack of therapeutic value or their potential safety hazards. The system fails to ensure that drugs, vaccines, and medical devices are adequately tested for safety and therapeutic value. The most vulnerable populations—children, the elderly, and the disabled—are unprotected from bad medicine, defective medical products, and unethical physicians.

A government-funded experiment, "fenfluramine challenge,"³⁹ encapsulates an enduring eugenics mindset within U.S. academic medicine. From 1993 to 1996, senior researchers at the New York State Psychiatric Institute (NYSPI) (including the current chairman of child psychiatry at Columbia University),⁴⁰ Queens College, and Mount Sinai School of Medicine,⁴¹ conducted pseudoscientific, wholly non-therapeutic, "predisposition to violence" experiments. State and federal governments funded the experiments. Researchers administered intravenously the neurotoxic drug fenfluramine⁴² to one hundred mostly African American and Hispanic boys, aged six to eleven. The researchers sought to prove a eugenic hypothesis,⁴³ that violent or criminal behavior could be predicted using biological markers, such as levels of brain chemicals.

Neither the researchers, nor the medical ethics reviewers at the institutions and at the National

Institute of Mental Health (the federal agency that funded the experiments), nor the journal editorial boards who published the research reports, considered the children's welfare and human rights. They all collaborated in violating the dignity of these children as human beings: None of these academic and governmental physicians had any qualms about exposing young children to risks of harm, causing them to suffer pain and trauma, or labeling them as "biologically predisposed to violence" in an experiment with absolutely no therapeutic rationale. Dr. John Oldham, director of the NYSPI, stated in an interview in the *New York Times* that such studies are "very important to study the biological basis of behavior.... Is there or is there not a correlation between certain biological markers and conduct disorders or antisocial behavior? This study was an effort to look at this with a relatively simple method using fenfluramine." Clearly, the medical research community in the United States remains infected with a racist, eugenic ideology that continues to pose a threat to vulnerable individuals, and children in particular.

LESSONS FROM THE HOLOCAUST

The shadows of Auschwitz and the revelations at the Doctors' Trial in Nuremberg are indelible—they cannot be redacted from history. The Holocaust is an object lesson of how the government's usurpation of individual civil liberties and the collapse of professional and institutional integrity—in particular, economic, medical, and legal integrity, which are the underpinnings of a civilized society—led an entire society to be swept into the realm of genocidal murder. The stated rationale for the medical atrocities that were “crimes against humanity” was that they were for “the greater good.”

The silence of the medical community—in both Germany and the United States—about its role and responsibility after it turned its back on the Hippocratic tradition in favor of eugenics is an indication that the medical community is conflicted. There has been no disavowal of eugenic healthcare practices carried out “for the greater good,” which threaten individual human rights and civilized medicine. Physicians' efforts to distance themselves from the atrocities at Auschwitz—the apex of murderous medicine—by spreading the myth that the Nazi medical atrocities were the work of deranged scientists is an attempt to delude the public and themselves about the profession's criminal culpability.

When medical trends veer from the moral Hippocratic tradition, professionals lose their moral footing and are capable of committing medical atrocities. Mandatory public health policies that trample on personal human rights for the claimed “greater good” threaten individual liberties and the very foundation of a civilized, democratic society. Doctors who practice medicine “for the greater good” participate in a culture that views the individual as a means to an end. Such a culture may set in motion increasingly abusive medical practices culminating in medical atrocities. Unless we confront these moral shortcomings and establish viable safeguards, no one can be safe, and the long shadows of Auschwitz and Nuremberg will continue to haunt us.

Chapter Ten

“THE GREATER GOOD”

Allen Tate

Political philosophy is not a staple of mainstream consciousness. The theories of Thomas Hobbes and John Locke rarely take priority over thoughts of carpools, soccer practice, and grocery shopping in the multitasking mind of the average parent. However, we experience the application of the philosophy of utilitarianism with far greater frequency than we may realize. Whenever we speak of “the greater good,” we invoke a utilitarian view. Whenever we take action to value the happiness or well-being of the group over that of the individual, we do so as utilitarians.

As with all philosophical theories applied in the real world, utilitarianism must meet specific criteria for its application to be sound or “good.” As utilitarianism necessarily usurps the rights of the individual, the need to meet these criteria is paramount. When utilitarianism is applied to an issue such as vaccination—which involves children, infectious diseases, and the virtual guarantee of death and debilitating side effects for some—it is of the utmost importance that vaccination policy decisions, and specifically vaccination mandates, meet the criteria to satisfy the theory.

When arguing theories, philosophers apply them to ideal worlds, in which they assume all criteria have been met. They do this so they can focus solely on the theory in the purest terms. These theoretical worlds are free of complicating factors such as corruption and human error that might affect one’s view of how the theory should be applied. Sadly, we are not afforded this same luxury in the real world, as the existence of corruption in the government cannot be refuted. For the sake of discussion, however, I will attempt to simplify the discussion as philosophers do.

A sound application of utilitarianism requires that an action or decision must deliver the greatest good for the greatest number. I should note that the greatest good does not necessarily need to be good in the sense of giving happiness or pleasure. The benefit could come in a number of other forms. For example, you might prefer to drive ninety miles per hour on the highway because it would shorten your commute and allow you to get more work done. However, your high-speed driving would also put other drivers at risk of serious injury. Utilitarians would place a higher value on the safety of all drivers on the road than on the pleasure you would obtain from a shortened commute. This is the basis for speed limits on our roads. A speed limit does not give pleasure or happiness to the group; however, it can easily be

argued that it provides the greatest good to the greatest number.

Now let us arbitrarily place the speed limit at fifteen miles per hour. While this would most certainly ensure the safety of all drivers, the traffic buildup, the loss of productivity at work, and the total unhappiness of drivers as they crawled to work each day would likely outweigh the benefit of guaranteed safety. Many might reasonably argue that they would prefer to have no speed limit and drive defensively if the only alternative is a painstakingly slow commute. Although the fifteen-miles-per-hour speed limit would aim to provide the greatest good, it would fail to meet the main criterion for sound utilitarianism. An application of utilitarianism is sound only if the decision made actually delivers the greatest good to the greatest number. Any application that fails to meet this criterion necessarily results in the removal of individual rights that cannot be justified within a utilitarian argument.

The justification for mandatory vaccination in the United States is based on utilitarian logic. On many occasions, public health officials have appealed to the American public regarding the necessity of vaccination in order to ensure the safety of the “herd.” States deny unvaccinated children admission to day care and public schools not because they are at risk but because they are perceived to pose a risk to other children. Utilitarian philosophers first introduced the concept of the greater good, and it is through this principle of utilitarianism that our government justifies compulsory childhood vaccination. In light of this claim, the burden of proof lies with the government to show that compulsory childhood vaccination does, in fact, provide the greatest good for the greatest number. If vaccination mandates are not truly for the greatest good, and the government has invoked utilitarianism to justify them, then the government would have offered a fraudulent, insufficient justification.

It is indisputable that the vaccination schedule has never been tested for safety in its entirety, or in the way that it is administered. In other words, while the government reviews, licenses, and compels individual vaccines, it does not test—or require vaccine makers to test—the safety and efficacy of vaccines given simultaneously or the cumulative effects of multiple vaccines. For example, while the government reviews manufacturer prelicensure tests and recommends the hepatitis B vaccine for two-month-old infants, it has not tested that vaccine together with the other vaccines it recommends to be administered simultaneously: rotavirus, diphtheria, tetanus, pertussis, *haemophilus influenzae* type b (Hib), pneumococcal, and inactivated poliovirus.⁴⁴ Furthermore, despite the public’s demand and congressional bills calling for it, there has never been a controlled study comparing long-term health outcomes of vaccinated and unvaccinated populations.⁴⁵ Thus it is impossible to determine the true benefits of the vaccination schedule. As it currently stands, it would be impossible to know if mandatory vaccination requirements, in fact, accomplish the greatest good for the greatest number. Because the burden has not been fulfilled, the hypothesis may not be accepted.

To obtain a better perspective of what it would take to justify that compulsory vaccination accomplishes the greatest good, we should consider the risks that the benefits of vaccination would need to outweigh. First, vaccination benefits would need to outweigh the risk of actually contracting infectious diseases, including diseases that have been virtually eradicated such as poliomyelitis, as well as diseases such as rotavirus (better known as childhood diarrhea) and hepatitis B, which is contracted from an infected parent, contaminated needle, or unprotected sexual intercourse. Second, vaccination benefits would need to outweigh the suffering caused by known and documented side effects of vaccination, such as encephalopathy (brain injury), seizure disorders, developmental delay, and death in affected children. Third, vaccination

benefits would need to account for the lost productivity and wages of those who die or are harmed by vaccines, and the lost productivity and wages of their caregivers. Finally, vaccination benefits would need to outweigh the cost to the public of compensating the families of vaccine-injured children and purchasing vaccines for children otherwise unable to afford them. Outweighing all of these combined risks is a tall order by any measure. In any case, since the childhood vaccination schedule has not been tested as it is administered, we cannot know the benefits of vaccination, and therefore, whether or not the utilitarian burden can be fulfilled. As it currently stands, utilitarianism cannot justify compulsory vaccination.

At a glance, vaccinations are conventional, prevailing medical procedures that have been standard protocol for over one hundred years and compulsory for our nation's children for over four decades. Nevertheless, it is startling to learn that while the first vaccine was compelled for adults during a smallpox epidemic, we vaccinate most of today's children at least thirty-five to forty times and recommend seventy doses of sixteen vaccines, including one for a sexually transmitted disease within hours of birth. How could we have paid so little attention to such a startling transition?

To explain our seeming acceptance of the dramatically increased number of vaccines children receive today, I will use a famous philosophical device known as the sorites paradox, or the paradox of the heap. This construct is meant to highlight a potential problem with the use of a vague term such as "heap," and in the case of vaccines, it highlights a potential problem with the use of the term "reasonable." I will first illustrate the concept using the term "short" as an example.

We would all likely agree that a fully grown man who is four feet tall is short. Furthermore, we would likely agree that a man who is one millimeter taller than this four-foot-tall man is also short, because a mere millimeter's difference cannot be what separates short from tall. Suppose that we continue this procession of short men, with each man one millimeter taller than the previous man. At the end of our very long line of fully grown men, we would find a nearly eight-foot-tall man who, based on our logic, would also be "short." It is obvious that we must have made some sort of error.

The same is true of our vaccination schedule. Many likely would agree that a single vaccine administered during an infectious disease epidemic is "reasonable." Furthermore, we would likely agree that the addition of one more vaccine would not suddenly make the schedule unreasonable. However, we now find ourselves "reasonably" administering seventy doses of sixteen vaccines to children, and we have the same perplexed feeling we might have when trying to explain why a man who is eight feet tall is "short." We can no longer justify the vaccination schedule in this way. We must not judge a vaccine in relation to previously scheduled vaccines but rather on its merit as an independent entity.

My aim is not to denounce utilitarianism. I seek to examine its application to the United States' compulsory childhood vaccination program. As Harvard Professor Michael Sandel writes in his book *Justice*, "The most glaring weakness of utilitarianism, many argue, is that it fails to respect individual rights."⁴⁶ I agree with this statement and, precisely for this reason, I contend that it is essential to ascertain whether the vaccination schedule our nation imposes on its children is truly for the greatest good. To accomplish the utilitarian's greatest good, the benefits of vaccination must verifiably outweigh great costs and suffering. Whether the benefits truly yield a tremendous good is simply unknown—and without this knowledge, the utilitarian's

burden of proof is unmet, and utilitarianism cannot justify this program.

As individuals, we will always act in our own best interest to the best of our ability. Without proof that compulsory vaccination is, in fact, what brings the greatest good to the greatest number, there is no utilitarian justification for us to sacrifice our individual rights to do what we discern is best for ourselves and our children.

Part II

NARRATIVES AND THE ECHOES OF “OMELAS” **THE CHILDREN, THE MILITARY, AND THE ADULTS**

The biggest difference in environmental exposures that happened during those three short years was the increase in their vaccines . . .

—Gay Tate, PhD, LSW, MLSP

What if it were true that the way we now vaccinate our children causes more death, chronic disease, and disability than it prevents in America?

—Judy Converse, MPH, RD, LD

I deeply regret my decision to allow Zeda to get this shot. She has lost all quality of life. I would do anything to get her better, but no one has any answers for me. The doctors still don't believe it was the vaccine.

—Amy Pingel

Unfortunately, these brave defenders of our freedom are defenseless against the mandatory use of dangerous vaccines, such as the anthrax vaccine.

—Capt. Richard Rovet, RN, BSN, B-C (USAF, ret)

Publisher's Note: Ursula K. Le Guin's short story "The Ones Who Walk Away from Omelas" appears here in the print version of *Vaccine Epidemic*. Unfortunately, it is not available for the electronic edition. It is widely available elsewhere, and we encourage you to read it before continuing with Part II of *Vaccine Epidemic*.

Chapter Eleven

THREE SHORT YEARS

Gay Tate, PhD, LSW, MLSP

Not many things can compare to the heartache of helplessly watching your young child lose developmental skills and regress into a world of mental confusion and physical pain. This is something you would never wish on any parent. Sadly, I have had to face this challenge not once, but twice. My name is Gay Tate, and I am a mother, former scientist, and practicing psychotherapist. My husband Allen and I have three children, ages twenty-one, eighteen, and fourteen. Our oldest was born in 1989 and was vaccinated according to the recommended schedule of the 1980s. He has always been strong and healthy. Our two younger children, born in 1992 and 1996, received their vaccinations according to a sharply expanded vaccination schedule, beginning at twelve hours old—it was the schedule typically followed for American children born in the 1990s. They have both been diagnosed with autism.

They are not alone.

This series of events and outcomes has repeated with thousands of other children and families, and autistic spectrum disorders have reached epidemic levels in this country. My family has experienced, firsthand and from the beginning, the unfolding of what I believe to be a man-made catastrophe. In less than two decades, we have moved from needing to explain what “autism” is, since so few had ever seen a person with autism, to seeing autism studies offered as a major in college.

This is our story.

Young Allen, my firstborn, was almost three years old when I was expecting my second child. I had left a rather intense and demanding life as a research scientist to experience motherhood full-time. Allen was sweet, precociously verbal, and very excited to be getting a new brother or sister. My pregnancy was smooth and uneventful, and Kenny was born in June, big and healthy, the day before my fourth wedding anniversary. Life was hectic, but good.

During his first year, Kenny hit his developmental milestones. He was good-natured, had a great appetite, and grew well. At his four-month well visit, he had developed a wheeze following a cold. His doctor prescribed a wide-spectrum antibiotic and a nebulizer, and because he was running a fever, she agreed to postpone his four-month round of vaccines for a week or two. Ten days later, although he still had a wheeze, he was not running a fever, and we went ahead with his shots. With time and a couple more rounds of antibiotics, his wheeze eventually resolved and

he continued to grow and progress.

I remember that Kenny spoke fifteen words at fifteen months old, just like his big brother. However, I was concerned that he was not walking yet and even seemed oddly fearful of cruising at times. When I reported this to his pediatrician, I was told not to worry: “Big babies are lazy, he’d rather talk than walk, the intellectual type.” The doctor was mildly concerned, however, because his head size had increased and veered off his growth curve slightly. Still, he gave Kenny his MMR vaccine. Just to be sure, off we went for a skull X-ray and ultrasound. Both were normal, no problem; but by eighteen months I was aware of a significant change. Kenny had slowed down. He spoke less and tended to sit in one spot, often with his head tilted to one side as if it was too heavy. He still was not walking on his own. Again, the doctor tried to reassure me that boys are slower to develop and that we should give him until twenty months to walk on his own. In my gut, I knew something was very wrong, but the people around me dismissed and minimized my concerns. It was a lonely and dreadful feeling.

Then Kenny’s disposition, which always had been sunny and affectionate, began to take on a quality of misery. Kenny often seemed disconnected, hypersensitive, and fearful. He was obsessed with ceiling fans and lights, and started to wake up many nights either laughing uncontrollably or screaming in pain from diarrhea. By now, my husband was very concerned. At age two and a half, the pediatrician finally agreed that Kenny showed developmental delays in all areas and recommended a specialist’s evaluation. I was desperate to know what this meant for his future, but doctors said that it would take a couple of years before anyone could say for sure. We would just have to wait and see. In the meantime, Kenny qualified for early intervention services. I watched Kenny constantly, calculating his every move in terms of the developmental charts. It sometimes took conscious effort to pull my eyes off him to pay attention to Allen, which added more guilt to my emotional load. We were also now on the treadmill of endless speech, physical, and occupational therapy sessions, usually with Kenny screaming, me sweating, and Allen trudging along with a toy and a book.

As Kenny made progress in some areas, new behaviors emerged. For example, as his walking improved, he went up on his toes and flapped his hands. As we got some language back, he began to verbalize with endless, loud *eeeeeeeeee* sounds. Moreover, he was obsessed with videos.

Discontent to wait years for an answer, I did my own research and concluded that Kenny’s behaviors fit the criteria for autism. As surprising as it might sound in today’s world, my doctors and therapists again minimized my concerns and tried to talk me out of it. Developmental delays, yes; some sensory issues, maybe; but not autism. It was early 1995, and the wave of regressive autism that is so prevalent today was just beginning. It was not until Kenny was nearly four and I was pregnant with my third child that I was gently informed that Kenny was “moderately to severely autistic,” as though it would be a terrible shock. I was past shock and it was certainly not news to me—I knew well before the “professionals.”

I also could not get satisfactory answers about all the physical maladies afflicting Kenny. His nose was constantly stuffy. He had crust behind his ears and nearly nonstop diaper rash. When I asked about his eyes rolling back in his head, the doctor said that as long as Kenny could respond to my voice when it happened, it was not a seizure (good . . . I think . . . but what was it?). The diarrhea was the worst, though—foul and discolored. It was obviously so painful for him. He would burst into tears and the diarrhea would start, sometimes so often that his bottom would

bleed. It was heart wrenching to see, and it just didn't make sense. He had been fine and was born healthy and beautiful. I was from a medical family with a strong background in science and was not aware of any disorders with this timing and this particular array of symptoms. He just seemed so sick.

I bounced for a while between anger and grief distorted into a form of aggressive industry. My husband Allen and I found a program that favored dropping diagnostic labels and treating problems like Kenny's as a brain injury. We hired a caregiver, attended a weeklong intensive training, and put together an extensive physical, behavioral, and academic program for Kenny. We tried a different diet, sound and smell therapies, set up a special gym, and looked at endless flashcards and photographs. My husband Allen, our caregiver, and I spent many hours doing creeping and crawling strengthening exercises with Kenny through the house, and we did patterning therapy most mornings with another family whose daughter had developmental delays. I can still remember young Allen demonstrating the patterning technique and coaxing the younger kids up onto the training table. It felt better for all of us to be doing something, and it did help—Kenny was getting stronger.

In the middle of putting this all together, my daughter Olivia was born. She was a joy, bright and curious, and always engaged with the people and activities around her. By now, Allen was seven, doing well in school and playing soccer. I was doing OK. When I started to feel sorry for myself, and overwhelmed by Kenny's disabilities, I told myself that I could handle it. I tried not to think, "Why my child?" but rather "Why not? There are no guarantees." With intensive work, he would get better. I had struck a fragile balance and life went on.

Olivia continued to flourish, and was more active and social than even young Allen had been at her age. She was physically precocious and had easily hit all her developmental milestones by her eighteen-month checkup, when she was given the MMR vaccine. (I can still remember the nurse practitioner's panic that Olivia, for some reason, had not been given the MMR at an earlier visit.) At two years old, she knew colors and shapes and loved the alphabet. However, I noticed that a change was occurring. In stores, she began rubbing the rugs instead of focusing on shopping, and although she knew many words, she wasn't stringing them together. When I expressed my uneasiness, friends and family told me I was understandably a little paranoid after dealing with Kenny's development. After all, the pediatrician had never found any cause for concern at her well visits. I latched onto this and managed to stay in denial for a few more months.

In late 1998, I was in New York City attending a conference on autism, hoping to gather the latest information for Kenny's program. Parent groups, along with a small but growing group of medical researchers, were mobilizing, trying to figure out what was happening to so many children. At the end of the day, I remember listening to a talk on a new developmental screening called a CHAT test (Checklist for Autism in Toddlers). Apparently, a lack of forefinger pointing at objects in a young toddler's behavior was the single most telling sign in predicting autism. It hit me with such force—Olivia had stopped pointing. Within seconds, my denial disappeared, and I felt as if someone had pushed me into an empty elevator shaft. To this day, I can still remember the suddenness of the realization and physical shock that Olivia was regressing toward autism. I am not sure how I made it home to Pennsylvania.

Over the next year, despite private speech therapy, my daughter's language slipped away and was replaced by occasional inappropriate words and phrases from Barney videos. Her behavior

changed from outgoing and curious to fearful and rigid. She cried a lot, and her facial expressions took on a distant, even bewildered, look. At three and a half, she was officially diagnosed with autism, and I was utterly heartbroken. I was no longer even superficially OK. I could not fathom how I would get through this again.

For a while, I struggled with feeling depressed and overwhelmed. Everyone has a limit, and I had reached mine. Nevertheless, I tried to keep my game face on and keep moving forward with interventions for Olivia. At this point, we scaled back Kenny's home program because he had entered school full-time as one of four boys in the first autism support classroom in our district.

We were still exhausted from the many nights Kenny would wake and stay up. From age three to almost nine, he slept on the couch in our den, often not more than four or five hours. In addition, our caregiver, only nineteen when we hired her, had understandably moved on with a new career, and finding a reliable replacement had been challenging. It was a difficult period. Looking back, I realize that I was also incredibly sad. Grief after an autism diagnosis is difficult to process. For me, it felt like there was no time, as if the window of opportunity would close for turning things around if I relaxed or got lost in emotions. There was a sense that I was never finished, that I hadn't done enough or had missed something crucial. There was a lot of guilt.

Eventually, though, things began to look up a bit. After a failed attempt at regular preschool, Olivia began attending a full-time autism support class. By this time, children with a PDD (pervasive developmental disorder) or autism diagnosis were not so rare and services had to adjust. I worried that a full-time preschool program would be too much for her, but she seemed to enjoy it, bus ride and all. Around the same time, we found a wonderful new caregiver. Young Allen had become quite involved with traveling soccer and basketball teams, guitar and dance lessons, and this gave his dad (coach) and me more time to support him and attend his games and performances together. Also, with the help of a good Defeat Autism Now! (DAN) doctor and developmental pediatrician, we were able to calm Kenny's raging intestines. Improving his intestinal health, along with a low dose of Risperdal, helped him finally sleep through the night and tolerate sleeping upstairs in his own room in a regular bed.

Over the next few years, we chiseled away at Kenny and Olivia's physical symptoms and behaviors with various prescription medications, supplements, diets, and therapies. Nothing dramatic happened with either child, just slow, steady progress. Both children had developed some very basic functional language. Although still in pull-ups, Kenny's muscle tone had improved, and he seemed happier and more comfortable in his own skin. Olivia sometimes struggled with anxiety and obsessive-compulsive tendencies, but she loved the structure of school and asked to go every day. Our district had developed a good autism support program and both kids had excellent, committed teachers and therapists. However, what seemed to be lacking there, and everywhere, was alarm—recognition that something very wrong was happening and causing autism diagnoses to skyrocket. In one school district, in just six years, the need for autism support had ballooned from Kenny's original class of four boys to seven full-time *classrooms* at the elementary school level!

In 2005, after sixteen years of being home full-time, I decided to venture out to go to graduate school, part-time, for a master's degree in clinical social work. Yes, it was still true that our family's needs and complexities were daunting, but I felt we had reached a comfortable equilibrium that could accommodate my new goals. However, although I finished my master's program, a challenge we could not have fully anticipated was the powerful impact of puberty on

Kenny and Olivia. Again, this was uncharted territory with this new wave of sick children.

During the first year of middle school, Kenny, usually sweet and cooperative, had some episodes of aggression with teachers and aides who were not familiar with his signals and behaviors. His school called Allen and me into several meetings with the rest of his team and the situation was easily resolved. Then, at age fifteen, the day after Christmas, Kenny had a massive grand mal seizure. Allen was coming back from driving young Allen to the airport on his way to a basketball tournament, and I was home alone with Kenny and Olivia. I had taken Kenny to sit on the toilet when he started to seize. He was fully grown by then and in the small bathroom, there was no place to get him down to the floor without one of us being injured. I don't remember how I dialed 911, but I did. Inexplicably, they did not arrive for fifteen minutes. In that time, his breathing stopped and started several times, and I had trouble finding a consistent pulse. When the paramedics finally arrived, they hustled me out of the house and began working on Kenny. I remember sobbing in our driveway while Olivia smoothed my hair and wiped tears off my cheeks. The ambulance transported Kenny to our local hospital, and then quickly airlifted him to Children's Hospital in Philadelphia. He was in intensive care and neurology for a week and has been on seizure medication ever since. I believe that if this had happened during the night or I had not been nearby, he would have died.

Olivia began middle school and her menstrual period at about the same time, in the fall of 2008. Her anxiety and obsessive-compulsive disorder (OCD) symptoms had already been escalating and the erratic cycle of hormone activity put them over the top. The girl who had loved to go to school now had more and more days of either lashing out physically at teachers and aides or curling up in a ball in the foyer of her classroom. Several times, her school asked me to come pick her up because she had her period and refused help in taking care of her hygiene needs. In January, our developmental pediatrician directed us to an adolescent specialist who suggested putting her on birth control pills to regulate her periods to four times a year. The doctor encouraged us to weather any early, unpleasant side effects, and stick with the pills for at least six months. She was miserable and we were desperate, so we tried it. Olivia went downhill fast, and her behavior deteriorated even more. In May of that year, a boy in her class had his first seizure. Olivia apparently became very agitated by the unusual activity in the classroom and began throwing things. When the paramedics arrived, she went after them, trying to shove them away from her classmate. That afternoon, her assistant principal informed me that she could not return to school because she was a threat to the safety of other students.

During the first few weeks at home, she spent most of the time in her bed, under covers. She looked haunted and miserable. We brought food to her and had to encourage her to eat. I could not get her in the bathtub for two weeks. It was so painful to see her suffering so much and unable to explain how she felt. When she did come downstairs occasionally, she sat in one spot on a wooden chest, but not on couches or chairs. This went on for several months. When her homebound tutoring began, her teacher sometimes had to work with her from the side of her bed. Olivia had always been physically talented and inclined. She loved to swim in our backyard pool, roller skate, and do yard work with Dad. All of that stopped. Olivia did not go outside for four months, and it felt like we had lost her all over again. It was devastating.

Over the past year, we have weaned her off hormones and worked more with supplements to restore normal neurotransmitter levels. Five months ago, Olivia was able to tolerate attending a specialized autism support class in an alternative school. It took two hours to coax her into the building, but she has been able to build up slowly, in half hour increments, to a full school day.

We are very proud of her courage and progress. However, her OCD symptoms remain a challenge for her and for others in the classroom, and these symptoms often rule our home.

Just as we were rejoicing over her school achievements, Olivia had her first seizure. Although it was not as life threatening as Kenny's, it brought her patient and unflappable father and me to tears.

And so our story goes. Just as we begin to exhale, or think we cannot possibly dig any deeper for strength, another scary challenge comes along that needs to be added to our pile of worries and uncertainties. At this stage, however, what is not uncertain for us anymore is that Kenny and Olivia's symptoms, which are labeled as "autism," are really symptoms of vaccine damage and mercury toxicity. The full realization of this came slowly, with times of resistance and disbelief, probably for several reasons. First, neither child had a sudden and obvious adverse reaction. In hindsight, Kenny had shown more of a slow deterioration with each round of vaccinations. Olivia's regression had been a little steeper, and seemed to begin around the time of her MMR, at around eighteen months. Second, they were born at the beginning of the autism epidemic, particularly Kenny. Looking back, I remember monitoring both children, as instructed, immediately following each round of shots, for symptoms such as "extremely rare" high-pitched screaming. However, I was not looking for any delayed signs of an adverse reaction, and therefore, did not connect later problems to their vaccines. I doubt if many parents did, especially back then. In the early 1990s, parents and most pediatricians had never seen this kind of physical deterioration and developmental regression in formerly healthy, normal toddlers. Today, less than twenty years later, with 1 percent of American children developing autism, the appearance of autistic symptoms is a major concern among new parents, and pediatricians now routinely screen toddlers at well visits.

Another source for my disbelief that vaccines could have caused such harm to my children is my age and background. I was born in the 1950s and was very aware of the excitement over the polio vaccine. My mother was a physical therapist, trained at a time when the career was in its early stages. In our home, I remember that she prominently displayed a framed picture from a magazine article about her working with a child with polio. My father was a family doctor and we lived in the country around horses and cows. We were not concerned if I fell and scraped my knees because a tetanus shot would save me. For several years, my older sister was one of the pediatric nurse practitioners doing well baby visits at the large pediatric practice where I eventually took my children. The belief system was (and for many still is) that vaccines were one of the greatest achievements of modern medicine, and it was irresponsible and very risky not to vaccinate your child. It was a powerful message all around me that eventually clouded my common sense and contributed to a disconnect between what I learned about the development of the immune system in graduate school and research, and the delivery of so many vaccines so early, beginning in the first twenty-four hours of life.

Although not from a medical family, my husband's parents raised him with a powerful belief system as well. He was a molecular biologist by training and we had met and briefly worked together in a research lab at New York University Medical Center. After a couple of years, he returned to graduate school for an MBA. With that combination of skills, he was quickly, and suitably, snapped up by the pharmaceutical industry. Even though he was never directly involved with vaccines, his work culture, understandably, had an impact on the process of piecing together what had happened to our children.

To be clear, I am not anti-vaccine. I am for safer vaccines and vaccination choice. Vaccines serve as important tools for controlling certain infectious diseases. Nevertheless, the reality is that they are not miracles; they are medicines, with potentially negative side effects expressed differently in different people and under different conditions. The side effects are additive with each individual vaccine as well as from combinations. From my graduate studies, I came to appreciate how highly evolved and intricately balanced the immune response is, and that one of the main tasks of the developing immune system in the first months of a child's life is to learn to differentiate between what is self and what is foreign. This is exactly when our vaccination schedule is applied most aggressively, artificially stimulating an immune response via an unnatural route of infection. It follows that some children, perhaps because they are sick or have a family history of autoimmune disorders (like mine do), will simply not be able to tolerate this bombardment, and chronic, systemic damage will likely ensue. All of this I knew intellectually (pangs of guilt). Yet when our government suddenly increased the number of vaccines in the early 1990s, the "vaccines are good and necessary" message somehow superseded my ability to make the connections. I put my faith in the pediatric experts to keep me up to date on the best and safest infant care.

The difference in the vaccination schedule in the three years between Allen and Kenny was dramatic. Our government had more than doubled the number of shots in the first six months, and they were also given earlier, beginning on the day of birth. However, I believe the most damaging aspect of the change was the sharp increase in the amount of mercury that Kenny, and later Olivia, received. Their pediatricians gave Kenny and Olivia the additional hepatitis B and *haemophilus influenzae* type b (Hib) vaccines, both containing the preservative thimerosal, which is 50 percent ethylmercury by weight. Mercury is a potent neurotoxin, and very damaging to the immune system. Kenny and Olivia each received three times the amount of mercury, beginning just days after birth, as Allen. Those in charge of the vaccination schedule apparently forgot to add up the amount of mercury that American children would receive because of the added shots. How careless! Even worse, how reprehensible to continue, to this day, to publicly deny the damage that was done.

How do I know Kenny and Olivia suffered from mercury toxicity? I have test results. We had each child's porphyrins tested. Porphyrins are derivatives of the heme synthesis pathway and are normally found in urine. Variations in urinary porphyrin metabolite patterns can be used to measure the overall body burden and toxicity of mercury, as well as other heavy metals and toxins. I can still remember staring, through angry tears, at the results of my three children's porphyrin profile tests. Kenny, cognitively and physically the most affected child, showed the highest level of mercury toxicity. Olivia, less affected, showed clear but less toxicity, and Allen's results showed no evidence of mercury toxicity at all. All three children shared the same parents, food, water, air, time spent nursing, and even the time of year they were born. The biggest difference in environmental exposures that happened during those three short years was the increase in their vaccines. There it was, clear data from my own family and a microcosm of what had happened to so many children. A sudden increase in autism, beginning in the 1990s, that coincided with a change in a single set of exposures—vaccines, received by all children in our country without regard to genetics, diet, socioeconomic status, geography, or quality of medical care.

Yes, my family has ridden the wave of this tragic, man-made disaster from the beginning. Autism, practically unknown when young Allen was born, now affects 1 percent of our

population and one in seventy boys. The pain and sickness it has caused the affected children and the toll it has taken on families is incalculable. Marriages have been hard hit, and the divorce rate is high. Fortunately, Allen and I have become tight partners during the last twenty years, but we struggle to find time for each other and respite from the full-time care needed for Kenny and Olivia.

Siblings are tremendously affected, not only as children, but also as adults who will carry the burden and face the challenges of the next generation. Young Allen has been an incredible older brother, from the beginning, in so many ways. As a young boy, he would carefully practice the best and most informative ways to explain Kenny's behaviors before a new friend came over. I can still remember his sad and stoic face when I told him that Olivia was going to need speech and some other therapies, like Kenny. He dug in and helped with her therapy. In high school, he would announce autism fundraisers, and urge other students to participate in autism walks and races. As a young man in college, he has expanded his advocacy to writing and speaking, as part of his involvement with such groups as the Elizabeth Birt Center for Autism Law and Advocacy (EBCALA) and the Center for Personal Rights. You will again be introduced to young Allen, as he is the author of chapter 10 of this book, "The Greater Good." Watching Allen with his brother and sister through the years and seeing his advocacy for children like them, who may be susceptible to vaccine regression, has been a quiet, steady lesson in unconditional love.

More than a few times, people have told me what an amazing kid Allen is. Then with the very best intentions, they mention that growing up with Kenny and Olivia must have given him extra compassion and maturity. Alternatively, people will comment on how very patient (my husband) Allen and I are, that we are the right people to be raising Kenny and Olivia. I thank them, and there is truth to what they say. However, a part of me bristles. Allen was an amazing four-year-old long before the word autism came into his life; my husband and I have always been patient people. One thing did not have to happen for the other to be true. The vaccine damage to Kenny and Olivia should not have happened at all. They and thousands of other children have been denied the opportunity to achieve their full potential at a great cost to our society, both financially and in terms of human resources. I don't want people to neatly arrange any part of this unnecessary tragedy in their heads. I don't want this to happen to anyone else.

With that in mind, I urge those who know the story of our family to pay close attention to the vaccine injury debate, to learn about the autism epidemic and the growing epidemics of neurological and autoimmune disorders happening today, and to demand both informed consent and a safer, individualized vaccination schedule from our public health officials.

Chapter Twelve

PEDIATRICS: SICK IS THE NEW HEALTHY

Judy Converse, MPH, RD, LD

I am struck by the contrasts in a certain three doctors I know. Two are pediatricians and the third is a renowned surgeon with expertise in immunology.

The first pediatrician's career included—in addition to a busy practice spanning three decades—defining and promoting health and immunization policy in conjunction with his state health department and an Ivy League university. It also included years of volunteer work for the autism community. He is a recognized expert witness in litigation related to vaccine injury. He is happily married to his first wife and has four children and twelve grandchildren.

The other pediatrician received his medical degree from the same Ivy League university, served in the National Health Service, has a master's degree in public health in addition to his medical degree, and has practiced with no particularly distinguishing achievements. He is married and has two children.

One unequivocally supports vaccination to the fullest, believes all vaccines are safe and effective, and vaccinates children daily without the slightest hesitation. The other now accepts the possibility that vaccines can trigger autism in susceptible children, supports findings that show a link between inflammatory bowel disease and MMR vaccine, and questions the current pediatric vaccination schedule.

One is knowledgeable about food allergies and sensitivities, and encourages special diets to mitigate them. The other is not informed about these issues, and has advocated the use of asthma medication for children with multiple food allergies but no asthma symptoms.

One has a grandchild with autism. The other has a child who committed suicide.

One operates within the status quo of pediatrics, assiduously following the guidelines of the Centers for Disease Control and Prevention (CDC) or American Academy of Pediatrics (AAP) in practice. The other is aghast by the degree of chronic illness and disability that has become normal in children in the new millennium, is relieved to be retired from practice because of this, and hopes for a dramatic change in his field.

For years, we were patrons of the pediatrician who seemed unable to answer my questions with anything other than broad-stroke missives from the CDC or the AAP. My son didn't particularly like or trust him. He once told us that rice was not allowed on gluten-free diets (not

true), and his head nurse did not know what a gliadin antibody test was (it checks gluten sensitivity; my son's test results are highly positive). Like many of the parents I've met in my pediatric nutrition care practice, I've felt frustrated by having a pediatrician who not only didn't understand our healthcare needs but was not interested in them, and much to our dismay, neither was anyone on his staff. He continues to practice, unfettered by controversy.

The other pediatrician described here is a former neighbor of mine, who is retired. In spite of his spotless record, expertise, and tireless service, he has been marginalized for investigating vaccine safety. He is trivialized for speaking up about the possible role of vaccines as a trigger for autism, seizures, sudden infant death syndrome (SIDS), autoimmune disorders and allergies in children, and shaken baby syndrome (SBS)—even though any vaccine package insert states that the product inside may trigger seizures, death, or allergic reactions, among many other adverse events.

I would like to have a pediatrician like him. He has an impeccable reputation among his patients, is kind and caring, and is an independent thinker who listens and then answers questions thoughtfully. My son knows him, likes him, trusts him, and always has—even when he was a young toddler with sensory issues that made him anxious around almost anybody. He felt instantly comforted by this man's reassuring manner with kids. When this doctor has no answer, he says so and directs me to someone who might know more. Unfortunately, I can't have him or a younger, unretired version of him as my pediatrician. A pediatrician who questions vaccines is not only unwelcome among his peers and professional organizations but is cast aside as unscientific, intellectually feeble, and even unpatriotic—a knee-jerk reaction that smacks of bias and zealotry.

I use the other pediatrician only because he is available. He is all that our beleaguered healthcare system sanctions. Insurance pays for doctors like him, but not for the ones who think independently. This pediatrician's scope of practice is in lockstep with what the health insurance industry dictates, which, in turn, is in lockstep with what the pharmaceutical industry dictates. If there is no need for prescription drugs or vaccines, there is no need for this pediatrician; indeed, we rarely see him. I am sure he is a good, kind, and even smart man. Why did he stop thinking independently and critically?

Imagine your child off drugs. All drugs. No antibiotics, vaccines, reflux medication, laxatives, statins, antipsychotics, sleep medication, stimulants, antidepressants, seizure meds, insulin, steroids, nebulizers, antiinflammatories, suppositories, or anything else I've missed. Imagine your child being so healthy that perhaps just one thing from this list is needed every five years or so. If you were born before 1970, you grew up with few drugs and vaccines. Odds favor polypharmacy for those born after 1990 or 1995.¹ If your child never used any of these things, would there be any reason left to go to the pediatrician? What else would be offered for care if not a medication or a shot? Incredibly, it is now the norm to turn the pharmaceutical spigot on children, starting at birth—and nobody blinks. I often ponder the colossal profitability of this. Through a persistent, pervasive hypnosis from pediatricians, news outlets, print ads, web content, governmental press, TV programs, and magazines, parents are being taught that it is normal to have a child who can't talk, poop, walk, eat, digest food, grow, attend school, or perhaps even breathe without the benefit of a litany of medications and vaccines. Worse, we are conditioned to believe that children who *don't* join in are somehow *not* normal, or—perhaps more inexplicable—that they are a danger to children who do submit to the dozens of vaccines, antibiotics, and drugs. It is arguably the other way around, but that's another conversation.

In the same time frame in which giving babies and children dozens of drugs and vaccines became normal, our children have gotten sicker, not healthier. It cannot be claimed that this style of healthcare works. My vantage point on this is different from your pediatrician's, by virtue of a different training in child health. I am a registered dietitian, and I have an undergraduate degree in nutrition sciences and a master's degree in public health nutrition. This training taught me that nutrition status is what drives a child's ability to fight infections. Low nutrition potentiates susceptibility to infection, and nutrition status declines during infection.² Ample and strong data agree—data that show that one-third to one-half of the millions of deaths in children across the world, caused by measles, diarrheal diseases, pneumonia, AIDS, and malaria, are due to undernutrition, not undervaccination.³ Data show that even mild malnutrition (the kind I see in practice here in the United States, especially in kids with autism) changes how often kids get sick and whether they live or die from an infectious disease.⁴

I was taught about vaccines too. When I finished a graduate degree in public health in 1988, nutrition and vaccines were not presented as mutually exclusive tools for maternal, infant, and child health. Now it seems that data on child nutrition are ignored—and parents are told that the only way to have healthy children is to fully vaccinate them. This is a myth that the body of evidence in child nutrition does not support. What is well supported is that nutrition drives learning, growth, development, and immune function in children. Look at it this way: For your child's first year of life, if you could afford only a box full of the thirty-odd vaccine doses now recommended for zero-to-twelve-month-old infants or a year's supply of nutritious food, which would you rather have?

I was trained to uphold the CDC's goals and objectives for public health. In 1988, its "goal number 1" for the year 2000 was to "increase span of health life."⁵ It is not difficult to see that American public health policy has failed at this: Data from several sources show that, for the first time in U.S. history, children's life expectancies may be shorter than their parents'.⁶ Despite the rapidly growing vaccination schedule, American children are more chronically ill and disabled than ever. They are more likely to die as babies than the children in more than forty other countries. We have an abysmal infant mortality ranking that has done nothing but slide from bad to worse since the 1950s. Children in the United States today have much higher rates of asthma, autism, diabetes, Crohn's disease, epilepsy, life-threatening food allergies, obesity, ADHD, learning and behavioral disorders, and suicide than kids did in the 1980s, when fewer vaccinations were given.

Were these genetic phenomena unnoticed before? Martha Herbert, a Harvard neurologist who also holds a PhD, put it this way: "Genes load the gun, but the environment pulls the trigger." The one trigger we pull dozens more times than ever before is vaccination. Children now get seventy doses of sixteen different vaccines through age eighteen. Among possible causes of the health problems plaguing our children are immune dysregulation and toxic exposures, so we must examine the role of vaccines as possible triggers.

What if it were true that the way we now vaccinate children causes more death, chronic disease, and disability than it prevents in America? Blanket assurances that this can't happen are naïve. Pharma-funded studies to diffuse concern—whether the money flows first through university foundations, hospitals, or nonprofits—are obviously flawed, inherently biased, and can't yield clear information. I am disturbed by how sick the children are who I meet each week in practice, but I am more concerned that their pediatricians seem nonchalant. They are like my

pediatrician—not well informed beyond pharma-driven information, not thinking critically, not using their training and skills to the fullest, and bending to the dictates of the insurance and pharmaceutical industries, who ultimately underwrite what they do every day. Is this the best we can offer?

My graduate training fully indoctrinated me in the reasons for vaccination. I need no instruction on its touted benefits. I was also privileged to have classmates in graduate school at the University of Hawaii who were doctors, nurses, and health workers from all over the world. As a *haole* (white) U.S. mainlander, I was in the minority. They had lived or worked in places like Vanuatu, Papua New Guinea, or Karachi, Pakistan, where they had seen children die of measles. They were from impoverished regions in Africa, Indonesia, or Taiwan, where children die of infectious diseases more often than in the United States. I understand what it means to lose children to preventable deaths. I also watched my brother die a slow, agonizing death from AIDS—a disease whose very existence some trace to unabashed negligence in the vaccine industry,⁷ and from which the same industry hopes to profit with a new product.

Any public health training teaches that vaccines do kill some babies and children. I was taught that infants who die from vaccine injuries are probably defective and would have died anyway, that these are necessary deaths, and that it's best to weed these children from the gene pool. Even then, years before I became a parent of a healthy full-term baby who would nearly die from a vaccine injury, this shocked me. Is this eugenics? Isn't public health for *all* of the public? How many parents would like their children's lives to become necessary collateral damage? Is it constitutional to kill or injure some children for the supposed good of others? Is it moral?

Is it good for others? Read the year-end summaries of reportable diseases in *Morbidity Mortality Weekly Report*, the CDC publication paid for with your tax dollars. Look historically—go back and view trends. You will see that infectious diseases wax and wane independent of vaccination, which is proof that it takes more than a vaccine to prevent a disease. You'll see discussions over the years about risks and benefits of preventive and treatment strategies, and research on how infectious diseases move through populations, what makes some of us die, what lets some of us live, and why some of us get no illness at all. It is never just about a vaccine.

The last physician in my story knew this. Francis Moore, MD, was the late-in-life spouse of my husband's grandmother, Kathryn Saltonstall. Both knew well what my son had endured from an adverse reaction at birth to the newborn hepatitis B vaccine; both knew of my testimony before a congressional subcommittee on this in 1999, and both knew I wrote a searing personal memoir about this family debacle.⁸

Some readers might recognize Dr. Moore's name. He was a Moseley Professor of Surgery, emeritus, at Harvard Medical School. He maintained an address on campus well into his eighties. He was surgeon-in-chief at Brigham and Women's Hospital in Boston. His accomplishments are too numerous to list. Hailed as one of the greatest surgeons of the twentieth century, he pioneered techniques in organ transplantation and the metabolic support of surgical patients. He led the team that performed the first successful human organ transplant—a kidney transplant in identical twins—in 1954. Dr. Moore authored hundreds of medical articles and six books, including a text that became a standard in the field. By the time I met him, through family gatherings, he was mostly busy traveling the globe to receive awards and honoraria, and having audiences of dignitaries the world over. Out of sheer respect for his stature in the medical community, I never told him my opinions of vaccines—but once I testified before the

congressional subcommittee reviewing hepatitis B vaccine safety in 1999, of course, he found me out.

The conversation I avoided for years took place when he phoned me to discuss this. As one might think, Dr. Moore had a very commanding manner and tone. I was more terrified to take this call than I was when I faced off with Henry Waxman (D-CA) at the subcommittee meeting, with news cameras rolling. I did not want to disrespect this man who had contributed and accomplished so much in his field, or my husband's grandmother, the kind, gentle matriarch of the Marion, Massachusetts Saltonstalls. I was certain Dr. Moore was about to crush me, using that signature booming voice, with a rant that would effectively bar me, my husband, and my son for good from further family discourse.

That never happened. Dr. Moore was kind. He listened. He was appalled and puzzled that newborns were being given hepatitis B vaccine, a shot he felt they could not possibly need. He did not know of this policy, though, at the time of our conversation. Babies nationwide had been receiving hepatitis B vaccine at birth for about ten years. He described a "window of vulnerability" for newborns, from ages zero to two months, in which he felt the immune system was too immature to receive a vaccine of any kind, lest it trigger damage. He thanked me for contributing my testimony. I hung up and dropped my face in my hands, overwhelmed by this unexpected reception from a physician at the zenith of accomplishment in his field, after being scoffed at for years by my son's doctors.

Dr. Moore's letter to me is in the appendix. He sent it after our chat on the phone. He calls for "absolute avoidance of neonatal vaccination" in this letter. Read it, and wonder: If one of the world's most respected medical achievers had this opinion, but has now passed on, who else of his stature can continue this conversation? Where are the sage experts to guide us? If he were alive and publicly voicing this point, would he too be dragged through a spurious trial and stripped of credentials and authority, as the British General Medical Council did to Dr. Andrew Wakefield for his research on vaccines and autism? When our doctors are no longer free to think independently, pioneer, investigate, and lead—as Dr. Moore did throughout his career and, as I believe, Dr. Wakefield endeavored to do—medicine is truly dead. Our children will suffer the most. It then falls upon you, the individual parent, to uphold your right to choose with your doctor how you vaccinate your children. It falls on you to investigate, read, explore, defer, or simply stop going to pediatricians if all they can offer is rote information and new needles at each visit. Support the independent thinkers. As Gandhi said, "First they ignore you, then they laugh at you, then they fight you, then you win."

Chapter Thirteen

MY DAUGHTER IS “ONE LESS”

Amy Pingel

I am a single mother of four children, two boys and two girls. We live in Lake Station, Indiana. Before my oldest daughter Zeda got sick, we had normal lives. I worked a full-time job. Thirteen-year-old Zeda was a cheerleader and straight-A student. She was also a big help to me with my other children. She was the daughter every mother dreams of having and her future was bright.

I have always done my best to keep my kids healthy. I made sure they received their wellness checkups and they always got whatever vaccines the doctor suggested. All my kids were completely healthy aside from simple colds here and there—completely healthy, that is, until it was time for Zeda’s well visit on November 5, 2008. Then her life, as she knew it, completely changed along with the lives of the rest of our family.

On November 5, 2008, at her annual checkup, Zeda’s pediatrician suggested that she receive the human papillomavirus (HPV) vaccine or, as I know it now, the Gardasil vaccine. I thought, “OK, this is what I am supposed to do to keep her healthy.” My doctor said to do it and so we did it. I knew absolutely nothing about the vaccine, other than it was for girls her age. The doctor did not advise me on any side effects, other than the potential for soreness around the injection site.

A week after Zeda got the shot, she started to complain that she wasn’t feeling well. She had headaches and felt sick to her stomach. Perhaps like other girls at her age, Zeda could be a drama queen. So when she told me these things, I would tell her to lie down, murmur to her that she had probably had a long day, or give her some Tylenol. It would have never occurred to me that those little signs could have been red flags until November 28, three weeks after she received her Gardasil vaccine. We were on our way to pick up her little sister from a friend’s house. While in the car, Zeda kept dropping her phone. Suddenly, my son said, “Mom, I think something is wrong with Zeda!” Zeda was crying, drooling, and her eyes were not looking right. She looked to me as if she had just had a seizure, which I recognized because my brother had seizures. I rushed her to the nearest emergency room at St. Margaret’s Hospital in Hammond, Indiana.

Little did I know that this was the beginning of an unbelievable nightmare for Zeda, for me, and for our entire family. The ER staff did not even know what was wrong with her. First, they accused Zeda of overdosing on drugs. They yelled right in her face, as if she was hard of hearing, that she needed to tell them what she had taken. I was scared out of my mind. I had no clue what

was going on, and these doctors and nurses were screaming at my daughter. Zeda was as scared as I was. I believe she knew that something was seriously wrong. She was confused and unable to say what she wanted. It wasn't until she had another major seizure, right in the ER, that the staff finally started to take us seriously. Of course, by then, they also had received her drug test results, which were negative for any illegal drugs.

After those first few horrible hours, they transferred Zeda to our local hospital where a pediatric neurologist and Zeda's pediatrician could see her. I thought we would surely get some answers there. The doctors started running all kinds of tests. At this point, Zeda was unable to say a whole sentence and could only say a few words at a time. She was terrified and was crying very hard. Zeda had an MRI, a CAT scan, an EEG, and a spinal tap. Whatever they were looking for, they did not find it. Every single test was negative. The MRI did show a "shadow" on the right side of her brain, which they treated as viral encephalitis.

During those four very long days at our local hospital, I began to lose my precious daughter. Zeda stopped talking, stopped eating, stopped walking, and started urinating on herself as she lost control of her bladder. Even as Zeda's health deteriorated rapidly, her pediatrician continued to say—unbelievably—that she was doing this to herself, that Zeda was "faking" it.

Words of reason finally came, not from the doctors, but from the nurses who agreed with me that something was terribly wrong. Zeda's symptoms were not taken seriously until a psychiatrist came in, tested her, and issued a professional opinion that she wasn't faking it. One nurse suggested we go to a specialty hospital, because we were getting nowhere. We agreed.

Within forty-five minutes, we were en route to Riley Hospital for Children in Indianapolis. Once again, I thought that we would finally get answers. We were not so lucky. Even there, the doctors accused Zeda of doing this to herself. They installed twenty-four-hour video surveillance on Zeda and monitored her for about two weeks to try to "catch" her in the act of faking it. They continued to perform test after test, all of which came back negative. Zeda developed uncontrollable movements, an extremely high heart rate (up to 180 beats per minute), and high fevers, including one that was 108.7 degrees. At one point, her doctors placed her in a "medically-induced coma." Through all this, they still couldn't tell us what was wrong or why this was happening to Zeda. They opted instead to spend most of their time blaming us and trying to prove that Zeda was faking her serious medical problems. Although I repeatedly asked if it could be vaccine injury, no one would touch that with a ten-foot pole. Not one medical professional would go on the record saying that the Gardasil vaccine did this to Zeda. They wouldn't even say that a vaccine *could* do this to her.

Zeda eventually lost lung function and her doctors placed her on a ventilator for several months. They also inserted a tracheotomy and feeding tube because she could no longer breathe or eat on her own. We were at Riley Hospital for four months and her doctors still could not tell us what happened to her, only that they were sure it was not a vaccine reaction. They refused to acknowledge Zeda's vaccine injury despite dozens of cases of similar reactions in previously healthy girls following the HPV vaccine.

Today, Zeda still breathes through her trach and eats with a tube. She is mostly nonresponsive and lives her life in a hospital bed in our living room with round-the-clock care and daily nursing visits. This has become the defining struggle of my life. I struggle every single day to do what I can to get Zeda better.

I deeply regret my decision to allow Zeda to get this shot. She has lost all quality of life. I would do anything to get her better, but no one has any answers for me. The doctors still don't believe it was the vaccine. Now that she's sick, no one knows how to help my baby girl.

Tragically, the number of "Gardasil Girls" like my daughter continues to grow. The *Truth About Gardasil* website (<http://truthaboutgardasil.org>) posts many of their stories. The federal government added Gardasil as a recommended shot for sixth grade girls in 2008, the same year that Zeda received this brand-new vaccine. I can't help but think, if only . . . if only I had read the editorial in the *New England Journal of Medicine* that someone recently showed me—"Human Papillomavirus—Reasons for Caution."¹ It was published two months before Zeda's doctor gave her the Gardasil shot. I now know that pap smears are just as effective, if not more effective in preventing cervical cancer. If this isn't already too much to bear, in the summer of 2010, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices added the recommendation that sixth grade boys should now receive the HPV vaccine. My sons and my younger daughter will never get this vaccination. We had to sacrifice Zeda to learn this hard lesson.

Even as I have been writing this chapter, another family contacted me to ask for help. They said their daughter had the same experience as Zeda. Our heartbreaking reality is now theirs and they too are being offered no diagnosis or help from their doctors, but only accusations that their daughter is "faking it." It is heartbreaking to watch this play out for them and to have no help to offer.

Judicial Watch, a nonprofit, nonpartisan watchdog organization, began investigating reports of adverse events from the HPV vaccine in 2007 and issued two critical reports detailing the adverse outcomes of the vaccine. After reviewing government reports on Gardasil, Tom Fitton, president of Judicial Watch, remarked, "The FDA adverse event reports on the HPV vaccine read like a catalog of horrors. Any state or local government now beset by Merck's lobbying campaigns to mandate this HPV vaccine for young girls ought to take a look at these adverse health reports."²

As of November 17, 2010, there have been 20,978 adverse HPV vaccine reactions reported. There are eighty-nine deaths associated with the vaccine. The U.S. Food and Drug Administration (FDA) has yet to issue a position on these cases. The Department of Health and Human Services (HHS) conceded an HPV vaccine injury-related case on October 5, 2010.³

I am here to tell you that I didn't know the harm vaccines could do. I think many parents are like me—they don't know either. I thought vaccines would keep my children safe and healthy. That's what the doctor told me. I never imagined that a vaccine could do this to my daughter. My doctor never told me the risks. No one else did either. I was never shown anything describing potential side effects of vaccines. If you do choose to vaccinate, you had better be very comfortable about the need for each vaccine, because every time you vaccinate your child, there is a risk of severe injury and death. It is crucial that parents understand what is at stake and that the choice is theirs to make. I am not telling you not to vaccinate. I am telling you that people who pressure you to vaccinate don't own the consequences. Only you, as parents, do.

Chapter Fourteen

A MOTHER-SON STORY

Sonja Hintz, RN, and Alexander Hintz

On May 26, 2010, my son Alexander Hintz, acting on his own decision to participate, spoke at the American Rally for Personal Rights about his life story and the need for vaccination choice. Alex regressed into autism following his childhood vaccinations and recovered from autism through biomedical intervention. In his own words, Alex can explain how he developed a personal conviction that all parents must have the right to make individual medical decisions for their children.

ALEX:

I am thirteen years old and in the eighth grade at St. Peter's Catholic School.

As a preschooler, I went to Lakeland School in Elkhorn, Wisconsin, where I received special education and help in learning important new communication, sensory, and social skills. I received physical, occupational, and speech therapy. I met many kids like me and I never thought much about it. I could see that other children had challenges. I didn't think I had any myself. My parents put me on a gluten-free, casein-free diet. It made me feel different from the other kids.

When I was in kindergarten, I attended Lakeland two days and St. Peter's three half-days each week. I felt lonely at St. Peter's. I wasn't interested in what the other children were doing. I didn't like loud noises and avoided the gym. At recess, I watched the kids play. My teacher helped me a lot at St. Peter's. She taught me how to be part of a group. She helped me learn my letters and colors. In kindergarten, I started working with a tutor. I kept up my speech therapy. In addition, this was the year I started to play my first sport—soccer. I remember being scared of the coach and the other kids. I remember having no idea how to play this sport.

My first grade teacher taught me to read my first book. She even noticed I was growing a lot more. I think it was because of my special diet. I had become less picky and starting eating new foods. In second grade, I continued to receive tutoring and speech therapy. I pretended to be sick because I had no friends and wanted to stay at home.

In third grade, I had to take my tests in a different way. The teacher had to read the test questions to me because I had "receptive speech delays." That meant that I had difficulty understanding the meaning of the words and what the questions meant. By the end of third grade, I had made some friends and enjoyed school a lot more. My friends were able to write in cursive. I still had to print because my hand cramped and hurt.

The summer after third grade, my parents started taking me for chelation therapy. Chelation therapy is the medicine that I received in my arm to drain out the heavy metals in my body. It helped me think more clearly and be more active in sports. In just a few weeks, my stick figure drawings developed into detailed pictures. I remember drawing myself walking my dog! I could also write in cursive.

Fourth grade was the biggest year of change for me. Chelation helped me with my schoolwork. Because of the changes over the summer with chelation, I was able to take written tests on my own. It was easier to write out my answers. I also became involved in new sports, including flag football. During fifth grade, I started to get better grades. I continued receiving tutoring.

In sixth grade, I was able to do all my schoolwork by myself. I didn't need tutoring. My parents and older sister didn't need to help me with my homework. I began to receive As and Bs on my report card. I started playing tackle football and baseball. In seventh grade, I made a lot of friends. I added a new sport—basketball. And I got almost all As.

I no longer follow a gluten-free diet, and I eat some dairy. I know that the therapies and biomedical treatments my parents gave me helped me to get better. I have made a lot of progress in the nine years since I was in kindergarten. My kindergarten teacher recently said to me, "Wow! Do you remember how we used to have to put cotton balls in your ears so you would enter the gym? And today, you play the drums in the gym!"

My mom tells me that many people don't understand how children with autism can be helped. She says that doctors offering biomedical treatments to children like me are criticized and threatened. I just want people to know that there's another side to this story. I am very lucky that my parents made these decisions for me. I am very lucky that my parents had the right to make these decisions for me.

SONJA:

My son's medical history is a complicated one and includes two severe vaccine reactions from shots that we—my husband and I—were pushed into giving him.

Alex showed signs of motor delays from birth. He was floppy when lying down and stiff when held upright. He did not gain weight normally; he had colic and severe reflux, which influenced his ability to suck, swallow, and breathe. Alex refluxed during his feeds and had to coordinate what he refluxed up as well as what was going down (double volume of fluids). In addition, doctors observed during a swallow study that he had silent aspiration with his reflux. I had to nurse him every hour and a half because he could not properly coordinate his feeding and became cyanotic around his mouth (his lips turned bluish with every feed).

After discussing his colic and reflux with his doctor, my husband, Gregg, and I made the decision to delay his vaccinations because of our concerns for Alex's health.

By six months of age, Alex had recovered from a severe case of chickenpox and continued to have serious reflux that caused him to stop breathing (apnea). One night I awoke at three o'clock (from six months of habitual night feeds) to find Alex cold and lifeless. I was so shocked at first that I screamed to my husband and forgot that I knew CPR. I actually had to slap myself in the face, remind myself that I was a registered nurse and tell myself, "You know CPR!" I started working on him and Alex came around. I had never been more afraid.

When we took Alex to the doctor that day, my husband and I were under a great deal of stress after seeing our son so close to death. We don't feel that we were properly prepared to make a good decision on the recommendation that came from the doctor. She wanted to vaccinate Alex during the visit.

The doctor pointedly asked, "You wouldn't want to lose him to pertussis, would you?" I felt a combination of pressure and guilt—pressure because even as a nurse, my training did not educate me to question the safety of vaccinations, and guilt because I had almost lost my son once and the doctor implied that not vaccinating him at that time would put Alex back in that terrifying place. Despite the fact that Alex's doctor did not take his risk factors and health status into account before making her vaccine recommendation, the not-so-subtle point hit its intended mark and we vaccinated Alex for the first time. The doctor gave him the combination diphtheria-tetanus-acellular pertussis (DTaP) vaccine and my baby had a severe reaction to his shot. That evening, Alex began to arch his back and then screamed for two days, nonstop. His doctor claimed that this was normal and failed to recognize this as an adverse vaccine reaction.

Alex had been receiving speech and occupational therapies since birth. He benefited from the sensory work from his occupational therapist and the oral motor therapy from his speech therapist. By two years of age, he had a few words, and would even appropriately use "me do" and "sorry" when he did something he was not supposed to do. He was improving in his development. However, when Alex received another series of vaccinations at twenty-five months, he lost those phrases, and everything changed. Regressing yet again, he lost weight, his hair thinned, and he exhibited a weakening muscle tone. He perspired from his head, had a pale complexion, and had severe constipation. He exhibited behaviors typically associated with autism, such as hand posturing, difficulty sleeping, and picky eating. He would only eat dry, crunchy foods, stopped repeating the few words he had acquired, and began to drift away from us. By thirty-seven months, he was extremely difficult to engage and spent much of the time

obsessively lining up toy cars. This is when his pediatrician told us that she thought Alex had autism.

Alex was also evaluated by a mitochondrial specialist. After reviewing the test results, he advised us to get Alex's affairs in order because he would always need support and care. I will never forget his parting words: "He will be low functioning. Don't expect much." We were further discouraged by the nutritionist at the hospital who recommended that Alex have a feeding tube inserted: "It would be easier to place a G-tube than to try and feed him."

During his medical workup, we also found that Alex had insufficient enzymes to break down carbohydrates, resulting in poor absorption of nutrients. The word "insufficient" was putting it mildly. There were no enzymes detected when they did the study.

Fortunately, our neurologist was supportive when I mentioned dietary intervention. During his initial workup, Alex had an abnormal electroencephalogram (EEG). After a six-month trial of the gluten-free, casein-free (GFCF) diet, Alex's repeated EEG results were normal.

The word "autism" had little meaning for me. Alex's body was struggling medically. Where others saw behaviors called "autism," I saw a sick child. I refused to settle for this diagnosis and instead pursued a biomedical route. The lab work showed that Alex had nutritional deficiencies, mitochondrial abnormality, severe gastrointestinal reflux, and lymphoid hyperplasia of the bowel. As devastating as it was to receive his lab results, it was also a relief. I now had something to work with. My intuition was right. While the diagnosis of *autism* offered no solutions, Alex had very real medical problems that we could address.

For ten years we treated Alex's medical problems and the result is a healthy, verbal, social young man. The conventional medical community does not think that it's possible that vaccines either caused or exacerbated his health challenges. I am highly skeptical of their view. My son's biology did not match up with the "one-size-fits-all" vaccination schedule. He suffered two clear vaccine adverse reactions. His behavioral symptoms and decline in health coincided with his shots, and the tests showed he was sick. As we addressed the medical problems, his "autism" began to get better and eventually went away.

It is difficult for me to understand how members of the medical community can see the thousands of cases like my son's and continue to deny that vaccine-induced autism—and recovery from autism through medical treatment—is a reality. My experiences have taught me that we must pay more attention to the individual children receiving vaccines because some are inherently more vulnerable than others. Unfortunately, my family—and others—had to learn this the hard way.

If the doctor had been compelled to offer information that constituted true informed consent prior to vaccination, Gregg and I never would have vaccinated Alex after his apnea event. True informed medical consent stems from the legal and ethical right to decide what medical interventions your child will undergo based on a complete understanding of the known benefits and risks of any procedure or drug. Our doctor did not give us the information we needed to make wise choices for our son. After his first adverse vaccine reaction, I wish our doctor had given us the option to check Alex's titers to see how his body responded immunologically to the vaccinations already given.

We were pressured into making the wrong choices for Alex.

This is true to varying degrees for nearly all families, because there is no true informed

consent in vaccination. Doctors are not required to fully disclose the risks of vaccination and, in many cases, have not been properly informed by the companies, agencies, schools, and professional organizations tasked with educating medical professionals. I know this because I was one of those uninformed medical professionals.

Eighteen years ago, I was a nurse who administered vaccines for the Milwaukee Public Health Department when the court charged families to vaccinate their children. In this program, parents were required to appear in court after the school had identified their children as not being up to date with the recommended vaccination schedule. The city government sent letters informing these families that school could deny their children admission because of vaccine noncompliance. Following the court hearing, I administered those vaccines.

What strikes me now is that, just as no one told me my options, no one told these parents their options either. I don't know if public health officials ever offered these families any information on vaccine exemptions. I did not evaluate or review the children's health status before I vaccinated them. I had the parents sign a consent form, but in some cases they may not have understood or have even been able to read these forms. I assumed they understood, and then I gave the vaccinations. That was it.

Even at that point, I began to ask questions about vaccine policy: Why do we vaccinate the way we do? How do we know the body needs the number of vaccinations we give? Can we measure the child's immune response before administering booster shots? The answers I received from health department officials did not seem to justify these policies:

“It is cheaper to vaccinate repeatedly than to check titers.”

“Moms are more willing to bring their babies than their older children for vaccination.”

“Herd immunity would not be achieved.”

“This is the way it is done.”

Little did I know that the birth of my son, Alex, would prompt me to ask the same questions again.

Vaccination is a serious medical intervention and only parents can assess the risk-benefit tradeoffs for their individual children. One-size-fits-all vaccination schedules and mandatory vaccination policies represent an outright challenge to parental rights and personal bodily autonomy. In Alex's case, vaccinations compounded his already complicated health challenges. The belief by the medical community that vaccinations are benign interventions robbed our son of his basic functioning skills in the early years of his life.

Fortunately, Alex has recovered from autism. On many levels, it would be easier for our family to pretend that it never happened. There is no social benefit to Alex for his friends to know about his old diagnosis. I think it's pretty extraordinary for a thirteen-year-old boy to make the decision to share his story. Alex and I hope our story inspires others and allows for an open discussion of the medical problems that these children face.

We are so grateful for Alex's healing. If not for doctors who have willingly become a part of this open discussion—like Dr. Anju Usman, who oversaw Alex's chelation and other therapies—

we do not believe that he would have recovered from autism. His improvement all started with our belief in the possibility of Alex's recovery.

Alex is living, thriving proof that autism is treatable and children can recover. I bear witness to this, as a parent and a nurse. I am opposed to vaccine intimidation. Vaccination choice is every parent's right.

Chapter Fifteen

WHO WILL DEFEND THE DEFENDERS?

Captain Richard Rovet, USAF (Ret.), with afterword by Colonel Felix M. Grieder, USAF (Ret.)

I write about some of the most vulnerable of society's members: our men and women in uniform. Right now, many are protecting our freedom in austere conditions and dangerous places around the globe. Some may have given their lives today, in support of that freedom to do exactly what this book aims to do—to protect the principles we hold dear.

Unfortunately, these brave defenders of our freedom are defenseless against the mandatory use of dangerous vaccines, such as the anthrax vaccine. For the past sixty-four years, the United States military and other government agencies have used our servicemen and women as test subjects, often in secret and without informed consent. Moreover, there is no end in sight; there are additional biodefense vaccines waiting in a pipeline to be tested on our soldiers.

Sadly, this is not a conspiracy theory. This is documented fact. In December 1994, right after the first Gulf War, the United States Senate released a report titled, "Is Military Research Hazardous to a Veteran's Health?"¹ This report outlined the unethical use of servicemen and women as test subjects. The report revealed that the Pentagon had quietly used soldiers in clinical trials and did not record the resulting information in their medical records, preventing the soldiers from receiving appropriate follow-up care. Many were simply left to die.

Witness the well-illustrated connection between Gulf War Illness and the anthrax vaccine. "Gulf War Illness" encompasses a wide range of acute and chronic health disorders, including chronic fatigue, severe joint pain, neurological problems, memory loss, and unexplained persistent rashes and sores, to name a few. Many illnesses are autoimmune in nature, meaning that a person's own immune system has turned on certain tissues and organs in his or her own body. Roughly one in four of the 697,000 veterans—my fellow servicemen and women, who served in the first Gulf War—are afflicted with Gulf War Illness. Multiple studies and governmental reports demonstrate a higher rate of Gulf War Illness in vaccinated veterans.² At the time that those fighting in the first Gulf War were vaccinated, the Department of Defense ordered medical staff not to annotate or identify the anthrax vaccine and the botulinum toxoid vaccine in soldiers' vaccination records. Instead, they mysteriously recorded these vaccines as "Vac A" or "Vac B."³

While investigating potential causes of Gulf War Illness, Vancouver neuroscientist Chris

Shaw and his research team were shocked to find that the aluminum hydroxide adjuvant in the military's anthrax vaccines caused massive brain-cell death in laboratory mice.⁴ Vaccine makers now routinely use this adjuvant in childhood vaccines.

There is no doubt that the first Gulf War was a toxic war, and that there may be other contributory factors to Gulf War Illness besides the anthrax vaccine. One of the most damning pieces of evidence implicating the anthrax vaccine, however, is that the coalition forces from other countries that fought alongside United States troops in the Gulf War, but did not receive the anthrax vaccine, have relatively few incidents of Gulf War Illness.⁵ Meanwhile, other coalition troops, such as British forces, who were also vaccinated against anthrax, do have significant incidence of Gulf War Illness, like their U.S. counterparts. The French report a small number of cases, which are primarily associated with the French soldiers who served with U.S. soldiers, and were given the anthrax vaccine.

General Douglas MacArthur outlined the damage done to a fighting force when such treatment of soldiers is undertaken:

The unfailing formula for production of morale is patriotism, self-respect, discipline, and self-confidence within a military unit, joined with fair treatment and merited appreciation from without. It cannot be produced by pampering or coddling an army, and is not necessarily destroyed by hardship, danger, or even calamity . . . It will quickly wither and die if soldiers come to believe themselves the victims of indifference or injustice on the part of their government, or ignorance, personal ambition, or ineptitude on the part of their leaders.

—General Douglas MacArthur, 1933 Annual Report of the Chief of Staff, U.S. Army <http://www.lanl.gov/external/news/reflections/0900.pdf> (pg 2 of 12)

Our soldiers' calls for help have not only been ignored, but their own government, the one they swore to serve and protect, has tried to discredit them. For many years, veterans of the first Gulf War and their families have begged for help and answers. Meanwhile, in a misguided effort to mislead Congress, the press, and the American people about the extent of the damage done to personnel during the conflict, the Pentagon launched Operation Bronze Anvil,⁶ a propaganda program designed to deflect any inquiries into the Gulf War Illness–anthrax vaccine connection and to harm the reputations of those who spoke out about the connection. This effort has branded honorable U.S. servicemen and women complaining of anthrax vaccine reactions as malingerers, liars, whiners, and malcontents.

This misuse of our military personnel did not stop after the Gulf War or after the Senate's 1994 report. Three key areas continue to provide fertile ground for the abuse of our servicemen and women as guinea pigs by the pharmaceutical industry in cooperation with senior military leaders.

First, the military may order soldiers to take medicines or receive vaccines against their will. If they refuse medications, these proud soldiers risk incarceration, forfeiture of pay, and a dishonorable or bad conduct discharge, which would lump them together with murderers and rapists.

Second, the military may waive informed consent for the use of untested or unstudied

medications and vaccines in two possible ways: when there is a Presidential Executive Order⁷ or if the defense or intelligence establishment deems that there is a credible military threat.

Third, servicemen and women are barred from suing the federal government under an archaic and arguably unconstitutional law from 1950 called the Feres Doctrine.⁸

Sadly, recent history has taught us nothing, and our soldiers continue to pay with their lives and their health.

Despite mounting concerns over anthrax vaccination as a contributing factor to Gulf War Illness, the U.S. military launched a mandatory anthrax immunization program in the late 1990s. I was at Dover Air Force Base in Delaware at the time and I witnessed a hotbed of illnesses and controversy surrounding the anthrax vaccine. Among the documented illnesses witnessed, many were autoimmune in nature, such as multiple sclerosis and rheumatoid arthritis. I have personally and sadly witnessed both of these conditions in relation to the anthrax vaccine. After receiving pressure from the Government Accountability Office (the watchdog arm of Congress), the maker of the vaccine, Bioport, was forced to list autoimmune diseases and all the symptoms of Gulf War Illness on the anthrax vaccine product insert.⁹

In May 1999, the USAF Surgeon General's Office arranged a "town hall meeting" at Dover Air Force Base to assuage the concerns of many who had become ill following anthrax vaccination. In attendance were the chief public health officer of Air Mobility Command, Colonel Denise VanHook; the USAF Surgeon General of the USAF Anthrax Vaccine Action, Officer Lieutenant Colonel Jack Davis; the medical head of Dover's anthrax program, Lieutenant Colonel Thomas Fadel-Luna; Wing Commander, Colonel Felix Grieder; and the men, women, and families of the 9th Airlift Squadron. It was during this meeting that Davis let the proverbial "cat out of the bag." While fielding a question from a military member in the audience, Davis stated that the military did indeed possess an experimental anthrax vaccine that contained an illegal adjuvant called squalene, and flippantly stated that no one at Dover received that vaccine. Another assertion came from my former squadron commander, Dr. and Lieutenant Colonel Thomas Fadel-Luna. When addressing the so-called rumor that *there was an increase of people with an autoimmune illness at Dover*, Luna stated the following:

That is incorrect. Autoimmune disease is something we do not typically see in flyers. If we do see it, it sends up a flag. In my nine-year career, I have seen five or less. We are simply not seeing it. We are looking at other clinics in the Medical Group to see if they are seeing an increase. And, basically they have not seen a problem.

Unfortunately, that was not the case. At that time, we had over fifteen cases of autoimmunity and over thirty cases of illnesses exactly the same as the ones the veterans had reported as associated with Gulf War Illness. In fact, many of our patients were sent for evaluation at Walter Reed's Gulf War Illness clinic.

In response to these town hall meetings, Dover AFB Wing Commander Colonel Felix Grieder temporarily halted anthrax injections on his base because of concerns about safety and after seeing his troops that had become severely ill after receiving the anthrax vaccine. It cost him his career. Greider has since alleged that his troops were used as guinea pigs in undisclosed military

medical experiments.¹⁰

He was right to be concerned. At Dover, the FDA tested anthrax vaccine lots in 2000 and discovered the presence of an experimental adjuvant and immune “turbo booster” called squalene or MF59—an adjuvant with potentially devastating health consequences. I want you to burn these two letters and two numbers into your consciousness so you will remember them because squalene will next be used in civilian vaccines.¹¹ I strongly urge you to read award-winning journalist Gary Matsumoto’s powerful exposé, *Vaccine A*, which is an outstanding example of the dying field of authentic investigative journalism.¹² The book blows open the military’s shameful history of secret medical experiments on its soldiers and especially its illicit use of an unlicensed additive in the anthrax vaccine that is proven to cause fatal autoimmune diseases in animals.

I have personally borne witness to the devastating effects of the anthrax vaccine. I will forever have etched upon my memory the vision of a young enlisted woman screaming and crying as she was forcibly held down while the needle delivering the anthrax vaccine was pushed into her body.¹³ I will never forget the sad day when my dear friend, Technical Sergeant Clarence Glover, died after anthrax vaccination.¹⁴ My memory holds the stories of those whose skin literally burned off due to anthrax vaccine-induced Stevens-Johnson syndrome¹⁵ and of the infants under my care who were born with severe birth defects after their pregnant mothers were vaccinated with the anthrax vaccine.

Corruption within government for the profit of private industry is nothing new. Go behind the curtain of the anthrax vaccination program and you will see bailouts, lucrative financial contracts,¹⁶ and a revolving door of crony capitalism with strong ties to the Department of Defense and the Department of Health and Human Services. Furthermore, all studies that tout the safety of the anthrax vaccine, reported by so-called independent experts, were anything but independent. The studies were funded by the Department of Defense.

I swore an oath to defend this nation against all enemies, foreign or domestic. However, I most certainly did not swear allegiance to defense contractors and the hard-hitting lobbyists of the pharmaceutical industry. Forensic evidence now exists to launch a full investigation into the use of experimental adjuvants as a controlled experiment on our troops from the first Gulf War to the present. The potential implications of such an investigation are shattering.

We can no longer tolerate the cruel and dishonorable use as guinea pigs of America’s sons and daughters who have sacrificed their lives to fight for our freedoms. We must loudly protest when the international legal standard of informed consent does not apply to those who courageously defend our country. We must end the current mandatory anthrax vaccination program and, in its place, launch a full-scale investigation.

I truly mean it each time I say, “God bless America.” I have fought to protect our freedoms and rights. I believe that vaccination choice is a fundamental human right for all Americans, including our brave military personnel.

Please read the appendix to this chapter for Captain Rovet’s March 25, 2005, letter of complaint to the Department of Defense Inspector General, and excerpts from his report to the House Committee on Oversight and Government Reform.

Editor's Note: The appendix to this chapter contains excerpts from Captain Rove's report on anthrax vaccine injury to his superiors while serving at Dover Air Force Base.

AFTERWORD BY COLONEL FELIX M. GRIEDER (USAF, RET)

In April 1999, late in my two-year tenure as Wing Commander at Dover Air Force Base (AFB), I became aware that several members of my command were experiencing adverse reactions shortly after receiving the anthrax vaccination. At that time, Dover was one of the first military bases to receive and to administer the anthrax vaccine (a protocol of six shots), a vaccine designed to protect our military against what was perceived to be Saddam Hussein's weapons of mass destruction (WMD), including biological weapons such as anthrax.

At Dover, we took pride in leading the way, whether it be with our strategically important airlift mission or, in this case, protecting our troops from the potential WMD threat. My strong support for the administration of the anthrax vaccine changed when I became aware of the adverse effects that a small, yet significant, number of my airmen were experiencing.

I called for an informational briefing. On May 5, 1999, when the Pentagon's supposed "expert" on the anthrax program stated in response to concerns being articulated in the briefing room, "I don't know and I don't care," I immediately ordered a "time-out" and suspended the vaccination program at Dover AFB.

I was simply doing my job as a commander. All military members take an oath to protect and defend our great country against all enemies, foreign and domestic. In this case, I clearly had the responsibility to protect my troops who were being put in harm's way by internal forces.

Six days later, after Lt. Gen. Charles Roadman, Air Force surgeon general, gave us his word "as an officer" during a public briefing session that squalene, an experimental vaccine adjuvant, was never used in the anthrax vaccine, I reinstated the vaccination program.

Subsequently, in September 2000, the FDA documented that squalene had been found in six lots of anthrax vaccine. Of these, four of them—FAV 08, FAV 030, FAV 043, and FAV 047—had been sent to Dover.¹⁷ Not only did these lots contain squalene, but they contained dosages of squalene which approximately doubled in value (from 10 to 20, to 40, to 80), similar to a dose-range study. Separately, Tulane Medical School confirmed that three additional lots of anthrax vaccine were found to induce anti-squalene antibodies, of which two—FAV 041 and FAV 070—were also sent to Dover.¹⁸ It is my belief that the Department of Defense, in its zeal to establish an effective and more immediate anti-anthrax vaccine, experimented with the untested adjuvant squalene at a few military installations, including Dover AFB.

Those responsible for this decision need to be held accountable. There are parallels in this unfortunate decision to what happened at the prison in Abu Ghraib in Iraq.

A nation and an organization should never forego its core values and standards. The United States stands for freedom, human rights, and the fair and humane treatment of all. When we set aside our values, even temporarily, for what may appear to be a justifiable reason, we lose our way as a nation and as a superpower.

Chapter Sixteen

“GET YOUR AFFAIRS IN ORDER”

Lisa Marks Smith

October 15, 2005, started like any other beautiful fall day. We rose early and went to my son, Nathan’s soccer game. While we were there, my mom called to say that CVS Pharmacy was having a flu shot clinic. My dad was having knee-replacement surgery in a few weeks and could be vulnerable to infection. We wanted to be sure that I did not get sick. After the game, I drove to the CVS store and registered for the shot. While I was there, my brother Jeff came in for his shot as well. We received the standard disclaimer form. Nowhere did it say this would be the last normal day I would have for four years.

The truth is, I did not put any thought into whether to get the shot. It was just a quick decision, but one that would change my entire life. If I had taken the time to do a little research, I like to think I would have skipped the shot. I had taken the shot one other time with no adverse reaction when the health department had offered them at my church.

Within days of getting the shot, I knew something was wrong. I called my parents and told them to skip my son’s orchestral concert on Tuesday. I wasn’t feeling right and didn’t want to get my dad sick before his surgery. When I set up at a craft show with my friend Jackie on Friday night, I complained of a tickle in my throat. I woke up terribly sick the next morning. The first appointment I could get with my family practitioner was Monday. By Monday, October 24, I felt like I was going to die.

That morning, my husband, Greg, rushed me to Mercy Hospital in Western Hills, Ohio. I was discharged the same day with a diagnosis of pneumonia. They gave me antibiotics and other medications, but I never improved. Early the following Saturday, Greg and Nathan left on a scheduled Boy Scout campout. When I woke up, my legs were strangely weak and they continued to get weaker throughout the day. By evening, I could no longer stand or walk. I was home by myself and had to wait alone and in pain on the bathroom floor for my older son, Matthew, to come home from a babysitting job and call for help. I had never felt so powerless or been in so much pain.

Matthew finally came home and called my brother, Jeff. Jeff came over and carried me into the family room. Just being carried was painful. Jeff called an ambulance. The paramedics had to hoist me onto the stretcher, as I was unable to use my legs. The pain was tremendous. If anything touched my legs, I cried out in agony. The ambulance took me back to Mercy Hospital. Right

away, the nurses started to ask me if I had received a flu shot. I wondered why everyone kept asking. At that point, I had no idea that spreading paralysis, or Guillain-Barré syndrome (GBS), was a known side effect of the flu vaccine. After several hours in the emergency room, they moved me to a regular room. A nurse urged me to go to a different hospital, one with a higher level of care. I wish I had listened, but I was just too sick to act. The nurses felt that I should be moved to intensive care; the paralysis was spreading and they could not provide the level of care I needed. I spent several days in intensive care. A nurse told me to call my family and get my affairs in order. It is very difficult to tell your children good-bye forever. It was the most heartbreaking moment of my life.

Nothing improved over the next week. I had two spinal taps, multiple IVs, and more tests and doctors than I can remember. I was on the strongest pain medicine available; nothing relieved the spasms and pain in my legs. I couldn't even bear the weight of a sheet on my legs. All I remember from this period was the overwhelming pain. At one point, I could only move my head. My feet dropped and my legs were totally limp from the damage done to my nerves. To this day, friends still comment on how my feet lay parallel to my legs.

The Mercy neurologist told me nothing was wrong with me. He said my symptoms were psychogenic; in other words, I was crazy and making up this entire disease. I asked how I could fake symptoms—including shaking and dropped feet—in my sleep. He didn't respond and, instead, forced me to do physical therapy, which further increased my pain. The neurologist ignored my neighbor, a doctor, who told him I was sane. He ruled out GBS since I didn't have the protein in my spinal column that normally is present with GBS. He never considered transverse myelitis or postinfectious myositis, well-known vaccine injuries with similar symptoms.

Greg and Jeff arranged to transfer me to a better hospital. Mercy tried to dissuade me from leaving. The caseworker insisted my insurance would not pay for the transfer or cover the bills. My Cigna representative assured us this was not true. While I was waiting to be transported to the new hospital, a nurse approached me with a syringe. I asked her what it was. The doctor had ordered a pneumonia vaccine! I told her if I could move, I would break her arm. I was furious. I was lying there paralyzed, possibly from the flu vaccine, and the doctor had ordered another vaccine.

When I got to Christ Hospital in Cincinnati, things improved immediately. Within two hours of my arrival, the hospitalist, Dr. Rajan Lakhia, had a diagnosis. He said, if the Mercy neurologist had simply repeated the creatine phosphokinase (CPK) blood test for muscle degradation, which was standard procedure, he would have noticed the protein level in my blood was extremely high. Anything over 100 is a problem. At Mercy, they only checked once and it was 60. When I arrived at Christ, the protein level was at 900 and climbed to a high of 1,600. The muscles in my legs were breaking down. Despite the bad news, I wanted to cry with relief because they had proof that I was sick. One major hurdle had been cleared. I could focus on getting well.

I felt safer at my new hospital. The nurse put in a peripherally inserted central catheter (PICC) line to deliver Dilaudid so I wouldn't require so many IVs. After five days at Christ, the protein level began to drop. Muscle damage had stopped, and I regained some movement. I could use my arms and sit up. I was able to support myself enough to use a portable toilet—a wonderful improvement after two weeks of lying flat on my back. The nurses told me about another patient

who was paralyzed by the flu shot. When I asked how she was doing, they didn't answer. I later learned that she never recovered.

Dr. Lakhia fought with my insurance company to get me intensive therapy. I was scared to go to a long-term care facility; I felt like I would be forgotten there. Instead, Christ transferred me to the acute rehabilitation unit. The therapy was grueling. Propped up, I stumbled two steps. I had "Barbie feet"—my feet pointed straight down and my heels would not rest on the floor. My immune system had destroyed the muscles and nerves in my legs. My official diagnosis was postinfectious myositis due to the flu vaccine.

I spent the next two weeks in the rehab unit learning to walk again. I had four hours of therapy each day. Braces forced my swollen feet into the proper position so I could walk. I missed wearing my regular shoes. They wouldn't let me go home until I could dress myself and navigate without help. I had to learn how to get in and out of a car safely, and how to get off the floor if I fell while home alone.

My occupational therapist wanted to see if I could make a bed. I told her I needed practical skills, for example, how to carry a food tray while using a walker. The therapist put a few balls on a tray and had me practice walking. It helped to laugh. I hadn't laughed much in the last few weeks. My doctor ordered a psychiatric exam to see how I was coping. I told the doctor I wasn't so depressed that I wouldn't do everything in my power to recover. I wanted to go home. She ruled me emotionally healthy and well-adjusted. One day, I nearly fell when trying to get to the bathroom. I cried with frustration that I wasn't getting better fast enough. The nurses told my mom they were glad to see me cry; they thought I had been too stoic.

I sobbed every time Greg and my boys left. I wanted to go home so badly. However, family and friends came to see me constantly. The nurses saw all the flowers and visitors and teased me that I must've been a lot of fun to be around when I was well. They said they would go to my house for a party when I recovered.

I went home on November 22, two days before Thanksgiving. I had been in the hospital for twenty-four days. I had to promise not to drive or go up and down the stairs without someone watching me. Matthew and my neighbors took turns driving me to therapy three times a week for twenty-two weeks. After all the hard work, I am proud to say that I don't limp.

My neurologist said that traditional medicine could do nothing further for me. She confirmed all of my problems stemmed from the flu shot and encouraged me to try alternative medicine.

I filed my own report with the government's Vaccine Adverse Event Reporting System (VAERS). Only one doctor ever mentioned the possibility of filing a report. The doctor who performed my EMGs at Aring Neurology told me that the flu shot had paralyzed another one of his patients. She has a diagnosis of transverse myelitis and is permanently confined to a wheelchair. He showed me her VAERS report. My VAERS ID is 251221.

Although the media has not been interested in my story, people with flu shot injuries continue to bombard me with messages. The official estimate of vaccine injury is one in one million people. My experience tells me otherwise.

My neighbor, Chris Sullivan, sat next to a woman who was on a flight to Cincinnati to see her brother who was just paralyzed from a flu shot.

A friend, Tracy Kroger, developed Guillain-Barré syndrome from her flu shot. Tracy still

struggles to use her arms.

I recently reconnected with a high school friend, Marianne Madaris. She has Rasmussen's encephalitis, also known as chronic focal encephalitis. While in nursing school, Marianne didn't have any vaccination records so they required her to repeat her vaccines. The doctors later told her that the encephalitis was caused by the MMR vaccine. Marianne has been sick for twenty-one years. She remains today in the same condition that I was in at the hospital. How rare can these reactions be when I seem to be adding to my list of vaccine victims every week?

In April 2006, I hired the law firm of Douglas and London, P.C. to pursue a vaccine injury claim through the National Vaccine Injury Compensation Program (VICP). The firm told me that I had a strong case since my doctor was willing to state for the record that I had a vaccine injury.

Most people have no idea that vaccine makers are protected from most liability by federal law. They are equally shocked that our government compensates people for vaccine injuries. The federal agency that oversees the VICP added the flu vaccine to the table of compensable injuries in July 2005, just three months before I was injured. To collect, you have to prove that a vaccine caused damage lasting more than six months. My attorney requested affidavits from my family and friends who could describe how my life had changed after the flu shot.

At one point during the case, the special master (judges do not administer the program) told my lawyer that I couldn't prove I ever had the vaccine. Following my paralysis and hospital stay, I couldn't find my flu vaccine paperwork. I pointed out that my VAERS report contained my lot number. Since I hadn't given the CDC or the FDA that information, they must have obtained it from Maxim Health Systems. Maxim never responded to my request for this information. The nurse who administered my vaccine didn't complete the section of the form containing the lot number. My attorney had to file a Freedom of Information Act (FOIA) request to get a copy of the bill from the government. Jeff and Greg filed affidavits that I went to CVS Pharmacy; Jeff confirmed that he witnessed my shot. I was lucky. How many people can provide a witness to their shot? In July 2009, Special Master Christian Moran ruled that a preponderance of evidence supported my claim that I received the flu shot.

It took over three years to receive official acknowledgement of my vaccine injury. In December 2009, I received a phone call from my attorney who said that the government had conceded my case. There would be no trial; I was to receive a settlement. I was elated. The money would help pay for my out-of-pocket treatment expenses. Most importantly, though, I felt vindicated. The government agreed that a flu shot caused my medical problems. If you google my name, Lisa Marks Smith, and HHS, you can read the court papers.

The check arrived on May 27, 2010, nearly five years after the fateful shot. Since then, I have heard about many vaccine-injured people who have not received compensation. Based on my own experience, I know it isn't easy.

Wherever I go, I talk about the dangers of the flu shot. The fall is an especially difficult time for me, when the big push for flu shots is on. A few weeks ago, a Walgreens clerk asked if I wanted a flu shot. I told her it took me four years to recover from my last one. She didn't know that the flu shot could cause paralysis. Visibly shocked, she said that our conversation would make her think twice. Every aisle in Walgreens has merchandise tagged with "get your flu shot" stickers. I see them at other drugstores and supermarkets too. I wonder who pays for all of these promotions. I still find it difficult to accept what happened to me. I am deeply fortunate because I

got better.

How many people know that one simple flu shot could change your life forever? It's ironic: Vaccines are supposed to be safe and effective. Vaccines are supposed to keep us healthy. Before my flu shot, I was so healthy. Had I gotten the flu, I probably would have been sick for a week or two, at most. After the shot, I was sick for years. Don't think a vaccine injury can't happen to you. It can. I don't tell people not to vaccinate—but I tell my story.

Part III

THE TOPICS IN DEBATE **THE BUSINESS OF VACCINES, MERCURY AND AUTISM, THE LAW AND OUR CHILDREN, THOUGHTFUL MEDICAL VIEWS, PARENTS AND THEIR VACCINATION CHOICES, AND THE SUPPRESSION OF SCIENCE**

I, and other involved researchers, would gladly debate these issues in public with CDC and other experts—if they had the courage to show up. They don't.

—Boyd Haley, PhD

We have exchanged temporary illnesses for pervasive lifelong diseases, disorders, dysfunctions, and disabilities. A chronic illness held in check by medication is not health. The well-being of children and a community must be gauged by more than high vaccination rates and low infection rates caused by a specific, short list of pathogens.

—Sherri Tenpenny, DO

The Center for Personal Rights is confident that the world will look back at the prosecution of Drs. Wakefield, Walker-Smith, and Murch with shame and remorse. Dr. Wakefield has joined in a long, honorable tradition of dissidents in science and human rights.

—Mary Holland, JD

We have gathered and summarized the views of nine board-certified pediatricians and other licensed professionals authorized to give medical advice. These views concur with and differ from the government's recommendations. Many of these professionals support vaccination choice and raise important questions and concerns about CDC-recommended vaccination protocols.

—Louise Kuo Habakus, MA

Chapter Seventeen

THE VACCINE BUBBLE AND THE PHARMACEUTICAL INDUSTRY

Michael Belkin

Vaccines can cause brain damage. Most people are completely unaware of this, but that is exactly how *The Merck Manual*, the largest-selling medical textbook, defines an adverse reaction to a vaccine:

Encephalitis is inflammation of the brain that occurs when a virus directly infects the brain or when a virus or something else triggers inflammation . . . Encephalitis can occur in the following ways: A virus directly infects the brain. A virus that caused an infection in the past becomes reactivated and directly damages the brain. *A virus or vaccine triggers a reaction that makes the immune system attack brain tissue (an autoimmune reaction)* [emphasis added].¹

An adverse vaccine reaction that causes brain damage (encephalitis) is the same thing as a complication from an infectious disease. Any pediatrician, doctor, or state or federal public health official who tells you that vaccines are completely safe, that adverse reactions to vaccines don't exist, or that vaccine-induced injuries are so rare that they virtually never occur is either ignorant or is committing scientific fraud. Is it worse to have your child vaccinated by a doctor who does not know the possible adverse reactions, or to be lied to by a doctor or government bureaucrat who does know the terrible damage vaccines can cause?

This is no trivial matter. Every day, uninformed physicians administer vaccines to vast numbers of children and adults with little thought about the possibility of adverse reactions. When an adverse reaction occurs—in the form of brain inflammation, convulsions, or another injury—the typical first step is to blame someone else. Doctors and the government accuse parents of child abuse (i.e., shaken baby syndrome) or bad luck (i.e., defective genes) and accuse teenagers of bad behavior (i.e., using illicit drugs). Medical professionals do not step up and ask whether they hold any responsibility for causing an adverse reaction to a vaccine.

The Merck Manual further defines the symptoms of encephalitis: “Symptoms of encephalitis include fever, headache, personality changes or confusion, seizures, paralysis or numbness, sleepiness that can progress to coma and death.” Many tens of thousands of parents whose

children were diagnosed with autism spectrum disorder reported that their kids were progressing normally until they received one or many vaccines, after which they had fevers, headaches, seizures, personality changes, and were never the same again. The symptoms reported by parents are the same symptoms of encephalitis that are defined in *The Merck Manual*. Health authorities in charge of defending and expanding universal immunization programs label these same symptoms “a coincidence.”²

When my five-week-old daughter, Lyla, died hours after receiving her hepatitis B vaccine, the New York medical examiner was more concerned about examining our apartment for evidence of child abuse than about the possibility that a vaccine caused her death. The medical examiner initially told us, our pediatrician, and an investigating pathologist that Lyla’s brain was so swollen that it led to her death. After consulting with Merck (the manufacturer of Lyla’s hepatitis B vaccine), the medical examiner left me, a devastated father who just lost his precious firstborn child to an avoidable vaccine-induced death, with these parting words: “We’ve changed our minds; her brain was not swollen. Vaccines do a lot of good things for people, Mr. Belkin.” Former *New York Times* journalist Melody Petersen, who covered the pharmaceutical industry in her book *Our Daily Meds*, reports that doctors who fill out death certificates are instructed to call a ‘therapeutic misadventure’ a natural death.³

Vaccine-caused diseases and deaths are an unacknowledged epidemic. The Centers for Disease Control and Prevention (CDC), state public health departments, Bill Gates, and doctors incessantly repeat the mantra calling for more vaccines to eliminate “vaccine-preventable disease.” However, my daughter experienced the opposite effect—the prophylactic treatment that was supposed to prevent a disease instead caused severe harm. The medical term for this outcome is iatrogenesis, the “inadvertent and preventable induction of disease or complications by the medical treatment or procedures of a physician or surgeon.”⁴ To put this in real world terms, you walk in to a doctor’s office in perfect health and you walk out with a lifelong neurological disability, or you even die, from prescribed vaccines. That is what happened to my daughter. Through immunization programs, modern medicine is creating the epidemic of neurological damage that it takes credit for preventing.

THE VACCINE HOLOCAUST

If you doubt the existence of adverse reactions to vaccines, you must first examine with your own eyes the U.S. Food and Drug Administration's (FDA) Vaccine Adverse Events Reporting System (VAERS), which is available and searchable online at www.medalerts.org. As of November 17, 2010, VAERS listed 352,650 reports of vaccine adverse events.⁵ Former Food and Drug Administration (FDA) commissioner David Kessler wrote in the *Journal of the American Medical Association* that "only about 1% of serious adverse events are reported to the FDA."⁶

Using that FDA commissioner's own estimate, there have been 35.2 million adverse reactions since the inception of VAERS in 1990, the vast majority of which were never acknowledged by doctors or public health officials. Regulators pull drugs such as Vioxx, Rezulin and Lotronex from the market after a few hundred or one thousand adverse reaction reports. Yet vaccines remain on the market, with hundreds of thousands of adverse reaction reports. The double standard is clear.

The following two recent VAERS reports, offered verbatim, are representative of thousands of others.

VAERS ID: 393346
Vaccinated: 2010-06-11

On 11 June 2010 the subject received 2nd dose of INFANRIX HEXA (intramuscular, unknown injection site), 2nd dose of ROTARIX (oral), 2nd dose of PREVENAR (intramuscular, unknown injection site). Lot numbers were not provided. On 12 June 2010, 23 hours after vaccination with INFANRIX HEXA, PREVENAR and ROTARIX, the subject experienced seizures. The healthcare professional considered the event was disabling. The subject was treated with EPILIM. At the time of reporting the event was unresolved. One month later, the subject was still having seizures. He was referred to a neurologist. The healthcare professional considered the event was possibly related to vaccination with INFANRIX HEXA, ROTARIX and PREVENAR.

VAERS ID: 391797
Vaccinated: 2010-06-19

A 6-month-old male subject who was vaccinated with ENGERIX B pediatric (GlaxoSmithKline). On 19 June 2010, the subject received 3rd dose of ENGERIX B pediatric (0,5 ml, intramuscular, unknown injection site). Lot number not provided. On 19 June 2010, within hours of vaccination with ENGERIX B

pediatric, the subject experienced high fever, 10 episodes of diarrhea and vomiting. 7 hours after vaccination, the subject was taken to emergency unit with severe dehydration and he experienced convulsion. At 19:35, the baby experienced cardiac arrest. The subject was treated with STESOLID, cardiopulmonary resuscitation and electrolytes. The subject died on 19 June 2010 at 20:18, cause of death was not reported. It was unknown whether an autopsy was performed.⁷

The CDC's Vaccine Safety Datalink dismisses seizures after vaccination without mentioning the difference between simple febrile seizures (70%-75% of seizures, transient, not caused by encephalitis), complex febrile seizures (20%-25% of seizures, prolonged, multiple seizures), and symptomatic febrile seizures (5% of seizures, neurological abnormality or acute illness).⁸

While *The Merck Manual* acknowledges that febrile seizures “occur after certain vaccinations such as measles, mumps, and rubella,”⁹ vaccination proponents claim that seizures are not associated with learning disabilities or death. The second VAERS report cited above suggests otherwise. The CDC's Vaccine Safety Datalink mentions cases like those described in the VAERS reports above and says, “Febrile seizures can occur after vaccination.” Febrile seizures “often result in a visit to an emergency room and can be very frightening for parents” and “cannot be prevented.... [C]hildren who have febrile seizures after receiving an MMR vaccine are no more likely to have epilepsy or learning or developmental problems than children who have febrile seizures that are not associated with a vaccine.”¹⁰ This is a roundabout way of saying exactly what *The Merck Manual* declares—adverse reactions to vaccines are the same thing as complications from an infectious disease. Let me paraphrase what it seems the CDC, with its contorted and deceptive syntax, is admitting: Seizures after vaccination—that may lead to permanent developmental problems—are no different than seizures from a nebulous other source. Clearly, the CDC needs to revise this information on the Vaccine Safety Datalink—it is too self-incriminating. People might decode it and realize the truth—that vaccines can cause (and have caused) permanent neurological damage to children. The CDC is in denial about the holocaust of vaccine adverse reactions being inflicted on America's children and adults. All of the CDC's published material appears to be carefully designed so that you—the prospective parent or patient—have complete faith in vaccines' safety and efficacy. Anyone who carefully studies VAERS cases can see that the CDC's vaccine safety proclamations reek of blatant propaganda.

After Lyla died, I learned about the risks of vaccinations. Perhaps you, like me, are wondering why the government doesn't do something about this.

Starting with the hepatitis B vaccine, I investigated the vaccine business and regulatory process. I followed the hepatitis B vaccine through a maze of FDA and CDC advisory committee meetings. I testified before the Congressional Government Reform Committee about my research and my family's experience,¹¹ and I continue to challenge the qualifications of so-called vaccine industry experts. I am an investment strategist, and therefore I am qualified to analyze and form an opinion of the statistical expertise of those who present themselves as medical statistics “experts.” The following is a summary of my conclusions.

In my opinion, the epidemiologist-statisticians from the CDC and state health departments are pseudoscientists. In my work, I use statistical models to forecast markets, so I am particularly

aware of the capabilities and limitations of statistics. In the financial markets, statistical fraud has a cost. If you fake the numbers, you will eventually get caught, fired, and prosecuted (as in the cases of Bernie Madoff, Enron, and others). The medical profession and government agencies like the CDC and the World Health Organization (WHO) seem to operate under a different standard. Estimates of disease prevalence are exaggerated,¹² academic medical studies are ghostwritten by pharmaceutical employees,¹³ and the WHO's declared global pandemic of H1N1 influenza fizzled out and turned into nothing more than a marketing campaign for flu vaccine manufacturers¹⁴—and yet, there is little accountability in the world of medicine for cooking the books or for putting pharmaceutical companies' profits above the public's interest.

When public health officials rely on questionable statistics to make blanket statements about the absolute safety and efficacy of vaccines, I am profoundly disturbed on personal and professional levels. Statistics is a world of probabilities, not absolutes. Statisticians make estimates about causation and the likelihood of future events based on mathematical odds, not certainties. It seems that vaccine epidemiology has been reduced to a pseudoscience, and its practitioners have sold out. They have become a de facto marketing department for the CDC and vaccine manufacturers.

I don't use these words lightly. With the Association of American Physicians and Surgeons, I filed a Freedom of Information Act (FOIA) request for two pieces of information more than ten years ago. We wanted all the safety data the CDC had prior to recommending the hepatitis B vaccine for new babies at birth, and we wanted the statistical model they used to prove its safety. We are still waiting for a response today. Their failure to respond is damning. The implication is that the at-birth hepatitis B vaccine recommendation was made without conducting proper safety studies in babies beforehand. Our babies are their guinea pigs.¹⁵

The government's FOIA refusal is a sad reflection on the dishonesty and incredibility of health officials. With a Wall Street background, I am particularly sensitive to fraud in the form of financial fiction and conflicts of interest. The government and industry have a cozy relationship and the public health arena offers no exception. There is a name for this: the revolving door. Julie Gerberding, the former head of the CDC, resigned from her government-appointed position in January 2009 and was named the president of Merck Vaccines in December 2009. Gerberding began her new job in January 2010, one year after leaving the CDC, which is the minimum amount of time she was legally required to wait before joining an industry that she previously regulated. It is clear that Dr. Gerberding received a professional reward for expanding universal immunization policies and, in effect, pharmaceutical company profits, for marginalizing the plight of victims of adverse reactions to vaccines.¹⁶ New Jersey's former deputy health commissioner, Eddy Bresnitz, was responsible for mandating the flu vaccine for babies and toddlers in the Garden State in 2008. He now oversees adult vaccines at the same New Jersey-based pharmaceutical firm, Merck & Company, Inc.¹⁷ Gerberding and Bresnitz are not the only ones to jump from governmental to industry positions.

Poul Thorsen—a Danish contributor to two articles¹⁸ that are regularly cited by CDC and Institute of Medicine (IOM) officials, which allegedly prove that vaccines and/ or thimerosal do not cause autism—has effectively been disowned by his former employer, the University of Aarhus, in Denmark. Thorsen managed the Danish data supporting those CDC-financed studies. According to a public statement released by the managing director of the University of Aarhus on January 10, 2010, “a considerable shortfall in funding at Aarhus University associated with the

CDC grant was discovered... [I] n March 2009, Dr. Thorsen resigned his faculty position . . . [but] has continued to act in a manner as to create the impression that he still retains a connection to Aarhus University.” The statement concluded, “Aarhus University wishes to confirm that Dr. Poul Thorsen no longer has any connection to Aarhus University and that Aarhus University will not be able to collaborate with Poul Thorsen in the future.”¹⁹

HOW VACCINES ARE LICENSED AND MANDATED

Vaccines affect you and your children through a three-step process:

1. Licensure—the FDA says the vaccine is safe and effective;
2. Recommendation—the CDC's Advisory Committee on Immunization Practices (ACIP) places the vaccine on the U.S. recommended vaccination schedule; and
3. Compulsion—state health departments mandate vaccines for day care and public school admission. Federal funding and the relentless lobbying efforts²⁰ of drug makers powerfully influence state decisions.

Every step of this process is tainted by financial conflicts of interest, scientific fraud, and statistical bias.

Licensure

The FDA must license a vaccine before it can be administered to the general public. A vaccine manufacturer is required to conduct prelicensure safety and efficacy studies. Most people don't realize several key points about the related vaccine safety science.

First, an industry performs its own studies to justify the licensure and selling of its products. The FDA reviews these studies and often provides important guidance to help facilitate the approval process. The FDA does not conduct independent research on proposed vaccines.

Second, the government uses epidemiological studies to disprove causation between adverse events and vaccines or vaccine ingredients. As Drs. Stott and Wakefield explain in chapter 7, the studies the government uses to report "no association" between vaccines and injuries are flawed, either because "they have been badly designed, or they have not been designed with the right hypothesis in mind in the first place."

Third, our public health officials do not require randomized controlled studies.²¹ They say that it is unethical to withhold vaccination from anyone, so they do not uphold a scientific gold standard in order to answer ethically troubling questions, especially regarding vaccine safety. Industries typically use other vaccines as placebos rather than using a truly neutral placebo such as saline solution.²² What better way to prove that your vaccine is safe than to show that it is precisely as safe as another unsafe vaccine? Remember that adverse neurological reactions to vaccines, such as encephalitis and febrile seizures, are no different than encephalitis and febrile seizures caused by disease. Using another vaccine as a placebo is a fail-safe mechanism used to ensure that a test vaccine will be upheld as safe.²³ No regulations govern placebo composition, which can influence research outcomes and merit reporting.²⁴ For another stark example, suppose a pharmaceutical company invented a new tranquilizer but discovered that it caused birth defects in the unborn children of pregnant women. Now suppose that company designed an FDA safety study using thalidomide (which is known to cause birth defects) as the placebo, to prove its new product was no less safe than other tranquilizers. Vaccine manufacturers follow this pattern in FDA licensure studies.

Recommendation

After obtaining licensure for an unsafe-as-any-other vaccine, the next step is to get it recommended. This involves getting the stamp of approval from the CDC Advisory Committee on Immunization Practices (ACIP). The ACIP is responsible for the federally recommended childhood vaccination schedule. This group tells doctors how many doses of which shots every child in this country should receive. Adult immunization is a new focus for this group. I attended an ACIP meeting and it was truly a farce. A dozen or so doctors from various medical centers around the country sat around a rectangular table and unanimously approved almost every proposal placed before them. Most of the voting members had conflicts of interest.²⁵ Members abstained from voting on specific proposals in which they were involved (typically, the proposals were vaccine studies financed by pharmaceutical companies, which the members or their medical centers managed), but they voted to approve every other proposal on the agenda. It was a classic case of “you scratch my back and I’ll scratch yours.” Vaccine safety was not honestly debated. There were no vaccine safety advocates as voting members. For members of this self-serving committee, the path towards professional advancement is clear: never rock the boat and approve every proposal put in front of you.

Compulsion

With an ACIP recommendation in hand, the next task as a vaccine promoter is to get a mandate enacted into law at the state level. This is a relatively simple task, but it is time consuming because every state is different and some states have pesky vaccination choice advocates that assert varying degrees of opposition. Epidemiologists in a state's public health department can reliably produce school mandates that are enacted by state legislative bodies whose members are not educated about vaccine risks, have never read *The Merck Manual* (or any other medical textbook), and have no idea that adverse reactions to vaccines, such as encephalitis and febrile seizures, exist and are indistinguishable from complications from infectious diseases. It is relatively easy to get the votes. Campaign contributions from Big Pharma grease the skids. There is a customary obeisance to modern vaccine technology as the miracle that has banished the ravages of infectious disease. Legislators pass laws requiring children to receive these vaccines to attend day care and public school. While not required, many private schools follow suit and adopt those mandates as well.

Consider, for a moment, schools' vaccination mandates from the drug manufacturers' perspective. Day care and school systems become free vaccine marketing departments. There is no need to train a sales force or to incur other marketing expenses. If you can force your customers to acquire your product, it eliminates all of the messy uncertainty and hassle of a competitive market. Instead of free market competition, their business strategies are built on compulsion. The public school system is an ATM for pharmaceutical companies—who are laughing all the way to the bank.

PATENT CLIFFS AND GOLDEN PARACHUTES

The clout that drug companies wield belies an emerging truth. In the stock market, pharmaceutical companies are no longer the gold-plated, recession-proof investments they once were. The Big Pharma business model has been simple and profitable: Find a natural substance known to have healing properties, invent a synthetic substitute for its active ingredient, give it a clinical name, add toxic additives and preservatives, press it into small white or colorful pills, and charge a price that is thousands of times the cost of production. Most notably, protect yourself from price competition via patent protection. Using this business model, the pharmaceutical industry has turned its stocks into popular, dividend-paying, high-yielding investments.

However, industry analysts understand what the rest of us are coming to realize: Patent protection does not last forever. Pharmaceutical industries now face what is known in the investment world as a “patent cliff.” Specifically, they are dreading the near-term expiration of about \$140 billion’ worth of patents on many of their key, blockbuster drugs.²⁶ When drugs lose patent protection and face generic competition, prices plummet and profits vanish. The pressure on research departments to invent viable replacement products has mostly drawn a blank. The industry is now experiencing financial pressure that has taken the bloom off stocks and industry prospects. Making drugs is now a cutthroat business. Blogs such as *Café Pharma*²⁷ offer an insider’s perspective.

PHARMA'S SURVIVAL STRATEGY

The pharmaceutical industry has devised a three-pronged survival strategy:

1. Expand to emerging markets,
2. Increase drug prescription compliance, and
3. Expand the vaccine market.

Expand to Emerging Markets

Drug companies are enthusiastic about growth prospects in countries that have low per capita healthcare spending, such as Brazil, China, and India; however, their ambition to gain big profits from patented blockbuster drugs in emerging markets probably won't work. Copycat knockoffs of high-priced American goods are endemic in China. The best-case scenario for pharmaceutical companies includes incremental generic drug profits, theft of intellectual property, and state-encouraged competition from national champions in China and India.²⁸ Drug companies seem intent on exporting vaccines. The United States can't manage to manufacture many products that the world wants to buy anymore, which is proven by the persistent U.S. trade deficit. However, the United States may end up successfully exporting its sky-high rates of autism and chronic childhood disorders. Recently, the drug industry-dominated World Health Organization and Bill Gates's Global Alliance for Vaccines and Immunisation (GAVI) have stated their intention to extend a U.S.-style childhood vaccination schedule to other countries.²⁹ Health officials and the pharmaceutical industry seem to think that selling the U.S. vaccination schedule globally can help balance U.S. terms of trade, through greater pharmaceutical profits. Foreign governments should be very wary.

Increase Drug Prescription Compliance

Vaccination mandates have worked so well that drug companies intend to extend the “strong recommendation” model to prescription drugs. The push for prescription drug compliance seems ironic, given the data provided in the latest CDC National Center for Health Statistics Data Brief Number 42, which details Americans’ prescription drug use from 2007 to 2008:

- One of every five children and nine out of ten older Americans reported using at least one prescription drug in the month prior to being surveyed.
- 22.4% of kids up to age 11 used at least one prescription drug.
- 29.9% of young people aged 12–19 used at least one prescription drug.
- 48.3% of people aged between 20 and 59 used at least one prescription drug.
- 88.4% of Americans aged 60 and over used at least one prescription drug, more than 76% used two or more prescription drugs in the past month, and 37% used five or more.³⁰

This study suggests that Americans are already overmedicated and prospects are poor for increased prescription compliance. It does not mean, however, that the pharmaceutical industry will not try.

The growth of the drug compliance movement is most evident in the recent “deputization” of pharmacists to market and administer flu shots at big-box stores and chain drugstores. The pharmaceutical industry is now commandeering drugstores in the same manner that it captured the public school system. Drugstores appear delighted to have this potential, new revenue source. They are conscripting pharmacists as foot soldiers in the crusade against infectious diseases. The public now faces a marketing onslaught for flu vaccination every time it walks through a drugstore or a grocery store that has a prescription drug department. *Medical News Today* has reported, “Last year, retail pharmacists were particularly influential in driving vaccinations, administering more than sixteen million vaccines and acting as a source of information for concerned citizens. Cardinal Health offers an array of support services to help retail pharmacy customers earn certification to offer and promote vaccination services to their local community.”³¹ I expect drug makers to expand the drugstore vaccine promotion with a flood of forthcoming adult vaccines; one example is the herpes zoster (shingles) shot. In the business world, this is called “channel stuffing.”

Expand the Vaccine Market

Big Pharma wants you to believe that you are vaccine deficient. There are currently 145 new vaccines in development.³²

Media-stoked public fears of terrorist biological-weapon attacks (e.g., anthrax) following the attack on the World Trade Center on September 11, 2001, and the subsequent overhyped H1N1 “pandemic” have convinced the drug industry that there are huge profits to be made in vaccines. The global vaccine revenues were \$22 billion in 2009—an increase of 16 percent since 2008. Industry analysts predict that vaccine revenues will hit \$35 billion by 2015.³³

Despite tremendous growth, vaccine revenues cannot blunt the entire impact of the \$140 billion that will be lost when blockbuster drug patents expire. That won’t stop the vaccine development binge, however. The drug industry sees vaccine development as a golden parachute to take them safely over their patent cliff.

As I previously discussed, the drug industry dominates the regulatory process and can jam new vaccines through the approval process by disguising adverse reactions with bogus placebos. The implications for a major increase in neurological damage are staggering. Having dominated the child vaccine market through school mandates, the vaccine industry is champing at the bit to compel adults to comply with their forthcoming campaign for adult immunization.

Moreover, there are severe quality limitations on vaccines for both adults and children. Some vaccines are ineffective or only protect against a small number of strains of a particular disease.³⁴ Some vaccines lose their supposed protective qualities when disease strains, like influenza, shift.³⁵ Other vaccine-derived antibodies only persist a few years.³⁶ These vaccines are economically attractive to vaccine manufacturers, though, because people will need repeated doses, or boosters. The industry’s repeat-revenue model favors rapidly obsolescing vaccines.

While far more dangerous due to its health implications, this model is reminiscent of the calculated obsolescence business model used by the U.S. automotive industry in the 1960s, which Ralph Nader criticized. The U.S. auto industry deliberately made junky cars that wore out or went out of fashion—a business strategy that ultimately destroyed the U.S. automotive industry because the Japanese and German manufacturers made better cars. According to this business model, just like American cars made in the 1960s and 1970s, ineffective vaccines that are quickly obsolete are preferable to ones that provide lifelong immunity. From the vaccine manufacturer’s perspective, it is essential to keep the customers coming back for more.

Medical sociologist Dr. Donald Light from the School of Public Health at the University of Medicine and Dentistry of New Jersey (UMDNJ)³⁷ recently presented a paper touching on this subject at the American Sociological Association’s annual meeting in Atlanta on August 17, 2010 (session 487), entitled “Pharmaceuticals: A Two-Tiered Market for Producing ‘Lemons’ and Serious Harm.” He argued,

The pharmaceutical market for “lemons,” differs from other markets for lemons in that companies develop and produce the lemons. Evidence in this paper indicates that the production of lemon-drugs with hidden dangers is widespread and results from the systematic exploitation of monopoly rights and the production of partial,

biased information about the efficacy and safety of new drugs.

I anticipate that vaccine makers will use their monopoly power and influence over the regulatory process to press for more vaccination mandates. Pharma's business model is compulsion: Take the right of informed consent away from the individual and replace it with the dictatorial requirement to be a captive customer for lemon vaccines and prescription drugs.

VACCINE BUBBLE PSYCHOLOGY

In the investment world, I have lived through several speculative bubbles. Lessons learned from those experiences apply to what I call the “vaccine bubble.” Two key forces create bubbles:

1. Promoters, who typically have a financial interest in creating mass public hysteria. In the case of the housing bubble, this would include the banking, mortgaging, and construction industries.
2. Do-gooder policy makers, who want to wave a magic wand and improve the world through well-intended interventions. These do-gooders are oblivious to the unintended consequences of their involvement, otherwise known as “blowback” in the political and investment worlds.

Osama Bin Laden is one example of blowback. CIA do-gooders funded a mujahideen resistance against the Soviet occupation of Afghanistan in the 1980s, providing training and weapons. What seemed like a great idea at the time became the most obvious example of blowback on September 11, 2001, when the World Trade Center was attacked. CIA-equipped terrorists, who had initially joined us in fighting our Soviet enemies, evolved into our enemies. Meanwhile, the Soviet Union had collapsed and its central successor, Russia, was no longer our enemy. Few, if any, policy makers anticipated this chain of events when the CIA originally orchestrated the mujahideen resistance. At the time, nearly everyone thought it was a fine idea.

Another glaring example of blowback from well-intentioned policies is the collapse of the U.S. housing market. The well-intentioned efforts of Congress to expand home ownership fostered a subprime mortgage bubble, allowing low-income renters who probably never would have qualified for a normal home loan (with the required 20 percent down payment and verifiable employment and income) to purchase homes. This process encouraged real estate speculation and mortgage-market insanity, which drove up prices to unrealistic levels in many areas of the country (e.g., Miami, Las Vegas, and Southern California). The blowback from this policy error is now obvious to everyone—homeowners who lost their homes, banks that busted, and other grim economic news.

The blowback from the vaccine bubble is a rising epidemic of neurological damage. Approximately one in ninety-one children (1.1 percent of children) in the United States now receives an autism diagnosis.³⁸ This is thirteen times more than the average autism rate (0.08 percent) found in a 1993 survey—before the U.S. childhood vaccination schedule expanded dramatically.³⁹ The latest CDC study shows that 9.5 percent of parents surveyed reported that their child had received a diagnosis of attention deficit hyperactivity disorder (ADHD).⁴⁰

This plague of neurological damage is expanding in direct proportion to the greater number of vaccines imposed on an unsuspecting public. The future economic costs to society of medical care and welfare for a neurologically disabled population are staggering.⁴¹ Policy makers must consider these costs now—and Americans must hold the corporate perpetrators economically and criminally liable.

Every bubble contains an element of crowd psychology, or a collective conception that shepherds unsuspecting individuals into wholeheartedly participating in an ill-fated popular delusion. Examples of this include buying the NASDAQ at the 5,000 level in early 2000, and buying an unaffordable house in 2007. During a bubble, people are dying to participate. The

bigger the bubble, the more powerful the promotional messages encouraging participation.

A similar force is at work regarding vaccination. Television, print, and online publications are constantly quoting CDC and public health officials, who tell everyone how dangerous the flu, measles, chickenpox, meningitis, pertussis, and cervical cancer are. Their messages include exhortations to vaccinate against vaccine-preventable diseases. *These health authorities are essentially selling fear and disease.*⁴² It appears that their intention is to whip up mass hysteria and persuade people to wait in line for the latest miracle vaccine against a deadly disease. These unsuspecting people remain unaware that adverse reactions to vaccines exist and are defined in medical textbooks as the same thing as infectious disease complications. We cluck at the bad judgment of those who invested their life savings in overpriced technology stocks when stockbrokers trumpeted a Dow advance to 24,000 (its peak was 14,164), and at others who bought Miami condominiums and Las Vegas ranch houses when mortgage brokers urged them to avoid missing the housing boom. Today, the pharmaceutical industry has convinced the government and the medical profession to do its bidding. Another group of jive-talking promoters, who have a vested personal and financial interest in fanning the flames of mass hysteria, is exploiting the public.

Incidentally, institutional portfolio managers (my clients) who resisted the NASDAQ and real estate bubbles lost customers who only wanted portfolio managers who purveyed the popular investment flavor of the month. In other words, there was tremendous institutional pressure to play the game, even though they did not believe in it and knew it would end in tears. There is undoubtedly similar pressure in the medical world for doctors to play along with CDC vaccination recommendations and to make patients into pincushions for pharmaceutical companies, even if they suspect that “something is rotten in Denmark,” as Shakespeare wrote in *Hamlet*. The overall result is that enormous psychological pressure is placed on people by medical professionals to receive vaccines, either in normal primary-care settings or during emergency-room visits for unrelated injuries or illnesses.⁴³

The aftermath of deviant psychology bubbles is typically a backlash against the bubble promoters. In the old days, the perpetrators would be tarred and feathered, or dispatched. After the NASDAQ bubble, investors’ sentiments toward stockbrokers and bubble cheerleaders soured. As we now know, through endless stories of people losing their homes through foreclosure, the public’s sentiment toward estate brokers, mortgage brokers, politicians, and overpaid “banksters” is vindictive. Victims want retribution.

When the vaccine bubble finally bursts, public sentiment toward government health officials, pharmaceutical companies, and doctors is likely to turn negative in the same way that it did after the collapse of the stock market and real estate bubbles. Today, the vaccine regulatory system is primed to approve and advance all of the vaccines Big Pharma can dream up. The sales pitch is germophobia and protection against diseases you didn’t know you had or could get, such as genital and anal warts—Merck’s latest justification for giving *male* sixth graders the female-oriented human papillomavirus (HPV) cervical cancer vaccine. In all likelihood, this will end badly (as if VAERS isn’t already disastrous enough). The greedy fearmongers will overstep their boundaries and create a catastrophically dangerous vaccine, like the 1976 swine flu vaccine that caused an estimated five hundred cases of Guillain-Barré-syndrome-induced paralysis and at least twenty-five deaths.⁴⁴ A similar disaster would ignite today’s vaccine safety controversy and rapidly turn the tide of public ideology against vaccines and vaccination mandates. Fraud always

becomes a public issue after a bubble bursts. All of the evidence is currently here before everyone's eyes, including fudged safety studies, the revolving door of health officials and pharmaceutical executives, denial about the basic scientific definition of neurological damage, and more. The public simply needs to connect the dots.

THE REFUSERS

In the meantime, we must preserve the right to opt out of compulsory vaccination requirements for our children and ourselves. Infectious disease specialists use the term “refuser” pejoratively, to cast aspersions on those who are intelligent, informed, and strong willed enough to “refuse” the corporate and governmental assault on our families’ bodies with their ineffective, unsafe, and toxic vaccines.⁴⁵ I admire their supposedly pejorative term “refuser” so much that I trademarked it and created a musical band around the concept—The Refusers.⁴⁶ This is my attempt to raise public awareness about vaccination risks that the pharmaceutical industry and the CDC are foisting on us. I fully support the right of all parents to make informed vaccination choices for their children, whatever their decisions may be. Indeed, the CDC claims that over ninety percent of American children younger than three years of age are now fully vaccinated.⁴⁷ So be it. After losing a daughter and investigating the so-called science behind our current vaccines, *I am a refuser*. Medical authorities and uninformed parents want to turn that informed decision around and paint people like me as a menace to society. The VAERS reports show that *adverse reactions to vaccines are the real menace to society*.

In my opinion, health officials and drug companies intend to abolish that right of refusal; meanwhile, they are causing an epidemic of neurological damage from vaccines and denying responsibility for it. They take credit for preventing neurological damage from disease epidemics. Nevertheless, *The Merck Manual* and VAERS tell us the truth. Public health officials have betrayed the public they pledged to protect. Postbubble forces will unleash a massive reform and bring the perpetrators of this vaccine bubble and the epidemic of neurological damage to justice. Until then, it is essential that we honor an individual’s choice to refuse a vaccine as a human right.

Chapter Eighteen

THE ROLE OF GOVERNMENT AND MEDIA

Ginger Taylor, MS

REVELATION OF HIGH MERCURY LEVELS IN THE CHILDHOOD VACCINATION SCHEDULE

The most recent chapter in the long and controversial history of vaccine safety began in the United States in July 1999. That is when the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS) issued a joint statement through the Department of Health and Human Services (HHS) on mercury and vaccines. They stated that in the U.S. vaccine program at the time, “some children could be exposed to a cumulative level of mercury over the first six months of life that exceeds one of the federal guidelines.”¹

The truth was that the amount of mercury in the childhood vaccination schedule grossly exceeded the Environmental Protection Agency’s (EPA) maximum daily adult exposure for methylmercury, the form of mercury most closely related to thimerosal, for which the government had established a guideline. The EPA sets the daily limit at 0.1 micrograms per kilogram of weight.² Based on that guideline, a baby weighing approximately five kilograms (eleven pounds) at two months of age should not receive more than 0.5 micrograms of mercury on the day of a doctor’s visit. At the time the AAP and USPHS joint statement was issued, infants at their two-month visit routinely received 62.5 micrograms of mercury, or 125 times the EPA’s limit. Studies have suggested that, for thimerosal (ethylmercury), “the accepted reference dose should be lowered to between 0.025 and 0.06 micrograms per kilogram per day,” meaning that the exposure at the two-month visit could be as high as 500—rather than 125—times the safe level.³

In November 2002, Dr. Neal Halsey, director at the Institute for Vaccine Safety at Johns Hopkins Bloomberg School of Public Health, told the *New York Times*:

My first reaction was simply disbelief . . . if the labels had had the mercury content in micrograms, this would have been uncovered years ago. But the fact is, no one did the calculation.⁴

At the time, USPHS claimed that, “there [are] no data or evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule.”⁵

However, the government made this safety claim *before* it had begun to look for evidence of harm. In November 1999, the Centers for Disease Control and Prevention (CDC) initiated a study to evaluate whether children receiving the highest amounts of thimerosal had suffered any ill effects. Thomas Verstraeten,⁶ the study’s lead epidemiologist, did not begin the study until four months after the government’s “no evidence of harm” claim. The CDC did not publish the results until 2003.⁷ The first phase of the Verstraeten study found an association between higher doses of thimerosal and neurodevelopmental disorders. In the second phase of his study, Verstraeten described his findings as “neutral.”⁸

HHS further asserted in July 1999:

Given that the risks of not vaccinating children *far outweigh the unknown and much smaller risk, if any, of exposure to thimerosal-containing vaccines* over the

first six months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.⁹ (emphasis added)

With this single statement, the government took the position that the risk posed to children from exposure to thimerosal was both “unknown” and a “smaller risk” than exposure to childhood diseases. This suggested that public health officials could perform a risk-benefit analysis with no risk information for half of the equation.

HHS further asserted, “[i]nfants and children who have received thimerosal-containing vaccines do not need to be tested for mercury exposure.”¹⁰ On what basis could HHS make this statement? It had not done (and still has not done) the underlying research to show that these children were not at risk and should not be screened for mercury toxicity. Without hard evidence, the government nonetheless seemed eager to reassure parents that “no evidence of harm” meant “no harm”—even as it failed to look for evidence.

The mainstream media did not investigate HHS’s claims or recommendations, nor did it investigate those of vaccine safety advocates. None of the problems with the joint statement, the investigation, or the CDC’s handling of the thimerosal question came to light until 2005, when investigative journalist and author David Kirby’s book *Evidence of Harm* was released. The searing and detailed account exposed the questionable behavior and judgments of the CDC and HHS.¹¹ Likely sensing the potential for public outrage, the CDC quickly took action and posted a notice on its website explaining that it would review the book and respond. By the end of 2005, however, the CDC had taken the notice down without responding. To this day, the government has offered no response to the book, and the media has done nothing to hold public health authorities accountable.

THIMEROSAL-CONTAINING VACCINES ARE LEGALLY CLASSIFIED AS HAZARDOUS MATERIALS

As potential hazards from vaccination began to be explored by the autism community, the EPA's rules on mercury disposal and their application to thimerosal-containing vaccines became a focus. The realization that mercury levels in vaccines were so high that they were legally classified as hazardous materials, and that the law required they be disposed of according to hazmat protocols, led many to further doubt the government's safety claims.

Wisconsin's hazardous waste disposal guidelines state that:

Some vaccines are preserved with 1:10,000 or 0.01 percent Thimerosal (see the vaccines in the table titled "Thimerosal Content in Some U.S. Licensed Vaccines" at www.vaccinesafety.edu/thi-table.htm that have .01% in the Thimerosal Concentration column). Thimerosal contains about 50 percent mercury by weight. Vaccines with 1:10,000 or 0.01 percent Thimerosal have about 50 mg/L mercury, which exceeds the 0.2 mg/L hazardous waste toxicity characteristic regulatory level for mercury. According to state and federal hazardous waste management requirements, discarded Thimerosal-preserved vaccines may need to be managed as hazardous waste, using the waste code D009 (mercury)... It is illegal to manage Thimerosal-preserved vaccines as infectious waste or regular trash.¹²

The mercury concentration in the previously used thimerosal-containing vaccines and the current flu vaccines is exponentially larger than what is considered hazmat material, or that is even allowed in safe drinking water, as outlined in *Pediatrics*:

0.5 parts per billion (ppb) of mercury kills human neuroblastoma cells.

2 ppb of mercury is the US EPA's limit for mercury in drinking water.

20 ppb of mercury destroys neurite membrane structure.¹³

200 ppb of mercury is the level in liquid that the EPA classifies as hazardous waste.

25,000 ppb of mercury is the concentration in the hepatitis B vaccine administered at birth in the United States from 1990 to 2001.

50,000 ppb of mercury is the concentration in multidose DTaP and Hib vaccines, administered four times each in the 1990s to children at two, four, six, twelve, and eighteen months of age; it is also the current "preservative" level in multidose flu vaccines (in 94 percent of the supply), meningococcal vaccines, and tetanus vaccines (for children age seven and older). This can be confirmed by analyzing the multidose vials.¹⁴

Parents who reviewed this information understood the inherent problem with the CDC's recommendation that was in place until approximately 2003, which stated that hazardous materials should be injected into infants beginning days after birth, and with its current

recommendation to inject hazardous materials into all Americans beginning at six months of age, via the current yearly flu vaccination campaign. They did not overlook that the vaccine being injected into children at flu shot clinics, if spilled onto the floor, would trigger laws requiring immediate evacuation of the building and clean up by hazmat teams. This information was, however, seemingly lost on the media, who neither carried this information to the public nor demanded that the federal government explain this dramatic contradiction.

The media's failure to bring this to light continued through the conclusion of the 2009–2010 flu vaccine campaign, even as toxic-waste management companies promoted their services to dispose of the more than eighty million unused doses of the H1N1 vaccine in publications like *Occupational Health and Safety Magazine*:

Clean Harbors, based in Norwell, Massachusetts, is offering the service to healthcare providers because multiple doses of the vaccine contain enough mercury-based Thimerosal to be treated as a hazardous waste.... Clean Harbors of Norwell, Massachusetts, now offers H1N1 Vaccination Incineration Services that will profile, collect, and dispose of unused 2009 H1N1 vaccine for healthcare customers nationwide. Multiple doses of the vaccine contain enough mercury-based Thimerosal to be treated by EPA as a hazardous waste and will be incinerated. ¹⁵

VACCINE ENCEPHALOPATHY AND AUTISM

The Health Resources and Services Administration's (HRSA) Vaccine Injury Compensation Program has a table of known vaccine-induced injuries for which the government offers compensation. The table lists "encephalopathy" as an outcome for the combination MMR (or any of the various individual measles, mumps, or rubella vaccines) and for the DTaP (or any pertussis-containing vaccines). The symptoms of this encephalopathy (a medical term meaning brain disorder, brain damage, or a change in brain functioning) in a child who is eighteen months or older include a "significantly decreased level of consciousness" which HRSA describes as follows:

1. Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
2. Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
3. Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).¹⁶

Many parents have reported these symptoms in their previously typically functioning children after neurological regression following measles, mumps, rubella (MMR) and pertussis-containing (DPT or DTaP) vaccines; however, those symptoms were not used to diagnose their children with a vaccine-induced encephalopathy but rather to diagnose them with autism. In addition, one of the signs of encephalopathy is seizure activity. Estimates suggest that one-quarter to one-third of those with an autism diagnosis also suffer from seizures.¹⁷

Were "vaccine-induced encephalopathy" and "autism" merely the same phenomenon, described from the vantage point of two different disciplines, medicine and mental health? Were cases of autism merely misdiagnosed vaccine-induced encephalopathy, due to the lack of physician training regarding the recognition of vaccine injury? These questions never surfaced when the media ran stories regarding parental concerns about vaccine-induced autism—that is, until 2008, when the Vaccine Injury Compensation Program (VICP) became national news.

THE HANNAH POLING CASE

In early 2008, Jon and Terry Poling announced to the press that HHS had conceded their daughter's case of vaccine-induced autism. Ten-year-old Hannah Poling had regressed into autism after receiving nine vaccines in five shots during one office visit. The Polings argued that their daughter had a preexisting, asymptomatic, and undiagnosed mitochondrial dysfunction and sustained a neurological regression into autism from receiving vaccines at eighteen months of age. Jon Poling was a well-respected neurologist at Johns Hopkins and his wife, Terry, was a registered nurse and attorney. The Polings' medical testing following their daughter's regression was so thorough and their case so strong that HRSA conceded the case and elected to pay compensation without a hearing before the VICP. The government acknowledged, albeit in very evasive language, that vaccines were the culprit that led to Hannah Poling's autism.

While the media had yet to rigorously scrutinize the vaccine-autism story, national and local consumer-safety and autism-awareness groups were organizing to share information and advocate for change. When CNN broadcast the Polings' press conference live, the event poured gasoline on the already fiery vaccine safety debate. Federal public health officials were forced to comment on how vaccines cannot cause autism, even though they seemed to have done just that in little Hannah Poling. The government's position on the Polings' case and on vaccine-autism causation were completely at odds. The government's clumsy and conflicting answers raised even more questions about vaccine safety:

- Did vaccines cause Hannah's autism?
- Is mitochondrial dysfunction rare?
- Did the government deliberately mislead the public about Hannah's injury?
- Did the media pursue this news story appropriately?

Our government would not say that Hannah had autism, which she indeed does have.¹⁸ The concession document¹⁹ said that Hannah has “a regressive encephalopathy with features of autism spectrum disorder.”²⁰ By definition, a person diagnosed with a disorder will have features of that disorder. Government attorneys had full access to Hannah Poling's extensive medical files, which disclose that she has DSM-diagnosed, full-syndrome autism. Yet, they referred to her neurological disorder using terms that sounded ambiguous, as if she has something like autism, but not autism. Hannah's parents repeatedly clarified to the media that their daughter has full-syndrome autism. A scientific journal article²¹ further confirmed her diagnosis.

Where was the mainstream media? It failed in two respects. First, it continued to repeat the government's euphemistic words, “autism-like symptoms,” thereby attempting to dodge the burning question—does the dramatic increase in the number of childhood vaccines correlate to the dramatic increase in autism incidence? Second, the media gave extensive airtime to vaccine-program defenders who seemed to turn the case on its head. In a twist of logic, they inferred that it wasn't really the vaccines' fault that Hannah was permanently injured; on the contrary, Hannah was merely a poor receptacle for lifesaving vaccines.

An article in the *New Scientist* declared, “Significantly, the government's decision says nothing about whether vaccines cause autism. Instead, government lawyers concluded only that vaccines aggravated a preexisting cellular disorder in the child, causing brain damage that included features of autism.”²² This vague government pronouncement prompted the tongue-in-cheek response from a commenter, “Do cigarettes only aggravate preexisting genetic factors,

causing lung damage including features of cancer?”²³

CDC DIRECTOR DR. GERBERDING APPEARS ON CNN

A few days after the announcement, CDC Director Dr. Julie Gerberding appeared on CNN with Dr. Sanjay Gupta to explain the government's position on the Poling case and vaccine-autism causation.

Gupta began the interview by noting that a child with regressive autism had been compensated and that the government had conceded that vaccines had caused her "autism-like symptoms." He zeroed in on a key question. Gupta asked whether Hannah had "autism" or "autism-like symptoms."

Gerberding never answered.

Instead she claimed that she had not read the Poling case file. Gupta failed to challenge this extraordinary and implausible statement. Gerberding was at the helm of the government agency responsible for the U.S. vaccine program and reported directly to Congress. A government agency conceded that vaccines caused Hannah Poling's autism-like symptoms and Gerberding had not read her case file before appearing on national television?

In another extraordinary statement, Gerberding proceeded to explain a way in which vaccines can cause autism:

My understanding is that the child has what we think is a rare mitochondrial disorder and when children have this disease, anything that stresses them creates a situation where their cells just can't make enough energy to keep their brains functioning normally. Now we all know that vaccines can occasionally cause fevers in kids, so if the child is immunized, got a fever or other complications from the vaccine then, if you are predisposed with a mitochondrial disorder, it can certainly set off some damage, some of the symptoms can be symptoms that have characteristics of autism.²⁴

Gerberding had just said that vaccines can cause autism in children with mitochondrial disorders.

Gupta passed right by this statement as well. Seeming not to have heard her, he instead asked, "As it stands, are we ready to say that vaccines do not cause autism?" Off the hook of the vaccine-autism causation question, Gerberding quickly responded,

What we can say absolutely, for sure, is that we don't really understand the causes of autism. We've got a long way to go before we get to the bottom of this, but there have been at least 15 very good scientific studies, and the Institute of Medicine which has searched this out and they have concluded that there really is no association between vaccines and autism.²⁵

Dr. Julie Gerberding, director of the CDC, had just explained an association between vaccines and autism on national news. She then said there is no association between vaccines and autism.

Gupta did not challenge her on her conflicting statements. Instead, he allowed Gerberding to reinforce the government's position that there is no link between vaccines and autism.

Two weeks earlier, the CDC had held a conference call with concerned physicians and insurance companies to discuss the Poling case.²⁶ During the call, experts presented information that Hannah's preexisting mitochondrial dysfunction may not be so rare. An unpublished study of thirty children with regressive autism revealed that they all shared Hannah's same biomarkers.²⁷ On the call, it was estimated that up to one in fifty children, or 2 percent of the general population, may have a genetic mutation that places them at risk for mitochondrial dysfunction.²⁸ This information had been in the press for three days when Dr. Gerberding gave the CNN interview and made the claim that Hannah's condition was "rare," but Gupta didn't challenge her claim.

In *The Washington Post*, Gerberding offered additional, unsubstantiated words of reassurance to a concerned public:

While we recognize, and have recognized, mitochondrial disorders are associated with . . . autism-like syndrome, there is nothing about this situation that should be generalized to the risks of vaccines for normal children.²⁹

Gerberding failed to explain the seemingly simple phrase "normal children." Hannah seemed "normal" before her shots, as did tens of thousands of children who regressed into autism after their shots. In fact, Hannah was above average socially and so highly verbal that, at the age of sixteen months, she had been chosen to be a "typical peer" to model appropriate social skills to developmentally disabled children in an early intervention program. Millions of concerned parents wonder about vaccine safety and which of their "normal" children might be at risk of developing autism after vaccination. How could they know?

Gerberding's *Washington Post* statement raised several troubling questions:

- By definition, regressive autism means that the children were, by all appearances, neurologically "normal" before their diagnosis. In the absence of criteria to identify susceptibility, aren't all children "normal" before they regress into autism after vaccination?
- How many other children with regressive autism following vaccination have asymptomatic, undiagnosed mitochondrial dysfunction like Hannah Poling? Was Hannah diagnosed only because her father is a neurologist?
- In the Hannah Poling scenario, a seemingly healthy child suffered a vaccine regression that gave her autism. Autism affects one percent of all U.S. children. Why aren't we screening children before vaccination to make sure they are not susceptible, just like Hannah was?

Dr. Anne Schuchat, the assistant surgeon general and director of the National Center for Immunization and Respiratory Diseases at the CDC at the time, answered the last question in an interview in *The Atlanta Journal Constitution*:

Some have suggested that infants and children be screened for mitochondrial disorders before getting recommended vaccinations. Unfortunately, mitochondrial diseases are very difficult to diagnose and it is usually not possible to identify children with such disorders until there are signs of developmental decline. A definitive diagnosis often requires multiple blood tests and may also require a muscle or brain biopsy (removal of a portion for testing, usually under anesthesia).

Therefore, providing routine screening tests on children who have no symptoms would bring other medical risks and raise many ethical questions.³⁰

Schuchat failed to mention that a simple blood test to screen for “soft biomarkers” of mitochondrial dysfunction is available and reasonably predictive.³¹ She further failed to mention the medical risks and ethical questions raised by blindly vaccinating nearly all children when we know that some will have mitochondrial dysfunction that puts them at risk for neurological injury.

The following year, Gerberding resigned from the CDC and joined Merck & Co., Inc., the pharmaceutical giant, as head of its vaccine division. Merck manufactures several childhood vaccines, including the MMR, which was among the vaccines that resulted in Hannah Poling’s regression into autism. While the autism advocacy community vigorously discussed and debated the Poling concession and Dr. Gerberding’s new employer, mainstream media once again remained mute.

AMERICAN ACADEMY OF PEDIATRICS PRESIDENT DR. TAYLOE APPEARS ON THE *TODAY SHOW*

Pediatricians are on the front lines of vaccine administration and sales. Their professional association, the American Academy of Pediatrics (AAP), has gone even further than the government in asserting vaccine safety. AAP President Dr. David Tayloe, Jr. appeared on the *Today Show* immediately following the Poling concession announcement and claimed that vaccines don't cause any permanent injuries. When asked if vaccines should be used on every child, he responded,

Yes. I think any of the vaccines we have today have been tested and proven to be safe, and the credible studies don't show any relationship between vaccines and permanent injury. So we favor this and we know that unless we have vaccination rates that are in the 90 to 95 percent range we are not going to prevent epidemics from coming into this country of measles, of polio, from countries where these diseases are still endemic. So it's very important that we vaccinate all our children.³²

Tayloe was incorrect. Not only are vaccines legally classified as unavoidably unsafe, vaccine package inserts list dozens of permanent injuries that occur following vaccination, and HHS itself oversees a table of known, compensable vaccine-induced injuries that include brain damage, paralysis, anaphylactic shock, seizure disorders, and death.³³

Despite the inaccuracy of Tayloe's statement that there is no relationship between vaccines and permanent injury, the AAP never offered a correction. Neither the CDC nor HRSA nor the FDA nor HHS offered clarification to the public. And the media, including *Today Show* interviewer Hoda Kotb, never challenged Tayloe's statements, even though the show invited Tayloe on the air to discuss Hannah Poling, who had received compensation because the government conceded that vaccines caused her autism.

It is important to note that Tayloe's father, physician David Tayloe, Sr., was the defendant in a well-known vaccine injury case.³⁴ The child sustained severe, lifelong brain damage when the elder Tayloe inappropriately administered a DTP vaccine after a previous adverse reaction to that same vaccine. The judgment was the largest jury verdict in North Carolina for a medical malpractice case at that time, amounting to \$3.5 million.³⁵ The reaction from doctors and pharmaceutical companies to this case and similar ones was swift and unequivocal. Led by the elder Tayloe, who was a local AAP official at the time, they demanded tort liability protection from injuries caused by vaccines. In 1986, Congress passed the National Childhood Vaccine Injury Act, which includes provisions to shield doctors and manufacturers from liability and to compensate vaccine injury from taxpayer funds.³⁶

HRSA'S PRESS STATEMENT ON VACCINE-AUTISM CAUSATION

During reporter David Kirby's investigation of the Poling case, he requested clarification of the government's position on whether or not vaccines could cause autism in light of the VICP decision. HRSA's Office of Communications responded,

From: Bowman, David (HRSA) [mailto:DBowman@hrsa.gov]

Sent: Friday, February 20, 2009 5:22 PM

To: 'dkirby@nyc.rr.com'

Subject: HRSA Statement

David,

In response to your most recent inquiry, HRSA has the following statement:

The government has never compensated, nor has it ever been ordered to compensate, any case based on a determination that autism was actually caused by vaccines. We have compensated cases in which children exhibited an encephalopathy, or general brain disease. Encephalopathy may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures.

Some children who have been compensated for vaccine injuries may have shown signs of autism before the decision to compensate, or may ultimately end up with autism or autistic symptoms, but we do not track cases on this basis.

Regards,

David Bowman

Office of Communications

Health Resources and Services Administration

301-443-3376³⁷

Bowman asserts that vaccines don't cause autism, but that they do cause brain damage that can result in autism. However, HRSA doesn't track that. Robert F. Kennedy, Jr., published this e-mail, but the mainstream media again failed to report it to the public.

ASSISTANT SURGEON GENERAL SCHUCHAT'S 2009 APPEARANCE ON *THE DOCTORS*

In the fall of 2009, Dr. Schuchat appeared on the television program, *The Doctors*³⁸ and told the public, “You can’t get seriously ill from a regular flu vaccine.” Schuchat is incorrect. Flu vaccine injury is well documented. The VICP has compensated cases of serious injury from the traditional flu vaccine, as we have described in Lisa Marks Smith’s case. Schuchat goes on to say,

Now the other questions people have—and, I get this all the time—is about mercury. It’s about the thimerosal preservative. I want to say there have been a lot of studies about that. There’s no scientific link between the thimerosal preservative and any kind of long-term problem.³⁹

Again, Schuchat is incorrect. In scientific and medical literature, there is extensive research linking mercury and the mercury-based vaccine preservative thimerosal to serious health problems. A sampling of this research is available in the appendix to this chapter. Again, the media failed to fulfill its duty to the public. The media made no challenge, inquiry, or even follow-up investigation after *The Doctors*.

PUBLIC HEALTH STATEMENTS ON VACCINE SAFETY TODAY

Thimerosal

Public health officials continue to mislead the public on vaccine safety. On its website discussing thimerosal, the CDC states,

There is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site.⁴⁰

Note that CDC no longer claims “no evidence of harm” as it did in 1999 but rather that there is “no *convincing* evidence of harm.”

Vaccines and Autism

The current CDC website offers this response to the question, “Do vaccines cause autism spectrum disorders?”

A: [There are] many studies that have looked at whether there is a relationship between vaccines and autism spectrum disorders (ASDs). To date, the studies continue to show that vaccines are *not* [sic] associated with ASDs.⁴¹

While some studies do not find evidence of an association between vaccines, heavy metal components such as thimerosal, and autism, many in fact do. Notably, one research review published in 2010 found that 74 percent of the studies examining the relationship between heavy metals like thimerosal and autism support the theory that they are associated with autism causation. It states that:

Of these 163 articles, 58 were research articles with empirical data relevant to the question of a link between autism and one or more toxic heavy metals. Fifteen were offered as evidence against a link between exposure to these metals and autism. In contrast, a sum of 43 papers were supporting a link between autism and exposure to those metals.⁴²

There are dozens of studies that support the autism-vaccine causation theory, but the CDC has denied their existence in this statement on their website. Parents attempting to make fully informed decisions about vaccinating their children who Google “Do vaccines cause autism spectrum disorders?” will see this page containing the CDC’s inaccurate claim as the first search result that is returned to them. The trust those parents have that the government is giving them accurate information is misplaced.

In late 2010, reporter Sharyl Attkisson of *CBS News* summed up HHS’s position most succinctly: “In acknowledging Hannah’s injuries, the government said vaccines aggravated an unknown mitochondrial disorder Hannah had which didn’t ‘cause’ her autism, but ‘resulted’ in it.”⁴³

These are just a few examples of incomplete or misleading government statements on vaccine safety. Why does the press allow them to continue? One answer may be because the government has asked the press to do so.

HHS Secretary Sebelius's "Don't Give Equal Weight" Request to the Media

In March 2010, while discussing the H1N1 flu, *Readers Digest* asked HHS Secretary Kathleen Sebelius, "What can be done about public mistrust of vaccines?" Sebelius replied,

There are groups out there that insist that vaccines are responsible for a variety of problems despite all scientific evidence to the contrary. We have reached out to media outlets to try to get them to not give the views of these people equal weight in their reporting to what science has shown and continues to show about the safety of vaccines.⁴⁴

Neither the Obama Administration nor *Readers Digest* clarified this remarkable disclosure, so it remains unclear which press outlets HHS contacted, what HHS asked the press not to report, or who complied with the request. But again, the mainstream media failed to pursue a story on potential vaccine injury, as well as a compelling story about the government's request for censorship.

A Modern-Day Semmelweis Reflex

Just as the government hails vaccines as a cornerstone of public health, the medical community upholds vaccination as a miracle of modern medicine. If it seems almost impossible that public denial of vaccine injury could exist on such a huge scale, it should be recognized that there is an established precedent for such a phenomenon.

In the mid-1800s in Vienna, Austria, mothers were dying shortly after childbirth from a now-extinct illness known as puerperal fever, or “childbed fever.” A woman entering the hospital to give birth had roughly a 16 percent chance that she would die before taking her baby home. The mortality rate of mothers giving birth in the midwife centers, however, was lower.

In 1847, Dr. Ignaz Semmelweis, professor of obstetrics at the University of Pest, performed an autopsy on a colleague who had died from the fever and then fell ill with it himself. He postulated that small particles of the disease may have been left on his hands, and surmised that the maternal death rate from childbed fever was so high because doctors and medical students at the teaching hospital were not properly washing their hands after exams and autopsies of fever patients, before delivering newborns.

He instituted new sterilization guidelines and the death rate in the obstetrics and gynecology ward fell to 1.27 percent.⁴⁵

When Semmelweis’s colleague published this information, rather than finding it cause for celebration, the medical community lashed out against Semmelweis. He was mocked, attacked, and run out of the profession. He subsequently suffered a nervous breakdown. Semmelweis was invited by a colleague to visit an asylum for the mentally ill under the pretense of offering his professional opinion, but was instead locked inside, where he died two weeks later. Conflicting stories report that he died after being physically assaulted by the staff, or alternatively, that he died from puerperal fever. Two decades would pass after Semmelweis’s discovery before the work of Louis Pasteur and Joseph Lister helped to usher in the modern era of sanitation and hygiene, including medical sterilization.

In serving the public, Semmelweis delivered the unwelcome news to doctors that they were largely responsible for the deaths of new mothers. It was bad news that they were not prepared to hear. This phenomenon has come to be known as the Semmelweis reflex—the reflexlike rejection, often in the medical community, of new scientific information without proper investigation.⁴⁶

Today’s vaccine injury denialism is a modern-day Semmelweis reflex. Pediatricians who care passionately about the welfare of children understandably find repulsive the idea that autism is largely iatrogenic. Statements offered by government agencies (i.e., HHS and the CDC) and medical professionals (i.e., the AAP) offer plausible deniability to those who do not want to know or admit that the vaccines they are administering are capable of causing serious damage to a population, let alone to the individual children in their own practices.

The Government and Media's Lack of Accountability

It is the responsibility of the government to pursue public health and to base its decisions on sound science.⁴⁷ It is the responsibility of the media to challenge governmental assertions and investigate their claims. The media's unwillingness to follow the story on vaccines and autism and to ask hard-hitting questions has resulted in a larger failure: an absence of accountability.

The public's trust in the government and the press continue to erode as stories of corruption, bad faith, and abuse of authority continue to surface. Despite government and media attempts to manage the vaccine safety narrative, parents, the main stakeholders of this debate, are catching on. In its October 2010 survey,⁴⁸ the University of Michigan revealed that vaccine safety is the top research priority for 89 percent of parents. As always, the American people are their own last line of defense. Today, the American people must bring reason, responsibility, and prudence to the national childhood vaccine program.

Chapter Nineteen

MERCURY TOXICITY AND VACCINE INJURY

Boyd Haley, PhD

I firmly believe that the Centers for Disease Control and Prevention's (CDC) vaccination program, recommended at the federal level but strongly influencing state mandates, has led to the dramatic rise in autism starting in or around 1988. That is a strong statement; however, it is supported by sound science, including the well-described toxicity of thimerosal- and aluminum-containing vaccines.

There is no doubt that thimerosal is toxic. For example, in 1977, a report¹ was published regarding the deaths of ten of thirteen infants treated for infected umbilical cords. These infants died from mercury toxicity due to the application of a thimerosal-containing antiseptic² externally to their skin. Thimerosal releases ethylmercury, which is insoluble in water and penetrates the skin and all organs of the body with great ease. Due to their lack of mature liver and kidney functions, infants could not effectively excrete this mercury, so it built up to toxic and ultimately lethal levels.

It is this same thimerosal that the CDC regards as safe to inject into children on the day of birth, at levels the Environmental Protection Agency (EPA) asserts are safe to be exposed to in your diet—if you are an adult weighing 275 pounds. Infants are not adults; they are dramatically weaker in their ability to fight off toxic environmental effects, and they are, of course, much smaller. Moreover, the EPA calculation for an exposure limit (from eating seafood) does not incorporate other factors that are known to synergistically increase the toxicity of thimerosal. Many of these cofactors are found in thimerosal-containing vaccines, with aluminum being the one of most concern. Not only is aluminum a neurotoxin on its own, but aluminum dramatically increases the neurotoxicity of thimerosal many times over.³ Given this knowledge, I find it incredible anyone could claim that a vaccine containing these two ingredients is safe.

How certain is it that vaccine-delivered thimerosal is a culprit in the current autism epidemic? After spending millions of dollars looking for “autism genes,” we can certainly say that no significant finding has occurred. Autism does not appear to be a solely genetic disorder. However, studies do indicate that certain individuals may have a genetic susceptibility to a particular environmental toxin.

How can we be sure that thimerosal is such a toxin? One way is by process of elimination. The toxin that caused the autism epidemic had to increase in all fifty states around 1988 to 1990. This

excludes many factory-produced toxins. Children had to be exposed to the toxin before they were two years old. This excludes many other toxins used for discretionary reasons. The toxin has to have a gender bias, in that it is more likely to affect boys than girls. Only mercury-containing compounds can explain such a profound difference; they have a stronger negative effect on human males than on females, in the form of neurological impairment and lethality.⁴ This makes thimerosal, delivered via the universal childhood vaccination program, a very likely suspect. In fact, it is the only item that I know of that fits these requirements and observations.

The toxin causing autism has a corresponding symptom: It also effectively and rapidly induces oxidative stress.⁵ Nothing is more effective than mercury at inducing oxidative stress, which is identified by exceptionally high mitochondrial dysfunction. Over 85 percent of autistic children who have been tested have been diagnosed with such a dysfunction.⁶ Biochemically, the exceptionally tight binding of mercury to the electron transporting system of mitochondria has been proven to cause high production of toxic chemical intermediates, leading to oxidative stress and to many of the biochemical abnormalities found most often in children with autism.⁷

Unlike the genetic studies performed by many scientists, biochemical studies have identified numerous biological abnormalities that are found in people with autism more often than in age-matched controls, and these studies have repeatedly shown that some of the same biochemical abnormalities can be induced under experimental conditions in test animals by the application of thimerosal.⁸ We have the list of biochemical abnormalities associated with autism and we have the published scientific observations that mercury can cause these same abnormalities. Yet we also have the CDC and the American Academy of Pediatrics (AAP) denying the existence of any studies showing the role of thimerosal in autism spectrum disorder.

In addition to oxidative stress, thimerosal and mercury will 1) suppress the immune system;⁹ 2) decrease methyl-B12 production and, among other things, the proper chemical modification of DNA and RNA;¹⁰ 3) cause membrane-tight junctions to become leaky, leading to intestinal dysbiosis;¹¹ 4) decrease molybdenum levels, which leads to 5) higher sulfite and lower sulfate levels,¹² which further leads to 6) abnormal myelination of the nervous system and corresponding neurological damage.¹³

I could continue listing many problems that are found in children with autism that are also known to be found in infants exposed to mercury. I know of nothing else that could do this so effectively and be so readily identified as a known exposure. I, and other involved researchers, would gladly debate these issues in public with CDC and other experts—if they had the courage to show up. They don't.

They would rather set up a kangaroo court system where mothers of children with autism are drawn into debate with self-identified experts, and where the input of knowledgeable researchers is excluded. And they would rather participate in biased media pieces where the input of anyone who offers dissenting opinions of the vaccine establishment orthodoxy ends up on the cutting-room floor, as recently happened in the PBS "Vaccine War" presentation on *Frontline*.¹⁴ This represents documentary manipulation at its worst, and is very common in our national media today. It is symptomatic of the media's pandering to the pharmaceutical and medical industries for advertising dollars.

Finally, of all countries, the United States has by far the earliest and highest level of vaccinations given to infants. Yet stunningly, we have nearly the worst record for infant

mortality¹⁵ and autism incidence when compared to other developed countries of the world. How can this be? Recent research from academic medical groups in North America has shown that the hepatitis B vaccine given in the United States on the day of birth leads to increased rates of developmental disability.¹⁶ It is fair to demand that our medical authorities and Congress tell us why our infants are dying at a shocking rate, relative to our peer nations. This nationally demonstrated crisis, using the government's own data on infant mortality, defies any claim of vaccine safety by the CDC. To the contrary, this exceptionally high death rate supports the concept that the CDC vaccination program is causing severe damage to our infants who live.

I am greatly in favor of a safe vaccination policy, but today's vaccination policy is not proven safe and appears to me to do more damage than good. Vaccination policy and safety in this country are biased. Those with decision-making authority are deeply attached—either directly or indirectly—to the pharmaceutical industry that produces the vaccines. These decisionmakers need to stay in the good graces of the vaccine manufacturers and thus rarely question what the industry proposes. It is obvious to me that we need a fundamental change in who determines vaccine safety if we are ever to accomplish a safe and effective national vaccine program. Until then, there can be no doubt that parents must be able to make their own free and informed vaccination choices for their children.

Chapter Twenty

FORCED CHILD REMOVAL

Kim Mack Rosenberg, JD

You have a religious exemption from vaccination for your child at school. You get a call from Child Protective Services. The caseworker says she wants to meet with you to discuss whether your child is the subject of “medical neglect.” Do you know your rights?

Few would dispute that Child Protective Services (CPS) serves a critical function in our society by protecting vulnerable children who have been harmed or are in harm’s way in their homes. New York State, for example, created a network of child protective service agencies to investigate cases of suspected abuse and to provide swift and competent protection and rehabilitative services to the child and family.¹

Despite good intentions, state agencies such as CPS, have long histories of abusing power² and failing to provide due process, to the detriment of children and their families.³ In the absence of actual or imminent harm, CPS’s role should not be to “protect” children from parents who make alternative healthcare choices.⁴ In these circumstances, the state should not use CPS to usurp parental authority and to instead assert its view of the child’s best interest.

What happens if CPS scrutinizes a parent’s medical choice not to follow vaccination mandates? There are two basic questions:

1. Is the parent at risk for investigation of “medical neglect”?
2. Regardless of the reason for the child’s removal, may the state vaccinate a child against the parent’s wishes?

There are no simple answers to these questions. Child protection laws and their enforcement vary widely among jurisdictions. Parents should be aware, however, that the answer to each of these questions may be “yes.” Through the misuse of CPS procedures, a state maybe able to forcibly impose vaccinations.

This issue is of critical concern to parents who do not vaccinate according to government-recommended schedules. Recent surveys also have found that a majority of parents have serious concerns about vaccine safety. Parents are concerned that vaccinations may result in or contribute to autism, ADHD, sudden infant death syndrome, and other health problems. When

families have a child with autism, for example, parents may provide their children with alternative medical and nutrition-based treatments. CPS has taken action against parents for medical neglect and has removed children because parents chose to make alternative healthcare choices for children on the autism spectrum. Many parents, including many parents of children with autism, make the decision not to vaccinate their children based on sincerely held religious beliefs. All but two states recognize religious exemptions from vaccination requirements but this may not, in every instance, protect a child from vaccination at the behest of CPS.

CPS and some courts have considered parents' choices for autism spectrum disorder treatments not "medically necessary." Many autism treatments—diets, auditory training, vitamin and mineral therapy, hyperbaric oxygen therapy, and chelation, to name a few—are hotly disputed.⁵ Parents seeking to make decisions in the best interests of their children with autism are pawns in a broader dispute—involving parents, government, the pharmaceutical industry, and concerned scientists and medical professionals—about the safety of vaccines and the etiology of autism.

MEDICAL NEGLECT

CPS is required to promptly investigate allegations of medical neglect. But what is “medical neglect”? While laws vary, neglect is generally an absence of appropriate care. *The Merck Manual* defines neglect as

the failure to provide for or meet a child’s basic physical, emotional, educational, and medical needs. Neglect differs from abuse in that it usually occurs without intent to harm.... Medical neglect is failure to ensure that a child receives appropriate preventive care (e.g., vaccinations, routine dental examinations) or needed treatment for injuries or physical or mental disorders.⁶

Similarly, under New York law, for example, a neglected child is one

whose physical, mental or emotional condition has been impaired or is in imminent danger of becoming impaired as a result of the failure of his parent . . . to exercise a minimum degree of care . . . in supplying the child with . . . medical, dental, optometrical or surgical care, though financially able to do so or offered financial or other reasonable means to do so.⁷

The above passages demonstrate that the definition of medical neglect is vague. If a parent does not vaccinate a child in accordance with state mandates, is the parent neglectful? There is not a clear-cut answer, in part because many sources fail to differentiate between parents with legitimate exemptions from vaccination requirements and parents who may have no objection but simply fail to vaccinate their children. Various documents from New York State, New York City, and other sources interpret the statutory definition of neglect to include the failure to vaccinate. For example, the New York City Children’s Services “Parent’s Guide to New York State Child Abuse and Neglect Laws” states:

A parent or caregiver is required to supply adequate medical, dental, optical and surgical care for a child under 18 years old. This medical care includes seeking adequate treatment for conditions that impair, or threaten to impair, the child’s mental, emotional or physical condition. You should follow the treatment prescribed for medical, psychiatric, and psychological care. *You should also obtain preventive care such as well-baby care checkups, and immunizations for polio, mumps, and measles.*⁸ (emphasis added)

Similarly, New York University Child Study Center defined medical neglect as “a failure to provide or comply with prescribed medical treatment for a child (e.g., such as immunization, surgery, medications).”⁹ A Pennsylvania presentation entitled “Keeping Your Children & Getting Them Back,” designed to provide parents with information concerning child abuse and neglect laws in that state, gave “not taking a child for medical checkups or shots” as a

straightforward example of medical neglect.¹⁰

While anyone may report suspected abuse or neglect to CPS, doctors, as a general rule, must report cases of medical neglect to CPS for investigation.¹¹ However, as noted above, what constitutes medical neglect is subject to interpretation. Doctors are the frontline in encouraging compliance with mandated vaccination schedules and, therefore, may view with suspicion parents who do not vaccinate in compliance with such schedules. For this reason, and because they are among the few people who have access to children's medical records, doctors may be the reporters to CPS in most vaccination-related medical neglect cases.

Simply put, a child's physician who believes that the parent's decision not to vaccinate is neglectful may report the parent to CPS. The American Academy of Pediatrics (AAP) has spoken to the issue of vaccinations and medical neglect and its opinions—while perhaps not appearing unreasonable on their face—are worrisome. The AAP in 2005 stated that:

[c]ontinued refusal [to vaccinate] after adequate discussion should be respected unless the child is put at significant risk of serious harm (as, for example, might be the case during an epidemic). Only then should state agencies be involved to override parental discretion on the basis of medical neglect. Physician concerns about liability should be addressed by good documentation of the discussion of the benefits of immunization and the risks associated with remaining unimmunized. Physicians also may wish to consider having the parents sign a refusal waiver.¹²

Several years earlier, in 1997, the AAP's Committee on Bioethics published an article concerning religious exemptions to medical care. In that paper, the AAP called for the repeal of all religious exemption laws, proposing instead that parents should be better educated about their children's medical needs.¹³ While the statement concerned exemptions from all forms of medical care, the committee took particular note of vaccines, stating that "some parents, acting in accord with state laws, refuse to have their children immunized because of religious beliefs. The AAP does not support the stringent application of medical neglect laws when children do not receive recommended immunizations."¹⁴ Recognizing that "the risk to unimmunized individuals is relatively low" and encouraging "universal immunization," the AAP stated that it "supports the use of appropriate public health measures, such as mandatory mass vaccinations in epidemic situations, when necessary to protect communities and their unimmunized members."¹⁵ In the 1997 statement, the AAP cautioned physicians that "threatening or seeking state intervention should be the last resort, undertaken only when treatment is likely to prevent substantial harm or death."¹⁶

These AAP statements raise several concerns. First, the undercurrent of both statements is paternalistic. Underpinning the AAP's position is the suggestion that not vaccinating a child is an illegitimate, scientifically or medically unsound choice,¹⁷ despite laws that grant that right. The 2005 statement demonstrates this when it refers to failure to vaccinate as a "problem."¹⁸ Further, the waiver that the AAP suggests doctors present to a non-vaccinating parent for signature contains language that arguably could later be used against the parent as a potential admission of neglect.¹⁹ First, it indicates that the parent has been advised of the risks and benefits of vaccination and is written in such a way as to imply that the parent agrees with what he or she has been told.²⁰ The form then states, "I know that failure to follow the recommendations about

vaccination may endanger the health or life of my child and others with which my child might come into contact.”²¹ While suggesting that “doctor knows best,” the AAP’s statements offer scant guidance about what constitutes an emergency that doctors should report. How does a doctor decide which emergency, which risk, which harm? With insufficient AAP guidance, there inevitably will be a lack of uniformity in application of this policy. Even the 2005 example of the epidemic is not clear-cut. One needs only to reflect on the 2009 H1N1 influenza outbreak to learn an object lesson on the subjectivity of identifying an epidemic. Finally, anecdotal evidence suggests that not all doctors are following the AAP’s policy; some are reporting families who choose not to vaccinate to CPS in the absence of an emergency or threat to the child’s health, such as a disease outbreak.

It is likely that only a small percentage of CPS referrals for medical neglect are based solely on noncompliance with vaccination mandates.²² Nonetheless, for any family who has to face investigation by CPS, the social, emotional, and financial toll is incalculable, even if ultimately vindicated. In one case, the court found that a parent who “impressed the court as a diligent, loving and concerned parent” was neglectful for failing to immunize his daughter against measles during a measles outbreak.²³ It found that his objections to the measles vaccine, while sincere, were based on medical and scientific information, not religion. Because there was no other evidence of any “neglect,” the court did not force vaccination of the child, at least in part, because the child was not yet attending school. The court might have decided differently if the child had been school-age and had determined that the parent’s objections were not religious. This case also shows how time-consuming the judicial process can be—it took the court almost two years to decide the case after the initial petition was filed.²⁴

As the number of parents exercising their rights to make vaccination exemptions grows, so does the opposition to that exercise. This is a contentious area and one that the Center for Personal Rights is closely monitoring.

FORCED VACCINATION

A child in foster care may be subject to vaccination unless his or her parent has made formal objections to vaccination, and even then, the parent's exercise of his or her rights is not guaranteed. Parents cannot rely on CPS to affirmatively enquire as to parental beliefs with respect to what are widely regarded as "routine" medical care practices and must take care to not waive their rights if they have valid exemptions against vaccination.

Vaccination according to federal recommendations and state mandates is a cornerstone of foster care, under both state and federal laws. Most children in foster care are eligible for federally-funded Medicaid.²⁵ In New York, for example, the Medicaid Early Periodic Screening Diagnosis and Treatment (EPSDT) requirements include "immunizations in accordance with the most current New York State or New York City Recommended Immunization Schedule, as appropriate."²⁶ Thus when a child enters the New York State foster care system, CPS attempts to obtain current immunization history.

The initial EPSDT medical assessment includes "preventive services, such as immunizations . . . appropriate for the child's age."²⁷ Following the initial assessment, pediatric visits include "immunizations consistent with current NYS/NYC DOH recommendations for age."²⁸ In fact, the EPSDT provider manual unequivocally states that "persons under 19 years of age must be immunized in accordance with the most current" state vaccination schedule. The manual also recommends "simultaneous administration of all routinely recommended vaccines appropriate to the age and previous vaccination status."²⁹ Of gravest concern to parents who elect not to follow vaccination mandates is the manual's encouragement to "catch up" on missed vaccinations. The manual states that "most of the widely used vaccines can generally be safely and effectively administered simultaneously. This is particularly important in scheduling children with missed immunizations."³⁰

Given the emphasis on vaccination in foster care, parents should document any objections to vaccination. They should consider providing CPS with a copy of any vaccination exemption they previously obtained and making sure that any medical authorization³¹ that they execute does not include consent for vaccination. If the child previously received vaccines, parents should consider providing CPS with a copy of the child's immunization history to avoid unnecessary revaccination. Depending on individual circumstances, a parent may also be able to participate in doctor visits while a child is in foster care.

Challenges to a parent's right to object to a child's vaccination on religious grounds when a child is in foster care vary by state. In New York, for example, courts have upheld exemptions for parents whose children are in foster care, but only if the parents meet all the usual requirements for vaccination exemptions. In New York, this means demonstrating a sincere and genuine religious objection to the court's satisfaction.³² In many states, religious exemptions are not as automatic as they may seem and, if CPS seeks court intervention to vaccinate a child, a parent may even be required to "prove up" his or her exemption, even if previously accepted.³³

In a decision upholding a parent's exemption, a mother with two children in foster care successfully defeated a CPS petition to compel vaccination.³⁴ Several years before, the mother had obtained a religious exemption for the elder child for day care, and neither child was vaccinated.³⁵ The agency's foster care paperwork noted the mother's opposition to vaccination

on religious grounds.³⁶ The court held a hearing to assess whether the mother's religious beliefs were genuine and sincere and found that they were. The agency's application to vaccinate was denied.³⁷

While the mother prevailed in this case, the facts of the case exposed a glaring hole in the system. The foster parent, acting on her own authority, had one of the children vaccinated "to protect her own family."³⁸ CPS then petitioned for the right to vaccinate the other child after the parent threatened to sue.³⁹ Even though the agency was aware of the mother's objections, a rogue action by the foster parent resulted in a child receiving a vaccination against the mother's religious beliefs. The foster parent's action violated the role of foster parents in New York. Foster parents "do not have legal authority to request or authorize immunizations."⁴⁰

In another New York case, the court decided against a parent exercising a religious exemption. A court recently determined that a mother whose child was found to be neglected based on, among other things, failure to maintain a sanitary home and failure to provide medical care, did not support her religious objection to vaccinations by a preponderance of the evidence.⁴¹ As a result, the court granted the Administration for Children's Services's motion to allow the child to be immunized in accordance with New York's vaccination mandates.⁴²

In a recent Arizona decision, a court found that a mother whose child had been placed in foster care still was entitled to exercise her religious objection to vaccination.⁴³ The court was careful to note that such cases needed to be determined on their individual facts and stated "we would not hesitate to find a compelling state interest had the Department shown that [the child] was especially vulnerable to diseases prevented by immunization, due perhaps to malnutrition or some other medical condition."⁴⁴ Finding that the child's risks were no greater than the risk to other children, the court upheld the mother's right to continue to exercise her religious objection while her child was out of her custody.⁴⁵ This case demonstrates that parents must be prepared not only to support their religious objections to vaccination but also perhaps to address medical or scientific concerns the court may have.

In other cases, courts have held that when parents lose custody of their children, either temporarily or permanently, they lose the right for their religious beliefs to control medical decision making. In a 2002 North Carolina case, parents who were adjudged neglectful and whose children were placed in foster care were denied the right to exercise their religious objection to vaccination.⁴⁶ The court did not examine the sincerity or bona fide nature of the parents' beliefs, instead finding that they had lost their rights to exercise a religious exemption—though their parental rights were not terminated.⁴⁷ The court found that only the department of social services could make immunization and other healthcare decisions for the children.⁴⁸ In 2002, a Georgia court decided to permanently remove a child because it found the child to be "deprived." As part of that decision, the mother lost the right to make medical decisions.⁴⁹ The court granted custody, which included the right to make medical decisions for the child, to the child's grandmother.⁵⁰

THE POTENTIALLY LIFE-ALTERING RESULTS OF FORCED VACCINATION

While this chapter has focused on parents' rights, children's rights are inextricably linked to their parents' rights. Forced vaccination of children, in violation of parents' rights, risks real physical harm to children. The results of forced vaccination while in foster care may be devastating.

Dan Olmsted, editor, *Age of Autism*, an online newspaper, wrote a story in 2008 about a young girl vaccinated while in foster care against her parents' religious convictions.⁵¹ CPS removed an Amish child from her family when she was one year old because CPS thought the family displayed "medical neglect" and failed to treat her chronic ear infection properly. In foster care, she was vaccinated, apparently with multiple vaccines in two sessions, presumably to "catch her up" to the mandated schedule. The child now has autism and is in her parents' care. In the Old Order Amish community, parents do not vaccinate their children and autism is almost unknown.

CPS may protect children from child abuse and neglect, but it also poses a potential risk to families when parents choose not to follow vaccination mandates. Even in those jurisdictions where, by law, CPS and foster parents must respect parent choices about vaccination, they do not always do so. When parents are faced with the reality of childremoval proceedings, they must carefully document and communicate vaccination exemptions to CPS and know their rights.

The author wishes to acknowledge Malika Felix, graduating law student and CPR intern, for her research assistance. This chapter is an introductory overview and is not legal advice. State law, especially on religious treatment exemptions, varies widely. Parents should consult a lawyer to discuss individual circumstances; the cases used here are examples only.

Chapter Twenty-One

GENETIC INFORMATION: WHERE DO WE GO FROM HERE?

Twila Brase, RN

When it comes to personal rights and parental protection of children, what could be more personal than the right of parents to protect the ownership and integrity of their children's DNA from the moment they are born? Parents must consider the potential for twenty-first-century medicine to compel genetic manipulation. This could happen as a result of compulsory state government newborn genetic testing programs. Today, state governments conduct genetic tests on infants, collecting and retaining DNA from every newborn, building state genetic registries, and using newborn genetic material to conduct genetic research without parental consent.¹

Laboratory technicians and genetic researchers are able to analyze newborns' DNA for biological, genetic, and medical weaknesses. For purposes of reducing costs in healthcare, will genetic therapy and genetic manipulation based on their findings be required in the twenty-first century? Will children be required to receive gene-based vaccinations to prevent the emergence of future medical conditions identified by the screening? For instance, if a government screening identifies a gene at birth that is connected, however loosely, to childhood cancer, could certain "cancer vaccinations" emerge and be compelled? This is not as farfetched as it may sound.

Every year in the United States, state public health laboratories genetically screen four million babies at birth through state newborn screening programs. The *American Journal of Public Health* calls newborn screening "the first and largest example of systematic, population-wide genetic testing" in the nation.² At the hospital, a nurse pricks the newborn's heel within twenty-four to seventy-two hours after birth and places blood samples on the filter paper of a government-issued blood spot card. The hospital does not perform the actual test. It sends the card directly to the state health department's public health laboratory for newborn screening, or as we at the Citizens' Council for Health Freedom prefer to call it, newborn genetic testing.

NO PARENTAL CONSENT REQUIRED

Newborn screening is often exempt from the written informed consent requirements of state genetic privacy laws. Most parents are completely unaware of the collection, storage, and use of their child's genetic material. If they know about the heel prick, they probably think the hospital is simply doing a standard test to make sure the baby is healthy. Many hospital staff members, including OB-GYN nurses, do not know that this procedure is for genetic testing by the state. In most states, even if parents know the far-reaching implications of this testing, they have no choice but to comply. All fifty states require genetic screening at birth, though the number of conditions for which children are screened varies from state to state. Thirty-three states allow only religious objection and thirteen additional states allow parental objection for any reason.³ However, in Nebraska, the health department will take parents to court if they refuse testing.⁴

After each newborn's blood sample is collected, the state's public health laboratory conducts genetic testing, stores the genetic test results in a government database, and keeps the excess blood—the baby's DNA—on file for future genetic research. In most states, the warehoused DNA and genetic test results are state government property. According to the Association of Public Health Laboratories, newborn screening “programs in 33 states and the District of Columbia—accounting for 46% of the annual newborn population—keep the residual blood spots anywhere from one month to three years. Seven states retain them for eighteen to twenty-seven years, and ten keep them indefinitely.”⁵

Governments often make babies' DNA available for genetic research both within and outside the state health department. In most states, parental consent is not required to use a baby's DNA for research. While only Maryland requires parental consent for screening,⁶ Oklahoma requires consent for the storage and use of newborns' DNA for research. South Carolina, Minnesota, and Texas have an opt-out (dissent) process, although the state of Minnesota does not require parents to be given a timely explanation of the storage or dissent option. In California, the Supreme Court ruled in 1990 that individuals have no property rights in body parts that are given up for testing or otherwise medically removed.⁷ California keeps babies' DNA indefinitely.

As Dr. Beth Tarini, MD, notes in her 2009 paper, “Not Without My Permission,” parents who discover the secret storage and use of babies' DNA are not happy about it. Parents are shocked when they learn of these practices and many believe that they should be illegal.

PARENTS FILE LAWSUITS

Parents in Texas and Minnesota have filed lawsuits against state health officials after discovering the retention and use of their newborns' DNA.⁸ Under the Fourth Amendment's protection against unlawful search and seizure, a judge required the Texas Department of Health to destroy the blood spots of more than five million children, which had been retained since 2002. As an internal department's documents later revealed, Texas not only retained babies' DNA, but also gave it to the U.S. military to create a law-enforcement DNA database, sold it for \$4 per spot to various corporations, and used it to barter with for-profit companies for laboratory equipment.⁹ These activities were not discovered during the litigation because the case was quickly decided and never made it to the discovery phase.¹⁰ The Texas news media later obtained the internal documents through the state's sunshine laws.

The Minnesota lawsuit continues: Following the first hearing in October 2009 at the county courthouse, the case was dismissed at the request of the Minnesota Department of Health. The state's attorney claimed that the Minnesota genetic privacy law, requiring written informed consent for the collection, storage, use, and dissemination of genetic information, does not supersede the newborn screening law, which does not require consent. The attorney for the families appealed the decision in January 2010.

In June 2010, a Minnesota appellate court agreed with the county court and upheld the dismissal. While the court recognized that the newborn screening law does not expressly authorize the storage and use or dissemination of newborns' blood, the court nonetheless ruled that the Minnesota health commissioner's broad, general authority under state law to conduct research permits genetic research using the blood spots. However, in a strike against the state health department, the court said the newborns' biological material—the blood spots—are genetic information as defined under the state's genetic privacy law and may not be used for any research not related to screening. The health department claims the blood spots are not genetic information and therefore not protected by the informed consent requirements of the genetic privacy law. The judge disagreed. This limitation is not reassuring, however, because the judge allowed the term "newborn screening research" to be broadly construed. The lawsuit was appealed to the Minnesota Supreme Court on September 23, 2010.

GENETIC VACCINATIONS?

Francis Collins, head of the National Institutes of Health, has said, “Like it or not, every newborn will soon be genetically sequenced at birth by the government.”¹¹ Assuming this happens, and unless new laws are put into place that allow parents to retain control of their child’s genetic material, state health officials will own each child’s unique genetic code, allowing them to assess the strengths and weaknesses of every child and eventually every adult.

The twenty-first century is an era of healthcare cost containment. To limit healthcare spending, are we looking at a future where parents—whose genetic code was either screened or discerned from their child’s screening—or their children will be required to submit to genetic engineering to avoid the birth of a less-than-perfect child? This would be the ultimate in government “vaccination” against disease and disability. Let us not mince words: This would be a twenty-first-century form of eugenics.

We must remember that with limited exceptions, particularly related to criminals, genetic testing—even by the government—cannot be imposed on adults without informed consent. Genetic testing of newborns takes away the child’s right to someday make an informed choice about genetic testing.

PRIVACY AND LIBERTY

There are broader privacy issues as well. Individuals may not want the impending Nationwide Health Information Network (NHIN) to catalog their genetic information. The NHIN is an online, permanent, linked, lifelong medical record now under government construction. The information on the NHIN will be available to the government and others—more than 2.2 million entities¹²—without the individual’s consent, as permitted by the so-called federal HIPAA “privacy” rule.

To eliminate these threats to liberty and privacy, fully informed written parental consent must be required before the government is allowed to take, store, use, or disseminate newborns’ DNA and genetic test results. The government must make clear all the benefits—and all the risks—of retention and research. State governments must also grant parents the right to limit newborn genetic screening to the tests of their choice, keeping in mind that these children, upon reaching adulthood, may not be pleased to have had their genes tested at birth and the results recorded.

Under the doctrine of *parens patriae*, health officials increasingly claim authority to override the will of parents in both newborn genetic screening and vaccination to impose these intrusive medical procedures on children with or without parental consent. *Parens patriae* is said to grant the state power and authority to protect persons who are legally unable to act on their own behalves. Except in cases of child abuse, however, such protection and choices rightfully belong to the actual parents of the child, not to the government.

Furthermore, individuals, including the children, have a right *not* to know, as well as a right to decide *when* to know, what their genes may say about their futures. Genetics are not always destiny;¹³ they can represent a vulnerability that may or may not be expressed. However, once the genetic test is performed, the findings, accurate or not, destiny or not, are recorded. Certain genetic assessments and assumptions about the child’s future could negatively affect the child’s employment, insurance, marriage, and reproductive choices.

Finally, newborn screening and genetic research using newborns’ DNA may eventually lead to a twenty-first-century vaccination program against detected genetic traits, biomarkers, and mutations. Parents must consider the options for protecting their children. Vaccination choice and parental informed consent are fundamental human rights.

The Citizens’ Council on Healthcare has a ten-point overview of the issues related to the retention of babies’ DNA, research, and newborn genetic screening, including contact information for facilities that conduct private newborn screening. It is available at www.itsmydna.org.

Chapter Twenty-Two

A DOCTOR'S VIEW OF VACCINES AND THE PUBLIC HEALTH

Sherri Tenpenny, DO, AOBNMM

According to the *Encyclopedia Britannica*, public health is “the science and art of preventing disease, prolonging life, and promoting health through organized community efforts.” Its mission, as led in the United States by the Centers for Disease Control and Prevention (CDC) includes developing sound public health policy for the population at large. There can be little argument that public health has played a significant and valuable role in sanitation, injury prevention, environmental toxicology, food safety, and clean water. However, in recent years, one of public health’s primary tools for disease prevention—vaccination—has come under attack. Its importance has been seriously brought into question.

Said to be the cornerstone of disease prevention, vaccination has become one of the most expansive areas of public health. All levels of government—local, state, national, and global—spend billions of dollars each year on the manufacture, procurement, distribution, and administration of vaccines. In 1983, the vaccination schedule from birth to eighteen years of age included twenty-four doses of seven different vaccines: polio, MMR (measles, mumps, and rubella), and DTP (diphtheria, tetanus, and pertussis). The federal government now recommends that children receive seventy doses of sixteen different vaccines by the time they graduate from high school. Parents have begun to question the necessity of so many vaccines. An ethical tug-of-war has arisen between the people’s right to choose what is injected into their bodies (and the bodies of their children) and the presumed benefits of vaccines to society as promoted by health officials.

Discussions about the right to refuse vaccination can become contentious, even hostile. Those who firmly believe that vaccines are safe, protective, and mostly harmless stand a chasm apart from those who have had a different experience with vaccination, involving serious injury, chronic illness, and even death. The debate has intensified, and so have the stakes. As more parents investigate and weigh the risks and benefits of vaccines, many have chosen to opt out. These parents have decided to take personal responsibility for the health of their children, refusing to accept that health must come through a needle. Every vaccination has potential side effects and many parents feel that the risk of the vaccine is unacceptably larger than the risk of the illness.

Moreover, scientists cannot prove the efficacy of a particular vaccine in a particular individual because it is impossible to predict the susceptibility of an individual to a specific pathogen. Parents know of children who have remained well without being vaccinated and of persons who have contracted an illness even though they received their respective shots. Public health officials and parents who advocate vaccination downplay reports of outbreaks among the vaccinated, fearing the value of the vaccination paradigm would be called into question.

With more individuals refusing vaccines, alarmed health officials are concerned that the unvaccinated will cause a loss of “herd immunity”—a vaccination level assumed to provide community-wide protection. They point to outbreaks of chickenpox, mumps, and pertussis over the last few years as proof of waning herd immunity. Officials have lodged blame for these occurrences squarely on unvaccinated children, even though most of the children who contracted the illnesses were *fully vaccinated*.

Vaccine makers and medical professionals claim vaccines were responsible for eradicating a large number of diseases, but official statistics clearly document vaccine-preventable illnesses were on their way out or, in many cases, nearly eliminated prior to the widespread use of the vaccines designed to prevent them. However, scientific facts rarely seem to change the perspectives of either side. Reasons for vaccination choice often reside in personal convictions. Many individuals insist that the separation between their person and the state begins at their skin. They have strong convictions that mandatory injections are an infringement of personal rights. The question, then, is whether society has a right—or perhaps a duty—to override personal choice for the good of the whole country. This argument has sparked debates for more than a century.

A fact that cannot be debated, however, is that we have a national epidemic of sick children. Today, parents schedule occupational therapy, physical therapy, and speech therapy into their weekly routines, as though these activities were as ordinary as soccer practice and piano lessons. Pediatricians have started to say, “two years of age is when kids get asthma,” or “children get autism before age three,” as though these were typical growth milestones.

Is there a common factor contributing to the epidemic of illness among children today? It’s not genetics: Different families have different genes. It’s not exercise: Some kids are athletes, others are couch potatoes. It’s not environmental exposures: Some sick kids live in unhygienic public housing projects, some live in pristine gated communities. It’s not food: Some eat only organic, some eat mostly fast food. What touches almost all children today and likely contributes to the plethora of chronic illnesses are seventy doses of sixteen vaccines—which include measurable amounts of chemicals, excipients, detergents, adjuvants, and heavy metals—by eighteen years of age. Science has not proven these ingredients to be harmless as administered. Why do we accept that vaccination cannot be a contributor to illness and poor health?

We have come to accept asthma, allergies, eczema, chronic ear infections, and learning difficulties as “normal” childhood conditions. In our zeal to eradicate a few infectious diseases, we have traded typically mild illnesses of childhood, such as chickenpox, mumps, and measles, for a lifetime of poor health and drugs. We have exchanged temporary illnesses for pervasive, lifelong diseases, disorders, dysfunctions, and disabilities. A chronic illness held in check by medication is not health. Society must gauge the well-being of children by more than high vaccination rates and low infection rates caused by a specific short list of pathogens.

ECONOMICS OF PUBLIC HEALTH: A SNAPSHOT

Since the 1970s, health economists have justified vaccination through cost-benefit analysis, a technique for quantifying and measuring the value of an intervention by weighing the likely costs of an illness against the positive benefit of the procedure. According to public health officials, vaccination has one of the best cost-benefit profiles for reducing medical care expenditures.¹ However, these calculations are based at the population level and do not include the potential costs to the individual. Policy makers admit that side effects occur, but consistently use large epidemiological studies to minimize the number of reactions and their catastrophic results. The story below, unfortunately, well illustrates this point.

Several years ago, I had a young patient in my practice who was a virtuoso violinist. She had won an impressive list of awards and competitions and was about to enter a prominent school of music. She had grown up healthy and unvaccinated in a state where her mother had exercised a philosophical right to refuse vaccines throughout her twelve years of primary education. The university where she intended to matriculate was unbending in their vaccination requirements, particularly insisting that she receive an MMR (measles, mumps, rubella) vaccine. While this was disconcerting to her parents, she was otherwise healthy and they agreed to the demands of the college. Within a few days of the inoculation, her health began to deteriorate and within months, she was unable to lift her arms due to excruciating pain in her joints and extreme weakness in her muscles. Despite the help of a long list of conventional and integrative medical practitioners, this aspiring musician was unable ever again to play her instrument. Today, she is on disability due to progressive neurological deterioration and chronic pain.²

Physicians and officials begrudgingly admit that vaccination side effects can occur. The CDC has written a fact sheet on each vaccine called a Vaccine Information Statement (VIS). The VIS provides basic information about the risks and presumed benefits of the vaccine. By federal law, all vaccination providers must give patients, or their parents or legal representatives, the appropriate VIS prior to administering a vaccine.³

Each VIS is written in clear and simple language so it is easily understood by parents. A VIS contains 1) a description of the illness the vaccine is designed to prevent; 2) a basic description of the vaccine; 3) a definition of who should receive the vaccine and when it should be administered; 4) the risks of the vaccine; and 5) a list of possible mild, moderate, and severe reactions to the vaccine.

A VIS is given to reassure parents they are making the correct decision to vaccinate. Depictions of the diseases are strong, and include incidence rates for hospitalization and death. This makes every infection seem serious and potentially deadly—a frightening perspective for a nonmedical person possessing no experience with which to place the statistics in context. On the other hand, a VIS tends to minimize the potential for serious vaccine side effects. Nearly all VIS forms state, in one way or another, that severe reactions are “exceedingly rare, less than one out of a million doses. These are so rare it is hard to tell if they are caused by the vaccine.”⁴

However, severe reactions are not nearly as rare as many doctors and public health officials would have us believe. In 1986, Congress passed the National Childhood Vaccine Injury Act, which included a national system to collect and evaluate the reports of possible adverse events. The Vaccine Adverse Event Reporting System (VAERS) is a passive surveillance system that relies on physicians, healthcare providers, parents, and vaccine manufacturers to submit reports of adverse reactions, typically within thirty days following vaccination. Since 1999, VAERS has received 11,000 to 12,000 individual reports per year. Approximately 15 percent of filed reports are classified as “an event that is fatal, life-threatening, requires or prolongs hospitalization, results in permanent disability, or in the judgment of the physician could lead to such an outcome in the absence of medical intervention.”⁵ In 1993, Dr. David Kessler, former head of the U.S. Food and Drug Administration, stated that only about one percent of serious adverse drug events (reactions) are reported. This could mean that there are potentially 1,200,000 adverse events from vaccines occurring *each year*.

In addition to filing a report, severely injured parties can file a claim for compensation through the Vaccine Injury Compensation Program (VICP). As of November 3, 2010, 13,613 claims have been filed and the VICP has committed to, or has paid, more than \$2 billion in awards to 2,541 persons, with more than 5,800 remaining to be adjudicated. The federal government grants awards for extreme reactions to vaccination, such as chronic arthritis, anaphylaxis, encephalopathy, and death. Mild to moderate disabilities and side effects are not eligible for damage awards.

The medical literature is rife with reports of autoimmune illness, hearing and vision loss, skin disorders, blood disorders, and a long list of neurological disorders occurring postvaccination. The positive cost-benefit analysis lauded by public health bureaucrats does not account for economic and personal losses sustained by the many thousands of affected persons who have been subjected to millions of dollars of tests searching for the cause of an illness that was sourced from a vaccine. If a true accounting of the vaccine program included these expenses—and the cost of drugs used to treat illnesses arising from vaccine side effects and reactions—the program’s economic cost-benefit ratio would seriously be called into question.

PUBLIC HEALTH: PULL OR PUSH?

Public health officials strike a delicate balance between cooperation, cajoling patients into vaccination compliance, and coercion, using subtle and not-so-subtle threats of serious consequences when people refuse. It is the classic carrot-and-stick approach applied to healthcare. A patient has the right to refuse medications and elective surgeries because an adverse outcome will affect only that individual's health. However, health officials fiercely challenge patients and parents when they refuse vaccination because officials fear that outbreaks of contagious diseases can affect the welfare of a community.

The negative attitude toward adults who choose not to vaccinate their children began almost a century ago. During the 1920s, the tenor of health officials' rhetoric transformed from gently urging the public to cooperate with diphtheria vaccination programs into a tone of stern authority. Strong language was used in public service announcements, pamphlets, and medical brochures. Officials insinuated that parents had culpability if their unvaccinated children became ill. In 1926, the American Child Health Association charged that "the time will come when every case of diphtheria will be an indictment against the intelligence of the parents and it will not be many years before every death from diphtheria will be referred to a coroner's jury for investigation to fix criminal responsibility."⁶

While no parents have yet been charged with criminal liability because their unvaccinated child contracted or died from a so-called vaccine-preventable disease, there have been coercive attempts by public health officials to forcibly vaccinate children against the wishes of their parents. For example, in 2007, when more than 2,300 children did not comply with the newly mandated chickenpox and hepatitis B vaccinations, the state of Maryland threatened parents with legal action as a last resort. Children were absent from the Prince George's county school district for nearly two months because of failure to meet vaccine requirements, creating what officials deemed a "truancy issue." Circuit Judge C. Philip Nichols, Jr., who handles juvenile matters, and Maryland Attorney General Glenn F. Ivey sent letters to the families who were not compliant, ordering them to appear for a hearing. The letter warned that their children's unexcused absences may subject them to criminal charges, which included a \$50-per-day penalty and up to ten days in jail. The state ordered parents to arrive at the courthouse with children in tow. If parents did not provide proof that their children had received all of the state-mandated vaccinations or hand over a valid vaccination-exemption letter, the children would be vaccinated on site.⁷ Many parents scrambled to update their children's records privately through their family physicians' offices and sent the records directly to the school system. However, nearly 1,700 children appeared with their parents at the courthouse on Saturday morning, November 11, 2007. The judge verbally reprimanded the parents, many children were immunized at the courthouse, and the students were told to return to school on Monday morning.

Another more serious example occurred in New York in 2008 when three children were removed from their mother's custody by the Department of Social Services while the court decided, among other issues, if the mother's opposition to immunizing her children as a school requirement qualified as a "genuine and sincere religious belief." In New York, parents have the burden to prove by a "preponderance of the evidence" that their opposition to immunization is "personal and sincere." In this instance, the court found that the mother had met her burden. The state granted her an exemption. The experience was no doubt terrifying to this family and sent a strong message to others that the state of New York enforces vaccination requirements with a

heavy hand.⁸

Compulsory vaccination laws have generated disagreements between officials and parents since the widespread use of the first vaccine for smallpox in the 1800s. As more vaccines have been developed, the question is, increasingly, whether all licensed vaccines are truly necessary to protect the public's health. For example, many states are debating school requirements for human papillomavirus (HPV) vaccination, Gardasil and Cervarix, which have been licensed and recommended for girls and boys as young as nine. HPV is not an airborne pathogen; it is spread by sexual intercourse and sexual contact. Is it reasonable to make this vaccine mandatory for sixth graders in exchange for a public education?

VACCINATION EXEMPTIONS: THE LEGAL RIGHT TO REFUSE

By 1968, nearly 50 percent of U.S. states had laws requiring one or more vaccinations for public school admission. By 1974, the number of states with vaccination laws had increased to forty.⁹ Today, all U.S. states and territories have vaccination requirements for entering public schools. Notably, when state governments first passed vaccination regulations, significantly fewer vaccines were in general use. Since 1985, when the only vaccines required for school were polio, MMR, and DTP, most state governments have added multiple doses of nine additional vaccines and more boosters to school requirements.¹⁰

Almost all state laws allow parents to refuse vaccinations for their children. However, the ease of obtaining exemptions varies significantly by state. School and public health officials are seldom forthcoming about the availability of vaccination exemptions. Each fall, parents receive a letter from their local school districts reminding them to have their children's vaccination records up-to-date before the first day of school. An exemption form is seldom, if ever, offered unless requested. Many parents are unaware that their state laws provide a mechanism to exempt their children from vaccination requirements. Currently, twenty states allow parents to opt out based on philosophical disagreement with the principles of vaccination, and forty-eight states, all but West Virginia and Mississippi, allow parents to refuse for religious reasons.¹¹

All fifty states allow medical exemptions from vaccination, but in practice, they are difficult to obtain. As a general rule, only medical exemptions signed by a medical doctor (MD) or doctor of osteopathic medicine (DO) are accepted. The letter must state that, in the opinion of the physician, the administration of one or more vaccines would be detrimental to the health of the child. States primarily grant medical exemptions on a vaccine-by-vaccine basis rather than as a blanket exemption to all vaccines. In some state health departments, medical directors have the authority to override the opinion of the patient's personal physician if they do not think the exemption is justified. Even when physicians agree that a child should be medically exempted, they are often hesitant to put their opinions in writing, fearing repercussions to their private practice. State health departments occasionally rebuke physicians who write too many medical-exemption letters.

The final type of exemption, rarely discussed, is the "proof of immunity," or serological, exemption. Establishing proof of immunity requires a blood test called a titer level. If the results demonstrate the presence of an acceptable level of protective antibody, this serves as proof that the person is protected, and no further vaccines for that disease are required. Acceptance of this type of exemption varies by state. It is often honored by military commanders for members who wish to avoid overvaccination.

VACCINE INGREDIENTS

There are more than sixty chemicals contained in measurable amounts in various vaccines. With just one dose of each vaccine, an individual receives a number of potentially toxic and carcinogenic substances. Skeptics claim that the concentration of chemicals is negligible, and people routinely consume many, such as gelatin. Scientists understand there is a significant difference between *ingestion* of a substance through the gastrointestinal tract and *injection* of a substance into the bloodstream, which can have a significantly different outcome.

For example, vaccine makers use gelatin in twelve different vaccines; it functions as a heat stabilizer.¹² For most people, consuming gelatin is safe. An odorless, tasteless, and colorless protein, it forms a jelly when heated and then cooled. Manufacturers produce gelatin by boiling the connective tissues, bones, and skins of animals, usually cows and pigs.¹³ Researchers document that gelatin in vaccines may cause systemic allergic reactions, including anaphylaxis, a massive and potentially deadly response.¹⁴ Additionally, a further cross-reaction between gelatin in vaccines and gelatin in food may occur, making once-safe foods potentially dangerous.¹⁵

The medical literature reports serious reactions to gelatin found in the MMR and chickenpox vaccines.¹⁶ The reason for these reactions may be due to the large amount contained in each shot. The chickenpox vaccine contains 12,500 micrograms (12.5 milligrams) of gelatin per dose. The MMR vaccine contains 14,500 micrograms (14.5 milligrams) of gelatin per dose.¹⁷ To put that into perspective, the volume of venom delivered by a wasp sting ranges from 2 to 15 micrograms. A bee sting, generally estimated to contain 50 micrograms of venom,¹⁸ can cause anaphylaxis and death. With thousands of micrograms of gelatin present in a single injection, there can be little surprise that some people have violent, even deadly, reactions to these vaccines.

While gelatin can cause severe reactions in some people, it is not the only ingredient of concern. Many have heard about thimerosal, a preservative containing mercury. Parents are told that childhood vaccines now are “mercury free.” This is misleading. While most childhood vaccines no longer contain thimerosal as a preservative, thimerosal is still used in the manufacturing of vaccines and is still found in many vaccines in trace amounts. Mercury is a potent neurotoxin and any amount, even a trace amount, is worrisome,¹⁹ especially when injected.

Most flu vaccines, including those encouraged for pregnant women and very young children, still contain thimerosal. A multidose flu shot contains 25 micrograms of mercury per dose. By comparison, the EPA announced in March 2004 that nearly all seafood contains traces of mercury²⁰ and the FDA warns that a serving of fish is unsafe if it contains more than one microgram of mercury per gram of fish. A normal serving of fish is about three ounces (18 grams). Both the FDA and EPA advise women who may become pregnant, pregnant women, nursing mothers, and young children to avoid shellfish and some types of fish due to elevated mercury content. It appears government officials are more concerned about ingesting 18 micrograms of mercury in a serving of fish than they are about injecting the 25 micrograms of mercury in a vaccine.

Many vaccines contain the adjuvant aluminum, in the form of aluminum phosphate, aluminum sulfate, or aluminum hydroxide. Aluminum is a potent neurotoxin used to strengthen the effect the antigen (the viral or the bacterial fragment) has on the immune response. An adjuvant

stimulates the immune system in a nonspecific manner, leading to the development of high antibody levels. At the time of this writing, aluminum-based salts are the only adjuvants approved for commercial use in the United States. Although vaccine makers have used aluminum in vaccines for more than fifty years, the mechanism of action of the aluminum adjuvant is complex and not completely understood.

Aluminum is primarily eliminated from the body through the kidneys. Infant kidney function, called the glomerular filtration rate, is low at birth and does not reach full capacity until at least one year of age. Infants, therefore, may not be able to excrete aluminum effectively, and the cumulative amount of aluminum from repeated vaccination may contribute to significant, unrecognized neurotoxicity.²¹ Notably, the American Academy of Pediatrics (AAP) admits that “aluminum has been implicated as interfering with metabolic processes in the nervous system and in other tissues.”²²

Aluminum is harmful enough on its own, but it is known to work synergistically with mercury. Where both are present, their effects are exponential, as Dr. Boyd Haley explains in chapter 19. Children’s exposure to aluminum has increased as the number of vaccine doses has increased. Examples of vaccines with aluminum are DTaP, pneumococcal conjugate (Prevnar), hepatitis A, some forms of Hib, and HPV (Gardasil). For example, the prescribing information for Gardasil²³ states,

Each 0.5-mL dose of the vaccine contains approximately 225 micrograms (0.225 milligrams) of aluminum (as amorphous aluminum hydroxy-phosphate sulfate adjuvant), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, less than 7 mcg yeast protein/dose, and water for injection.

The Prevnar vaccine package insert²⁴ states,

Prevnar is manufactured as a liquid preparation. Each 0.5 mL dose is formulated to contain: 2 µg of each saccharide for serotypes 4, 9V, 14, 18C, 19F, and 23F, and 4 µg of serotype 6B per dose (16 µg total bacterial wall saccharide); approximately 20 µg of CRM 197 carrier protein (diphtheria); and 0.125 milligrams of aluminum per 0.5 mL dose as aluminum phosphate adjuvant.

The FDA states that the amount of aluminum in an individual dose of a biological product shall not exceed:

1. 0.85 milligrams if determined by assay;
2. 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or
3. 1.25 milligrams determined by assay provided that data demonstrating the amount of aluminum used is safe and necessary to produce the intended effect.²⁵

Multiple vaccines are often given together. If DTaP (Infanrix—0.625 micrograms), hepatitis A/B (Twinrix—0.850 micrograms), and pneumococcal conjugate (Prevnar—0.125 micrograms) vaccines are given at the same time, the infant will receive 1.6 milligrams of aluminum, thereby

exceeding the FDA-recommended allowable dose of aluminum on a given day. This increases the risk of both short- and long-term complications, which is especially worrisome because the effects of cumulative doses of aluminum injected into babies have not been studied.

DOCTORS AND VACCINATION

It is a rare doctor who supports the rights of parents and patients to refuse vaccination. Doctors who challenge the medical dogma and the value of vaccination are professionally castigated by their peers, personally embarrassed within their communities, and can be legally silenced by their government and state medical boards. On the other hand, physicians who promote vaccination have begun to pressure patients into vaccinating by the use of coercion.

Physician coercion can take many forms. One coercive technique is threatening to report parents of unvaccinated children to state child protective services for medical neglect. A more common method of coercion is to post an office policy that includes discharging entire families from a medical practice for non-compliance with the AAP's vaccination recommendations.²⁶

The one-size-fits-all, inflexible stance on vaccination increasingly assumed by physicians seems to be having an unintended effect: It is strengthening the resolve of parents to refuse.

Parents simply don't want to be told what to do. Many parents today want to be actively involved in healthcare decisions for their children, especially decisions about vaccination. Parents who inquire about vaccine safety are often more familiar with the ingredients and the potential side effects than their doctors. Some doctors perceive this involvement as opposition, and many do not like having their authority questioned. Unfortunately, most physicians know little about vaccines beyond what they are told by the pharmaceutical sales representatives who sell them. Doctors accept that vaccines are safe and provide protection with few side effects—this is an assumption made with little or no personal investigation beyond the statements made by the CDC. They read medical literature about their specialty but do not scrutinize research about the vaccines they administer. Few, if any, medical school courses discuss vaccination in detail. Even pediatric residencies focus on only the perceived benefits of vaccines, how to administer them, and how to catch children up if doses are missing.

In general, doctors wholly accept that vaccines single-handedly eradicated polio and smallpox. They believe that vaccines are harmless and five or more shots can be safely given at the same time. Medical histories are infrequently assessed for contraindications to vaccination, and detailed information on vaccine package inserts is ignored. In the rush to vaccinate and marshal patients through time-limited office visits, doctors do not discuss vaccination options. In fact, when parents want to discuss non-standard pediatric vaccine options, pediatricians are encouraged to charge patients an extra fee to compensate for their time.²⁷

When an adverse event occurs, doctors undertake an extensive and expensive array of medical tests to find the cause of a new problem that seems to have randomly materialized out of nowhere. The rare physician will admit that the symptom or illness—that began shortly after an injection—could be a side effect of a vaccine. More disturbing, physicians will seldom know enough about vaccine side effects to make the connection.

There is a double standard when it comes to vaccine reactions. Doctors readily acknowledge a serious reaction to a shot of penicillin. They will place prominent drug alert labels on the patient's chart and advise the patient to wear a medical alert tag. This is not the case with vaccination. Doctors consider a vaccine reaction to be an anomaly. If a patient is allergic to a substance in a vaccine, the medical literature advises that it is safe to administer a vaccine containing that substance, as long as it is "under supervision of a physician,"²⁸—as though the mere presence of a doctor in the room will eliminate a serious, possibly deadly, side effect. It is

disquieting that physicians would risk a reaction just to be sure a patient was vaccinated.

Doctors must adhere to their promise to first, do no harm. If medical doctors will not stand behind a patient's right to refuse vaccination, then patients must stand up for themselves. Vaccination choice must become a legally guaranteed personal right. Infectious diseases come and go. With an immune system supported by clean water, exercise, adequate sleep, decent living conditions, reasonably good food, and a 25-hydroxy vitamin D level of greater than 60 milligrams per milliliter,²⁹ few will be at risk of dying from an infection. In fact, most won't get sick at all. Health, after all, does not come through a needle.

Chapter Twenty-Three

A HOLISTIC HEALTH PERSPECTIVE

Annemarie Colbin, PhD

“I regard it as fundamental that any doctor applying a remedy to a patient should be conversant, so far as possible, with its ill effects as well as with its good effects.”

—Sir Graham S. Wilson, twentieth-century British microbiologist

“Science . . . will snatch the babies from the water sprinkling and inoculate them with disease to save them from catching it accidentally.”

—George Bernard Shaw, Man and Superman

“None [are] so blind as those that will not see.”

—Matthew Henry, eighteenth-century Presbyterian minister

OVERVIEW

Vaccination is generally accepted as a given: “Of course you vaccinate your children—that’s how you protect them from disease.” In some communities, however, vaccination is controversial. Many consider it a dangerous practice that threatens the integrity of the immune system. While the media, medical professionals, lawmakers, and the general public largely accept vaccine theory, many researchers and the holistic health community (including chiropractors, homeopaths, and anthroposophic physicians) increasingly believe that the risks outweigh the benefits.

Contemporary societal mores dictate that children receive all of their shots according to the recommended schedule. Proponents of the practice state that vaccines are a safe and effective way to avoid childhood diseases and thereby improve public health. They consider adverse effects rare and believe the benefits of vaccination far outweigh the risks. In order to attend public school, children must provide evidence of vaccination. The practical effect of these requirements is a government mandate. Although neither the state nor the federal government directly presses the needle through the skin without consent, they promote vaccines, pressure families to vaccinate, impose mandates as a condition of day care and school admission, and do not readily and fully disclose potential adverse effects or the availability of exemptions. Therefore, it could be said that the government practices medicine without a license.

In this chapter, I examine vaccination theory, safety and efficacy, politics and public pressure, and offer suggestions on what parents can do, including their options and the possible consequences.

THEORY OF VACCINES

In the Middle Ages, the method of treating an illness by the use of its own products, such as pus or other exudates, was known as “isopathy.” Evidence suggests that this practice dates back to the druids in Great Britain. It was based on observation that those exposed to a certain illness either never got the illness or, after having it, never got it again.

Edward Jenner, a barber and podiatrist, is credited with establishing the smallpox vaccination program in 1796. He heard from a farmer that milkmaids suffering from cowpox did not get smallpox. He assumed it might be true for horsepox as well, and started to inoculate people directly from diseased horses. He claimed that once successfully vaccinated, a person would not contract smallpox ever again. Vaccination against smallpox became a popular and common practice during the nineteenth century in Europe; yet smallpox became an epidemic disease in spite of, or perhaps because of, the vaccination programs.¹ Today, smallpox is no longer an active disease—a fact that modern medicine credits to twentieth-century vaccination practices. On the other hand, we do not have the black plague any more either, and there was never a vaccine for that.

Louis Pasteur, a nineteenth-century French chemist, clarified the role of microorganisms in the fermentation of beer, wine, vinegar, and milk products and eventually extended this research to human and animal diseases. Focusing on the role of microorganisms, he concluded that they were the exclusive cause of infectious diseases (this is known as the germ theory). In his view, the condition of the host played no part. From there, it was a simple step to decide that the best way to eliminate diseases was to eliminate the microorganisms. Conversely, his contemporary, the biologist Antoine Béchamp, maintained that the microorganisms were not external but arose from the disease process itself, and that diseases had more to do with the host’s condition (this is known as the pleomorphic theory). Therefore, he believed that the way to eliminate disease was to strengthen the body’s immune system. Once that was accomplished, the bacteria would simply disappear.

Modern vaccination theory is, at its core, a hybrid of Jenner’s and Pasteur’s models. It claims that microorganisms cause disease, and the way to avoid a particular disease is to introduce the disease artificially so that the body can set up defenses in the event that the “real” disease shows up later. A healthy immune system creates antibodies in the blood to specific diseases, and these antibodies depend on what we have been exposed to in the environment since birth. Vaccines introduce the microorganisms, either live or inactivated, to provoke the body’s production of antibodies to that disease. Vaccination theory posits that a vaccine offers “protection against an infectious disease by inducing a mild attack of the disease beforehand.”² The theory also assumes that the body will react to the introduction of the disease by setting up a defense mechanism, or immunity, to that same disease *only*; the theory ignores or minimizes other reactions.

Proponents of the vaccination schedule also argue that aggressive vaccination is necessary to maintain “herd immunity.” This theory holds that if a high percentage—between eighty-five percent and ninety-six percent, according to the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO)—of the population is immunized, they will protect the unimmunized.³

This theory ignores many crucial facts: In many outbreaks, a significant portion of those

contracting the disease have been vaccinated; for certain vaccines, recipients may shed the virus following vaccination, risking the spread of disease; and vaccination does not prevent individuals from being carriers of a disease although they may remain asymptomatic.

VACCINE INGREDIENTS

We always should read labels and know what is in whatever we eat, drink, or take by mouth or injection. It may give us pause, push us to do more research, or cause us to make a different choice. Yet, most people fail to ask, “What’s in the shot?” as the pediatrician injects the child.⁴

A review of the vaccine “excipients” lists, available on the CDC’s website,⁵ is eyeopening. You can review the information by vaccine or by ingredient. Vaccine ingredients include several types of aluminum, antibiotics, benzethonium chloride, dye, DNA, albumin, bovine calf serum, formaldehyde, gelatin, monosodium glutamate (MSG), polysorbate (20 and 80) and other surfactants, thimerosal (mercury), yeast protein, and urea.

The two with which most people are probably familiar are aluminum, used as an adjuvant to provoke a stronger immune response, and thimerosal, a mercury salt used as part of the production process or added as a preservative to some vaccines, such as flu vaccines. Aluminum and mercury are both potent neurotoxins. It may take a lifetime for the body to deal with these heavy metals. Mercury is a toxic heavy metal, and there is great concern about mercury in dental fillings. In addition, fears of mercury contamination in seafood have been widespread since the 1970s.

While mercury and aluminum may be the best-known ingredients of concern in vaccines, there are many unanswered questions surrounding other ingredients, as well. The potential long-term impact on babies and children of these vaccine ingredients is unknown. The truth is that we do not have any firm longitudinal data about their safety from proper randomized, controlled clinical trials or official epidemiological tracking.

We also must ask questions about the safety of vaccine “active ingredients.” Where do scientists find the virus or bacteria necessary to create a vaccine? The primary place that these organisms are found is in the victims of the diseases. Recently, some vaccines have been produced through genetic engineering, a new and unproven modality whose safety will be tested ultimately by time.

The hepatitis B vaccine is produced by genetic engineering. Its pre-licensure testing was short and based on two questionable assumptions: that the older, serum-based hepatitis B vaccine had been used successfully for years and that the genetic-engineering process could not possibly be a risk factor. However, the antigen for the hepatitis B vaccine is produced by recombinant technology in yeast (*saccharomyces cerevisiae*), and hypersensitivity to yeast is therefore a contraindication to vaccination.⁶

Many parents believe that the government tests vaccines rigorously before licensure and marketing. This is not the case. For many vaccines, pre-licensure testing is brief and undertaken by the manufacturer primarily to look at efficacy and at only acute reactions. Testing protocols sometimes follow vaccine recipients for only days or weeks. The manufacturer tests safety, but with an obvious stake in a successful outcome. Vaccines come to market with scant evidence of their safety or efficacy. Instead, only after vaccines are on the market and thousands begin receiving them in routine practice are their effects monitored in what is known as “post-marketing surveillance.” We need long-term, controlled studies to ascertain the effects of injecting genetically-engineered products into infants and toddlers. In the interim, children are essentially used as experimental human subjects in this practice.

ARE VACCINES EFFECTIVE? ARE THEY SAFE?

The prevailing wisdom is that vaccines have kept children and others from getting certain diseases. However, some researchers disagree. Thomas McKeown states in *The Modern Rise of Population* that vaccinations were introduced after infectious diseases, such as whooping cough and measles, had declined by about ninety percent.⁷ The physician and noted researcher on human longevity Leonard Sagan points out in *The Health of Nations* that the level of generalized resistance to disease may be more important in controlling disease mortality than the eradication of any infectious agent.⁸

EFFECTIVENESS

Vaccination may not be truly effective in keeping illness at bay. In some instances, the opposite may be true. Researchers implicate vaccines as a cause in some epidemics. For example, in the 1870 to 1871 smallpox epidemic in Germany, as many as ninety-six percent of those who had the disease had been vaccinated at least once before they became ill. The same happened in an 1881 smallpox epidemic in Great Britain. Diphtheria increased by thirty to fifty percent in Europe after the introduction of mass, compulsory vaccinations.⁹ Measles also went up. For example, before a vaccination program was established, there were 4,056 cases of measles recorded in the Los Angeles County Health Index; after a vaccination program was established, there were 13,912 cases.¹⁰ There were at least eighteen reports of measles outbreaks during the 1980s, all among school populations where 71 percent to 99.8 percent of the children had been fully immunized.¹¹ In 1994, there was a measles outbreak in Cincinnati, even though eighty percent of the children had had at least three doses of the vaccine.¹² In 2009, the department of health confirmed over two dozen cases of pertussis in Hunterdon County, New Jersey; all the infected children had been vaccinated prior to contracting the disease.¹³ In 2010, there was a mumps outbreak in New York City, primarily among Orthodox Jews. According to the CDC, most of those who contracted mumps had been vaccinated against the disease. The CDC conceded that the “mumps portion of the vaccine is less effective than the other parts” of the MMR.¹⁴

Do vaccines really prevent epidemics? European authorities at the end of the nineteenth century decided they did not, so they began to rely more on isolation and improved hygiene to combat disease. These methods met with surprising success and led to the decline in the incidence of smallpox. Smallpox incidence declined everywhere, among vaccinated and unvaccinated populations.¹⁵ After the WHO's final smallpox vaccination effort in 1978, mandates ended in the 1980s. People credit vaccines with the eradication of this once-feared disease. On the other hand, smallpox became epidemic after, not before, vaccination began. Did the illness lead to the vaccine, which, in turn, increased the illness that increased vaccination? Did the illness decrease because vaccination decreased? The smallpox virus supposedly does not exist anymore; however, there are new viruses associated with pox diseases, such as monkeypox and white pox, which are indistinguishable from the variola (smallpox) virus.¹⁶

Dr. Robert Mendelsohn, the late pediatrician and author, was adamantly opposed to mass vaccination. He noted that while we attribute the end of polio epidemics in the 1940s and 1950s to vaccination programs, polio ended simultaneously in Europe where people did not use the vaccine extensively.¹⁷ Diseases are known to be cyclical, and some, such as bubonic plague, and scarlet fever, have disappeared without any vaccinations whatsoever. This fact weakens the claims about vaccines' effectiveness in preventing epidemics. When epidemics do not appear, the preventive factor could have been the vaccine, or increased hygiene, or better food supplies, or simply just the times.

We cannot prove why something does not happen. If a child gets a polio shot and does not get polio, there is no way to prove that he or she would have or would not have gotten polio in the absence of the vaccine. We do not know whether it was the child's immune strength, herd immunity from vaccination, or just good luck. Believing that one child did not get polio because of a vaccine is simply an assumption, as there are other children who did not get the vaccine who

did not get polio either.

Vaccines do not necessarily lower overall mortality rates. Dr. Sagan notes that, even though smallpox deaths in the early 1800s fell after the introduction of vaccination, “the overall death rate was relatively unaffected as deaths from gastrointestinal and other diseases subsequently rose. One cause of death was replaced by another.”¹⁸

Dr. McKeown flatly states that the contribution of medical intervention to the prevention of sickness and premature death was minimal. Of much higher impact was the increase in the available food supply leading to improved nutrition, as well as “the purification of water, efficient sewage disposal, and improved food hygiene, particularly the pasteurization of milk, the item in the diet most likely to spread disease.” He notes that, according to the WHO, the best inoculation against common infectious diseases is an adequate diet.¹⁹ Dr. Ignaz Semmelweis,²⁰ best known for the eponymous Semmelweis effect,²¹ would surely add that the simple act of thorough and consistent hand washing can drastically cut the spread of disease.

What are the long-term effects of vaccination on the possibility of epidemics? It may turn out that in the long run, diseases become more severe and widespread. For example, Dr. David L. Levy created a computer model to forecast the effects of a measles elimination program on the number of people susceptible to the disease. He found that in the pre-vaccine era, approximately ten percent of the population was susceptible to measles, most of whom were children under ten. According to the computer model, with the institution of the immunization program, the proportion of susceptible people fell at first, to 3.1 percent in 1981, but then began to rise about 0.1 percent per year until it reached 10.9 percent in 2050. Levy predicts that, at that time, susceptibility will range across the entire population. He concludes that long-range projections indicate that the proportion of people susceptible to measles may eventually be greater than in the pre-vaccine era.²² We may already have an example of this effect. The WHO instituted a polio eradication program in Oman, achieving a ninety-eight percent vaccination rate. Six months later, the community experienced a massive polio epidemic.²³

Biologist Robert May postulated that, according to chaos theory, the cycles of epidemics will change with the introduction of a vaccination program. Chaos theory, also known as “nonlinear dynamics,” looks at humans and other biological systems as dynamic, complex systems that move continuously over time. Therefore, linear predictions of behavior rarely bear out. In the public health field, once vaccine programs are implemented, instead of changing smoothly downward, as is the expectation of vaccination theory, May predicted that the downward trend would be dotted with large peaks of the same illness. He mentioned that data from campaigns such as the one to eliminate rubella in Great Britain show precisely such peaks.²⁴ There is also strong evidence that the incidence of shingles, a painful disease generally associated with the elderly and caused by a reactivation of the same virus that causes chickenpox, is increasing, perhaps due to people’s inability, as a result of the chickenpox vaccination, to develop antibodies to the virus because of exposure to a different but related strain of wild chickenpox in the air. Moreover, shingles is now even seen in children who have been vaccinated against chickenpox. In other words, vaccine programs often do not eliminate a disease; they simply rearrange its occurrence, causing it to mutate, or rise in related areas. Rather than recognizing the frightening implications of the mutating disease strains, vaccine developers have taken this “opportunity” to develop new vaccines to address new strains (e.g., new pediatric pneumococcal vaccines for thirteen strains instead of seven) or to vaccinate against diseases previously not vaccinated

against (e.g., shingles). However, the vaccine developers will never have the upper hand on diseases; illnesses always will be one step ahead. New vaccine strains are just an invitation for viruses to mutate. In short, manufacturers are creating their own market for new vaccines.

POST-VACCINATION ENCEPHALITIS

According to medical historian Harris Coulter, PhD, the occurrence of encephalitis, or brain inflammation, after vaccination is much more common than we think. Different vaccines (i.e., measles, polio, and rabies) have been shown upon autopsy to produce both myelin destruction and encephalitis.²⁵ Myelin is the sheath that covers and protects the nerves; it is inexplicably destroyed in diseases such as multiple sclerosis and adrenoleukodystrophy²⁶ (ADL). Autopsies show that as a result of post-vaccination encephalitis, there are “many small yellowish-red lesions in the white matter of the cerebrum, cerebellum, brain stem, and spinal cord,” indicating destruction of the myelin sheaths.²⁷

Encephalitis, among other causes, may come from an allergic reaction to foreign protein. Vaccines may provide some of these damaging proteins, because they contain traces of monkey kidney cells and chick embryo cell cultures, as well as casein, or milk protein. The presence of these foreign proteins injected in the blood may sensitize the child to develop allergic reactions that may later manifest as allergies.

How would the foreign proteins get into the brain? The body protects the brain very carefully from unregulated fluctuations of elements in the blood (such as hormones, amino acids, mineral ions, and others) with the blood-brain barrier. Endothelial cells inside the capillaries that bring blood to the brain establish this barrier. The cells are so tightly packed that only certain necessary nutrients, such as glucose, are able to pass through the capillary walls into the brain. Experiments have shown that a strong solution of sugar in the blood loosens the tightly packed endothelial cells and thereby increases the permeability of the blood-brain barrier. Interestingly, once the sugar concentration disappears, the barrier returns to normal.²⁸

High-pitched crying, inconsolable screaming, head banging, rocking, seizures, convulsions, and staring episodes (which may be absence seizures) are all indications of brain inflammation. The aftermath of brain inflammation may include speech, hearing, and vision difficulties; hyperactivity; retardation; learning disabilities; dyslexia; antisocial behavior; personality disorders; and “flat affect,” or the inability to respond to emotion. Disturbingly, there has been an increased incidence of children having encephalitis after having a childhood disease and after receiving a vaccination against that childhood disease, for many decades.²⁹ Anna-Lisa Annell pointed out in 1953 that common childhood diseases showed an increased tendency to attack the nervous system since the 1920s, when only rare individual cases affected the nervous system.³⁰ Coulter blamed the increase on “the emergence of an allergic dimension that had not been there before.” That is, there are more neurological complications with both diseases and vaccinations because a new element has been introduced that has rendered children more susceptible to allergic reactions. This new element, Coulter postulated, is the increased number of vaccinations children receive.

We really do not have enough data on what the subtle long-term effects of vaccinations are. We cannot predict which children will respond with serious reactions and which will not. As the title of the 1982 documentary so aptly identified, “vaccine roulette”³¹ maybe a dangerous game.

GENERATIONAL EFFECT

Can vaccines damage DNA? Is vaccine damage cumulative? Can it be inherited? Dr. Robert Mendelsohn called immunization “a medical time bomb” and urged parents to reject all vaccinations for their children. He stated that there is no convincing scientific evidence that mass inoculation eliminated any disease. He further stated that there are significant risks and numerous contraindications that make giving vaccines dangerous. He believed that the mass vaccination program might be at the root of the increase in autoimmune diseases in this century.³² Harold E. Buttram, MD, predicted in 1982 that “there may be large scale immune malfunction following current childhood vaccination programs . . . a weakening which may be cumulative from one generation to the next.”³³

Live or attenuated viral vaccines may be particularly dangerous, according to Professor Richard DeLong, a retired microbiologist.³⁴ He has been warning the medical community since 1960 of the dangers of live or attenuated viral vaccines. These vaccines can cause mutations, chromosomal aberrations, birth defects, cancer, and new diseases; they may revert to virulence; and they may be contaminated with other viruses and other microbes.³⁵ Professor DeLong emphasizes that live viral vaccines may originate new diseases in four different ways:

1. Gene recombination occurring among two or more different viruses infecting the same cell;
2. Adventitious viruses in the live vaccine that come from the cells that were used to produce the vaccine;
3. The vaccine viruses having gene changes occurring during reproduction in the *in vitro* phase of vaccine production; and
4. The vaccine viruses having gene changes during *in vivo* reproduction in the vaccine recipient.

Mass vaccination increases the probability of all these things. He considers attenuated and live vaccine viruses nothing less than uncontrolled, genetic manipulation, which may be transmitted from one generation to another.³⁶

Professor DeLong’s theory is receiving further support from information that came to light in the 1990s concerning disturbing aspects of the polio vaccination program. We have known since the 1950s that the polio vaccine, grown on kidney cells of the African green monkey, was contaminated with a monkey virus named simian virus 40 (SV40) that had cancer-causing effects in hamsters. Microbiologist Howard Urnovitz has suggested that the human immunodeficiency virus (HIV) could have originated from the contaminated polio vaccines through recombination with human genes.³⁷

In short, instead of eradicating childhood illnesses with vaccines, we may have simply shifted their timing and virulence. We used to have a population that generally contracted mild versions of childhood diseases when young and then became naturally immune for life. Now we have a growing worldwide population that is artificially immune for a short time, and is becoming susceptible to diseases that were mild in children but that pose dangers to adults. The population may also be at risk for a host of new viral and immune system diseases that did not exist before the vaccination era. We cannot assume that these events are unrelated.

WHO IS AT RISK FOR ADVERSE EFFECTS?

Some children react violently to vaccines and others do not. Could there be a connection for some children between nutritional status and the likelihood of an adverse reaction? Certainly, the status of maternal nutrition and the type of infant feeding (breast or bottle, home-cooked food or commercial and fast food) play a major role in the basic immuno-competence of human beings. For example, in Australia, it was found that malnourished aboriginal children who received routine immunizations had a death rate as high as 500 per 1,000. Once their nutritional status was supplemented with vitamin C, their reactions to the vaccines diminished and the death rate went down.³⁸ We should consider carefully what this hypothesis means for our population.

What are the variables that would allow vaccines to cause neurological damage and encephalitis? According to the natural healing model that I follow, the following list names the worst risk factors because they weaken the entire system:

- Parents' malnutrition and use of drugs and alcohol
- Mothers' weak nutritional status
- Bottle feeding
- High intake of milk products
- High reliance on commercially processed foods
- High intake of sugared snacks and juices
- A lack of fresh vegetables and whole grains
- Insufficient good-quality protein foods

The more of these factors that are present in a child's life, the higher the risk would be of susceptibility to adverse reactions. Additional risk factors include a personal or family history of allergies, convulsions, seizures, food or mold sensitivities, or any condition that has compromised the immune system.

To prevent adverse reactions, it is important to be aware of contraindications. Vaccine manufacturers, the American Academy of Pediatrics (AAP), and the CDC's Advisory Committee on Immunization Practices, and individual pediatricians establish contraindications. I suggest paying special attention to the manufacturers' warnings and contraindications listed on the package inserts for vaccines, as they will be the most detailed. It is reasonable and certainly within a parent's legal right to firmly refuse vaccines on medical grounds when manufacturers' contraindications are present.

Many vaccinated children do not show obvious adverse effects. Even if no overt reactions appear, I must assume that vaccines seriously stress the immune system. I believe that there have to be consequences when, over the first two years of life, a child is injected with many viruses and viral particles, plus their respective preservatives and adjuvants. By definition, vaccines make a healthy child sick.

We do not know if or how the vaccines influence illnesses later in life. According to the chaos theory, human beings are complex and dynamic systems that show a "sensitive dependence on initial conditions."³⁹ Therefore, vaccines administered early in life present a small variation, which could spread out into a considerable change later in life. As nature makes no value judgments, this change could be for good or ill in human terms. We do not know if vaccinated people would have contracted the diseases in the absence of vaccination. One cannot prove why something does not happen. The only way we can attempt to demonstrate the efficacy of these

practices is through rigorous, unbiased scientific research.

Parents who decide to immunize should make sure their children are well nourished and should review all manufacturer contraindications for each specific vaccine to minimize the risk of injuries. Careful pediatricians would follow this same protocol.

PUBLIC PRESSURE AND VACCINATION CHOICE

Vaccination choice is a thorny issue. Vaccination is demanded by schools, day care centers, doctors, and even other parents, including friends and neighbors. Regardless of their position on vaccines, all parents ultimately have a common goal: healthy and happy children. Because they have been told so by the public health system, many parents believe that vaccinations help achieve this goal. They follow the systems set up by their culture and society. Often these systems work; sometimes they do not. They surely are not working when well-meaning parents follow our prescribed healthcare model scrupulously and then find themselves with a neurologically impaired child who requires lifelong care. This is a tragedy.

The marketing technique used most extensively to promote vaccination is fear. Both the media and the health establishment whip up irrational fears of disease in the population, so that people buy the products recommended without hesitation. One excellent book on this subject, debunking the fear of viruses as well as the practice of vaccination, is *Fear of the Invisible*, by investigative reporter Janine Roberts (Impact Investigative Media Productions, Bristol, U.K., 2008). For example, she uncovers that evidence had been presented to the U.S. Congress that linked summer polio epidemics to the common use of heavy metal or organophosphate pesticides in the summer. If that is true—and it possibly is, as these pesticides work by irreversibly inactivating enzymes essential to nerve function in insects as well as in humans—this dreaded illness may have had more to do with pesticides than the polio virus.

RISKS OF THE DISEASE VERSUS RISKS OF THE VACCINE

Is the risk posed by the disease higher or lower than the risk posed by the vaccine? This is a difficult question to answer, because there are risks on both sides. Vaccine promoters downplay the risks of adverse events—both their frequency and their severity. The risks of vaccination, however, have been shown to be real, and should not be ignored.

For many years, it has been known that the statistics concerning exposure to “childhood” disease risks are questionable. One symposium addressed the issue of “Immunization, Benefit Versus Risk Factors.” W. Schumacher, one of the presenters, stated the following:

Inoculations are applied to healthy persons in order to protect them from a disease to whose risk of infection the inoculated subject will perhaps never be exposed. The risk is a mere statistical value. As no medical treatment and no inoculation are free from the risk of undesired side effects, one must judge in every case whether the risk of catching the disease is considerably higher than the risk of vaccination side effects . . . The subject affected by an inoculation has, without doubt, made a special sacrifice in the interest of the general public.⁴⁰

According to a leading medical ethicist,⁴¹ if we are to consider the “best interest of the child,” healthy children should not have to be vaccinated to protect others. “We don’t require adults to serve as kidney donors or even blood donors,” so it is discriminatory to require children to be “splendid Samaritans . . .” for the health of others.⁴²

It is important to understand the facts about the childhood illnesses against which we vaccinate. Measles, mumps, chickenpox, and whooping cough were in decline well before vaccines became available.⁴³ These decreases were largely attributable to improvements in nutrition, hygiene, sanitation, the advent of running potable water, the refrigeration of food, and the invention and increased popularity of indoor flushing toilets. In addition, we have many more treatment options today than we had at the beginning of the century when these diseases were common, including countless drugs and antibiotics, as well as “alternative” medicine such as homeopathy, herbs, dietary management, and acupuncture. In countries with good public hygiene and access to healthcare, these diseases are rarely fatal. In fact, most childhood diseases do not have as many adverse effects as the vaccines for those diseases. While there is the risk of severe injury or death for any disease, millions worldwide have survived measles and mumps without any lasting damage and at the same time have acquired lifelong immunity.

There are several diseases that are more serious, such as diphtheria, polio, tetanus, and hepatitis B. However, good hygiene, good nutrition (especially a diet low in sugar and milk products, high in vegetables and whole grains, and providing sufficient protein), healthy vitamin D levels, and clean living conditions can go far in preventing those illnesses.

Since at least 1979, polio has been largely an iatrogenic illness: most of the cases since then have been vaccine-induced, a condition called vaccine-associated paralytic polio or VAPP.⁴⁴ Tetanus and hepatitis B are not contagious childhood illnesses. Tetanus is very rare in the United States and affects more adults than young children.⁴⁵ It may be a danger if one steps barefoot on a rusty nail in a horse stable and has a weak resistance to disease. This fails to justify the insistence of most emergency medical departments to administer tetanus shots to everyone

without any wound at all. The best prevention for this disease is proper wound hygiene, including allowing the wound to bleed (for cleansing) and to be in contact with the air (the tetanus microorganism is anaerobic; that is, it develops in the absence of air). Tetanus is treatable with antibiotics.⁴⁶

Since the early 1990s, most newborns in the United States receive their first dose of hepatitis B vaccine before they leave the hospital. The reason for this, which is the same reason for vaccinating at well-child visits, is simply because the babies are there, within reach. The vaccine is useless yet poses real risks for the vast majority of infants (an exception might be those born to hepatitis B surface-antigen positive mothers). Hepatitis B is a disease communicable only by the exchange of bodily fluids; it is rarely contracted before the age of sexual maturity. Moreover, vaccinating newborns against hepatitis B does not necessarily protect them later. Because immunity from the vaccine fades, children receiving the vaccine at birth may need boosters before they become teens and are actually at risk for the disease. Outside the United States, most countries with a low prevalence of chronic hepatitis B virus infection do not administer a dose of the hepatitis B vaccine at birth.⁴⁷

THE REMEDY MAY BE WORSE THAN THE DISEASE

Those who promote vaccinations make the major assumption that infectious diseases are a bad thing and should be avoided at all costs. The system we have in place for avoiding a disease actually provokes the disease in mild form; it does not avoid it. In other words, a person who receives a vaccine against measles gets the measles, but usually without the visible symptoms (i.e., the rash). The medical assumption is that this is preferable to getting the real thing, and that the antibodies created by the vaccine exposure to the disease will help protect the vaccinated against the disease in the event of later exposure.

Very few studies have compared “real” disease with vaccine-induced disease. With respect to the measles virus, however, a Danish study showed a marked relationship between the presence of measles antibodies, such as those elicited by the measles vaccine, the absence of a history of an actual measles rash, and certain serious illnesses in adulthood.⁴⁸ These diseases, manifested in adulthood, included immune diseases, skin diseases, bone and cartilage disorders, arthritis, lupus, connective tissue disease, Crohn’s disease, lung disease, nerve paralysis, and various tumors. The author states, “It is assumed that individuals who are at risk of developing non-measles associated disease are those who have been infected with measles virus, but who never manifested a rash.” These diseases were not considered adverse effects of a vaccine, but they were more frequent in the subjects that had not had the measles rash.

Is getting measles naturally, with the rash, so bad? Naturopathic doctors, especially those who follow the anthroposophic philosophy of Rudolf Steiner,⁴⁹ believe it is not. Some believe that, through these diseases, the body cleanses itself of unnecessary matter.⁵⁰ In fact, when children get minor diseases early in life, they are considered a form of natural vaccination, because they prevent the same disease from reappearing later.⁵¹ Doctors have long known that, when a childhood illness is acquired naturally, its immunity lasts for life. This is particularly important because childhood diseases such as chickenpox, measles, and mumps are much more severe in adulthood. When allowed to vanquish the disease on its own, a child’s immune system will have a sort of “workout.” Just as for all other body systems, the immune system is strengthened by use and repeated exposure. It will get stronger after each bout of a minor illness. Each illness a child overcomes naturally provides training for the immune system and increases its effectiveness later in life.

The natural healing model posits that the proper way to deal with childhood diseases is to allow a disease to complete its course. Fasting, rest, and natural remedies help this process. In some instances, using drug treatment to “stop” the symptoms of a disease interferes with the immune system and causes the illness to get worse, or leads to other illnesses.

I believe strongly that vaccines are worse than natural disease. The possibility of catching a natural disease is contingent upon the body’s resistance and strength of its immune system; we can be exposed to an illness and not catch it because of a strong immune system that gives us resistance. With a vaccine, a pathogen is injected directly into the bloodstream and, because we cannot predict what our reactions may be, there is no foolproof way to protect ourselves or our children against any possible adverse effects. These risks may or may not be statistically small, but they are risks nevertheless, and some of them are serious, especially those for potential neurological damage. Frankly, we don’t really know exactly how often adverse events occur, because there is no active tracking system for adverse effects. If properly informed, I doubt there

are many parents who would willingly subject their children to the risks of neurological damage, no matter how small they are. I certainly would prefer that my children get measles or whooping cough naturally and thereby probably develop lifelong immunity, rather than be exposed to the threat of brain damage, convulsions, Guillain-Barré syndrome, juvenile diabetes, uncontrollable seizures, and other serious adverse reactions of a vaccine.

UNVACCINATED CHILDREN

How is the health of unvaccinated children? Do they die of childhood diseases in droves? The answer is no, they don't. There is a general notion that unvaccinated children get sick more often. Indeed, it may be the opposite.

When I interviewed anthroposophic physician Dr. Philip Incao in the 1990s, he treated about 500 children in his Harlemville, New York practice,⁵² and a large number of them were not immunized. I inquired about the health of these unimmunized children and asked if he saw more or less incidence of asthma, allergies, hyperactivity, learning disabilities, and seizures among them. He said he saw much less—almost none—and if he had the money to do a study of the patient populations of the several different anthroposophical doctors in the country, he felt sure there would be far fewer of those problems among them as well.⁵³

Serious epidemiological study of unvaccinated people would be highly beneficial. There are pockets of them here and there—among the anthroposophists, the Christian Scientists, and similar groups. A most interesting field study was done by a journalist, Dan Olmsted, who went looking for autism cases among the Amish, many of whom do not vaccinate their children. Statistically, he should have found at least 50+ in the population size he was studying; instead, he found three cases—an adopted girl from China, and two children who were local and had been vaccinated.⁵⁴

Among those who favor vaccinations, the thought of unvaccinated children in their midst stirs up fears usually reserved for contagious epidemics. One colleague told me that when she tried to put her daughter in a playgroup and the other parents discovered that her child was unvaccinated, they asked her to remove her child. “I felt for the first time what it is like to be discriminated against,” she said. The thought that unvaccinated children pose a danger to the vaccinated population is totally irrational if the vaccines are really effective. Allowing an unvaccinated population to exist next to a vaccinated one is not dangerous to the latter; it may be dangerous to the former, as in the cases where adults contracted paralytic polio from recently vaccinated infants.⁵⁵ When there is a disease “outbreak” it is always assumed that it was started by an unvaccinated person. But unless “patient zero” is positively identified as such, it is always possible that a vaccinated person started the outbreak.

If unvaccinated people get a disease naturally, they can self-quarantine. Another colleague mentioned to me that his five unvaccinated children were at one time exposed to measles. The measles vaccine offers no protection after one has been exposed, so when the school authorities gave them the choice of vaccines or quarantine, he chose the latter. All of his children had a mild case of measles and overcame it easily. “They were sick and unhappy,” he says now, “but in the long run I believe their immune systems got stronger.”⁵⁶ Moreover, they are immune to measles for life.

If vaccination programs were halted, the major concern of those who promote vaccines is that we would face epidemics of childhood diseases. However, such a scenario is unlikely. Current data show that these diseases appear among the vaccinated populations anyway.⁵⁷ In some parts of the country, a high proportion of children may be unimmunized or partially immunized. Most adults are not routinely vaccinated and their childhood vaccines have likely worn off. Where, then, are these epidemics? Herd immunity cannot explain these inconsistencies.

POLITICS AND PUBLIC PRESSURE

Public health authorities promote the idea that vaccinating is what *good* parents and *good* physicians do; therefore, if you do not vaccinate, you are probably a *bad* or *neglectful* parent. In my experience, however, parents who do not vaccinate tend to be much more health-conscious and mindful than average parents. The irony is that the social healthcare system is stacked against them. There have been cases in which a parent's conscious refusal to vaccinate, for health reasons, has been used against him or her in custody disputes. There are numerous cases in which the parents have refused to vaccinate, for any reason, and then health authorities have removed the children from the legal custody of their parents and, under custody of the courts, vaccinated them, alleging child abuse or medical neglect. Then the children are returned to the parents, who are left to deal with adverse effects, if there are any. (See chapter 20 for more information on vaccination and forced child removal.)

OFFICIAL INFORMATION

In April 1992, the U.S. Department of Health and Human Services (HHS) began distributing a series of informative booklets concerning vaccines to pediatricians and public health clinics. While the booklets insisted that the benefits of vaccines outweighed the risks, they also clearly identified the potential adverse effects and encouraged parents to communicate any adverse effects to their doctors. Parents were required to read the booklets carefully and sign a form before submitting their children to vaccination.⁵⁸ This procedure implied that parents could choose not to vaccinate their children after receiving information about the potential adverse effects. Doctors complained that it took too long for patients to read the booklets and that parents were asking “too many” questions.⁵⁹ Doctors also thought that excessive emphasis on the adverse effects would discourage parents from complying with the vaccination schedule. As a result, by 1995 the CDC replaced the booklets with a single sheet for each vaccine, offering a more upbeat tone about the benefits of vaccination, and including cute drawings of children. These sheets that are used today, usually entitled, “What you need to know,” provide incomplete risk information, minimize adverse effects, and require no signature. Parents simply do not receive enough information to give truly informed consent for the vaccination of their children.

PEDIATRICIANS AND HEALTHCARE WORKERS

Imposing healthcare upon people against their will is dictatorial. It is reasonable to expect that our democratic political system would allow individuals to make healthcare choices for themselves and their children based on free and informed consent. Even if vaccinations are supposed to protect the public from epidemics and disease, the acknowledgement that this protection entails the sacrifice of some members of the public should give us pause.

If parents do not wish to vaccinate, and they voice their concerns to a pediatrician, one of the following scenarios will happen:

1. The doctor, who may agree or not, will believe the parents have a right to choose what type of medical care they want for their child and will encourage the parents to make choices in accordance with their conscience.
2. The doctor, who believes immunization is not a choice, will protest strongly and may even refuse the child as a patient. In extreme cases, the doctor also may alert authorities and potentially raise concerns about the parents' failure to vaccinate as evidence of child neglect.

Parents are entitled to use legal exemptions to opt out of vaccination mandates. Depending on the state, parents may be able to obtain religious, medical, or philosophical exemptions. Parents should also inquire about the possibility of "documented immunity," whereby a lab test can demonstrate proof of immunity (in the form of antibody titers) showing the vaccination is therefore not required. The difficulty with which parents can obtain exemptions varies from state to state.

Obtaining natural immunity through disease must be an allowable choice. Society has developed the strange notion that getting sick with a disease for which there is a vaccine should be punishable by law, fine, or child removal for parental neglect. This idea is dangerous. Physicians of earlier times noted that after a bout of illness, children entered growth spurts and became healthier. In any case, there are available treatments for most diseases against which we vaccinate. For example, the administration of high doses of vitamin A, which will alter the course and severity of measles, is used for the treatment of measles in developing countries. Deciding not to vaccinate or to vaccinate selectively must be legitimate choices in a society that respects human rights.

WHAT TO DO? THE PARENTS' CHOICE

Good health is not always due to good luck: It is very often the result of our choices, even if we are not aware of which choices caused what. There are many educated, well-informed parents who believe that the best and safest way to keep their children healthy is to breastfeed them, to give them natural, organic food with plenty of vegetables, and to avoid drugs and vaccines.

Parents who elect not to vaccinate or to vaccinate selectively need to make their own choices about how much they will discuss the issue with others, in light of the possible social repercussions. It should be noted that parents who decide not to vaccinate their children generally do so as a conscious choice, after much research and soul-searching. These parents often give one or more of the following reasons for refusing vaccines.

1. Religious arguments. They belong to a religious or spiritual group that is opposed to the introduction of foreign substances such as drugs into the human body (e.g., Christian Scientists), as the body is considered holy and the temple of the soul. Many parents also have a strong, valid, personal spiritual belief system, which may or may not be officially sanctioned by an official religious group.

2. Health-related arguments. One or more of their children suffered from the adverse effects of a vaccine, and they do not wish to risk further damage to the health of this child, or to risk harming their other children. They may also have seen firsthand incidents of vaccine-induced injury in other children.

3. Philosophical and health theory-based arguments. While Western medicine promotes vaccination, there are other healing systems, such as the naturopathic or anthroposophic, which believe it is better for the immune system to fight off the real illness naturally, rather than to deal with vaccines' inactivated or live viruses and toxoids. These health systems assert that vaccination causes more damage than it prevents.

4. Research-based arguments. After researching and studying popular and scientific literature, especially the many papers on adverse effects, a number of parents simply conclude that childhood diseases are rare, the related vaccines carry too many serious risks, and the theory behind their widespread use does not hold up. They decide to avoid the risk of lifelong seizures and brain damage, and accept the risks of childhood diseases, which, when treated with natural remedies, fasting, and rest, usually run their course.

FACING THE ISSUES

As the number of parents voicing concerns about vaccine safety and policy increases, and as more parents refuse to vaccinate their children in accordance with federal recommendations and state mandates, the rhetoric of vaccine promoters escalates as well. I recommend the following course of action when facing these issues.

1. **Become informed.** Read the scientific literature and books questioning vaccines, talk to parents, and ask your healthcare practitioners.
2. **Make a clear choice.** You can change your mind later on if new information comes your way. The choices are:
 - Vaccinate
 - Vaccinate partially or later than recommended
 - Do not vaccinate
3. **Learn the law.** Know the operative vaccination or immunization laws in your state. Study them carefully.
4. **Act according to your principles, legally.** Find the mode of action that allows you to follow your choice within the law. If you are just trying to take care of your family in the best way you know how and if your community follows the medical system and you don't, the prudent approach is to not argue about it—just do what you want to do. If you choose to become an activist, then it is worth the effort to speak up and to be willing to accept the consequences.
5. **Demand your right to informed consent.** Under the doctrine of informed consent, adults are allowed to refuse vaccination. On the other hand, parents' right to make the same choice for their own children is severely constrained by state laws and school regulations. The doctrine of informed consent legally requires physicians to explain the following points, among other things.
 - The benefits of the recommended treatment or procedure;
 - The risks associated with the recommended treatment or procedure; and
 - Alternatives to the treatment or procedure.

Health consumers have a legal right to make choices regarding their health and medical care needs. Informed consent to what type of healthcare to accept, including vaccination, is a human right.

A FINAL VIEW

Regardless of what we do, children do get sick from time to time. Even those who promote vaccination will admit that it does not protect against all sickness. The choice we have is between the risk of man-made, iatrogenic sickness, and the risk of natural disease. Let us be very clear that this is our own, personal choice—and not the choice of the government or of healthcare practitioners.

Chapter Twenty-Four

WHAT SHOULD PARENTS DO?

Louise Kuo Habakus, MA

“Who shall decide when doctors disagree?”

—Alexander Pope, eighteenth century English poet

WHERE CAN PARENTS TURN FOR MEDICAL ADVICE REGARDING VACCINATION?

Many parents are deeply concerned about vaccine safety. The Center for Personal Rights (CPR) upholds the rights of individuals to make vaccination decisions with their healthcare practitioners.

The following list illustrates the broad spectrum of medical perspectives on vaccination. It starts, at one end, with a recommendation to give all scheduled vaccinations, and concludes, at the other end, with a world-famous pediatrician's argument against vaccination. Many inquiring parents find it helpful to review a wide range of views. We have gathered and summarized the views of nine board-certified pediatricians and other licensed professionals. These views concur with and differ from the government's recommendations. Many of these professionals support vaccination choice and raise important questions and concerns about Centers for Disease Control and Prevention (CDC)-recommended vaccination protocols. A medical association or medical doctor authorized to give medical advice has published each of the following perspectives.

1. The CDC and AAP Childhood Vaccination Schedule

Most doctors follow the CDC's recommended vaccination schedule for children. The American Academy of Pediatrics (AAP) urges its 60,000 member pediatricians and pediatric specialists to endorse and adhere to this schedule:

In 2008, the AAP published a letter in its official monthly newsmagazine, *AAP News*, from All Star Pediatrics, a member pediatric practice in Exton, Pennsylvania. Excerpts from this letter echo the medical advice the CDC and AAP offer:

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

Please be advised . . . that delaying or "breaking up the vaccines" to give one or two at a time over two or more visits goes against expert recommendations, and can put your child at risk for serious illness (or even death)....

Finally, if you should absolutely refuse to vaccinate your child despite all our efforts, we will ask you to find another healthcare provider who shares your views. We do not keep a list of such providers, nor would we recommend any such physician.... [B]y not vaccinating you are putting your child at unnecessary risk for life-threatening illness and disability, and even death.^{1, 2}

Immunization providers and departments of health receive significant financial support from CDC-funded programs at the state and local level. Through its Section 317 Immunization Program, the CDC supports the "activities needed to assure vaccination of a population."³ These include the "integration of new vaccines into routine medical care" and "strategies to increase vaccination coverage rates."⁴ Section 317 funding has exceeded \$500 million annually over the past five years. The American Recovery and Reinvestment Act of 2009 provided an *additional* one-time appropriation of \$300 million that "provides a historic opportunity to make the benefits of vaccination available to more Americans by providing a 40 percent increase in funding over the two-year funding period."⁵

The AAP is similarly concerned with maintaining high vaccination rates. The following are excerpts from their press release dated October 2010:

Deadly diseases are making a comeback. . . .

At the heart of all these outbreaks: Parents who have chosen not to vaccinate their children. . . .

"We are at a crossroads," said Dr. [Paul] Offit. "If population immunity continues to break down, the door will open wider to diseases that we thought had been vanquished by vaccines."⁶

In 1982, the AAP rejected a resolution of its members to give comprehensive information to

parents about vaccine risks and benefits.⁷ In 1993, the AAP led the successful effort to substantially reduce the amount of information that doctors were required to give patients under the 1986 National Childhood Vaccine Injury Act.⁸ Public health and mainstream medicine prioritize vaccine compliance above the individual's right to free and informed consent.

2. Vaccines: What You Should Know

Paul A. Offit, MD, FAAP and Louis M. Bell, MD, FAAP (John Wiley & Sons, Inc., 2003)

Drs. Offit and Bell are pro-vaccine medical doctors who believe that individuals should follow the recommendations of the experts, namely, the CDC and AAP. Offit and Bell are board-certified pediatricians. This revised edition, which updates a 1999 book by the authors, covers vaccines for children and adults. In simple language, it addresses the need for vaccines, how they work, how they are made, safety, and who recommends them. It also covers special situations, including vaccines for travelers, bioterrorist agents, rabies, Lyme disease, and AIDS. There is a chapter for each vaccine, with a discussion of the disease and its incidence, the vaccine and its side effects, and the AAP's recommendation for number of doses and the ages at which they should be administered. In a chapter on "Practical Tips," they offer brief observations regarding the fear of shots, who shouldn't get shots, vaccinating children who are ill or who have allergies, premature babies, giving vaccines simultaneously, missed vaccines, and vaccinating children who are adopted from other countries.

Offit and Bell state no concerns about death or severe injuries from vaccines given to children and nearly all vaccines given to adults.⁹ The authors explain that vaccines are not "completely free of any possible negative effects." However, they list many other "gambles" individuals unconsciously make every day, including bathing, eating, being struck by lightning, and even contamination from money which may harbor bacteria and viruses.¹⁰ When asked if vaccines are safe, they believe the more relevant question is whether the benefits outweigh the risks. Their answer is a resounding yes.¹¹

The authors support the use of multiple vaccines in one visit: "All routinely recommended vaccines can be given simultaneously. There is no evidence that giving one vaccine significantly interferes with the immunity caused by another. Nor is there any evidence that any of the vaccines increases the rate of side effects of another."¹² They welcome the arrival of new combination vaccines that make it easier for children to get vaccines without getting so many shots: "The good news is that help is on the way. Several companies are now working together to combine vaccines."¹³ (See the appendix to this chapter for a list of combination vaccines available today.)

The authors also maintain that "it is safe to give all of the recommended vaccines to children with "minor illnesses." Minor illnesses include low-grade fever, ear infections, cough, runny nose, diarrhea, or vomiting. Several studies "found [these children] were not at greater risk of side effects and had similar immune response after immunization as children without minor illnesses."¹⁴

In the "Common Concerns about Vaccines" chapter, the authors give the background for Dr. Offit's public statement that a child could safely receive 100,000 vaccines at once. They offer the theory of two immunologists from the Salk Institute in San Diego:¹⁵

The number of microorganisms to which a body can respond depends on the number of cells in blood that can make antibodies sufficient to recognize all the

relevant parts of the microorganism.... the number of microorganisms to which one responds depends on size. [They] estimated that elephants can produce immunity to about a hundred times more microorganisms than humans... The scientists estimated that even young infants could respond to about 100,000 different organisms at one time. Therefore, the eleven vaccines required for all children will use up only about 0.01 percent of the immunity that is available.

Offit and Bell acknowledge that Americans are entitled to refuse vaccines by law but question the wisdom of exemptions: "One could argue that an individual's rights should not include the right to catch and spread contagious and potentially fatal diseases."¹⁶ They offer two examples of outbreaks that occurred within communities that refused vaccinations on religious grounds.

3. The Vaccine Book: Making the Right Decision for Your Child

Robert W. Sears, MD, FAAP (Little, Brown and Company, 2007)

Dr. Sears is a pro-vaccine medical doctor who endorses vaccination choice. He is board-certified in pediatrics. This book is for parents. In his words, “vaccination isn’t an all-or-nothing decision” and he urges doctors to give medical care to children whose parents choose all, some, or no vaccines. He does not believe that all vaccines are equally important, and explains that some diseases are more common and are more deadly. In his book, Sears reviews each childhood disease and vaccine, and offers information on combination vaccines, vaccine safety research, side effects, ingredients, and exemptions. He is a leading proponent of alternate vaccination schedules and offers his own schedule, which is guided by the following principles:

- No more than two vaccines at any one time to limit potential side effects
- No more than one live virus vaccine at a time
- No more than one aluminum-containing vaccine at a time (aluminumfree if possible)
- Avoid combination vaccines where possible
- Avoid mercury-containing vaccines where possible
- Start at two months of age instead of at birth

Sears tells parents exactly what he thinks in the “The Way I See It” section for each vaccine. He lists what he considers the most important vaccines (DTaP, rotavirus, Hib, pneumococcal), recommends delayed vaccination for diseases that are usually mild for infants (hepatitis A, rubella, chickenpox), and supports parents who choose to skip vaccines for diseases that children are unlikely to get (hepatitis B, polio, and flu). He advocated giving infants the individual measles, mumps, and rubella vaccines until sole manufacturer Merck decided in 2008 to stop making them. More information is available at www.thevaccinebook.com.

4. What Your Doctor May Not Tell You About Children's Vaccinations (revised)

Stephanie Cave, MD, FAAFP (Wellness Central, 2010)

Dr. Cave is a medical doctor who supports the use of some vaccines and endorses vaccination choice. She is a board-certified family physician. This book is for parents. She is concerned about the rise in chronic childhood medical conditions that mirror the rise in recommended and mandated vaccination. "There's much we don't know, but this much I am certain of: parents who blindly listen to their doctors can no longer afford to do so. It's time for parents to ask questions and learn all they can about vaccines before a shot is scheduled."¹⁷ Her book discusses vaccine safety, autoimmunity, autism, and mercury in vaccines. She reviews each childhood disease and its corresponding vaccine. Cave lists questions for parents to ask the doctor and questions parents should ask themselves before vaccinating. She offers tips to reduce vaccine reactions including:

- Ensure the child is in good health and, in particular, does not have a fever or recent bacterial or viral infection.
- Give the doctor your child's complete family and personal medical history.
- Supplement with vitamins A and C to protect against adverse reactions.
- Request single-dose vials and thimerosal-free vaccines.

Cave is also specific in her recommendations. Her top-priority vaccines are the ones she believes are "safer for the general population": Hib, polio, and DTaP.¹⁸ The hepatitis B vaccine is only recommended for an infant if the mother has tested positive for the disease. The combination MMR vaccine is not recommended. She asks parents to contact Merck and ask them to resume manufacture of the single measles, mumps, and rubella vaccines. Cave does not recommend the remaining childhood vaccines—varicella, influenza, hepatitis A, rotavirus, meningococcal, and human papillomavirus¹⁹—and her counsel is instead designed to help parents meet state requirements for day care and school. She advocates postponing the mandated vaccinations as long as possible to reduce the possibility of adverse reactions while still staying within state laws. Cave urges parents to get informed and not be satisfied with one-sided answers.

5. Vaccinations: A Thoughtful Parent's Guide

Aviva Romm, MD (Healing Arts Press, 2001)

Dr. Romm supports vaccine use and she also supports parents' informed and educated choice. This book is for parents. Romm is a medical doctor and a recognized expert in midwifery and pediatric herbal medicine. Her vaccination book reflects these multiple perspectives. She believes no single approach is appropriate for every child and, therefore, does not make specific vaccine recommendations in her book. She addresses each disease at length and includes data on incidence, symptoms, risks and complications, and conventional treatment. She also provides a section called "food for thought" that provides related information to further support a parent's decision. For example, she describes pertussis as "a generally self-limiting disease that causes discomfort and inconvenience but little damage in a well-nourished, healthy population. It also confers permanent immunity."²⁰ In the section on vaccine risks, Romm observes:

[Vaccines] can have immediate short-term consequences that are both mild and serious. However, we also saw that vaccines are implicated in a number of chronic health problems, such as allergies, asthma, diabetes, and rheumatoid arthritis. When we consider the consequences of such insidious and pernicious problems as mercury toxicity and learning disabilities, and the rise in chronic autoimmune conditions, we must consider whether avoiding certain diseases is a trade-off courting others. Our children deserve long and healthy lives. Vaccines offer benefits, but they are also a bit of a gamble. Perhaps vaccinations are only one small part of disease prevention and more emphasis needs to be placed on enhancing immunity through other (and safer) means.²¹

In addition to reviewing each childhood vaccine, she covers vaccine history, research on safety and efficacy, and the risks of adverse events from vaccines. She outlines personal choices, public policies, and natural approaches to health and immunity. Her book is evenhanded and offers herbal and homeopathic options for parents who do not vaccinate. She respects many vaccination choices and encourages parents to do what is appropriate. This includes an identification of the circumstances in which they might be able to be delayed or avoided. More information is available at <http://avivaromm.com/books>.

6. *The Vaccine Guide: Risks and Benefits for Children and Adults (revised)*

Randall Neustaedter, OMD, LAc (North Atlantic Books, 2002)

Dr. Neustaedter is a medical doctor who opposes vaccination and endorses vaccination choice. He holds a doctorate in oriental medicine and has practiced holistic medicine for over thirty years, specializing in children's health. This book is for anyone who is considering vaccination. He begins his book with four facts:²²

1. Compulsory vaccine laws exist in every state.
2. All vaccines carry risks of adverse reactions.
3. Every parent has the legal right to exempt children from vaccinations.
4. The vaccination campaign has traded diseases of childhood for chronic immune and autoimmune diseases that afflict both children and adults.

Neustaedter's book is divided into two parts: Choices and Vaccines. Part I covers adverse vaccine reactions, contaminated vaccines, chemicals in vaccines, conventional studies, the role of alternative medicine in achieving health, building a strong immune system, and the legal requirements of vaccination. Part II addresses the diseases and their vaccines. He presents the details needed to make an informed choice and acknowledges that people "must decide what is best based on their philosophy, comfort level, and understanding of the real issues surrounding vaccinations. Only then will your choice be based upon intelligent reasoning and not blind faith."²³ In his preface, he mentions the political goal to garner popular support for vaccinations and notes the actions of four presidents: Ford's ill-fated 1976 swine flu program; Carter's campaign that increased federal vaccination funding nearly sevenfold; Reagan's passage of the 1986 Act to protect vaccine manufacturers from lawsuits; and Clinton's passage of the Comprehensive Child Immunization Act of 1993.²⁴ Neustaedter addresses the role of natural medicine, the treatment of vaccine reactions, and legal requirements, including compulsory vaccination, exemptions, immigration, and military service. In addition to the childhood vaccines, he covers anthrax, smallpox, and Lyme disease vaccines. More information is available at www.cure-guide.com.

7. Make an Informed Vaccine Decision: A Parent's Guide to Childhood Shots

Mayer Eisenstein, MD, JD, MPH with Neil Miller (New Atlantean Press, 2010)

Dr. Eisenstein is a medical doctor who opposes vaccination and endorses vaccination choice. He is board-certified in preventive medicine and holds graduate degrees in law and public health. This book is for parents. Since 1973, his medical practice has offered medical care to 35,000 children who received few or no vaccines; this unvaccinated population has no autism and virtually no asthma, allergies, respiratory illnesses, or diabetes. When vaccinated children contract so-called vaccine-preventable diseases, Eisenstein says, people should direct their outrage towards the drug company that manufactured and falsely promoted an ineffective product, not towards unvaccinated children.²⁵ He says alternative schedules are “probably more sensible than taking all of the shots at once.... However, you’re merely mitigating the potential damage. I don’t believe you’re going to eliminate it altogether.”²⁶ In response to claims that vaccines reduce the incidence of disease, he retorts: “Several diseases—tuberculosis, scarlet fever, plague—infected thousands of people every year but virtually disappeared without any vaccines. How do we explain this?”²⁷

With Neil Miller, a medical research journalist, Eisenstein reviews each disease and its corresponding vaccine. They offer detailed information on the incidence and complications of the diseases, and on issues of manufacturing, safety, efficacy, and adverse events associated with each vaccine. They discuss the role of vitamin supplementation, such as vitamin D3 for influenza; vitamin A for measles; and vitamin C for cancer. There is a chapter devoted to autism, a neurodevelopmental disorder that was “extremely rare prior to 1943” and now affects one in ninety-one children and one in fifty-eight boys.²⁸ He quotes Congressman Chip Pickering: “More children will be diagnosed with autism this year [2006] than AIDS, diabetes, and cancer combined.”²⁹ The book closes with a discussion of multiple vaccines given simultaneously, the use of aluminum and other vaccine ingredients, and questions about social obligation and herd immunity. Additional books and resources about vaccination are available at www.thinktwice.com.

8. Saying No To Vaccines: A Resource Guide for All Ages

Sherri Tenpenny, DO, AOBNMM (NMA Media Press, 2008)

Dr. Tenpenny is a doctor of osteopathic medicine who opposes vaccination and endorses vaccination choice. She is board-certified in emergency medicine (through 2006) and in neuromusculoskeletal medicine. This book discusses vaccines for children and adults. Tenpenny compiles medical, governmental, and scientific sources that demonstrate that vaccines are less safe and less protective than advertised. In addition to a discussion of childhood vaccines, Tenpenny addresses the vaccines recommended for adolescents, adults, healthcare workers, soldiers, and international travel. The book refutes twenty-five common arguments used to promote vaccination. The table of contents allows readers to easily find the answers to their questions. Topics include:

- Safety and efficacy studies for approved vaccines;
- The smallpox vaccine and myths regarding smallpox's "eradication;"
- A detailed discussion of pertussis and its vaccine;
- Antibody production as an inaccurate measure of protection against infectious diseases; and
- The impact of stray viruses, heavy metals, chemicals, and other vaccine components.

Tenpenny argues for the importance of fevers and the need to allow a disease to run its course. Unwarranted or excessive treatment hinders recovery and makes the original disease appear more severe. She offers practical advice on how to manage a fever at home and when a doctor's care is necessary. Tenpenny explains influenza viruses, the politics of mass vaccination policies, and the relationship between war and malnutrition in global flu outbreaks. The book contains more than 300 references to medical journals. The final 100 pages contain cross-referenced tables, detailed charts, and other resources, such as a list of ingredients in the most commonly used vaccines, examples of refusal forms for newborns, school exemption letters, and suggested websites. More vaccination information is available at www.tenpennyvaccineinfo.com.

9. How to Raise a Healthy Child in Spite of Your Doctor

Robert Mendelsohn, MD (Ballantine Books, 1984)

The late Dr. Mendelsohn, a professor and renowned pediatrician in practice for thirty years, opposed vaccination. President Lyndon Johnson appointed him national medical director of Project Head Start, a program of the federal government that provides comprehensive health education and programming to low-income families. Mendelsohn was also chairman of the Medical Licensure Committee for the state of Illinois, and associate professor of Preventive Medicine and Community Health in the School of Medicine of the University of Illinois. He believed “every vaccine causes neurological damage.”³⁰ He vaccinated patients early in his career, until he realized they were causing more harm than good.³¹ His book stops short of advising parents to reject vaccination (in 1984) because “parents in about half the states have lost the right to make that choice.”³² Mendelsohn argued:

- There is no convincing scientific evidence that mass vaccination eliminated any childhood disease. If vaccines eradicated disease in the U.S., why did the diseases disappear simultaneously in Europe, where mass immunization did not take place?
- There are significant known risks and numerous contraindications associated with every vaccine, yet strong reluctance to abandon vaccination persists within the medical community. For three decades before ending its use, the smallpox vaccine remained the only source of smallpox-related deaths. “Think of it! For 30 years, kids died from smallpox vaccinations even though no longer threatened by the disease.”
- No one knows the long-term consequences of injecting foreign proteins into children. There are growing suspicions that vaccination may be responsible for the dramatic increase in autoimmune diseases since mass inoculations were introduced.³³

His book covers mumps, measles, rubella, pertussis, diphtheria, chickenpox, scarlet fever, meningitis, tuberculosis, sudden infant death syndrome (SIDS), poliomyelitis, and infectious mononucleosis. In his own words:

Scarlet fever is another example of a once feared disease that has virtually disappeared. If a vaccine had ever been developed for it, doctors would undoubtedly credit that with the elimination of the disease. Since there is no vaccine, they give the credit to penicillin, despite the fact that the disease was already disappearing before the first antibiotics appeared. In all probability, as with other diseases, the true reason for its waning incidence is improved living conditions and better nutrition.³⁴

In view of the rarity of [diphtheria], the effective antibiotic treatment now available, the questionable effectiveness of the vaccine, the multimillion-dollar annual cost of administering it, and the ever-present potential for harmful, long-term effects from this or any other vaccine, I consider continued mass immunization against diphtheria indefensible. I grant that no significant harmful effects from the vaccine have been identified, but that doesn't mean they aren't there. In the half-century that the vaccine has been used no research has ever been undertaken to determine what the long-term effects of the vaccine may be!³⁵

Mendelsohn's 1984 book, which remains in print, highlights the views of a prominent pediatrician just prior to passage of the 1986 Act. He described the "bitter controversy over immunization" that raged among the medical professionals, the media, and parents:

- Commenting on the AAP's rejection of a resolution to make available clear and concise information that a reasonable parent would want to know about the risks and benefits of vaccination, Mendelsohn wrote: "Apparently the doctors assembled did not believe that 'reasonable parents' were entitled to this kind of information."³⁶
- As an increasing number of parents were rejecting vaccination, parents of vaccine-injured children were filing malpractice suits against the manufacturers and doctors who administered the vaccines, and some vaccine manufacturers stopped making vaccines.³⁷ "Many doctors are becoming nervous about giving [the DPT vaccine], fearing malpractice suits. They should be nervous because in a recent Chicago case a child damaged by a pertussis inoculation received a \$5.5 million settlement award."³⁸
- Doctors were attacking their own. In 1982, Mendelsohn stated in an NBC television documentary: "The danger [from the DPT vaccine] is far greater than any doctors here have ever been willing to admit." The *Journal of the American Medical Association (JAMA)* criticized the television program and questioned the credentials of the experts, including Mendelsohn's. The same *JAMA* issue stated, "[the DPT vaccine is] relatively crude and toxic, and the advent of a safer vaccine is eagerly awaited. Almost from the inception of widespread DPT immunization, severe reactions have been reported, beginning with Byers's and Moll's study of vaccine-associated encephalopathy in 1948."³⁹

Mendelsohn fought against the passage of the 1986 Act that provided liability protection to vaccine makers. The 1986 Act paved the way for a three-fold increase in the number of federally recommended vaccines for American children during the past twenty-five years.



Most pediatricians and family doctors endorse and follow the CDC's recommended schedule. However, there are well-respected physicians who depart from this regimen and support vaccination choice. While they do not agree on every point, these physicians suggest that parents and individuals consider the following, to guide their vaccination decisions:

1. A family history of autoimmune, chronic, neurological, or developmental disorders, including adverse reactions to vaccines.
2. The child's medical history, including recent illness, and fevers, and use of prescription medications.
3. The number of vaccines received at a single visit, with special attention to live virus, aluminum- and mercury-containing, and combination vaccines.
4. Any indication of an adverse reaction or developmental delay is a reason to stop or slow down vaccination.
5. The use of vitamins, herbal medicine, and homeopathic remedies before, after, or instead of vaccination.
6. Case-by-case decision making, based on the individual, the vaccine, and timing. Delaying vaccines is a common strategy of many doctors who employ alternate vaccination schedules.
7. A review of the scientific and medical literature and manufacturers' package inserts regarding vaccine adverse events.

CPR offers one additional perspective. No country in the world vaccinates as early or as often as the United States. In the 1950s, we had the third best infant mortality in the world; more babies lived past twelve months of age in only two other countries. In the 1960s, the United States began requiring universal, mandatory vaccination for school admission and has gradually and significantly increased the number of required vaccines since then. The United States' infant mortality ranking has dropped precipitously over this same time frame; today, America ranks forty-sixth, behind every developed country but one (Poland), and many developing countries.⁴⁰ This trend holds true for other serious pediatric disorders, including asthma, autism, and ADHD. CPR does not assert that there is a vaccine link because comprehensive research has not been done. But it is reasonable to ask what role, if any, vaccines may be playing.

In the absence of definitive science, CPR advocates the precautionary principle and urges doctors to support parents in their right to exercise vaccination choice. Medicine is for the best interest of the individual patient. Public health is for the best interest of the population. When the state demands that doctors prioritize public health requirements above the needs of an individual patient, and there is no free and informed consent, the consequences are severe: Doctors are no longer practicing medicine, and the sacred trust between physician and patient is broken.

LEGAL EXEMPTIONS TO MANDATORY VACCINATION

The CDC offers a *recommended* schedule. Until your child enters publicly funded day care, preschool, or school, specific vaccination decisions—if, when, and which the child should receive—remain the privilege and responsibility of parents, guided by the healthcare practitioners of their choosing.

Each state has its own mandatory school vaccination schedule. The National Conference of State Legislatures offers a summary of state laws on its website, www.NCSL.org. Type “School Immunization” in the search box and click on the link “School Immunization Exemption State Laws.” You can also try www.tinyurl.com/3aayesb.

The United States offers a “no-choice choice” in practice. State laws provide for vaccination choice, but they rarely disclose this information, and exemptions can be difficult to obtain. All fifty states offer medical exemptions, if the letter is signed by a medical doctor or doctor of osteopathy; however, the state departments of health can and do override medical exemptions at their discretion. Forty-eight states offer religious exemptions. Twenty states offer philosophical or personal belief exemptions.

CPR works to obtain full vaccination choice in every state. This means that vaccination choice is both available and honored. Please visit our website, www.centerforpersonalrights.com, for more information. We provide resources to help individuals and parents make the best choices for themselves and their families.

Chapter Twenty-Five

WHO IS DR. ANDREW WAKEFIELD?

Mary Holland, JD

If you've heard Dr. Wakefield's name—and you probably have—you've heard two tales. You've heard that Dr. Wakefield is a charlatan, an unethical researcher, and a huckster who was “erased” from the British medical registry and whose 1998 article on autism and gastrointestinal disease was “retracted” by a leading medical journal. You've also heard a very different story, that Dr. Wakefield is a brilliant and courageous scientist, a compassionate physician beloved by his patients, and a champion for families with autism and vaccine injury. What's the truth?

BACKGROUND ON THE CONTROVERSY

Dr. Wakefield graduated from St. Mary's Hospital Medical School of the University of London in 1981; he was one in the fourth generation of his family to study medicine at that teaching hospital. He pursued a career in gastrointestinal surgery with a specialty in inflammatory bowel disease. He became a Fellow of the Royal College of Surgeons in 1985 and was accepted into the Royal College of Pathologists in 2001. He held academic positions at the Royal Free Hospital and has published over 140 original scientific articles, book chapters, and invited scientific commentaries.

In the early 1990s, Dr. Wakefield began to study a possible link between the measles virus and bowel disease. He published a 1993 study, "Evidence of persistent measles virus infection in Crohn's disease"¹ and coauthored a 1995 article published in *The Lancet*, "Is measles vaccine a risk factor for inflammatory bowel disease?"² At roughly the same time, Dr. Wakefield wrote an unpublished 250-page manuscript reviewing available scientific literature on the safety of measles vaccines.³ He was rapidly emerging as one of the world's experts on measles vaccination.

In 1996, an attorney, Solicitor Barr of the law firm Dawbarns, contacted Dr. Wakefield to ask if he would serve as an expert in a legal case on behalf of children injured by vaccines containing the measles virus. The lawyer was bringing the suit on behalf of parents who alleged that vaccines had caused their children's disabilities, including autism. Six months before this, and independent of the litigation effort, parents of children with autism and severe gastrointestinal symptoms began contacting Dr. Wakefield because of his publications on the measles vaccine, asking for help for their children's pain and suffering, which they believed was vaccine-induced. Dr. Wakefield made two major, but separate, decisions at about this time—to try to help the families dealing with autism and gastrointestinal problems, and to become an expert in the legal case regarding vaccines and autism.⁴

Barr asked Dr. Wakefield to study two questions: (1) whether measles could persist after measles infection or the receipt of the MMR vaccine; and (2) whether the measles virus could lead to complications, such as Crohn's disease or autism. Due to bureaucratic delays at his hospital, however, Dr. Wakefield did not begin this litigation-related study until October 1997.⁵

By July 1997, Dr. Wakefield and his colleague, Professor John Walker-Smith, had already examined the "Lancet 12"—twelve patients with autism and gastrointestinal symptoms that were the basis for the case study in the 1998 article published in *The Lancet*. Dr. Wakefield and others had recommended the referral of these patients to Prof. Walker-Smith, an eminent physician described by his peers as one of the world's leading pediatric gastroenterologists.⁶ Prof. Walker-Smith had recently moved to St. Mary's Hospital from a different institution and brought with him the same clinical privileges and ethical clearances that he enjoyed at his previous hospital. He, a colleague, Dr. Simon Murch, and a team of other physicians, did extensive clinical workups on these sick children that Prof. Walker-Smith deemed "clinically indicated," while Dr. Wakefield coordinated a detailed research review of the tissues obtained at biopsy. The clinical tests included colonoscopies, MRI scans, and lumbar punctures to assess mitochondrial disorders. "Clinically indicated studies" did not require permissions from The Royal Free Hospital ethics committee because the tests were required for the benefit of the individual patients.⁷ Dr. Wakefield's research was covered by an appropriate ethical approval.

In 1998, to announce the publication of *The Lancet* article coauthored by Dr. Wakefield and twelve other scientists, the dean of St. Mary's Medical School called a press conference. While this was not standard practice, the dean presumably was seeking to enhance the school's visibility in cutting edge research. The article was labeled in the medical journal as an "early report," stating that it "did not prove an association between measles, mumps and rubella vaccine and the syndrome described. Virological studies are underway that may help to resolve this issue."⁸

At the press conference, Dr. Wakefield was asked about the safety of the MMR vaccine. In 1992, two different combination MMR vaccines had been withdrawn from the U.K. marketplace because they were unsafe, so MMR vaccination was already a hot topic before *The Lancet* article was published. Dr. Wakefield responded that, given the paucity of combination MMR vaccine safety research, and until further safety studies were done, the vaccines should be separated into their component parts. He had previously informed his colleagues that this was his view and that he would express it if asked.⁹

The 1998 press conference set off a media firestorm, with large numbers of parents raising uncomfortable questions about the safety of the "triple jab" and requesting single measles, mumps, and rubella vaccines. In the midst of the controversy, in August 1998, the British government took an extraordinary step. It made separate measles, mumps, and rubella vaccine components *unavailable*,¹⁰ thereby forcing the hand of concerned parents. At that point, measles vaccination rates among children in the United Kingdom fell significantly. Measles disease outbreaks became more prevalent, and included a handful of cases of serious complications and deaths. Some sought to blame Dr. Wakefield for irresponsibly scaring parents and triggering a public health crisis.¹¹ The British government had a big problem on its hands—one that would soon make its way to the United States.

The controversy surrounding Dr. Wakefield simmered. In February 2004, it reached a boiling point when Dr. Richard Horton, editor of *The Lancet*, held a news conference to declare that the 1998 article was "fatally flawed" because Dr. Wakefield had failed to disclose financial conflicts of interest with the litigation-related study he conducted. British reporter Brian Deer published the story in the *Sunday Times*, detailing alleged undisclosed conflicts of interest. Immediately following publication, Mr. Deer sent a detailed letter to the British General Medical Council (GMC), which regulates the practice of medicine.¹² The GMC then initiated proceedings against Dr. Wakefield that culminated in Dr. Wakefield's delicensure¹³ in May 2010 and the retraction of the 1998 article from *The Lancet*.¹⁴

THE ALLEGATIONS AGAINST DR. WAKEFIELD

The highly publicized, multi-year, multi-million dollar prosecution against Dr. Wakefield alleged that:

- Dr. Wakefield was paid 55,000 British pound sterling (about US \$90,000) by litigators for the study published in *The Lancet*, and he failed to disclose this conflict of interest;
- He and his colleagues performed medically unnecessary tests on the children in the 1998 study and lacked appropriate ethical clearances;
- The children in the 1998 study were selected for litigation purposes (as described in the *Sunday Times* article) and not referred by local physicians; and
- He drew blood from children at his son's birthday party for control samples in the 1998 study with callous disregard for the distress that this might cause children.¹⁵

Based on its findings, the GMC concluded that Dr. Wakefield had engaged in “serious professional misconduct,” and “dishonest,” “misleading,” and “irresponsible” behavior, warranting the sanction of his removal from the medical profession.¹⁶

Let's examine the GMC's charges and the evidence.

Failure to Disclose Payment from Litigators

Dr. Wakefield accepted 55,000 pounds to conduct a study for the class action suit regarding vaccines and autism. This was a research grant from which Dr. Wakefield personally received no compensation. Dr. Wakefield did not start this study until after the case series for the Lancet 12 had been submitted. Legal documents prove that Dr. Wakefield's hospital knew about this study and knew about the amount of money he received, most of which went to pay the salary of a designated laboratory technician. Documents further demonstrate that Dr. Wakefield disclosed in a national newspaper over one year before publication of the 1998 article that he was working with the litigators.¹⁷ Dr. Horton, editor of *The Lancet*, had been informed and should have been well aware of Dr. Wakefield's role in the vaccine-related litigation before the publication of the 1998 article.¹⁸

“Medical Necessity” and Ethical Clearances

The Lancet 12 were sick. Each child was administered tests with the intent to aid that child. The hospital administration was fully aware of the tests being conducted and made no objections. Because all of the tests were “clinically indicated” and not for research purposes, no ethical clearance beyond what Prof. Walker-Smith already possessed was required. Notably, no patient, parent, or guardian has ever made accusations against Dr. Wakefield or testified against him for ethical violations or medically unnecessary procedures. Dr. Wakefield and his colleagues reject the GMC’s ruling that the tests for the Lancet 12 were unnecessary.

The Lancet 12's Referrals

The GMC charged that the children were referred through the litigation effort and not through ordinary medical channels. This is incorrect. Parents started contacting Dr. Wakefield long before the litigation started, and independently of it. Since the litigation study was not yet started by the time *The Lancet* study was completed and submitted to the journal, this finding is false. Dr. Wakefield and his colleagues reject that claim; the families contacted them directly because of their medical expertise.¹⁹

Control Blood Samples from a Child's Birthday Party

Dr. Wakefield arranged for control blood samples from healthy, typically developing children to be taken at his son's birthday party. Most of the children's parents were medical colleagues and friends. He did this with the children's and parents' fully informed consent and gave the children 5 pounds each for their trouble. The procedure was undertaken by an appropriately qualified doctor using a standard technique. The children were happy to be helpful and went on to enjoy the birthday party. While this is admittedly an unconventional method of collecting control blood samples, it hardly amounts to "serious professional misconduct" or an ethical breach warranting delicensure. The GMC's description of this incident as an example of "callous disregard" for children's distress seems to be a gross exaggeration.²⁰



The GMC failed to prove its case against Dr. Wakefield. Using Brian Deer's reporting as evidence, the GMC appears to have purposefully conflated the Lancet 12 study and the subsequent litigation study to create the appearance of a financial conflict of interest.²¹ Similarly, the GMC appears to have wrongfully applied ethical research standards to tests that were "clinically indicated" for severely ill children.²² Conflating treatment and research not only grievously harmed Dr. Wakefield and his colleagues, but set a threatening precedent for the practice of medicine. The government's medical regulators (of uncertain expertise) second-guessed Prof. Walker-Smith, the world's preeminent authority on pediatric gastroenterology, on his clinical judgment about what tests were necessary.²³ Which medical decisions will regulators second-guess next?

The press, and specifically reporter Brian Deer, tried Dr. Wakefield in the court of public opinion while the GMC was prosecuting him in its regulatory court. Deer alleged that Dr. Wakefield had a pending patent application for a separate measles vaccine and hoped to "cash in" by urging parents to forego the MMR for separate measles vaccines. The evidence proves that Dr. Wakefield was not a patent holder for a separate measles vaccine. St. Mary's Hospital held a patent for a *therapeutic* single measles vaccine using the beneficial immune properties of transfer factor, intended for people already infected with the measles virus. This measles vaccine was not a preventive product for people unexposed to the virus; in other words, there was no possible financial competition between the MMR vaccine and the single measles vaccine for which the hospital, and not Dr. Wakefield, held a patent.²⁴

In 2009, Deer made additional allegations that Dr. Wakefield fabricated data.²⁵ The GMC never made this charge, but the media picked it up and, notably, the U.S. Department of Justice used it frequently in the Omnibus Autism Proceeding in the U.S. Court of Federal Claims. In those proceedings to determine whether families could receive compensation for MMR-induced autism, the US Department of Justice went out of its way to depict Dr. Wakefield as a scientific fraud, although he was not directly relevant to the proceedings.²⁶ In his 2010 book, *Callous Disregard*, Dr. Wakefield shows Deer's allegations of fraud to be fabrications.²⁷

CPR finds no evidence of Dr. Wakefield's scientific fraud. On the contrary, many scientists and laboratories around the world have confirmed Dr. Wakefield's findings regarding severe gastrointestinal inflammation and symptoms in a high percentage of children with autism.²⁸

In its February 2, 2010 retraction, *The Lancet* did not allege fraud.²⁹ Relying solely on the

GMC proceeding, it retracted the article, asserting that the authors had not referred the patients as represented and the study team had not received the hospital's ethics committee's approval. The GMC's conclusions and *The Lancet's* reliance on them appear unfounded.

THE MEANING OF THE WAKEFIELD PROSECUTION

What, then, was this high-profile prosecution really about? If there was no scientific fraud, no undisclosed financial conflicts of interest, no ethical breaches in performing tests on sick children, and no complaints from patients or their families, then what was the big deal? Did the international scandal and multi-million dollar prosecution proceed merely to chastise a doctor for drawing blood from children at a birthday party, with their consent and their parents' consent? Of course not.

Dr. Wakefield was, and remains, a dissident from medical orthodoxy. The medical establishment subjected him to a modern-day medical show trial for his dissent.³⁰ Dr. Wakefield's research raised fundamental doubts about the safety of vaccines and the etiology of autism. Dr. Wakefield was punished for his temerity to caution the public about vaccine risks and to urge them to use their own judgment. *Dr. Wakefield was punished for upholding vaccination choice.*

The purpose of the proceeding, as in any show trial, was to communicate to other doctors and scientists, and to the public, the error of the perpetrator's ways. A show trial offers a veneer of due process but, at its core, displays naked power. The apparent intent of the prosecution was to intimidate others from following Dr. Wakefield's footsteps and to teach the lesson that anyone in the medical or scientific community who dares to publicly question the safety and efficacy of vaccines will be punished with utmost severity. The GMC appears to have decided that if the price of such a lesson was scientific ignorance about vaccine-autism links and the suffering of severely ill children, then so be it. Dr. Wakefield was made an example.

The GMC destroyed Dr. Wakefield's professional reputation and livelihood, and *The Lancet* and other publications confiscated his professional accomplishment through retraction. The GMC colluded with *The Lancet*, the media, the British Department of Health, the pharmaceutical industry, and even with the U.S. Department of Health and Human Services and the U.S. Department of Justice, to discredit Dr. Wakefield.

The Center for Personal Rights is confident that the world will look back at the prosecution of Drs. Wakefield, Walker-Smith, and Murch with shame and remorse.

Dr. Wakefield has joined in a long, honorable tradition of dissidents in science and human rights. The world has benefitted profoundly from other courageous dissidents in science—Galileo, who argued that the sun is the center of the universe; Semmelweis, who reasoned that doctors must wash their hands to prevent transmission of infection; Needleman, who proved that lead exposure causes neurological damage in developing children; and McBride, who demonstrated that thalidomide caused birth defects.³¹ As Thomas Kuhn explained, changing scientific paradigms is a revolutionary process, with the wrenching upheaval that revolution brings.³²

In due course, the world has paid tribute to human rights dissidents, as well—Nelson Mandela moved from prison in South Africa under apartheid to become its most beloved President; Andrei Sakharov left Russia's internal exile to become its moral beacon; Vaclav Havel left a Czech prison to become its first post-communist President; and Liu Xiabo, a Chinese human rights advocate, received the 2010 Nobel Peace Prize in absentia because he remains incarcerated. In time, China will embrace Mr. Liu and look to him to help create a better future.

Before long, the world will likely recognize that it was Dr. Wakefield, not his detractors, who stood up for the practice of medicine and the pursuit of science. Dr. Wakefield remains an unbowed dissident in the face of a repressive medical and scientific establishment. He continues to lead autism research. He now directs the Strategic Autism Initiative whose mission is to explore the biological causes of autism. We include as an appendix to this chapter his statement regarding the GMC sanctions. This book also includes his scientific work in chapter 7 (An Urgent Call for More Research on Science) and his perspectives in chapter 26 (The Suppression of Science). The Center for Personal Rights is proud to be associated with Dr. Wakefield and to present his views.

Chapter Twenty-Six

THE SUPPRESSION OF SCIENCE

Andrew Wakefield, MB, BS, FRCS, FRCPath

I believe that we are coming to the end of a very dark time in the relatively short but dramatic history of autism. That we are in a time of rapid and dramatic change is clearly evident. Earlier denial of the epidemic in the United States and the United Kingdom is giving way to the reality of a pandemic throughout the developed world and the exclusive genetic model of autism is yielding to realization of an environmentallydriven catastrophe. The rejection of a parent's insights by many in the medical system and the prejudice against children through exclusive insurance coverage, medical ignorance, and refusal to honor parental vaccination choices is driving a grassroots revolution.

The medical system—rooted in a profound ignorance of this disorder, yet unwilling to take the clues that parents' narratives and appropriate investigation of affected children have to offer—has failed you, for which I am ashamed. Science has failed parents and children alike, with investment in poor and corrupted population studies reminiscent of the “tobacco is good for you” pseudoscience of the 1950s and 1960s. Inevitably, however, that failure is being exposed: the corruption, the collusion of influence, and the rife and undisclosed conflicts of interest are floating to the surface.

We also have had to deal, inevitably, with a systematic and ruthless attack on the science that is indicative of a vaccine-autism link, in the form of an expensive, deceitful, and ultimately futile public relations campaign intended to protect policy and profit. Unfortunately, this has been at the expense of children.

As explained so clearly by Brian Martin, Professor of Social Sciences in Woolongon, Australia, supporters of dominant scientific theories—in this case, the inviolable status of the vaccine program—sometimes attack competing, less favored theories in ways that conflict with expectations of proper scientific behavior.¹ To reduce concern about their actions, supporters of the dominant theory can—as they do in the case of the vaccine-autism debate—use a variety of techniques:

- Cover up the violation of expectations;
- Devalue the competing theory and its advocates;
- Interpret their own process as proper;
- Use expert panels, meetings, and other formal processes to give a stamp of approval to the

- dominant view; and
- Intimidate opponents.

All of these methods, and more, are used regularly by perpetrators of actions widely seen as unjust. The ability to exploit these methods is enhanced by seemingly limitless resources, which is vastly disproportionate to the ability and financial resources of those concerned about vaccine safety and vaccination choice.

The media is an obvious and favored conduit through which supporters of orthodoxy have a tactical advantage over challengers. Various, journalists are “educated” in-house by the Centers for Diseases Control and Prevention (CDC), recruited and paid, lazy, or just plain ignorant of the facts. For those journalists who have been sympathetic to parental and medical concerns, the consequences have been open criticism, intimidation, and dismissal. Mainstream media outlets not only are frequently dependent upon advertising revenues and share board members with Big Pharma companies, but also are very susceptible to the threat that “if you give any credibility to this theory and children die as a consequence, you will be to blame.” When these methods fail, however—as they most certainly will—the attack can backfire on the attackers.

Social media, on the other hand, is an Achilles’ heel in the ability of orthodoxy to sustain the big, hungry lie. It is also the device through which the backfire is being felt by an increasingly desperate and disconsolate system.

Turning specifically to my own experience in the arena of MMR vaccine and autism, what has happened to me and my colleagues in the United Kingdom is intended as a lesson, as Voltaire observed, “to encourage the others.”

When investigated diligently and appropriately, the twelve *Lancet* children featured in the humble 1998 case series, and thousands who came after them, turned out to have intestinal inflammation, and there are reasons to believe that this inflammation may, in turn, be linked to their neurological disorder. Thus, the paper captured the essential elements of a new disease syndrome—a potentially treatable syndrome—and that should have been cause for some small celebration. Had the children’s regression followed natural chickenpox, the response would have been very different. It didn’t. For nine children, behavioral changes and subsequent developmental regression followed exposure to the MMR vaccine; and thereby hangs my own tale.

Those potentially responsible for the catastrophe had a problem, however. The 1998 *Lancet* paper that ignited the fuse of the autism-vaccine wars had to be extinguished in florid, repetitious sound bites delivered through a media sometimes conflicted by corporate cross-pollination, compromised by dependence on advertising revenues, and assisted by pharmaceutical special interest groups.

In an act of editorial genocide, there has been a ruthless effort to expunge these children and their disease from the scientific record.

In 1998, I recommended that children continue to be protected against serious infectious diseases by vaccination, but that single vaccines were my preferred option. I urged that parents be given the choice of how to protect their children. Why? Because as part of the process of due diligence, I researched the safety studies of the combination MMR vaccine and came to the conclusion that they were inadequate. Others have since come to this same conclusion.

In the fall of 1998, six months after *The Lancet* paper was published, choice in the United Kingdom was denied to parents when the government removed the license for the importation of the single measles vaccine. Let me state that again. At a time when demand for single vaccines was at its highest and parents were choosing to continue vaccinating against measles, mumps, and rubella with the single vaccines, choice was removed. When I asked a senior member of the United Kingdom's equivalent of the CDC why, she said that allowing parents to choose single vaccines would destroy their established MMR program. Nevertheless, removing the choice between the triple vaccine and single vaccines did not have the effect they intended—parents chose not to vaccinate against MMR rather than to use the triple vaccine, and MMR vaccination rates fell in the United Kingdom. The regulators chose to protect policy above children.

The more I looked, the more concerned I became. I found a government whistleblower, evidence of a secret deal between the government and pharma, the licensing of a dangerous MMR vaccine, collusion, lies, and cover-up; all are now revealed in *Callous Disregard: Autism and Vaccines—The Truth Behind a Tragedy*. And this is just the beginning. I am not alone; what befell me also befell my friend and colleague Arthur Krigsman, a U.S. gastroenterologist who has devoted his career to helping heal children with autism. His story also will be told.

Choice involves informed consent. Informed consent is a crucial element of the foundation upon which ethical medical practice rests. Providing parents with an honest assessment of the risks and benefits of any medical procedure allows them to make an informed choice. The process requires the physician to be, to the best of his or her ability, informed. My research revealed that there is no information available on the medium- to long-term health outcomes in vaccinated versus unvaccinated children. As an example of this, the U.K. government introduced and received cursory twenty-one-day follow-up “safety” data on two dangerous MMR vaccines that caused meningitis that, in the majority of cases, didn't even start until after twenty-one days.² They knew this. They missed the signal and it was four years later—four years too late—that this dangerous vaccine that should never have been licensed was withdrawn.

Those who are a threat to public confidence, who do not mandate a “safety first” agenda, who deny choice, are the greatest threat to the vaccine program; they are the ones who are ultimately anti-vaccine. Where do the regulators and the vaccine industry stand in 2011 with their coercive vaccination mandates, their costly public relations programs, their ruthless, pragmatic exorcism of dissent, and their public confidence rating? A recent study from University of Michigan shows that one in four parents think vaccines cause autism³ and fifty-four percent of parents are worried about serious adverse effects caused by vaccines. The Harris Interactive survey⁴ conducted just three months later suggests that vaccine safety, parental rights, and vaccination choice are mainstream parental concerns. The regulators and vaccine industry have failed.

The latest initiative: the American Academy of Pediatrics' industry-sponsored Protect Tomorrow campaign is being thrust into our faces and claims to “[bring] to life the memories of the terrible diseases of the past.” It is a campaign rooted in fear. The campaign is a measure of the failure of its architects, rather than the success of their policies.

To parents I would say, trust your instincts above all else. When considering how to vaccinate your children, read, get educated, and demand fully informed consent and answers to your questions. When you are stonewalled or these answers are not to your satisfaction, trust your instinct. I say this as someone who has studied and engaged in the science and who has become aware of the limitations of our knowledge and understanding of vaccine safety issues. Maternal

instinct, in contrast, has been a steady hand upon the tiller of evolution; we would not be here without it. As the Buddha said, “Believe nothing, no matter where you read it, or who said it, unless your own reason and your own common sense agree.”

To the vaccine industry, regulators, public health officials and doctors, pediatricians, and Bill and Melinda Gates, I would say this: the success of vaccination programs requires the willing participation of consumers. The key to any success, therefore, is public confidence in the scientists, doctors, and policy makers—including the pharmaceutical industry—that shape these programs. In turn, the key to that confidence is a safety first vaccine agenda. Those whose priority is safety first are not anti-vaccine. By analogy, those who ordered the recall of multiple Toyota brands for sticking gas pedals are not anti-car.

Callous Disregard might have been the log of a doomed captain written in the cabin of a war-torn frigate, tacking on shredded sails, running from another—perhaps final—broadside; but it is not. It was written from the bridge, the helm secure, the wind at our backs, and the sails full as the aggressor slips back below an uncertain horizon. The day will belong to Reason. Vaccination choice is a human right.

There will be victory of a sort, and it will be a victory from the bottom up. In the true spirit of the U.S. Constitution, the people will have their say—vaccination choice is a human right. The victory will not come from the top down because a phalanx of lobbyists, “experts,” and true believers stands between the President and the people he is sworn to serve. In your commitment to achieving this victory, remember: “Every man is guilty of all the good he did not do.”

AFTERWORD

MOVING FROM WORDS TO ACTION

Let us not mince words: the right to vaccination choice is at extreme risk in this country. It already exists more in theory than in practice. But now the American Academy of Pediatrics and its spokespeople are suggesting the abolition of philosophical and religious exemption rights. They have a lot of influential support behind them—the pharmaceutical industry, public health, government, and media.

We are in a crisis. You can expect more federally recommended vaccines to be added to the schedule; more mandated vaccines for day care, school, and employment; more vaccines of unproven safety to reach the market; more efforts by industry and government to deny adverse events; more efforts to dismiss liability for vaccine injury; more infectious disease scares on the H1N1 swine flu model; more vaccine-induced injuries and death; and more strenuous efforts to abolish your right to vaccination choice. These are the trends that have been well-established since compulsory vaccination began and that have been accelerating since the 1990s. Unless we change course, these projections will likely become reality.

If you care about your right to make individual vaccination decisions, there is a lot of work to do. The Center for Personal Rights has started a petition, “The Chicago Principles on Vaccination Choice,” (appendix B). The petition articulates five basic principles that follow from this book:

1. The human right to vaccination choice;
2. The right to non-discrimination based on vaccination status;
3. The right to complete disclosure of vaccination risks;
4. A safety first agenda for national vaccine policy; and
5. Zero tolerance for actual or perceived conflicts of interest in national vaccine policy.

CPR has also called for the following immediate actions in the United States:

1. The philosophical exemption to vaccination in every state;
2. Congressional oversight hearings on the national vaccine program;
3. A prospective study of vaccinated versus unvaccinated populations for long-term health outcomes;
4. Amendment of the 1986 National Childhood Vaccine Injury Act to reintroduce ordinary tort liability for vaccine manufacturers and medical professionals; and
5. Dissolution of the Vaccine Injury Compensation Program as currently constituted.

Things You Can Do Now

If you care about this issue, here's what you can do.

1. Take a Stand.

After reading the Chicago Principles on Vaccination Choice and the Calls for Immediate Action in the United States, sign the petition supporting vaccination choice at www.centerforpersonalrights.org. Send the link to your friends and ask them to sign too.

2. Stay Informed.

Join our mailing list for news updates relating to personal rights and vaccination choice.

3. Reach Out.

Talk to a friend about this book. Give a copy to your pediatrician, legislator, or colleague. Recommend the book for reading lists in ethics, law, philosophy, history of science, public health, and other classes. Use the Public Discussion Presentation (see appendix) to hold your own meetings. Contact CPR and make arrangements for one of the authors to speak at your church, college, support group, or Parent Teacher Association.

4. Donate.

Give what you can. Make a financial contribution or volunteer your time to raise public awareness about the need for vaccination choice. The majority of American parents support vaccination choice—they just don't yet know that they are the majority. Learn more at www.centerforpersonalrights.org.

Join with the Center for Personal Rights to protect the human right to vaccination choice. This is an idea whose time has come.

ACKNOWLEDGEMENTS

CPR extends our deepest appreciation to the contributing authors. They are an extraordinary group—generous, courageous, and dedicated—and the book would not have been possible without them. We are especially indebted to Ed & Teri Arranga, Maureen Drummond, Jennifer VanDerHorst-Larson & David Larson, Barbara Mullarkey, and F. Edward Yazbak, MD, FAAP. We gratefully acknowledge many others who donated their expertise, time, and resources to support CPR:

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From Louise: I am grateful to my brave and devoted parents. I owe a deep debt to my in-laws who saw us through. I acknowledge friends, mentors, and colleagues in the trenches. Above all, this is for R, I, and N, with my love.

From Mary: To A, with love and appreciation. I thank many guides who have led the way and my parents for their steadfast love and support.

From Kim: To H, my inspiration for this work, and C, for all of their love, support, and tolerance. To my family and in-laws for always being there. To all those along this journey who have inspired, shared, and supported me, I am grateful for each of you.

From Ginger: To C, with all my devotion. I am grateful to God for blessing me with such a loving husband, such wonderful sons, and parents who would not let us fall in times of difficulty. To all who have given of themselves to support us on our journey, you have my undying gratitude.

APPENDIX A: SUPPORTING DOCUMENTS

i. Chapter Seven:

An Urgent Call for More Research
Abstracts from Underlying Studies

ii. Chapter Twelve:

Pediatrics: Sick is the New Healthy
Letter from Francis Moore, MD, to Judy Converse

iii. Chapter Fifteen:

Who Will Defend the Defenders?
Excerpts from Captain Rovet's Report on Anthrax Vaccine Injury

iv. Chapter Eighteen:

Government and the Media
Research Supporting the Vaccine-Autism Causation Theory

v. Chapter Twenty-Four:

What Should Parents Do?
Counting Vaccine Doses and Combination Vaccines

vi. Chapter Twenty-Five:

Who Is Dr. Andrew Wakefield?
Statement from Dr. Andrew Wakefield Regarding
the GMC Hearing Sanctions

APPENDIX TO CHAPTER SEVEN: AN URGENT CALL FOR MORE RESEARCH

Abstracts from Underlying Scientific Studies

Acta Neurobiol Exp (Wars). 2010;70(2):165-76.

SORTING OUT THE SPINNING OF AUTISM: HEAVY METALS AND THE QUESTION OF INCIDENCE

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ABSTRACT

The reasons for the rise in autism prevalence are a subject of heated professional debate. Featuring a critical appraisal of some research used to question whether rising levels of autism are related to environmental exposure to toxins (Soden et al. 2007, Barbaresi et al. 2009, Thompson et al. 2007) we aim to evaluate the actual state of scientific knowledge. In addition, we surveyed the empirical research on the topic of autism and heavy metal toxins. In our opinion empirical investigations are finding support for a link with heavy metal toxins. The various causes that have led to the increase in autism diagnosis are likely multi-faceted, and understanding the causes is one of the most important health topics today. We argue that scientific research does not support rejecting the link between the neurodevelopmental disorder of autism and toxic exposures.

PMID: 20628440 [PubMed - in process]

J Toxicol Environ Health A. 2010 Jan;73 (24):1665-77.

**HEPATITIS B VACCINATION OF MALE NEONATES AND
AUTISM DIAGNOSIS, NHIS 1997-2002.**

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ABSTRACT

Universal hepatitis B vaccination was recommended for U.S. newborns in 1991; however, safety findings are mixed. The association between hepatitis B vaccination of male neonates and parental report of autism diagnosis was determined. This cross-sectional study used weighted probability samples obtained from National Health Interview Survey 1997-2002 data sets. Vaccination status was determined from the vaccination record. Logistic regression was used to estimate the odds for autism diagnosis associated with neonatal hepatitis B vaccination among boys age 3-17 years, born before 1999, adjusted for race, maternal education, and two-parent household. Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life. Non-Hispanic white boys were 64% less likely to have autism diagnosis relative to non white boys. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk.

PMID: 21058170 [PubMed - in process]

Acta Neurobiol Exp (Wars). 2010;70(2):147-64.

**INFLUENCE OF PEDIATRIC VACCINES ON AMYGDALA
GROWTH AND OPIOID LIGAND BINDING IN RHESUS
MACAQUE INFANTS: A PILOT STUDY.**

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ABSTRACT

This longitudinal, case-control pilot study examined amygdala growth in rhesus macaque infants receiving the complete US childhood vaccine schedule (1994-1999). Longitudinal structural and functional neuroimaging was undertaken to examine central effects of the vaccine regimen on the developing brain. Vaccine-exposed and saline-injected control infants underwent MRI and PET imaging at approximately 4 and 6 months of age, representing two specific timeframes within the vaccination schedule. Volumetric analyses showed that exposed animals did not undergo the maturational changes over time in amygdala volume that was observed in unexposed animals. After controlling for left amygdala volume, the binding of the opioid antagonist [(11)C]diprenorphine (DPN) in exposed animals remained relatively constant over time, compared with unexposed animals, in which a significant decrease in [(11)C]DPN binding occurred. These results suggest that maturational changes in amygdala volume and the binding capacity of [(11) C]DPN in the amygdala was significantly altered in infant macaques receiving the vaccine schedule. The macaque infant is a relevant animal model in which to investigate specific environmental exposures and structural/functional neuroimaging during neurodevelopment.

PMID: 20628439 [PubMed - in process]

J Toxicol Environ Health A. 2010 Jan;73(19):1298-313.

**DELAYED ACQUISITION OF NEONATAL REFLEXES IN
NEWBORN PRIMATES RECEIVING A THIMEROSAL-
CONTAINING HEPATITIS B VACCINE: INFLUENCE OF
GESTATIONAL AGE AND BIRTH WEIGHT**

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ABSTRACT

This study examined whether acquisition of neonatal reflexes in newborn rhesus macaques was influenced by receipt of a single neonatal dose of hepatitis B vaccine containing the preservative thimerosal (Th). Hepatitis B vaccine containing a weight-adjusted Th dose was administered to male macaques within 24 h of birth (n = 13). Unexposed animals received saline placebo (n = 4) or no injection (n = 3). Infants were tested daily for acquisition of nine survival, motor, and sensorimotor reflexes. In exposed animals there was a significant delay in the acquisition of root, snout, and suck reflexes, compared with unexposed animals. No neonatal responses were significantly delayed in unexposed animals. Gestational age (GA) and birth weight (BW) were not significantly correlated. Cox regression models were used to evaluate main effects and interactions of exposure with BW and GA as independent predictors and time-invariant covariates. Significant main effects remained for exposure on root and suck when controlling for GA and BW, such that exposed animals were relatively delayed in time-to-criterion. Interaction models indicated there were various interactions between exposure, GA, and BW and that inclusion of the relevant interaction terms significantly improved model fit. This, in turn, indicated that lower BW and/or lower GA exacerbated the adverse effects following vaccine exposure. This primate model provides a possible means of assessing adverse neurodevelopmental outcomes from neonatal Th-containing hepatitis B vaccine exposure, particularly in infants of lower GA or BW. The mechanisms underlying these effects and the requirements for Th requires further study.

PMID: 20711932 [PubMed - indexed for MEDLINE]

Neurotoxicology. 2009 May;30(3):331-7. Epub 2009 Mar 21.

**OCKHAM'S RAZOR AND AUTISM: THE CASE FOR
DEVELOPMENTAL NEUROTOXINS CONTRIBUTING TO A
DISEASE OF NEURODEVELOPMENT**

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ABSTRACT

Much professional awareness regarding environmental triggers for ASD has been narrowly focused on a single possible exposure pathway (vaccines). Meanwhile, empirical support for environmental toxins as a broad class has been quietly accumulating. Recent research has shown that persons with ASD have comparatively higher levels of various toxins and are more likely to have reduced detoxifying ability, and, that rates of ASD may be higher in areas with greater pollution. This report documents that within the state with the highest rate of ASD, the rate is higher for schools near EPA Superfund sites, $t(332)=3.84$, $p=.0001$. The reasons for the rise in diagnoses likely involve genetically predisposed individuals being exposed to various environmental triggers at higher rates than in past generations.

Health & Place, 2009 15(1) 18-24

**PROXIMITY TO POINT SOURCES OF ENVIRONMENTAL
MERCURY RELEASE AS A PREDICTOR OF AUTISM
PREVALENCE**

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ABSTRACT

The objective of this study was to determine if proximity to sources of mercury pollution in 1998 were related to autism prevalence in 2002. Autism count data from the Texas Educational Agency and environmental mercury release data from the Environmental Protection Agency were used. We found that for every 1000 pounds of industrial release, there was a corresponding 2.6% increase in autism rates ($p < .05$) and a 3.7% increase associated with power plant emissions ($P < .05$). Distances to these sources were independent predictors after adjustment for relevant covariates. For every 10 miles from industrial or power plant sources, there was an associated decreased autism Incident Risk of 2.0% and 1.4%, respectively ($p < .05$). While design limitations preclude interpretation of individual risk, further investigations of environmental risks to child development issues are warranted.

Toxicological & Environmental Chemistry, 1029-0486, Volume 90, Issue 5, 2008, Pages 997–1008

HEPATITIS B TRIPLE SERIES VACCINE AND DEVELOPMENTAL DISABILITY IN U.S. CHILDREN AGED 1–9 YEARS

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This study investigated the association between vaccination with the Hepatitis B triple series vaccine prior to 2000 and developmental disability in children aged 1–9 years (n¼1824), proxied by parental report that their child receives early intervention or special education services (EIS). National Health and Nutrition Examination Survey 1999– 2000 data were analyzed and adjusted for survey design by Taylor Linearization using SAS version 9.1 software, with SAS callable SUDAAN version 9.0.1. The odds of receiving EIS were approximately nine times as great for vaccinated boys (n¼46) as for unvaccinated boys (n¼7), after adjustment for confounders. This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys.

J Allergy Clin Immunol. 2008 Mar;121(3):626-31. Epub 2008 Jan 18.

**DELAY IN DIPHTHERIA, PERTUSSIS, TETANUS VACCINATION
IS ASSOCIATED WITH A REDUCED RISK OF CHILDHOOD
ASTHMA**

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ABSTRACT

BACKGROUND: Early childhood immunizations have been viewed as promoters of asthma development by stimulating a T(H)2-type immune response or decreasing microbial pressure, which shifts the balance between T(H)1 and T(H)2 immunity.

OBJECTIVE: Differing time schedules for childhood immunizations may explain the discrepant findings of an association with asthma reported in observational studies. This research was undertaken to determine whether timing of diphtheria, pertussis, tetanus (DPT) immunization has an effect on the development of childhood asthma by age 7 years.

METHODS: This was a retrospective longitudinal study of a cohort of children born in Manitoba in 1995. The complete immunization and healthcare records of cohort children from birth until age 7 years were available for analysis. The adjusted odds ratio for asthma at age 7 years according to timing of DPT immunization was computed from multivariable logistic regression.

RESULTS: Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months. The likelihood of asthma in children with delays in all 3 doses was 0.39 (95% CI, 0.18-0.86).

CONCLUSION: We found a negative association between delay in administration of the first dose of whole-cell DPT immunization in childhood and the development of asthma; the association was greater with delays in all of the first 3 doses. The mechanism for this phenomenon requires further research.

PMID: 18207561 [PubMed - indexed for MEDLINE]

Pediatrics. 2008 Jul;122(1):149-53.

PROTECTING PUBLIC TRUST IN IMMUNIZATION

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ABSTRACT

Public trust in the safety and efficacy of vaccines is one key to the remarkable success of immunization programs within the United States and globally. Allegations of harm from vaccination have raised parental, political, and clinical anxiety to a level that now threatens the ability of children to receive timely, full immunization. Multiple factors have contributed to current concerns, including the interdependent issues of an evolving communications environment and shortfalls in structure and resources that constrain research on immunization safety (immunization-safety science). Prompt attention by public health leadership to spreading concern about the safety of immunization is essential for protecting deserved public trust in immunization.

PMID: 18595998 [PubMed - indexed for MEDLINE]

Environ Health Perspect. 2007 May;115(5):792-8. Epub 2007 Jan 4.

ORGANOPHOSPHATE PESTICIDE EXPOSURE AND NEURODEVELOPMENT IN YOUNG MEXICAN-AMERICAN CHILDREN

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ABSTRACT

BACKGROUND: Organophosphate (OP) pesticides are widely used in agriculture and homes. Animal studies suggest that even moderate doses are neurodevelopmental toxicants, but there are few studies in humans.

OBJECTIVES: We investigated the relationship of prenatal and child OP urinary metabolite levels with children's neurodevelopment.

METHODS: Participating children were from a longitudinal birth cohort of primarily Latino farm-worker families in California. We measured six nonspecific dialkylphosphate (DAP) metabolites in maternal and child urine as well as metabolites specific to malathion (MDA) and chlorpyrifos (TCPy) in maternal urine. We examined their association with children's performance at 6 (n = 396), 12 (n = 395), and 24 (n = 372) months of age on the Bayley Scales of Infant Development [Mental Development (MDI) and Psychomotor Development (PDI) Indices] and mother's report on the Child Behavior Checklist (CBCL) (n = 356).

RESULTS: Generally, pregnancy DAP levels were negatively associated with MDI, but child measures were positively associated. At 24 months of age, these associations reached statistical significance [per 10-fold increase in prenatal DAPs: beta = -3.5 points; 95% confidence interval (CI), -6.6 to -0.5; child DAPs: beta = 2.4 points; 95% CI, 0.5 to 4.2]. Neither prenatal nor child DAPs were associated with PDI or CBCL attention problems, but both prenatal and postnatal DAPs were associated with risk of pervasive developmental disorder [per 10-fold increase in prenatal DAPs: odds ratio (OR) = 2.3, p = 0.05; child DAPs OR = 1.7, p = 0.04]. MDA and TCPy were not associated with any outcome.

CONCLUSIONS: We report adverse associations of prenatal DAPs with mental development and pervasive developmental problems at 24 months of age. Results should be interpreted with caution given the observed positive relationship with postnatal DAPs.

**HIGH SUSCEPTIBILITY OF NEURAL STEM CELLS TO
METHYLMERCURY TOXICITY: EFFECTS ON CELL SURVIVAL
AND NEURONAL DIFFERENTIATION**

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ABSTRACT

Neural stem cells (NSCs) play an essential role in both the developing embryonic nervous system through to adulthood where the capacity for self-renewal may be important for normal function of the CNS, such as in learning, memory and response to injury. There has been much excitement about the possibility of transplantation of NSCs to replace damaged or lost neurones, or by recruitment of endogenous precursors. However, before the full potential of NSCs can be realized, it is essential to understand the physiological pathways that control their proliferation and differentiation, as well as the influence of extrinsic factors on these processes. In the present study we used the NSC line C17.2 and primary embryonic cortical NSCs (cNSCs) to investigate the effects of the environmental contaminant methylmercury (MeHg) on survival and differentiation of NSCs. The results show that NSCs, in particular cNSCs, are highly sensitive to MeHg. MeHg induced apoptosis in both models via Bax activation, cytochrome c translocation, and caspase and calpain activation. Remarkably, exposure to MeHg at concentrations comparable to the current developmental exposure (via cord blood) of the general population in many countries inhibited spontaneous neuronal differentiation of NSCs. Our studies also identified the intracellular pathway leading to MeHg-induced apoptosis, and indicate that NSCs are more sensitive than differentiated neurones or glia to MeHg-induced cytotoxicity. The observed effects of MeHg on NSC differentiation offer new perspectives for evaluating the biological significance of MeHg exposure at low levels.

PMID: 16524380 [PubMed - indexed for MEDLINE]

Environ Res. 2004 Jul;95(3):363-74.

**TEMPORAL VARIATION OF BLOOD AND HAIR MERCURY
LEVELS IN PREGNANCY IN RELATION TO FISH
CONSUMPTION HISTORY IN A POPULATION LIVING ALONG
THE ST. LAWRENCE RIVER**

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ABSTRACT

Fish consumption from the Great Lakes and the St. Lawrence River has been decreasing over the last years due to advisories and increased awareness of the presence of several contaminants. Methylmercury (MeHg), a well-established neurotoxicant even at low levels of exposure, bioaccumulates to differing degrees in various fish species and can have serious adverse effects on the development and functioning of the human central nervous system, especially during prenatal exposure. Most studies on MeHg exposure have focussed on high-level consumers from local fish sources, although mercury (Hg) is also present in fresh, frozen, and canned market fish. Moreover, little information exists on the temporal variation of blood and hair Hg in pregnant women, particularly in populations with low levels of Hg. The aim of the present study was to characterize the temporal variation of Hg during pregnancy and to investigate the relation between fish consumption from various sources prior to and during pregnancy and maternal cord blood and mother's hair Hg levels. We recruited 159 pregnant women from Southwest Quebec through two prenatal clinics of the Quebec Public Health System. All women completed two detailed questionnaires concerning their fish consumption (species and frequency) prior to and during pregnancy. The women also provided blood samples for all three trimesters of pregnancy and hair samples after delivery of up to 9 cm in length. Blood and hair Hg levels were analyzed by cold-vapor atomic-absorption and -fluorescence spectrometry methods, respectively. Results showed that maternal blood and hair Hg levels decreased significantly between the second and third trimesters of pregnancy. However, cord blood Hg was significantly higher than maternal blood at birth. Maternal hair was correlated with Hg blood concentration and was highly predictive of the organic fraction in cord blood. A strong dose relation was observed between the frequency of fish consumption before and during pregnancy and Hg exposure in mothers and newborns. Fish consumption prior to and during pregnancy explained 26% and 20% of cord blood Hg variance, respectively. For this population, detailed multivariate analyses showed that during pregnancy market fish (fresh, canned, and frozen) were more important sources of Hg exposure than were fish from the St. Lawrence River. These results should be taken into account for future advisories and intervention strategies, which should consider Hg levels in different species from all sources in order to maximize the nutritional input from fish and minimize the toxic risk.

Environ Health Perspect. 2003 Sep; 111 (12): 1465-70.

**AN ASSESSMENT OF THE CORD BLOOD: MATERNAL BLOOD
METHYLMERCURY RATIO: IMPLICATIONS FOR RISK
ASSESSMENT**

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ABSTRACT

In the current U.S. Environmental Protection Agency reference dose (RfD) for methylmercury, the one-compartment pharmacokinetic model is used to convert fetal cord blood mercury (Hg) concentration to a maternal intake dose. This requires a ratio relating cord blood Hg concentration to maternal blood Hg concentration. No formal analysis of either the central tendency or variability of this ratio has been done. This variability contributes to the overall variability in the dose estimate. A ratio of 1.0 is implicitly used in the model, but an uncertainty factor adjustment is applied to the central tendency estimate of dose to address variability in that estimate. Thus, incorporation of the cord:maternal ratio and its variability into the estimate of intake dose could result in a significant change in the value of the RfD. We analyzed studies providing data on the cord:maternal blood Hg ratio and conducted a Monte Carlo-based meta-analysis of 10 studies meeting all inclusion criteria to generate a comprehensive estimate of the central tendency and variability of the ratio. This analysis results in a recommended central tendency estimate of 1.7, a coefficient of variation of 0.56, and a 95th percentile of 3.4. By analogy to the impact of the similar hair:blood Hg ratio on the overall variability in the dose estimate, incorporation of the cord:maternal ratio may support a 3-fold uncertainty factor adjustment to the central tendency estimate of dose to account for pharmacokinetic variability. Whether the information generated in this analysis is sufficient to warrant a revision to the RfD will depend on the outcome of a comprehensive reanalysis of the entire one-compartment model. We are currently engaged in such an analysis.

PMID: 12948885 [PubMed - indexed for MEDLINE] PMCID: PMC1241648

Vaccine. 1997 Jun;15(8):903-8.

NONHUMAN PRIMATE MODELS TO EVALUATE VACCINE SAFETY AND IMMUNOGENICITY

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ABSTRACT

When considering preclinical studies to evaluate the safety and immunogenicity of putative vaccine candidates, such as nucleic acid vaccines, species most closely related to humans should be considered. Phylogenetically, the great apes (chimpanzees, orangutans, gorillas, and gibbons) are most closely related to humans. However, the great apes, which diverged from humans over 5 million years ago, represent endangered or threatened species that limits their utility in preclinical studies. In addition, cost considerations for using great apes in biomedical studies represents another serious limitation. The Old World monkeys, (macaques, baboons, mandrills, and mangabeys), diverged from humans over 15 million years ago. A number of the Old World monkey species including rhesus, cynomolgus, and African green monkeys, have also been employed in biomedical research to evaluate vaccine safety and immunogenicity. New World monkeys (aotus, owl, cebus monkeys, and marmosets) are the most phylogenetically divergent from humans, yet they have also been utilized to develop nonhuman primate models for a number of human infectious diseases and tumors. The advantages and disadvantages in selecting a particular nonhuman primate species for studies to evaluate DNA vaccine safety and immunogenicity are briefly discussed. Comparative immunology, reproductive physiology, endogenous infectious agents, and cost considerations are briefly described.

PMID: 9234544 [PubMed - indexed for MEDLINE]

APPENDIX TO CHAPTER TWELVE: PEDIATRICS: SICK IS THE NEW HEALTHY

HARVARD MEDICAL SCHOOL DEPARTMENT OF SURGERY

FRANCIS D. MOORE, M. D.
*Moseley Professor of Surgery, Emeritus
Harvard Medical School Emeritus
Surgeon-in-Chief, Emeritus
Peter Bent Brigham Hospital*

*The Countway Library
10 Shattuck Street
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December 2, 1999

Judy Converse, MPH, RD
P.O. Box 992
West Falmouth, MA 02574

Dear Judy:

Thanks for your very full letter and also for your card with the lovely picture of Ben.

I know you had a wonderful time in Honolulu, and I hope that Ben “weathered” it very well.

As regards neonatal active immunization (“vaccination”) as a possible cause of autism, maybe the matter can rest temporarily in its present state.

The point that I am so anxious to emphasize is that the “window of vulnerability” occurs right around the time of birth, and is probably of longer duration in babies that are “slightly premature.”

Very few women make notes of their monthly periods with sufficient accuracy to date the exact time of insemination. Therefore, the exact pregnancy duration of many so-called “full-term” infants may vary over a length of time as much as a month. Stated otherwise, many full-term infants are actually somewhat premature.

The spotty, random, and unpredictable nature of this “random prematurity of full-term infants” may well be involved in the spotty, random, and unpredictable incidence of immunological consequences of neonatal active immunization.

Judy Converse, MPH, RD
December 2, 1999
Page 2.

I am sending a copy of this letter to Dr. Yazbak, because I am very impressed with his knowledge of this field and his interest in the problem.

The only solution that I know for this is the absolute avoidance of neonatal immunization, particularly against hepatitis B, which is a disease of very young children that is of the utmost rarity. To put any child at hazard of autism with the excuse of avoiding this extremely rare disease, is of course preposterous.

Let's keep in touch.

Very truly yours,

A small, square image showing a handwritten signature in black ink on a white background. The signature is cursive and appears to be "F. D. Moore". Above the signature, the words "y yours," are printed in a small, sans-serif font.

Francis D. Moore, M.D.

FDM:sml

cc: F. Edward Yazbak, M.D., F.A.A.P.

APPENDIX TO CHAPTER FIFTEEN: WHO WILL DEFEND THE DEFENDERS?

Excerpts from Richard Rovet's report on anthrax vaccine injury to his superiors while serving at Dover Air Force Base from 1997 to 1999:

DOVER AFB 1997-1999

“It was clearly delineated in my job description to collect, review, and coordinate information with various healthcare providers and case manage all patients who were on our long-term ill list. This included those who displayed a systemic illness to the anthrax vaccine. I often coordinated care with Walter Reed Army Hospital’s Gulf War Illness Clinic called the Medical Evaluation and Treatment Unit (METU) for our patients who had fallen ill in so called “temporal relation” to anthrax inoculation. I find it disturbing that my medical leadership, at the time, counseled me for inquiring and reporting to them the number of individuals who had systemic reaction to the anthrax vaccine and subsequently seroconverted to display a documented blood marker for autoimmunity.”



“For instance, Patient TSGT D.B. (active duty aircrew member) became ill following anthrax vaccination. He developed myocarditis, (possible autoimmune etiology) cardiac arrhythmia and inflammation around the heart sac. A short time later, patient D.B. had to have his heart shocked out of an arrhythmia. Several days later a clot dislodged from his heart and he suffered a mini stroke. To the best of my knowledge this vital aircrew member was medically boarded never to fly again. This was not an isolated incident.”



“In fact Dover’s Chief of Safety, Colonel J, a C-5 Galaxy pilot, became so ill following vaccination that he reportedly had to turn the flight controls over to the co-pilot and slept on the aircraft’s bunk during a flight over the Atlantic. Another pilot who also was in transient flight over the Atlantic reported a similar problem. His name was Captain ██████ He developed unexplained vertigo (GRAY-OUTS), severe joint aches and pain and rare lesions throughout his internal organs.”



“Another detailed fact concerning a rapid systemic reaction was from an African American Female Staff Sergeant. SSGT W. became extremely ill following anthrax vaccination . . . Several hours later the patient reportedly developed a fever of 104-105 degrees and a large injection site nodule with severe arm soreness. On 25 FEB 1999 the patient deployed to Saudi Arabia. SSGT W. stated that while in transit she experienced severe vertigo (GRAY-OUT) and almost passed out. She reported being very ill for several days. On 6 MAR 1999 SSGT W. reported to the deployment hospital to receive her second vaccination. She related her persistent medical problems since she initially received her first anthrax vaccination to the hospital’s medical officer. According to SSGT W. this individual stated that her illness was in no way related to the anthrax vaccine and the Dover personnel administered the shot improperly. Despite her concern and illness the patient was given her second anthrax vaccination from Lot # FAV 036. SSGT W.’s health steadily declined. Her headaches became worse she developed ringing in her ears, frequent bouts of dizziness, severe joint aches and pain, chronic fatigue and unexplained rashes.

According to the anthrax vaccine package insert SSGT W. was having a purported “rare” systemic reaction to the anthrax vaccine. This precludes further vaccination. Nevertheless after explaining this to the USAF medical professional in Saudi Arabia she was given her third vaccination on 20 MAR 1999 from Lot # FAV 033. When she arrived back at Dover she was once again ordered to continue the series of vaccinations . . . After months of suffering, the patient was sent to Walter Reed Army Hospital where she was diagnosed with an

AUTOIMMUNE ARTHRITIC condition, chronic fatigue and was reportedly told by Colonel ██████ that she had signs and symptoms consistent with Gulf War Illness.”



“On 21 SEP 1999, at approximately 1700 a reserve aircrew member walked into my office in physical distress. He was pale and gaunt and his gross motor ability appeared to be impaired. He was drooling. He appeared drunk, yet was intellectually lucid. He comprehended what I was saying. He stated, “I want someone here to see one of my spells when it’s happening.” I sat him down and began to take his vital signs. I was then about to go to get the flight surgeon when Major ██████ came into the room and demanded that the patient, in acute physical distress, stand to attention when she walked unannounced into my office. The patient, in civilian clothes, whom she never met before, attempted to get up and fell back and hit his head on the wall.”



“Former Senior Airman M.D. developed severe bone and joint pain following vaccination. In addition she was diagnosed with autoimmune optic neuritis which is a condition seen in Multiple Sclerosis (MS).”



“Captain J.R. a versatile and combat tested pilot found it difficult to get out of bed due to arthritic bone and joint pain. His experience with the anthrax vaccine is well documented in congressional record. His post vaccination blood work showed seroconversion to the autoimmune marker, ANA.”



“Lieutenant Colonel Jay Lacklen is a decorated combat pilot who had no pre-existing arthritic symptoms. Post vaccination he developed an autoimmune arthritic condition and displayed a positive blood marker for autoimmunity.”



“Captain Cheryl Angerer, another highly skilled pilot developed numbness and tingling (paresthesias) on one side of her body following anthrax vaccination from the same lot number as others who had fallen ill. Captain Angerer was so incensed at her medical treatment and anthrax vaccine induced illness that she resigned publicly after developing an autoimmune condition. Her post vaccination blood work showed the blood marker for autoimmunity, ANA.”



“TSGT J.M. is a former enlisted aircrew member who is permanently grounded due to a severe autoimmune condition involving severe bone and joint pain, memory loss and unexplained “gray-outs.” His pre-vaccination blood work showed no evidence of autoimmunity while his post vaccination blood work showed positive evidence of autoimmunity.”



“Master Sergeant M.M. developed life threatening autoimmune condition, Gullain-Barré syndrome following vaccination and was placed on a respirator, in Intensive Care for weeks.”



“Master Sergeant (RET) J.K. developed autoimmune diabetes following anthrax vaccination in addition to severely elevated liver and pancreatic enzymes.”



“Master Sergeant J. B. developed severe bone and joint pain following vaccination. His blood

work showed positive evidence of autoimmunity.”



“Major D.D. developed autoimmune optic neuritis following vaccination. He also developed numbness and tingling on one half of his body. He has signs and symptoms consistent with Multiple Sclerosis (MS). To the best of my knowledge he no longer flies.”



“Technical Sergeant Earl Stauffer developed severe dizziness, gray-outs with continued ringing in his ears following vaccination.”



“Former Staff Sergeant James Picconi suffered dizziness, gray-outs and severe heart arrhythmia following vaccination.”



“Technical Sergeant M.M. suffered unexplained seizures and gray-outs, ringing in the ears (tinnitus), dizziness, bone and joint pain following vaccination.”



“Colonel J.M. developed bone and joint pain, chronic fatigue, ringing in the ears and memory loss following vaccination.”



“Staff Sergeant N. P. lost over sixty pounds and developed lesions on his throat and lungs following vaccination.”



“Technical Sergeant B.B. developed severe bone and joint pain following vaccination. He also lost a great deal of weight and developed lesions on his pelvis and ribs.”



“Lieutenant Jamie Martin developed severe bone and joint pain following vaccination. This highly trained pilot refused his third vaccination due to previously encountered illness associated with the anthrax vaccine and was discharged from the service.”



“As stated in her testimony (under oath) Captain Michelle Piel experienced a severe autoimmune reaction following vaccination from lot # FAV 030. A disturbing fact that was not related to Captain Piel prior to her testimony was that her pre-vaccination blood work showed NO evidence of autoimmunity and her post vaccination blood work showed POSITIVE evidence of autoimmunity.

Unbeknownst to this USAF Academy graduate and pilot, Lieutenant Colonel (Dr.) Thomas ██████, on several occasions called her a “malingerer, liar and whiner” in front of his medical staff. Please note that Doctor ██████ was a field grade officer, a commander and the head of the anthrax program at Dover.”



“Another highly qualified pilot from the USAFR at Dover also testified that day (under oath), Captain Jon Richter. He developed autoimmune arthritis following vaccination.”



“There were more individuals within the Reserve Airlift Wing at Dover AFB who received the same lot number of vaccines that also reported severe and sub-clinical unexplained illness and autoimmunity. There were also many more individuals with sub-clinical ailments who were afraid to come forward for fear of reprisal. In the end the problems at Dover were ascribed to: whining pilots, malingerers, children, troublemakers, liars, rumormongers, group-think, stress, psychosomatic maladies and artifact in reporting. Unfortunately this view is the accepted assessment of the anthrax vaccine problems at Dover by our military and civilian leadership as well as a corporate media that has abandoned its obligation to roll up its sleeves and ferret out the truth. In the end something very wrong occurred at Dover.”



“Lt. Gen. Roadman assured everyone the vaccine was completely safe and that only a minute percentage of those military personnel inoculated had had a negative reaction. Meanwhile, I was encountering more of my squadron mates who were vaccinated that said they too had experienced various reactions including tinnitus, dizziness, muscle and joint pain and in one case black-outs. However, most were attempting to keep a low profile and did not readily discuss these matters for fear of reprisal.”



“The National Academy of Sciences’ Institute of Medicine in 2002 conducted a comprehensive review of anthrax vaccine safety and effectiveness. Personnel from Dover Air Force Base contributed to the information gathered for their review. This prestigious group of independent experts concluded that trace amounts of squalene are not associated with an increase in the rates of adverse events and that further investigation of possible contamination is not warranted.”

William Winkenwerder, Jr., MD, MBA
Former Assistant Secretary of Defense Health Affairs
Letter to reporter Lester Holt of MSNBC”



“In Memory

Specialist Rachel Lacy, USAFR, combat medic, died on 4 April 2003 from an autoimmune “lupus-like” illness. She also had diffuse alveolar lung tissue damage and inflammation of the heart sac.

Technical Sergeant Clarence Glover

NCOIC Flight Medicine Clinic Dover AFB, Delaware

TSGT Glover passed away in February 2000 from a “heart condition” following anthrax vaccination.

To the best of my knowledge the autopsy results were not made public.”



Richard Rovet’s letter of complaint concerning his treatment following his reports on the anthrax vaccine adverse reactions:

[REDACTED] RICHARD J. ROVET

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dear Sir or Ma'am:

On 21 July 1999 I delivered protected communication before the now National Security Subcommittee that was investigating anthrax vaccine adverse reactions and the challenges of reporting them. I accepted this obligation freely and without reservation after exhausting all means within my chain-of-command. My protected communication was delivered in accordance with my duty as an officer in the USAF, a medical professional and most importantly as a Christian. It is within that spirit that I will pursue the truth in regards to this important issue. For over five years now I have faced overt and subtle reprisal for delivering my protected communication to the subcommittee. My intentions were to bring to light the illnesses associated with the vaccine and the challenges related to the reporting of these illnesses.

On 3 April 2003, I brought these aforementioned actions, which violate United States Code Military Justice (UCMJ), to the attention of HQ ASC/IG, Wright Patterson Air Force Base Ohio. I was told by the Air Systems Command Inspector General (IG), [REDACTED] that "I shouldn't hang my hat on any resolution to my case" and that I needed to "move on." After months of transferring my complaint through Air Force channels I was finally given an action officer to conduct an investigation addressing my allegations. To my dismay and protestations my case was to be handled by the IG from my former base, the 81st Training Wing, Keesler Air Force Base, Mississippi. This was the very same office that I approached in the spring of 2001 that in turn disclosed my protected communication to them and threatened me to "back off " my complaint and allegations concerning the problems and illnesses associated with the anthrax vaccine. I was told in May of 2001 that Master Sergeant [REDACTED] of 81st TW/IG conveyed this threat through my former Non Commissioned Officer In Charge (NCOIC) of KAFB ER. This occurred during the same time frame that public scrutiny was heightened, once again, concerning

the anthrax vaccine: In the spring of 2001 the trial of the first military physician to refuse the anthrax vaccine was underway at Keesler AFB. Please review the statement provided to me by Master Sergeant [REDACTED].

My interactions with the USAF Inspector General system since 1999 to present indicate an unwillingness to ferret out the truth and protect whistleblowers in accordance with Title 10 United States Code Section 1034, Department of Defense Directive 7050.6 and Air Force Instruction 90-301.

The information contained herein will not focus on the willful reprisal and damage to my career that has occurred since I testified before the subcommittee on 21 July 1999. That evidence will be delivered in a separate report. However, in some instances I will include excerpts from the USAF Inspector General's Reprisal Complaint Analysis (RCA, completed by the 81st TW KAFB) to provide the necessary framework that will illustrate the less-than-forthcoming behavior by some who continue to defend the indefensible.

To this day the light of truth has not penetrated the misinformation and continued patterns of deception that have become the hallmark of the anthrax vaccination program. Unfortunately public, congressional and media scrutiny have yet been able to breach the public affairs barbed wire that surrounds the program since the first Gulf War. Program protection seems to have replaced force protection.

Before proceeding I must make perfectly clear that I do not have an anti-vaccine agenda (my own shot record is a testimony). I also fully support biological countermeasures in this age of asymmetrical combat. As a medic to think otherwise would be akin to negligence. I also fully agree that the anthrax vaccine seems to be well tolerated by the majority of individuals despite the lack of long-term health data and a transparent active surveillance system. Yet, there are those individuals who have been injured by the anthrax vaccine beyond the purported "rare" systemic event. It is either through ignorance or as the General Accounting Office stated "a continued pattern of deception" that this mythology is propagated; propagated by an active Public Affairs (PA) apparatus worthy of a "Bronze Anvil Award."

I fully understand the nature of my allegations and will provide evidence to verify my charges. I further understand that a considerable amount of time has passed. Yet, due to the nature of my allegations and information that I am providing you, I sincerely hope that any investigation will, at a minimum, be unbiased in its approach. I will also provide evidence that senior officials at Dover in 1999 may have provided false information to federal investigators concerning the extent of anthrax vaccine adverse reactions at Dover AFB, Delaware.

I am a veteran of over nineteen years' service to our great country. During the first Gulf War I served stateside as an enlisted aircraft mechanic. After the War I noticed many individuals that were deployed to theater of operation, and some of those who were not in theater, developed unexplained illnesses collectively known as Gulf War Illness. I also worked briefly at the Veterans Administration following the war and further witnessed more "unexplained illnesses" from service during that time frame. In 1997 I was stationed at Dover AFB, Delaware. In the course my tenure at Dover I helped follow-up on ill Gulf War era veterans for the Comprehensive Clinical Evaluation Program (CCEP) in the Tri-State region. Most reported autoimmune illnesses such as: severe arthritic pain, rashes, nervous system damage, numbness and tingling in extremities, excessive fatigue, Multiple Sclerosis, vertigo and "gray-outs," cardiac and gastrointestinal problems. They also complained of problems receiving care, often citing

active duty medical providers who told them that their illnesses were all in their head. Unfortunately this message is still being propagated in military medicine and being reportedly conveyed to new medical providers who enter active service.

In the fall of 1998 I began noticing similar clusters of unexplained illnesses within our healthy and young aircrew population. I had witnessed first hand bizarre symptomatology and illnesses atypical for the population and age group. Strikingly the illness reported were many of the same as were previously reported by Gulf War era veterans seven years earlier. Unfortunately the common denominator was the anthrax vaccine. Equally unfortunate, the patients were treated the same as veterans who had served seven years earlier. It is interesting to note that a recent Veterans Affairs report in fall of 2004 by the esteemed Research Advisory Counsel For Gulf War Veteran Illnesses recognizes sick veterans from the first Gulf War as no longer having a syndrome but rather an illness connected with service. It further implies that the anthrax vaccine may be a precipitous factor in some of the illnesses being reported. I also would like to share an excerpt from After Action Report (AAR) from the first Gulf War, which states that, the anthrax vaccine was associated with “high rate of side effects.” It is also interesting to note that according to Jeffery Smith of the *Washington Post* stated in his January 1991 article that,

Military officials told Glenn’s (Senator John Glenn) committee in August 1989 that the only available anthrax vaccine was not suited to mass troop vaccinations because of a ‘higher than normal rate of reactogenicity’, or adverse medical effects and its relative lack of effectiveness once troops were exposed to the germ.

Over the past decade congressional hearing after hearing has been devoted to the problems associated with the anthrax vaccine. The General Accounting Office (GAO) also clearly demonstrated that there are significant problems with the anthrax vaccine and the vaccine injury surveillance system. The most damning report on the anthrax vaccine occurred on 27 SEP 2000 before the National Security, Veterans Affairs, and International Relations congressional subcommittee delivered by former Congressman Jack Metcalf. His report was the culmination of a three-year investigation into the use of an experimental substance called squalene that has been found in certain lot numbers of the anthrax vaccine. Many of those contaminated lots of anthrax vaccine were used at Dover AFB, Delaware. Many reportedly were used in the first Gulf War. Metcalf’s report also extensively documents, at length, “stonewalling” on the squalene issue and a consistent “pattern of deception” by Defense officials involved with the anthrax vaccination program.

On 5 May 1999 the first of two “town hall” meetings arrived at Dover. Lieutenant Colonel introduced himself as an action officer from the USAF Surgeon General’s office. When posed a question by a concerned aircrew member about squalene in the anthrax vaccine ██████ stated, “Not in the licensed human vaccine. There is a difference there. Squalene has been used in a human experimental vaccine, but not in the licensed vaccine. The licensed vaccine is what we all have been given.”

On 11 May 1999 during the next “town hall meeting” at Dover AFB, Delaware, the former Surgeon General USAF, General Roadman gave his word as an officer that squalene was never used in the anthrax vaccine and the issue was a “red herring.” In a video of that meeting one can see Colonel Alving, of USAMRID, behind General Roadman. It has been reported that Colonel Alving apparently conducted extensive research on squalene adjuvants and reproduced similar

autoimmune illnesses in laboratory animals as those seen in individuals who were harmed by the anthrax vaccine.

Why is it that the DOD denied the use of squalene as an adjuvant in an experimental vaccine when they had indeed used it in clinical trials?

If squalene is naturally occurring in the vaccine, then where is the peer reviewed science to prove this?

In September 2000 the FDA found squalene in several of the lots of anthrax vaccine that were used at Dover. The majority of illnesses that I had personally witnessed were in people who were injected with these lots of vaccine. Several statements made by DOD officials attributed the squalene found in the vaccine to the oil from someone's fingers in the manufacturing process. Does this mean that America's sons and daughters were injected with a contaminated, unsterile product?

Why is it that several ill individuals at Dover developed antibodies to squalene after receiving the anthrax vaccine?

To understand how this dangerous and controversial pharmaceutical has been able to endure public, congressional and legal scrutiny since the first Gulf War one must look at the shield it has hidden behind. The public relation shield was originally named Office of Special Assistant for Gulf War Illness (OSAGWI). Currently it operates under the name Deployment Health Support Directorate. A tactic used by this organization is outlined clearly in their public relations strategy," Bronze Anvil Communication Plan." This information was previously presented (under oath) to the Senate Veterans Affairs Committee on July 10, 2002 by Richard Weidman and Dr. Linda Spoonster-Schwartz of the Vietnam Veterans of America (VVA).

I strongly believe that on 11 May 1999 the "Bronze Anvil" strike team arrived at Dover AFB, DE to provide damage control over the "problems" that had arisen there. The team was comprised of researchers, adjuvant specialists, scientists, the USAF Surgeon General and members from Office of Special Assistant for OSAGWI. If the anthrax vaccination is not related to Gulf War Illness, then why was their presence necessary?

At the very heart of this travesty are the men, women and families who have suffered because of a dangerous pharmaceutical. Why is it that America's sons and daughters (of an all-volunteer force) can be entrusted with the defense of this great nation, often serving in austere conditions while operating millions of dollars worth of sophisticated equipment? Why is it that they can be trusted with this, yet when they raise legitimate concerns about their health and with a vaccine that has a conspicuous past they are deemed malingerers, liars, whiners, malcontents, misinformed and sent to mental health for so called psychosomatic illnesses? We will never, ever, get a handle on this problem as long as civilian and military leaders and those injured from the vaccine are afraid to come forward because they fear reprisal. From my own personal experience I now understand why.

Sincerely,

RICHARD J. ROVET, [REDACTED]

APPENDIX TO CHAPTER EIGHTEEN: THE ROLE OF GOVERNMENT AND MEDIA

Research supporting the vaccine-autism causation theory:

MERCURY–AUTISM RESEARCH

1. Gallagher, Carolyn, and Melody Goodman. "Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years," *Journal of Toxicological & Environmental Chemistry* 90, no. 5 (Sep 2008): 997-1008.
Boys who received the triple series of mercury-containing hepatitis B vaccine were more susceptible to developmental disability than were boys who were unvaccinated.
2. Gallagher, C.M., and M.S. Goodman. "Hepatitis B Vaccination of Male Neonates and Autism," *Annals of Epidemiology* 19 no. 9 (Sep 2009): 651-80.
The birth dose of the thimerosal-containing hepatitis B vaccine triples a boy's chance of developing autism.
3. Windham, Gayle C., Lixia Zhang, Robert Gunier, Lisa A. Croen, and Judith K. Grether. "Autism Spectrum Disorders in Relation to Distribution of Hazardous Air Pollutants in the San Francisco Bay Area," *Environmental Health Perspectives* 114 no. 9 (Sep 2006).
Results suggest a potential association between autism and estimated metal concentrations, and possibly solvents, in ambient air around the birth residence.
4. Palmer, Raymond F., Stephen Blanchard, and Robert Wood. "Proximity to point sources of environmental mercury release as a predictor of autism prevalence," *Health & Place* 15 no. 1 (2008): 18-24.
The closer a child lives to a mercury emitting, coal-burning power plant, the greater is his chance of developing autism.
5. Palmer, Raymond F., Stephen Blanchard, Zachary Stein, David Mandell, and Claudia Miller. "Environmental mercury release, special education rates, and autism disorder: an ecological study of Texas," *Health & Place* 12 no. 2 (2006): 203-9.
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The rise in autism rates is not a statistical artifact explained away by better diagnosing or diagnostic substitution. The increase in diagnosis represents a true rise in cases of autism. As there is no such thing as a genetic epidemic, the cause of the autism epidemic cannot be genetic, but must be change in the environment in which children are being raised.

APPENDIX TO CHAPTER TWENTY-FOUR: WHAT SHOULD PARENTS DO?

COUNTING VACCINE DOSES AND COMBINATION VACCINES

The Centers for Disease Control and Prevention (CDC) recommends seventy doses of sixteen different vaccines. Certain childhood vaccines are only available in combination with others (DTaP and MMR). Combination vaccines are “generally preferred” by the CDC and the American Academy of Pediatrics.¹ For the purpose of counting doses, however, their component parts represent separate vaccines against discrete diseases and should be tallied individually. See the color photo insert in the center of the book for the CDC schedules for children.

COUNTING DOSES

Children Ages 0 Through 6 Years

The CDC recommends 50 doses of fourteen vaccines for all children ages 0 through six years, except certain high-risk groups:

5 Diphtheria, Tetanus, Pertussis or “DTaP” = 15 total doses

5 Diphtheria

5 Tetanus

5 Pertussis

2 Hepatitis A or “HepA”

3 Hepatitis B or “HepB”

4 *Haemophilus influenzae* type b or “Hib”

2 Measles, mumps, rubella or “MMR” = 6 total doses

2 Measles

2 Mumps

2 Rubella

7 Influenza²

4 Pneumococcal or “PCV” (*Prevnar*)³

4 Polio or “IPV”

3 Rotavirus or “RV”

2 Chickenpox or “varicella”

DTaP and MMR are combination vaccines; one syringe contains one dose each of three vaccines. When DTaP or MMR is administered, the child receives one injection, but the body experiences the impacts of three vaccines against three different diseases.

Children Ages 7 Through 18 Years

The CDC recommends 20 doses of six vaccines for all children ages 7 through 18, except certain high-risk groups:

2 Meningococcal or “MCV” (*Menactra*)⁴

1 Tetanus, diphtheria, pertussis or “Tdap” = 3 total doses

1 Tetanus

1 Diphtheria

1 Pertussis

12 Influenza

3 Human papillomavirus or “HPV” (*Gardasil, Cervarix*)

COMBINATION VACCINES

In 2010, the CDC and the American Academy of Pediatrics announced that “the use of a combination vaccine series is now considered generally preferred over separate injections of the equivalent component vaccines.”⁵ This is a stronger statement of support than the previous recommendation which deferred to the clinician to make the final decision.⁶ The reasons for the preference of combination vaccines include cost, storage considerations, product availability, fewer injections and visits, provider assessment, improved recordkeeping and tracking, and enhanced patient compliance.⁷

The development of combination vaccines is not a simple matter of mixing vaccine A, vaccine B, and vaccine C into the same syringe and rolling up a child’s sleeve. In his textbook *Combination Vaccines: Development, Clinical Research, and Approval*, editor Ronald Ellis and his contributing authors acknowledge some important challenges: “Vaccine antigens, which have been developed and licensed separately as vaccines, are brought together in physical mixtures which are not always stable and potent.”⁸ To justify the use of a combination vaccine relative to its individual component vaccines, it is important to demonstrate “equivalence” with respect to safety (rates of injury) and efficacy (antibody levels).⁹

Safety

In their chapter on pediatric combination vaccines, rubella vaccine inventor and industry adviser Stanley Plotkin and colleagues admit that “little is known about the immunological interactions among vaccine components.”¹⁰ When multiple antigens are placed into one injection, the combination may cause more *reactogenicity*, or an “undesirable immunological reaction.”¹¹ Therefore, when it comes to prioritizing combination vaccines over individual component vaccines, “safety is the single most important issue.”¹² The science of vaccine development describes different mechanisms or routes by which combination vaccines can cause a greater degree of injury.¹³

When evaluating the safety of combination vaccines, the trials “should be prospective, randomized, double blinded and have appropriate control (comparison) groups.”¹⁴ Safety must be evaluated in absolute terms, in comparison to the separately-administered components, based on standard practice, and when administered with other vaccines typically given at the same time.¹⁵

Merck’s MMRV or *ProQuad* is a recent example of a combination vaccine’s greater risk of causing harm. In 2008, the CDC announced that it no longer preferred the combination measles, mumps, rubella, and varicella vaccine (MMRV) relative to separate injections of equivalent component vaccines (MMR-V) because MMRV was associated with a higher incidence of febrile seizures in children aged 12 to 23 months.¹⁶ In 2009, the CDC said that the MMRV vaccine was acceptable but “physicians should discuss the risks and benefits of both options with parents.”¹⁷ In 2010, the CDC resumed its preference for MMRV in children aged 4 years and older. Children aged 12 to 47 months receiving the first dose could receive either vaccine. Children receiving a second dose, and any child with personal or family history of seizures, should not receive MMRV.¹⁸

Efficacy

In the past, most vaccines were generic. Today, vaccine development uses new technologies that result in a greater diversity of final products.¹⁹ When scientists talk about the immune response a vaccine induces, they use the term *immunogenicity*. Vaccines contain antigens, which are substances that produce antibodies when injected. A variety of issues can cause quantitative and qualitative differences in overall effectiveness of a combination vaccine. Antigens that are combined in a single injection can “interfere” with each other. When live viruses are combined, for example, one may inhibit the replication of another. Another example involves engineering to boost weak antigens by attaching them to a different carrier to get the job done (“conjugation”). When the efficacy of vaccine components is diminished in combination, the phenomenon is known as “interference.”²⁰

On the pharmaceutical side, some vaccines are less effective when paired with certain ingredients, for example:²¹

- Certain vaccines—measles, mumps, rubella, varicella, and inactivated polio—are less effective when combined with the mercury-based preservative thimerosal
- *Haemophilus influenzae* type b vaccine (Hib) is less effective when combined with an adjuvant derived from aluminum salts

When conducting efficacy trials,²² the combination vaccine must have an effectiveness that is equivalent to or greater than the separately-administered components. There must also be consistency or reliability of the immune response. This means that different vaccine lots must be tested and their effectiveness cannot vary statistically from lot to lot.

Public health officials prefer combination vaccines because they make it easier to vaccinate larger numbers of children, thereby facilitating compliance. Vaccine manufacturers prefer combination vaccines because they are more profitable. Parents want childhood vaccines that are safe and effective. While clinicians play a key role in supporting public health, they are required to serve the best interests of their patients. Vaccine package inserts provide detailed information to help parents and physicians make their decisions.

Combination Vaccines for Use in Children²³

Two

Comvax® = Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine

DECAVAC® = Tetanus and Diphtheria Toxoids Adsorbed

TENAVAC® = Tetanus and Diphtheria Toxoids Adsorbed

Three

Adacel® = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed

Boostrix® = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed

DAPTACEL® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Infanrix® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Tripedia® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

MMR II® = Measles, Mumps, and Rubella Virus Vaccine, Live

Four

KINRIX® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine

ProQuad® = Measles, Mumps, Rubella and Varicella Virus Vaccine Live

Five

Pediarix® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined

Pentacel® = Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

APPENDIX TO CHAPTER TWENTY-FIVE: WHO IS DR. AN DREW WAKEFIELD?

Statement from Dr. Andrew Wakefield Regarding the GMC Hearing Sanctions April 5, 2010

On Wednesday April 7th, General Medical Council (GMC) lawyers will demand that I and likely two other doctors involved in the MMR-autism case should be erased from the U.K.'s medical register, removing our license to practice medicine. Doctors' regulators have found the three of us—Professor John Walker-Smith, Professor Simon Murch and me—guilty of undertaking research on children with autism without approval from an ethics committee. We can prove, with extensive documentary evidence, that this conclusion is false.

Let me make it absolutely clear that, at its heart, the GMC hearing has been about the protection of MMR vaccination policy. The case has been driven by an agenda to crush dissent that in my opinion serves the government and the pharmaceutical industry—not the welfare of children. It's important to note that there has never been a complaint against any of the doctors by any parent involved in this case—only universal parental support and gratitude.

My colleagues, Professors Walker-Smith and Murch, are outstanding pediatricians and pediatric gastroenterologists. They have led the field of pediatric gastroenterology for decades, devoting their lives to caring for sick children. Our only "crime" in this matter has been to listen to the concerns of parents, act according to the demands of our professional training, and provide appropriate care to this neglected population of children. It is unthinkable that at the end of an unimpeachable career, Professor Walker-Smith would even consider unethical experimentation on children under his care.

In the course of our work, we discovered and treated a new intestinal disease syndrome in children with autism, alleviating suffering in affected children around the world. This should be cause for celebration. Instead, we have been vilified in the press, and demonized by a wasteful PR campaign by the Department of Health. The aim of this negative publicity was to discredit my criticism of vaccine safety research.

Sadly, my colleagues have suffered severe collateral damage in this effort to prevent valid scientific enquiry. They should be exonerated, and left alone with their reputations intact, in the certain knowledge that they have done only what is right.

The loss of my own medical license is, unfortunately, the cost of doing business. Although I

do not take this loss lightly, the suffering—so much of it unnecessary—that I have seen among those affected by this devastating disease makes the professional consequences for me a small price to pay by comparison.

As long as a question mark remains over vaccine safety; as long as a safety-first vaccine policy is subordinate to profit and self-interest; as long as the benefits of vaccines are threatened by those who have compromised public confidence by denial of vaccine damage, and as long as these children need help; I will continue my work.

*Dr. Wakefield Statement on GMC Hearing Sanctions available at www.ageofautism.com/2010/04/statement-from-dr-andrew-wakefield-regarding-gmchearing-sanctions.html.

APPENDIX B: TOOLS FOR VACCINATION CHOICE

i. Chicago Principles on Vaccination Choice

ii. Calls for Immediate Action in the United States

iii. Harris Interactive Poll—May 2010

iv. Public Discussion Presentation

v. Frequently Asked Questions about Vaccines

vi. Discussion Guide to “The Ones Who Walk Away from Omelas”

THE CHICAGO PRINCIPLES ON VACCINATION CHOICE

We, the people who affirm our belief in personal rights, in order to promote the general health and welfare for ourselves and our children and to establish justice, advocate the following principles:

1. The right to free and informed consent to all medical interventions, including vaccination, is a fundamental human right. This includes the right to refuse any medical intervention, including vaccination.
2. Laws that make education, employment, day care and public benefits contingent on vaccination status, except in extreme public health emergencies, violate the fundamental human right to vaccination choice.
3. Laws that sanction nondisclosure of known medical risks, including risks of vaccination, violate the fundamental human right to free and informed consent for all medical interventions.
4. A safety first agenda must apply to vaccination policy. No government should have the right to recommend or mandate vaccines until impartial scientific research has documented their relative safety.
5. Individuals who evaluate, recommend, and mandate vaccines must be free of all actual and perceived conflicts of interest.

For more information:

www.centerforpersonalrights.org

CALLS FOR IMMEDIATE ACTION IN THE UNITED STATES

1. Every state should permit philosophical exemption to vaccination mandates, upholding the human right to free and informed consent for all medical interventions. Without the real right to say no, current policy is coercive and lacks legitimacy.
2. Congress should conduct oversight hearings on the national vaccine program, including mandates for the military and immigrants, vaccine safety, conflicts of interest, suppression of science, evidence of vaccine injury, and comparative empirical data from countries with differing vaccination schedules.
3. Congress should immediately initiate a prospective study of vaccinated versus unvaccinated populations for long-term health outcomes. Such a baseline study has never been done, suggesting that the vaccination schedule as a whole is an experiment on human subjects. This bill is called the “Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act” and was originally cosponsored by Rep. Maloney (D-NY) and Rep. Osborne (R-NE).
4. Congress should amend the 1986 National Childhood Vaccine Injury Act to reinstate ordinary tort liability for vaccine manufacturers and medical professionals. Liability protections in the 1986 Law have fueled the expansion of the vaccine schedule and have not made vaccines safer, as the Law required.
5. Congress should abolish the Vaccine Injury Compensation Program or make it optional. The Program has failed in its purpose to quickly, generously, and administratively compensate families for vaccine injury.

HARRIS INTERACTIVE POLL—MAY 2010

In May 2010, global marketing research firm Harris Interactive conducted an online survey of 1,144 parents with children age seventeen or younger within the United States. This survey was conducted on behalf of the Center for Personal Rights, Inc. via its ParentQuery omnibus product.

Figures for age, sex, race and ethnicity, education, region, household income, and the age of children in the household were weighted where necessary to bring them into line with their actual proportions in the population. Propensity score weighting was used to adjust for respondents' propensity to be online.

Respondents for this survey were selected from among those who have agreed to participate in Harris Interactive surveys. The data have been weighted to reflect the composition of the parent population. Because the sample is based on those who agreed to participate in the Harris Interactive panel, no estimates of theoretical sampling error can be calculated.

According to the final report:

- 52% believe that “parents should have the right to decide which vaccines their children receive without government mandates.”
- 54% of parents are “concerned that the pharmaceutical industry has undue influence over government vaccine mandates.”
- 54% of parents agree that “the government should fund an independent scientific study of fully vaccinated vs. unvaccinated individuals to assess long-term health outcomes.”
- 48% of parents are “concerned about serious adverse effects of vaccines.”
- 42% of parents, a minority, agree that “all children should receive 69 doses of 16 vaccines before age 18, as recommended by the federal government.”*

For full poll results and complete survey methodology, including weighting variables, see the seventy-eight-page full statistical report available at www.centerforpersonalrights.org.

Summary Of Strongly/Somewhat Agree

Base: Qualified Parents

	Parent Gender				Parent Age				Region				Parent Education				# of Parents in HH				HH Income																
	Male		Female		18-34		35-44		45+		North-east		Mid-west		South		West		H.S. or Less		Some College		College Grad+		Single Parent		2 Parents		<\$35K		\$35K - \$49.9K		\$50K - \$74.9K		\$75K+		
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)	(T)	(U)	(V)	(W)	(X)	(Y)	(Z)	(AA)	(AB)	(AC)	(AD)	(AE)	(AF)	(AG)	(AH)			
Unweighted Base	1144	494	650	380	482	282	258	320	363	203	207	433	504	226	918	275	152	254	353																		
Weighted Base	1144	473	671	361	474	309	245	272	378	249	417	342	385	216	928	254	129*	216	433																		
I am concerned that the pharmaceutical industry has not done enough to fund government vaccine mandates.	618	268	349	168	273	176	137	153	212	116	220	190	208	125	493	131	78	121	225																		
The government should fund an independent scientific study of the effectiveness of government mandated individuals to assess long-term health outcomes.	613	251	362	200	248	166	128	150	207	128	212	186	215	129	484	140	84	118	220																		
Parents should have the right to decide which vaccines their children receive without government mandates.	592	254	338	179	255	158	125	155	191	121	211	195	186	126	465	137	74	114	206																		
I am concerned about serious adverse effects of vaccines.	544	208	336	170	229	144	113	130	195	106	197	171	175	119	425	131	81	95	187																		
All children should receive 69 doses of 16 vaccines before age 18, as recommended by the federal government.	477	204	273	148	211	118	100	105	164	108	148	126	203	81	397	99	49	78	214																		

Proportions/Mean: Columns Tested (5%, 10% risk level) - B/C - D/E/F - G/H/I/J - K/L/M - N/O - P/Q/R/S
 Overlap formulae used. * small base

CENTER FOR PERSONAL RIGHTS

Public Discussion Presentations

The Center for Personal Rights (CPR) is a non-profit organization that advocates for the rights to life, liberty, and personal security for ourselves and our children. CPR demands the universal human rights standard of informed consent to all medical interventions. Compulsory vaccination is morally and legally unjustifiable.

As part of its mission, CPR has compiled information and data on vaccination choice for public presentations. Below are a few slides from the presentation, "The Conversation: Vaccination Is A Human Right." You can download the full PowerPoint presentation at www.centerforpersonalrights.org.

Childhood in America

The "New Normal"

1 in 3	Overweight
1 in 6	Learning Disabilities
1 in 9	Asthma
1 in 12	ADHD
1 in 25	Food Allergies
1 in 100	Seizures
3-5 in 100	Birth Defects
1 in 110	Autism
1 in 450	Diabetes
1 in 6,000	Cancer

50% of children are chronically ill or overweight

tinypurl.com/y4e85f3 (ADHD), tinypurl.com/y6d8d8y (asthma), tinypurl.com/y7oht5u (autism), tinypurl.com/y4sh2hc (birth defects), tinypurl.com/y3g7b6a (children's health), tinypurl.com/y2tr9z2 (chronic illness), tinypurl.com/y4z2f3p (diabetes), tinypurl.com/y2j4f4z (food allergies), tinypurl.com/y6q3k3d (learning disabilities), tinypurl.com/y6evf4g (obesity), tinypurl.com/y2cz9pw (obese young adults), tinypurl.com/y64p9oq (seizures), tinypurl.com/2d88944 (cancer)

A Cornerstone of Sound Public Health?

1 in 143 American babies dies before age one.
We trail every developed country except Poland.

YEAR	USA INFANT MORTALITY RANK
1950 (before mass immunization)	3 rd
1986	17 th
1995	23 rd
2000	31 st
2010	46 th

We lag behind Macau, Anguilla, Andorra, Slovenia, Gibraltar, San Marino, Jersey, Guernsey, Isle of Man, Faroe Islands, Cuba, and Taiwan. We barely edge out Croatia, Belarus, Lithuania, Guam.

America's Health Rankings 2009, <http://tinypurl.com/2cqw1j9>, The World Factbook, CIA, 2010, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html>

Childhood Vaccines

2010 CDC Recommended Schedule

Birth to age 6:

5 DTaP (15)	2 MMR (6)	2 Hep A	3 Hep B
4 Hib	7 Flu*	4 Polio	4 Prevnar
3 Rotavirus	2 Varicella		

Ages 7 to 18:

2 Menactra*	1 Tdap (3)	12 Flu**	3 HPV
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70 doses of 16 vaccines by age 18

* CDC panel (ACIP) added second meningococcal vaccination at age 16 on 10/24/10
** 2010-2011 seasonal flu vaccine contains H1N1 strain

Where's The Research?

- No randomized longitudinal studies on vaccinated vs. unvaccinated populations
- No studies of U.S. vaccine schedule as a whole
- No studies of health outcomes for individual vaccines
- Failure to study the alleged vaccine-injured
- Studies "proving" no causation are flawed (14studies.org)
- Vaccine safety science budget is .5% of total \$4 billion vaccine budget for purchase, promotion, delivery (2008)

The only line item for vaccine safety research is . . . a little less than \$2 million per year . . . everything else has been begged, borrowed and stolen. - Dr. Robert Chen, Chief, Vaccine Safety, CDC

Advisory Commission on Childhood Vaccines (ACCV) and National Vaccine Advisory Committee (NVAC) Subcommittees on Vaccine Safety, May 31, 1995.

FREQUENTLY ASKED QUESTIONS ABOUT VACCINES

“Vaccines are Effective”

- 1. Vaccines are modern medicine’s greatest achievement. Haven’t they saved the developed world from the scourge of infectious disease?**

Response: Better nutrition, clean water, modern sanitation, hygiene, improved living and working conditions, and antibiotics have played essential and under-appreciated roles in public health. Many infectious diseases were almost gone by the time vaccination mandates began. Vaccines have played a role in decreasing infectious disease, but they’ve also injured and taken lives. Vaccine package inserts document a long list of possible side effects and death that can occur after vaccination. The government administers a special program to compensate for vaccine injury or death. Because every vaccination decision is potentially a life-and-death decision or may affect future quality of life, free and informed consent is imperative. Individuals must have the right to decide for themselves and their children if and when to vaccinate. If vaccines are truly safe and effective, the vast majority will want them, with no need for mandates.

- 2. Vaccines save lives. Don’t vaccines overwhelmingly benefit the individual and society?**

Response: Look at the health of children in the United States today. One in six has a learning disability; one in nine has asthma; one in twelve has ADD; one in one hundred ten has autism. The United States ranks forty-sixth in infant mortality in the world, below every industrialized country except Poland (www.tinyurl.com/yw2nt5). Vaccines have helped to diminish infectious diseases, but they have not ensured good health. We are experiencing an alarming increase in a wide range of chronic, neurological, and autoimmune childhood diseases and disorders. The extent to which vaccines play a role in these childhood diseases and disorders is largely unstudied, but some evidence suggests strong associations.

- 3. Vaccines work. Don’t vaccines protect us against deadly diseases?**

Response: Immunity from vaccines is temporary; it wears off over time. Only natural immunity acquired through actual infection and boosted through exposure to disease in the community gives lifelong immunity. Vaccines rely on “booster” shots to maintain antibodies. This is the reason it is recommended that children get six doses of each vaccine for diphtheria, pertussis, and tetanus, four doses of each vaccine for polio, *haemophilus influenzae* type b and pneumococcal disease, three doses of each vaccine for hepatitis B, rotavirus and human papillomavirus, and two doses of each vaccine for measles, mumps, rubella, chickenpox and hepatitis A. Scientists initially believed that vaccines would afford lifelong immunity. As disease outbreaks increasingly occurred among the vaccinated, mandates for vaccine boosters became commonplace. Even in communities where 98+% of the population is “fully vaccinated” for a particular disease, creating so-called herd immunity, outbreaks among the vaccinated still occur (www.tinyurl.com/d5l8vm, www.tinyurl.com/27sexxd).

“Vaccines Are Safe”

- 4. Adverse reactions to vaccines are exceptionally rare. Aren’t death and injuries caused by vaccines necessary risks that all members of the community must accept as the price of citizenship?**

Response: All human beings are entitled to life, liberty, and security of person. A society that protects fundamental human rights does not discriminate on the basis of age or genetic

predisposition or mandate a practice in peacetime or in the absence of a true public health emergency that is known to cause injury and death. Doctors often fail to recognize injuries and underreport them because we have a voluntary Vaccine Adverse Events Reporting System (VAERS). There are no penalties for failure to report injuries and it is estimated that one to ten percent of adverse events are reported. Inclusion in VAERS does not prove causation, and little research has investigated alleged vaccine injuries. Most doctors are uninformed about vaccine adverse events and are unaware of how to best help their patients when these adverse events happen. By law, doctors bear no liability for vaccine injury. Furthermore, our understanding of the nature and mechanism of vaccine-induced injury and death is limited, in part because we have failed to study the long-term health outcomes of fully vaccinated compared with unvaccinated individuals.

5. Vaccines are scientifically sound. Aren't vaccines extremely well-researched for optimal safety by independent government scientists with children's and society's best interests at heart?

Response: Like all prescription medications, vaccines are considered “unavoidably unsafe” by law. Doctors give infants over thirty doses of “unavoidably unsafe” medications by fifteen months of age, usually without full and detailed informed consent. Nonetheless, the Centers for Disease Control and Prevention (CDC) states on its website that “vaccines are held to the highest standard of safety” (www.tinyurl.com/2dwf8x9). In reality, vaccines have not been well-researched. There has never been a study comparing the long-term health outcomes of vaccinated versus unvaccinated populations. Vaccines have not been studied cumulatively, in the way that they are administered. They are tested individually, in isolation, for very short periods of time by the vaccine manufacturers themselves, who are protected from almost all legal liability. Furthermore, many of the decision makers for vaccination recommendations and mandates have serious conflicts of interest—some are even vaccine patent holders. In 2007, a majority of outside scientific expert advisors to the CDC were found to have potential violations of the agency's conflict of interest regulations (www.tinyurl.com/24u4jen).

6. Side effects are slight. To the extent that there are any side effects from vaccines, aren't they are mild, such as soreness at the site of vaccination and short-term fever?

Response: All vaccines can result in injury or death; legally, they are “unavoidably unsafe” products. This is the reason that Congress created the Vaccine Injury Compensation Program—because it recognized that vaccines injure and cause death in some individuals. Although screening mechanisms and risk factors could be identified to protect those at risk, they do not exist today. Leading voices, such as Dr. Bernadine Healy, former head of the National Institutes of Health (www.tinyurl.com/59wns7.) have called for studies of those who may have been vaccine-injured. Nonetheless, all fifty U.S. states impose “one-size-fits-all” vaccination mandates as a requirement for day care and school admission, regardless of family medical history and infant weight.

7. The book is closed. Every major study looking for connections between vaccines and autism has failed to find any link. Isn't this book closed?

Response: Dr. Robert Chen, Chief of Vaccine Safety and Development at the CDC, said in 1995, “the only line item for vaccine safety research is I think on the order of a little less than \$2 million per year. That basically covers operation of VAERS (Vaccine Adverse Events Reporting System) period, and nothing else.” (Advisory Commission on Childhood Vaccines (ACCV) and National Vaccine Advisory Committee (NVAC) Subcommittees on

Vaccine Safety, May 31, 1995.) More recently, Dr. Louis Cooper, vaccine inventor and former President of the American Academy of Pediatrics admitted that the vaccine safety science research budget was twenty million dollars or a mere 0.5 percent of the four billion dollar total vaccine budget for purchase, promotion, and delivery in 2008. (www.pediatrics.org/cgi/content/full/122/1/149). This is especially significant if you consider the dramatic rise in autism incidence in the past two decades, from four to five in 10,000 in the early 1990s, to one in 110 today.

The studies that the U.S. government uses to disprove causation of harm are limited and flawed (see www.fourteenstudies.org). Several rigorous studies have found links between vaccines, developmental disability, and chronic illness. These include the Gallagher-Goodman Stony Brook University Medical Center study tying hepatitis B triple series vaccine and developmental disability (www.tinyurl.com/2ejdrd8.) and the University of Manitoba study funded by the Canadian Institutes of Health Research that found an association between delayed diphtheria, pertussis, and tetanus vaccination and a reduced risk of childhood asthma (www.tinyurl.com/2edrl7c). There have been few studies on children with regressive autism. The 2004 Institute of Medicine Report did not rule out the possible existence of a vulnerable subset of children in whom vaccines could cause autism. And, in late 2009, the government spokesman on autism, Dr. Thomas Insel, acknowledged that the real rise in autism prevalence must be attributed at least in part to environmental causes.

8. Thimerosal is no smoking gun. Isn't it true that we know that vaccines don't cause autism because thimerosal, the mercury-based preservative, has been removed from all pediatric vaccines and autism rates have continued to rise?

Response: It is misleading to assume a direct and causal relationship between those two facts; the inference fails to account for confounding factors. In other words, there were other potentially significant events occurring at the same time that must be considered. For example, as we decreased the amount of thimerosal in pediatric vaccines, we increased the total number of vaccines as well as the cumulative exposure to other neurotoxic ingredients, including aluminum. It is not possible to ascertain whether vaccines cause autism until we dedicate the funds to pursue a long-term controlled study. Furthermore, thimerosal remains in some childhood vaccines today. Flu shots are recommended for all children and most seasonal flu shots, including those routinely given to children and pregnant women, contain ten to twenty-five micrograms of thimerosal or approximately 10,000 to 25,000 parts per billion (ppb). Thimerosal is nearly fifty percent ethylmercury by weight (www.tinyurl.com/y7pdm5m) and continues to be used in the manufacturing process of many vaccines. After filtration, vaccines still have "trace" amounts of thimerosal equivalent to 0.5 microgram or 2,000 ppb. Two hundred ppb meets the EPA classification for hazardous waste and two ppb is the EPA's limit for safe drinking water (www.tinyurl.com/y2zfe58). Mercury is the most neurotoxic nonradioactive substance on the planet. It has been removed from over-the-counter medicines and veterinary vaccines. It should not be injected in any amount into humans of any age.

9. Pediatricians are knowledgeable. Pediatricians are well-educated about the risks and benefits of vaccines. Can't they tell if a vaccine is contraindicated for a particular child?

Response: The full ramifications of the vaccination schedule are unknown because researchers have not studied vaccines cumulatively in the way that they are administered.

Pediatricians and family practice doctors receive little education about the possible adverse consequences that can occur after the administration of vaccines. The information they do receive is typically limited to a description of the vaccines on the CDC schedule, how to administer them, the importance of full compliance, and how to catch children up who have missed doses. State departments of health apply pressure on physicians who write “too many” medical exemptions. Many doctors are not eager to discuss vaccination decisions with parents and rarely inform them of their rights and the legal exemptions available to them. Pediatricians are even supported in their decision to discharge parents who are not willing to vaccinate their children according to CDC-recommended vaccination schedules (www.tinyurl.com/4mdze2).

“Vaccination Compulsion is Ethical”

10. Public health trumps individual choice. If you don’t vaccinate yourself and your children, aren’t you endangering others?

Response: If you have been vaccinated against an infectious disease and your blood antibody titers indicate that you have levels providing specific immunity, you cannot contract that disease from someone, whether that person was vaccinated or not. People who are unvaccinated, and those who are vaccinated but whose immunity has worn off, can be disease carriers if they do not stay at home when they are sick. In the event of an infectious disease outbreak, schools require that unvaccinated students remain at home. Due to viral shedding from live virus vaccines, a recently vaccinated person can infect the unvaccinated and those who are vaccinated but whose immunity has worn off. Vaccine package inserts do not rule out the possibility of disease transmission via viral shedding and close personal contact (www.tinyurl.com/24ldtn).

Admittedly, some people are unable to be vaccinated due to age or health status. There have been vitriolic discussions about the selfishness of parents who do not vaccinate their children. In the absence of a true public health emergency, the morality of requiring someone to vaccinate to protect others must be carefully weighed against the morality of mandating a medical intervention for healthy individuals that is known to injure and cause death to some. The government has committed or paid out over two billion dollars to about 2,500 families to compensate for vaccine injury and death. A society that protects fundamental human rights does not discriminate on the basis of genetic predisposition or mandate a practice that inevitably causes injury and death, regardless of the number of victims. This is especially true when the scientific foundation supporting long-term safety and efficacy is unknown due to government failure to provide rigorous unbiased science on vaccine safety. The decision to be vaccinated should rest with the individual or the parent, not the state.

11. Mandatory vaccination is legal: Aren’t vaccination laws constitutional and for the public good?

Response: *Jacobson v. Massachusetts*, a 1905 U.S. Supreme Court case, established the precedent that states may impose vaccination mandates during public health emergencies. This decision, arising from a deadly smallpox epidemic in a different era, predates the doctrines of free and informed consent and medical autonomy and most of the scientific advances of the twentieth century. State-mandated vaccination during a smallpox epidemic in 1905 reflects a radically different reality than ours today. In 1905, there was a single vaccination mandate at issue during a widespread and contagious smallpox epidemic, and

Jacobson's noncompliance resulted in a monetary fine. At no point was Jacobson denied employment, or his child denied school admission, due to the failure to vaccinate. Jacobson and his son did not face mandates with up to seventy doses of sixteen vaccines that included foreign proteins and neurotoxic chemicals. And even *Jacobson v. Massachusetts*, which upheld state mandates, noted the risks of "regulations so arbitrary and oppressive" that they would be "cruel and inhuman in the last degree." Jacobson also provided for the medical exemption to mandatory vaccination which is upheld in all fifty states. Current vaccination mandates, required in non-emergency situations, based on inadequate science, rest on a questionable constitutional foundation.

12. Justified liability protection. Congress rightly limited the liability of doctors and vaccine manufacturers in 1986 to safeguard the nation's vaccine supply. Don't we need insulation of doctors and industry from liability to protect the vaccine supply?

Response: In 1986, Congress granted tort liability protection to doctors and the vaccine industry against vaccine injuries and death. This means that people harmed by vaccines cannot sue vaccine manufacturers or the physicians who administered the vaccines. Blanket liability protection and the lack of free and informed consent, have led to the large increase in compulsory childhood vaccination mandates. A responsible universal vaccination program must include rigorous, impartial science on vaccine safety, free and informed consent of individuals to vaccination, and corporate accountability for vaccines. We must change the laws that underpin today's childhood mass vaccination program to create real choice and real accountability.

13. Schools as the gatekeeper: It makes sense to have schools police kids' vaccination status. Shouldn't schools require immunization?

Response: Education is a fundamental right for children to receive and a responsibility for parents to provide. The right to education should not be contingent on vaccination status. It is profoundly unwise to turn schools into vaccination police. In the event of infectious disease outbreaks, unvaccinated children may be required to stay at home. This does not interfere with their general right to participate in school.

"Vaccines Promise Ever-Increasing Benefits"

14. Unlimited benefits: There appear to be no limits to the diseases we can conquer through vaccines. Scientists are working on vaccines for cancer and HIV. Isn't this welcome?

Response: As is the case with all medical interventions, people should have the right to free and informed consent for vaccination. This means there should be complete disclosure regarding the risks and benefits and all vaccines must be rigorously studied for safety and effectiveness before use. For a variety of reasons, including family history, prior disease exposure, and a varying assessment of the dangers and likelihood of contracting the disease, all people will not make the same decisions about the risk-reward tradeoffs. Individuals must make those choices, not government officials or scientists.

15. More is better: Aren't relatively new compulsory vaccines, such as vaccines for flu, hepatitis B, and HPV, welcome because they protect us from deadly diseases?

Response: The legal justification for compulsory vaccination is to protect people in the event of contagious, widespread infectious disease epidemics or true public health emergencies. The U.S. Supreme Court's 1905 decision, *Jacobson v. Massachusetts*, created this precedent during a smallpox outbreak. Citizens have the right today to obtain

exemption from vaccination for medical, religious and philosophical reasons, depending on the state. The scope of vaccination mandates must be proportionate to the public health emergency. While there are no epidemics of hepatitis B or cervical cancer in the United States, these vaccination mandates are compulsory in many states, based on the false premise that government may impose vaccines for the “greater good.” More vaccination mandates are not necessarily better, and state requirements must respect fundamental human rights.

“THE ONES WHO WALK AWAY FROM OMELAS” DISCUSSION GUIDE

by **Kim Mack Rosenberg**

Disclaimer: The statements and questions reflect Kim Mack Rosenberg’s own interpretation of “The Ones Who Walk Away From Omelas” and should not be attributed to Ursula Le Guin.

This short story is a modern parable. Its vagueness allows each reader’s own perspective and life experiences to create a unique “Omelas.” Ursula Le Guin does not offer pat, easy answers to the difficult moral questions she raises. We encourage you to reread the story to absorb and reflect on its many nuances.

Readers may find that the story’s questions resonate with the vaccination questions in the rest of the book. Should we accept vaccination mandates for the “greater good” of our society? What greater good do mandates achieve? Does society ignore the vaccine injured? How can we mandate something that is known to do serious harm? Do we walk away? Do we stay and fight?

After reading the story, the following are some questions to consider and discuss:

- Did you like the story? Why or why not?
- Did your opinion of the story change while reading it?
- When you began the story, did Omelas sound like a place where you might want to live?
- What aspects of the story did you find most surprising?
- What is the narrator’s idea of utopia? Do you share it?
- The narrator notes: “The joy built upon successful slaughter is not the right kind of joy.” Do you think Omelas has the “right kind of joy”?
- “[T]he victory they celebrate is that of life.” Do you agree with this statement about Omelas? Are they celebrating the collective “life” or the individual?
- Why do you think the child in the cellar is necessary to the continued existence of Omelas as its citizens know it?
- Are the people of Omelas complacent? Happy? Evil? Compassionate, as they claim?
- Is Omelas a place where wrongdoing can go unchecked? Why or why not?
- Who or what do you think the narrator represents?
- What was your reaction upon encountering the child in the cellar?
- Who or what do you think the child represents?
- What event do you think precipitated making the child in the cellar a scapegoat?
- Do you think it matters, in ethical terms, how the child was chosen?
- The child in the cellar promises to be “good” if released. Does the child perceive that his fate is the result of his having been “bad”? Why or why not?
- How old do you think the child was when he was put in the cellar? What do you think became of his parents?
- The child is able to speak. What does that tell you about the child?
- What lessons are being taught to the young people of Omelas by showing them the child as a rite of passage? Why do you think their initial outrage disappears?
- Why do some adults return to visit the child?
- Who do you think is responsible for bringing food and water to the child?

- When you heard the child was kicked, what was your reaction?
- Why doesn't the child try to escape?
- Does the narrator entertain the possibility that the child's treatment might be morally justifiable?
- Some of the citizens know why the child was put in the cellar, others do not, but all accept the child being there. Is one worse than the other?
- The people of Omelas rationalize that the child would obtain only marginal gains if brought out.
 - How does this contrast with the child begging for his release?
 - What does this contrast say about the child?
 - What does this contrast say about the people of Omelas?
- How did you feel about the ones who walk away? Is walking away an act of bravery or cowardice?
- Do you interpret the story as a critique of modern society? Of utilitarianism? Of moral absolutism?
- What does this story say about a society that would sacrifice a child for the greater good of the society as a whole?
- Why do you think no one in Omelas ever tries to help the child?
- Le Guin tells us that those who live in Omelas are happy and that "[h]appiness is based on a just discrimination of what is necessary, what is neither necessary nor destructive, and what is destructive." How do you interpret this in light of the child in the cellar? Is the happiness of those in Omelas based on destruction?
- Can we only understand their happiness by juxtaposing it to the suffering of the child in the cellar?
- Le Guin writes, "to throw away the happiness of thousands for the chance of the happiness of one: that would be to let guilt within the walls indeed." Do the citizens of Omelas feel any guilt for their happiness? Is the child locked away a metaphor for their own guilt locked away and unexamined?
- Do you know someone injured by vaccines? Do you think this affected your perceptions in reading the story?
- Do you know someone who was injured or died from diseases for which there are vaccines? Do you think this type of experience affects public health officials and legislators responsible for setting compulsory vaccination policies?

"The Ones Who Walk Away From Omelas" has received extensive recognition since its publication, including receipt of the 1974 Hugo Award for best short story. It is often used in curricula for ethics, philosophy, English, and other courses in universities and colleges around the country, and used as a teaching tool in the public and private sectors.

NOTES

CHAPTER 1: VACCINATION CHOICE IS A HUMAN RIGHT — MARY HOLLAND, JD

1 The U.N. Charter states in its Preamble, “We the peoples of the United Nations determined . . . to reaffirm faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women.” www.un.org/en/documents/charter/index.shtml.

2 Preamble, the Universal Declaration of Human Rights, www.un.org/en/documents/udhr/index.shtml.

3 The Nuremberg Code states as the first principle that “[t]he voluntary consent of the human subject is absolutely essential,” www.hhs.gov/ohrp/irb/irb_appendices.htm#j5.

4 The Council of Europe’s 1997 Convention on Human Rights and Biomedicine Article 5 states: “An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it,” <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>. UNESCO’s 2005 Universal Declaration on Bioethics and Human Rights Article 6 states: “Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information,” [www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human](http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights) rights. For more on contemporary international human rights norms on bioethics and medicine, see chapter 2.

5 The 1986 National Childhood Vaccine Injury Act acknowledges that vaccine injury or death may be “unavoidable even though the vaccine was properly prepared and accompanied by proper directions and warnings.” 42 U.S.C. 300aa-22(b)(1). The “unavoidable” language in the Act is from the Restatement (Second) of Torts that applies to “products which, in the present state of human knowledge, are quite incapable of being made safe.” Restatement (Second) of Torts Section 402A, comment k (1965).

6 Vaccine Information Statements (VISs) are information sheets produced by the CDC. Federal law requires that VISs be handed out before certain vaccinations are given. See the Center for Disease Control and Prevention’s website, www.cdc.gov/vaccines/pubs/vis/default.htm.

7 The 1986 National Childhood Vaccine Injury Act states that vaccine manufacturers are free from tort liability “if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” 42 U.S.C. 300aa-22 (b)(1).

8 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

9 Recording of Martin Luther King, www.entertainment.com/clips/cbrtmrrvb—Arc-of-the-moral-universeMartin-Luther-King-Jr-MLK-Civil-Rights-How-long-. For discussion of the origin of the Theodore Parker quotation, see National Public Radio’s website, www.npr.org/templates/story/story.php?storyId=129609461.

10 For a detailed account of the legal problems with compulsory vaccination, *Jacobson v.*

Massachusetts and the 1986 National Childhood Vaccine Injury Act, see Mary Holland, *Reconsidering Compulsory Childhood Vaccination*, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1677565.

CHAPTER 2: THE INTERNATIONAL HUMAN RIGHTS STANDARD —SOOKYUNG SONG

1 The trovafloxacin experiment on 100 Nigerian children took a heavy toll, causing death to five and inflicting severe injuries to many others. The survivors subsequently brought an action against Pfizer, Inc., which orchestrated the clinical trials, claiming that the doctors working on Pfizer's behalf failed to acquire informed consent prior to the experiments and thus had violated customary international law. *Abdullahi v. Pfizer, Inc.*, 562 F. 3d 163 (2009). In a landmark decision, the Second Circuit upheld the court's jurisdiction and found a binding customary international law norm prohibiting nonconsensual medical experimentation. The parties eventually settled.

2 See Trials of War Criminals before the Nuremberg Military Tribunal, Vol. I and II, The Medical Case, U.S. Government Printing Office (1949) at the National Institutes of Health website, <http://ohsr.od.nih.gov/guidelines/nuremberg.html>.

3 General Assembly resolution 217A (III), U.N. Doc A/810 at 71 (1948) at the United Nations website, www.un.org/en/documents/udhr/.

4 Ibid, art. 5.

5 G.A. res. 2200A (XXI), Dec. 16, 1966, 993 U.N.T.S. 3 at the United Nations website, <http://treaties.un.org/doc/Publication/UNTS/Volume%20999/volume-999-I-14668-English.pdf>.

6 Jonathan Todres, "Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations?" 16 N.Y.L. SCH. J. HUM. RTS. 737, 745 (2000).

7 Convention on Human Rights and Biomedicine, Apr. 4, 1997, 2137 U.N.T.S. 171 at the Council of Europe website, <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

8 Explanatory Report on the Convention on Human Rights and Biomedicine, at para. 34, <http://conventions.coe.int/Treaty/en/Reports/Html/164.htm>.

9 Ibid

10 UNESCO website, http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

11 Ibid, art. 3.

CHAPTER 3: A HUMAN RIGHTS ASSESSMENT —LOUISE KUO HABAKUS, MA

1 Jonathan Mann et al, *Health and Human Rights, A Reader*, (New York: Routledge, 1999), 3.

2 Ibid, 9.

3 Ibid, 47-48.

4 Preamble, Charter of the United Nations, signed June 26, 1945, www.un.org/en/documents/charter/preamble.shtml.

5 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), 31.

6 Ibid, 28.

7 “FACA: Conflicts of Interest and Vaccine Development—Preserving the Integrity of the Process,” Hearing before the Committee on Government Reform, House of Representatives, One Hundred Sixth Congress, Second Session, June 15, 2000, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:73042.wais.

8 Mary Holland, “Reconsidering Compulsory Childhood Vaccination,” http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1677565.

9 Bernard Guyer et al., “Annual Summary of Vital Statistics: Trends in Health of Americans During the 20th Century,” *Pediatrics*, 106 (2000):1315, www.pediatrics.org/cgi/content/full/106/6/1307.

10 Ibid.

11 Tetanus Immune Globulin, Medscape, www.medscape.com/druginfo/monograph?cid=med&drugid=150460&drugname=Tetanus+Immune+Globulin.

12 Takis Panagiotopoulos et al., “Increase in congenital rubella occurrence after immunization in Greece: retrospective survey and systematic review,” *BMJ* (1999), December 4, 319(7223):1462–1467, www.ncbi.nlm.nih.gov/pmc/articles/PMC28289/?tool=pubmed.

13 “Exemptions from School Immunization Requirements,” Table of the National Conference of State Legislatures June 2010, www.ncsl.org/IssuesResearch/Health/SchoolImmunizationExemptionLaws/tabid/14376/Default.aspx.

14 James Colgrove, *State of Immunity: The Politics of Vaccination in Twentieth-Century America* (Berkeley: University of California Press, 2006), 158.

15 Ibid.

16 Ibid, 81.

17 Ibid, 113.

18 Ibid, 158.

19 Benjamin M. Nkowane et al., “Measles Outbreak in a Vaccinated School Population: Epidemiology, Chains of Transmission and the Role of Vaccine Failures,” *American Journal of Public Health*, 1987 April; 77(4): 434–438, www.ncbi.nlm.nih.gov/pmc/articles/PMC1646939/; TL Gustafson et al., “Measles outbreak in a fully immunized secondary-school population,” *New England Journal of Medicine*, 1987 March 26, 316(13):771-4, www.ncbi.nlm.nih.gov/pubmed/3821823; HJ Brockoff et al., “Mumps Outbreak in a Highly Vaccinated Student Population, The Netherlands, 2004,” *Vaccine*, 2010 April 9, 28(17):2932-6, E-pub 2010 Feb 25, www.ncbi.nlm.nih.gov/pubmed/20188683; and BD Tugwell et al., “Chickenpox outbreak in a highly vaccinated school population,” *Pediatrics*, 2004 March, 113(3 Pt 1):455–9, www.ncbi.nlm.nih.gov/pubmed/14993534.

20 “CDC: Most U.S. children receiving recommended vaccinations,” *Pediatric Supersite*, September 16, 2010, www.pediatricsupersite.com/view.aspx?rid=70382.

21 GM Lee et al., “Pertussis in adolescents and adults: should we vaccinate?” *Pediatrics*, 2005 June, 115(6):1675–84, www.ncbi.nlm.nih.gov/pubmed/15930232.

22 “Pertussis (Whooping Cough)—What You Need to Know,” Centers for Disease Control and Prevention, www.cdc.gov/features/pertussis/.

CHAPTER 4: DUE PROCESS AND THE AMERICAN CONSTITUTION — JAMES TURNER, JD

1 National Vaccine Injury Compensation Program, www.hrsa.gov/vaccinecompensation/statistics_report.htm.

2 The Center for Biologics Evaluation and Research (CBER) is a center within the Food and Drug Administration, an agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

3 Joseph Edward Smadel was a U.S. physician and virologist. He was the first recipient of the Albert Lasker Award for Clinical Medical Research. In the 1950s, under Smadel's leadership, Walter Reed Army Institute of Research established itself as one of the premier institutes for the study of infectious diseases, http://en.wikipedia.org/wiki/Joseph_Edward_Smadel.

4 Statement of Barbara Loe Fisher, President, National Vaccine Information Center, to California State Senate Committee on Health and Human Services, January 23, 2002, www.whale.to/v/fisher7.html.

5 Testimony of Barbara Loe Fisher, Co-Founder and President, National Vaccine Information Center, U.S. House Government Reform Committee, August 3, 1999, "Vaccines: Finding a Balance Between Public Safety and Personal Choice," www.whale.to/vaccines/fisher.html.

6 [www.exemptmychild.com/media//DIR_16101/Arkansas\\$20Vaccine\\$20Exemption\\$20Laws.pdf](http://www.exemptmychild.com/media//DIR_16101/Arkansas$20Vaccine$20Exemption$20Laws.pdf) section d(4).

7 All fifty states have legislation mandating specified vaccines for students. Although exemptions vary from state to state, all school immunization laws grant exemptions to children for medical reasons. Almost all states, except Mississippi and West Virginia, grant religious exemptions for people who have religious beliefs against immunizations. Twenty states allow philosophical exemptions for those who object to immunizations because of personal, moral or other beliefs. The National Conference of State Legislatures June 2010 Table "Exemptions from School Immunization Requirements" show individual state exemptions, www.ncsl.org/IssuesResearch/Health/SchoolImmunizationExemptionLaws/tabid/14376/Default.a

8 *Furman v. Georgia*, 408 U.S. 238 (1972).

9 In rare situations when the voluntary incidence rate is low and the population effect of the vaccine so well established that the government can prove the requirement for a vaccine, a mandate might be required for certain vaccines. However this should be a rare occurrence.

10 *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990).

11 *Parham v. J.R.*, 422 U.S. 584, 602; see also, *Troxel v. Granville*, 530 U.S. 57 (2000).

12 See, e.g. *Dela Rosa v. Sec’y of HHS*, 2001 U.S. Claims LEXIS 173, No. 93-433V at *3, 4 (encephalitis, intractable seizures, pancreatitis, and parotitis. Dela Rosa also suffered from dementia with a decline in IQ from 115 to 77, agitation and aggressive behaviors, and medically intractable localization-related epilepsy, according to medical records submitted in the case by the Mayo Clinic.); *Rice v. Sec’y of HHS*, 2001 U.S. Claims LEXIS 68, No. 98-438V at *39 (encephalopathy and seizures); *Miller v. Sec’y of HHS*, 2000 U.S. Claims Lexis 277, No. 95-0196 V, reissued 2002, at *1, 33 (acute encephalopathy and its sequelae, namely, permanent neurological damage including seizures and developmental delays).

13 See generally National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-1 et seq.

14 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

15 *McCarthy v. Boozman*, 212 F.Supp.2d 945 (W.D. Ark. 2002); and *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002).

16 *Jacobson*, note 14, 30 (emphasis added).

17 *Ibid*, 33, citing *Wisconsin & R.R. Co. v. Jacobson*, 179 U.S. 287, 301; 1 *Dillon Mun. Corp.*, 4th ed., §§319 to 325 and *Freund’s Police Power*, §63 et seq.

18 *State v. Martin & Lipe*, 134 Ark. 420 (1918) and *Brazil v. State*, 134 Ark. 420 (1918).

19 *Ibid*, *Brazil v. State*, 427.

20 *Brazil*, 428.

21 Brockman, Leslie N., “Enforcing The Right To a Public Education For Children Afflicted With AIDS,” 36 *Emory Law Journal*, 603, 615 n.70 (1987). The cases include *Burroughs v. Mortensen*, 312 Ill. 163, (1924); *Blue v. Beach*, 155 Ind. 121 (1900); *Osborn v. Russell*, 64 Kan. 507 (1902); *People ex rel. Hill v. Board of Educ.*, 224 Mich. 388 (1923); *State ex rel. Freeman v. Zimmerman*, 86 Minn. 353 (1902); *State ex rel. O’Bannon v. Cole*, 220 Mo. 697 (1909); *Glover v. Board of Educ.*, 14 S.D. 139 (1900); *McSween v. Board of School Trustees*, 60 Tex. Civ.App. 270 (1910); *State ex rel. Adams v. Burdge*, 95 Wis. 390 (1897).

22 *Ibid*, 615 n. 70. The cases include *People ex rel. Jenkins v. Board of Educ.*, 234 Ill. 422 (1908); *People ex rel. Lawbaugh v. Board of Educ.*, 177 Ill. 572 (1899); *Potts v. Breen*, 167 Ill. 67 (1897); *Rhea v. Board of Educ.*, 41 N.D. 449 (1919).

23 *United States v. Quinones*, 205 F. Supp. 2d 256 (S.D.N.Y.), rev’d, 313 F.3d 49 (2d Cir. 2002), cert. denied, 540 U.S. 1051 (2003).

24 *United States v. Quinones*, 196 F. Supp. 2d 416, 420 (S.D.N.Y.), rev’d, 313 F.3d 49 (2d Cir. 2002), cert. denied, 540 U.S. 1051 (2003).

25 *Quinones*, 205 F. Supp. 2d, 256.

26 *Quinones*, 196 F. Supp. 2d, 420.

27 *United States v. Quinones*, 313 F.3d 49 (2d Cir. 2002), cert. denied, 540 U.S. 1051 (2003).

28 *Herrera v. Collins*, 506 U.S. 390 (1993), concurring opinion.

CHAPTER 5: THE RIGHT TO LEGAL REDRESS —MARY HOLLAND, JD, AND ROBERT J. KRAKOW, JD

1 The 1986 National Childhood Vaccine Injury Act acknowledges that vaccine injury or death may be “unavoidable even though the vaccine was properly prepared and accompanied by proper directions and warnings.” 42 U.S.C. 300aa-22(b)(1). The “unavoidable” language in the Act is from the Restatement (Second) of Torts that applies to “products which, in the present state of human knowledge, are quite incapable of being made safe.” Restatement (Second) of Torts Section 402A, comment k (1965).

2 According to the Centers for Disease Control and Prevention, “[y]ears of testing are required by law before a vaccine can be licensed. Once licensed and in use, vaccines are continuously monitored for safety and efficacy,” www.cdc.gov/vaccinesafety/Vaccines/Index1.html.

3 The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 et seq.

4 42 U.S.C. § 300aa- 14; see also www.hrsa.gov/vaccinecompensation/table.htm.

5 HHS information on vaccine injury compensation, www.hrsa.gov/vaccinecompensation/statistics_report.htm.

6 For example, Dr. Martin Smith, the President of the American Academy of Pediatrics, wrote in an article about the 1986 act to his members that “[t]his was the best compromise settlement . . . that could be reached.” Martin H. Smith, National Childhood Vaccine Injury Act, *Pediatrics* 82 (1988):264. From a different perspective, Barbara Loe Fisher, President of the National Vaccine Information Center, said in an address to the Advisory Commission on Childhood Vaccines about the work of parents in crafting the 1986 Act, “[w]e believed we were participating in the development of a law which would give—in the words of the then AAP Chairman—‘simple justice to children,’” www.nvic.org/injury-compensation/vaccineinjury.aspx.

7 Remarks of Robert Krakow at American Rally for Personal Rights, Chicago, IL, May 26, 2010, www.americanpersonalrights.org.

8 See note 5 for HHS information.

9 The Omnibus Autism Proceeding was a set of six test cases chosen from approximately 5,000 petitions to determine whether vaccines caused autism in those cases. The cases lasted approximately eight years, presenting thousands of pages of science and testimony and tens of witnesses on two theories, that the mercury-containing preservative thimerosal causes autism alone and that thimerosal together with the measles-mumps-rubella vaccine causes autism, www.uscfc.uscourts.gov/sites/default/files/autism.background.2010_0.pdf.

10 To be sure, there is evidence that individual Special Masters exercise appropriate independence. Our critique is directed to the VICP as an institution and not to the performance of individual Special Masters.

11 Information on the Vaccine Safety Datalink at the CDC website, www.cdc.gov/vaccinesafety/Activities/VSD.html.

12 Institute of Medicine, “Vaccine Safety Research, Data Access, and Public Trust,” www.iom.edu/Reports/2005/Vaccine-Safety-Research-Data-Accessand-Public-Trust.aspx, noting that the CDC’s handling of the VSD thimerosal data suffered from a “lack of transparency,” that datasets “were not archived in a standard manner,” and “are not available for reanalysis,” and that CDC officials should “seek legal advice” regarding possible violations of the Federal Data Quality Act. The critical VSD information is allegedly available offshore in the archives of a private healthcare provider. The Special Masters of the Court of Federal Claims presumably could have issued subpoenas for this information but did not. For a detailed discussion of the VSD and the possible thimerosal-autism link, see David Kirby, *Evidence of Harm: Mercury in Vaccines and the Autism Epidemic: A Medical Controversy* (New York: St. Martin’s Press, 2005).

13 *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005).

14 Concession agreement linked to David Kirby, “Government Concedes Vaccine-Autism Case in Federal Court—Now What?” *Huffington Post*, February 25, 2008, www.huffingtonpost.com/david-kirby/government-concedesvacci_b_88323.html.

15 Compensation decisions at the Court of Federal Claims website, *Child Doe/77 v. Secretary of HHS*, 2010, <http://www.uscfc.uscourts.gov/sites/default/files/CAMPBELLSMITH.%20DOE77082710.pdf>.

16 *Hazlehurst v. HHS*, Court of Federal Claims, 2009, <ftp://autism.uscfc.uscourts.gov/autism/vaccine/Campbell-Smith%20Hazlehurst%20Decision.pdf>; and *Hazlehurst v. HHS*, U.S. Court of Appeals for the Federal Circuit, 2010, www.cafc.uscourts.gov/images/stories/opinions-orders/09-5128.pdf.

17 The Special Master in the VICP admitted DOJ’s expert report of Dr. George Bustin without admitting the underlying data verifying his expert report. This data was crucial to the final decision that Michelle Cedillo’s autism was not caused by the measles virus. The judges of the U.S. Court of Appeals for the Federal Circuit acknowledged that the lack of underlying data for the Bustin report was “troubling,” but did not require that the data be produced in part because the formal rules of civil procedure do not apply. *Cedillo v. HHS*, 2010-5004, (Fed. Cir. August 27, 2010), www.cafc.uscourts.gov/images/stories/opinions-orders/10-5004.pdf.

18 In the Omnibus Autism Proceeding, DOJ frequently referred to Dr. Andrew Wakefield’s character and laboratory, although he was not a party to the litigation and had no direct relevance to it. DOJ had Dr. Chadwick testify because Dr. Chadwick had worked in Dr. Wakefield’s laboratory, although he had no knowledge about the laboratory where Michelle Cedillo’s measles biopsy laboratory analyses were actually done. *Cedillo v. HHS*, 2009 WL 331968 at 56. Similarly, in closing arguments DOJ’s lead attorney Vincent Matanoski stated that “all the strands through these cases come back to him [Andrew Wakefield]. He presented bad science.” *Cedillo* Transcript, June 26, 2007, 2898-99 at A599–A600.

19 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995).

20 *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1280.

21 Rebecca Estepp, parent of child in the Omnibus Autism Proceeding and vaccine safety advocate, as quoted in Coalition for Vaccine Safety press release, www.coalitionforvaccinesafety.org/press.htm.

22 See, e.g., Carolyn Gallagher & Melody Goodman, "Hepatitis B Triple Series Vaccine and Developmental Disability in U.S. Children Aged 1-9 Years," *Toxicology and Environmental Chemistry* 997 (2008); Kara L. McDonald et al., "Delay in Diphtheria, Pertussis, Tetanus Vaccination Is Associated With a Reduced Risk of Childhood Asthma," *Journal of Allergy and Clinical Immunology* 121 (2008):626.

23 Transcript of oral argument, *Bruesewitz v. Wyeth*, No. 09-152, October 12, 2010, 30, www.supremecourt.gov/oral_arguments/argument_transcripts/09-152.pdf.

CHAPTER 6: GOD AND THE GOVERNMENT —WILLIAM WAGNER, JD

1 Early in history, God, through Moses, introduces the divine law and mandates that parents are to talk about these commandments at home and impress them upon their children. Children are to obey and honor their parents. Deuteronomy 5:16; Ephesians 6:1–3. Here God also promises a long life and that it will go well for those who follow the commandments. Later, in Proverbs, God provides divine wisdom, guiding parents to “train” their children in the way they should go, so that when they grow old they “will not depart from it.” Proverbs 22:6. In the raising of children, God provides that parents should exercise appropriate corrective discipline, that is to say, discipline grounded in love. Proverbs 13:24. In Paul’s letter to the Ephesians, God confirms that parents are to bring up their children “in the training and instruction of the Lord.” Ephesians 6:4.

2 See Joshua 24:15.

3 The writings of Pufendorf, Grotius, and Locke, for example, all expressly recognized the right of parents to direct and control decisions concerning the upbringing of their children. See, e.g., PUFENDORF, *The Two Books on the duty of man and citizen according to the natural law*, Chapter 3, sections 1 and 2, www.constitution.org/puf/puf-dut_203.txt. Pufendorf, when discussing parents and children, writes:

From marriage spring children, over whom paternal authority has been established—the most ancient and at the same time the most sacred kind of rule, under which children are bound to respect the commands and recognize the superiority of parents.

The authority of parents over their children arises from two main causes: first, because the natural law itself, in commanding man to be social, enjoined upon parents the care of their children; and that this might not be neglected, Nature at the same time implanted in them the tenderest affection for their offspring. For the exercise of that care there is needed the power to direct the actions of children for their own welfare, which they do not yet understand themselves, owing to their lack of judgment. And then that authority rests upon the tacit consent also of the offspring. For it is rightly presumed that, if an infant had had the use of reason at the time of its birth, and had seen that it could not save its life without the parents’ care and the authority therewith connected, it would gladly have consented to it, and would in turn have made an agreement with them for a suitable bringing-up. Actually, however, the parents’ authority over their offspring is established when they take up the child and nurture it, and undertake to form it, to the best of their ability, into a fit member of human society.

Thus, for Pufendorf, it is for the parent to “support their children in comfort, and so shape their body and mind by skillful and wise education, that they become fit and useful members of human and civil society.” *Ibid.*, section 11. Such parental direction results in “good” and “wise” adult children of character.

Grotius, in his writings on the natural law likewise recognized the right of parents to direct and

control the upbringing of their children. HUGO GROTIUS, *The Rights of War and Peace*, Book 1, The Preliminary Discourse XV.

Locke, too, understood that parents have the natural right to direct and control the upbringing of their children for their good, including their instruction. JOHN LOCKE, *The Second Treatise of Government*, 96 (PRENTICE HALL 1952) (1690).

4 See JOHN LOCKE, *The Second Treatise of Government*, 96-99 (Prentice Hall 1952) (1690). Locke writes: Section 169. “THOUGH I have had occasion to speak of these separately before, yet the great mistakes of late about government, having, as I suppose, arisen from confounding these distinct powers one with another, it may not, perhaps, be amiss to consider them here together.” Locke states:

First, then, Paternal or parental power is nothing but that which parents have over their children, to govern them for the children’s good.... The affection and tenderness which God hath planted in the breast of parents toward their children, makes it evident, that this is not intended to be a severe arbitrary government, but only for the help, instruction, and preservation of their offspring. Section 170, 96–97.

And thus, ‘tis true, the paternal is a natural government, but not at all extending itself to the ends and jurisdictions of that which is political. The power of the father doth not reach at all to the property of the child, which is only in his own disposing. Section 170, 97.

Secondly, Political power is that power, which every man having in the state of nature, has given up into the hands of the society, and therein to the governors, whom the society hath set over itself, with this express or tacit trust, that it shall be employed for their good, and the preservation of their property. Section 171.

Nature gives the first of these, viz. paternal power to parents for the benefit of their children during their minority, to supply their want of ability, and understanding how to manage their property. . . . Voluntary agreement gives the second, viz. political power to governors for the benefit of their subjects, to secure them in the possession and use of their properties. And forfeiture gives the third despotical power to lords for their own benefit, over those who are stripped of all property. Section 173, 98–99.

Thus, the natural law thinkers also recognized that a parent may delegate, while retaining oversight of the delegation, aspects of the upbringing of their children. Pufendorf writes:

[A]lthough the obligation to educate their children has been imposed upon parents by nature, this does not prevent the direction of the same from being entrusted to another, if the advantage or need of the child require, with the understanding, however, that the parent reserves to himself the oversight of the person so delegated. (emphasis added) PUFENDORF, *The Two Books on the duty of man and citizen according to the natural law*, Chapter 3, section 9, www.constitution.org/puf/puf-dut_203.txt.

5 In particular, parents hold the authority and responsibility over the maintenance, protection, and education of their children. For example, Blackstone writes in *The Rights of Persons*, Book I. Ch. 16, 435-36; 439-42, Chapter 16, “Parent and Child”)

THE duty of parents to provide for the maintenance of their children is a principle of natural law; an obligation, says Pufendorf, laid on them not only by nature herself, but by their own proper act, in bringing them into the world: for they would be in the highest manner injurious to their issue, if they only gave the children life, that they might afterward see them perish. By begetting them therefore they have entered into a voluntary obligation, to endeavour, as far as in them lies, that the life which they have bestowed shall be supported and preserved. And thus the children will have a perfect right of receiving maintenance from their parents....

THE last duty of parents to their children is that of giving them an education suitable to their station in life: a duty pointed out by reason, and of far the greatest importance of any. For, as Pufendorf very well observes, it is not easy to imagine or allow, that a parent has conferred any considerable benefit upon his child, by bringing him into the world; if he afterward entirely neglects his culture and education, and suffers him to grow up like a mere beast, to lead a life useless to others, and shameful to himself.

6 *Pierce v. Society of Sisters*, 268 U.S. 510 (1925).

7 *Wisconsin v. Yoder*, 406 U.S. 205 (1972).

8 See e.g., the Declaration of Independence.

9 The state-mandated vaccination progeny of the Supreme Court decision *Jacobson v Massachusetts*, 197 U.S. 11 (1905), is a case in point. In the midst of a national smallpox epidemic, the Supreme Court upheld a government mandated adult vaccination program. The *Jacobson* Court opined that “the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to [government] restraint . . . as the safety of the general public may demand.” 197 U.S. at 26. Chapter 1 explains how governments subsequently relied on this decision improperly to justify mandated vaccinations for exponentially milder public safety interests.

**CHAPTER 7: AN URGENT CALL FOR MORE RESEARCH —
CAROL STOTT, PHD (CANTAB), MSC (EPIDEMIOLOGY), CSCI,
CPSYCHOL, AND ANDREW WAKEFIELD, MB, BS, FRCS,
FRCPATH**

1 Institute of Medicine, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (Inst. of Med., 2002), ix.

2 Institute of Medicine (1991) ‘Adverse Effects of Pertussis and Rubella Vaccines’, *Institute of Medicine*, 8.

3 Institute of Medicine, *Research Strategies for Assessing Adverse Events Associated with Vaccines*, (Inst. of Med., 1994), 1.

4 Ibid, 16.

5 Ibid, 16–17.

6 Institute of Medicine, *Vaccine Safety Forum: Summaries of Two Workshops* (Inst. of Med., 1997), 1.

7 Ibid, 2.

8 Institute of Medicine, *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders* (Inst. of Med., 2001), 82.

9 Ibid, 74.

10 Ibid, 65.

11 Ibid, 66.

12 Ibid, 75.

13 Institute of Medicine, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (Inst. of Med., 2002), 18.

14 Ibid, 36.

15 Ibid, 14.

16 Institute of Medicine *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction*, (Inst. of Med., 2002), 2.

17 Advisory Commission on Childhood Vaccines (ACCV) and National Vaccine Advisory Committee (NVAC) Subcommittees on Vaccine Safety, May 31, 1995, Parklawn Building, Conference Room D, Rockville, Maryland, at 75. Transcript available from Division of Vaccine Injury Compensation, Parklawn Building, Room 8A-35, 5600 Fishers Lane, Rockville, Maryland

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18 Louis Z. Cooper et al., "Protecting Public Trust in Immunization," *Pediatrics* 122:1 (2008): 149–153, www.pediatrics.org/cgi/content/full/122/1/149.

19 R. Nordness, *Epidemiology and Biostatistics Secrets* (Philadelphia: Elsevier, 2006), 27.

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21 Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (Inst. of Med., 2004), www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx.

22 Wikipedia, "Evidence-based medicine," from http://en.wikipedia.org/wiki/Evidence-based_medicine.

23 Wikipedia, "Randomized Controlled Trial," http://en.wikipedia.org/wiki/Randomized_controlled_trial.

24 Passage of H.R. 3069 requires the Secretary of Health and Human Services (HHS), acting through the Director of the National Institutes of Health (NIH), to conduct a comprehensive study to (1) compare the total health outcomes, including the risk of autism, between vaccinated and unvaccinated U.S. populations; and (2) determine whether vaccines or vaccine components play a role in the development of autism spectrum or other neurological conditions. It also requires the Secretary to seek to include in the study U.S. populations that have traditionally remained unvaccinated for religious or other reasons.

25 Mark Blaxill, "From the Roman to the Wakefield Inquisition," *Age of Autism* blog, www.ageofautism.com/2010/01/from-the-roman-to-the-wakefield-inquisition.html.

26 Sharyl Attkisson, "Leading Doctor: Vaccines-Autism Worth Study," *CBS News*, May 12, 2008, www.cbsnews.com/stories/2008/05/12/cbsnews_investigates/main4086809.shtml.

27 *Ibid*, 9.

28 *Ibid*, 6.

29 *Ibid*, 7.

30 Institute of Medicine, *Immunization Safety Review: Vaccines and Autism*, Opening Statement, May 18, 2004, http://vaccinesafety.ecbt.org/ecbt/Website_documents/IOM_Executive_Summary/Opening_State

31 *Associated Press*, "1 in 4 parents think shots cause autism," March 1, 2010, www.msnbc.msn.com/id/35638229/ns/health-kids_and_parenting/.

32 T. Neale, "Vaccine and Drug Safety Top Parents' Research Priorities," *Medpage Today*, October 12, 2010, www.medpagetoday.com/Pediatrics/GeneralPediatrics/22696.

- 33 American Academy of Pediatrics News Release, “How the Anti-Vaccine Movement Threatens America’s Children,” October 4, 2010, www.aap.org/pressroom/Offitfinalantivaccine.pdf.
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- 35 Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines*, (Inst. of Med., 1991), 7; Stratton et al., “Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella,” *JAMA*, 271:20 (1994):1602-1605, <http://jama.ama-assn.org/cgi/content/abstract/271/20/1602>.
National Vaccine Injury Compensation Program Vaccine Injury Table, www.hrsa.gov/vaccinecompensation/table.htm.
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CHAPTER 19: MERCURY TOXICITY AND VACCINE INJURY — BOYD HALEY, PHD

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CHAPTER 20: FORCED CHILD REMOVAL —KIM MACK ROSENBERG, JD

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- 3 An example of this abuse of power is the use of children in foster care in drug trials, in some cases without appropriate informed consent. Such abuse implicates both state agencies and the federal government. For more on this topic, see www.ahrp.org. Another example of misuse of state power and perhaps the good intention to protect children run amok is the 1980s prosecutions of Violet Amirault and her adult children, convicted of crimes against children in their care. Their day care center in Massachusetts had been well-regarded. Journalist Dorothy Rabinowitz has written extensively on this case and the “evidence” against the Amiraults in the *Wall Street Journal* and in *No Crueler Tyrannies: Accusations, False Witness And Other Terrors of Our Times* (Free Press, 2003).
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- 5 It is not just the children and families who are being investigated; doctors who treat these children also are being investigated.
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30 Ibid.

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32 *In re: A.Y. v. R.B.*, 2008 N.Y. Misc. LEXIS 7311 (Fam. Ct., Nassau Co., Dec. 18, 2008) (court denied motion by Nassau County Department of Social Services to immunize previously unvaccinated children in foster care pending determination of neglect petition, including medical neglect, where children had previously attended school unvaccinated based on written information supplied by mother and her religious leader); see also the unpublished decision in *In re Shmuel and Ester G*, 6 Misc. 3d 1018A, 800 N.Y.S.2d 357, 2005 N.Y. LEXIS 199 (Fam. Ct., Kings Co. Feb. 7, 2005).

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34 *In re Shmuel and Ester G*, note 32.

35 Ibid, *2-3.

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37 Ibid, *11.

38 Ibid, *6.

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CHAPTER 21: GENETIC INFORMATION: WHERE DO WE GO FROM HERE?—TWILA BRASE, RN

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CHAPTER 22: A DOCTOR'S VIEW OF VACCINES AND THE PUBLIC HEALTH—SHERRI TENPENNY, DO

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CHAPTER 23: A HOLISTIC HEALTH PERSPECTIVE — ANNEMARIE COLBIN, PHD

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CHAPTER 24: WHAT SHOULD PARENTS DO? —LOUISE KUO HABAKUS, MA

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“The diphtheria vaccine doesn’t cause serious side effects.” 41.

“The tetanus vaccine is safe.” 44.

“IPV [is] completely safe.” 48.

“Is the Hib vaccine safe? Yes. Side effects are mild.” 53.

“The chance of serious side effects or death from the measles vaccine is about zero.” 60.

“The mumps vaccine does not cause any serious side effects . . . the chance of having a serious reaction from the mumps vaccine is about zero.” 62.

“The most serious side effect from rubella vaccine is the development of shortlived—less than one week, and not chronic—arthritis.” 65.

“No one has ever died as a result of hepatitis B vaccination.” 74.

“The [varicella] vaccine does not cause serious side effects.” 82.

“The pneumococcal vaccine does not have serious side effects.” 86.

“More than 1 million doses of the rabies vaccine have been given, and the vaccine is safe.” 123.

“Because the [flu] vaccine does not cause serious reactions, the benefits of the vaccine clearly outweigh its risk in *all* young children.” 130. (emphasis theirs)

“Is the meningococcal vaccine safe? Yes. There are no serious side effects from the vaccine.” 133.

“The tuberculosis vaccine is safe.” 139.

“Although it is relatively new, hundreds of thousands of people have been given the hepatitis A vaccine without any serious side effects.” 149.

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CHAPTER 25: WHO IS DR. ANDREW WAKEFIELD? —MARY HOLLAND, JD

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CHAPTER 26: THE SUPPRESSION OF SCIENCE —ANDREW WAKEFIELD, MB, BS, FRCS, FRCPATH

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APPENDIX TO CHAPTER 24: WHAT SHOULD PARENTS DO? — LOUISE KUO HABAKUS, MA

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9 Dennis M. Katkocin and Chia-Lung Hsieh, "Pharmaceutical Aspects of Combination Vaccines," in Ellis, *Combination Vaccines*, *ibid*, 56, 62.

10 Emmanuel Vidor, Agnes Hoffenbach, and Stanley Plotkin, "Pediatric Combination Vaccines," in Ellis, *Combination Vaccines: Development, Clinical Research, and Approval*, (Totowa: Humana Press, Inc., 1999), 1.

11 Katkocin and Hsieh, 57.

12 *Ibid*, 56.

13 Col SK Jatana and Brig MNG Nair, "Combination Vaccines," *MJAFI* 2007; 63 : 167–168.; Boaventura Antonio dos Santos et al., "An evaluation of the adverse reaction potential of three measles-mumps-rubella vaccines," *Rev Panam Salud Publica/Pan Am J Public Health* 12(4), 2002, 240–247. Some different mechanisms or routes by which combination vaccines can cause a greater degree of injury include:

Certain bacteria release toxins. The increased endotoxin load of the formulated bulk can cause health problems.

A toxoid is a substance that is modified to become less toxic but is still able to stimulate an immune response. When a toxoid is used as a carrier protein for a conjugate vaccine, it may contain trace levels of residual toxins that, when combined, result in an excessive total level of toxoid.

Adjuvants are added to vaccines to stimulate a greater immune response. When adjuvanted vaccines are added to nonadjuvanted antigens, the combination can be damaging.

The use of other ingredients in combination with each other, such as preservatives, buffers, and stabilizers, can cause injuries.

14 Kathryn M. Edwards and Michael D. Decker, "Practitioners in the Use of Combination Vaccines," *Combination Vaccines*, note 8, 254.

15 Peter R. Paradiso and Robert Kohberger, "Pediatric Combination Vaccines: Clinical Issues," *ibid*, 96.

16 Laurie Barclay, "Guidelines Updated for Administration of Combination MMRV Vaccine," *Medscape Medical News*, March 18, 2008, <http://cme.medscape.com/viewarticle/571595>. .

17 Mitchell, *AAFP News Now*.

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19 Katkocin and Hsieh, 58.

- 20 Ellis, ix.; Jatana and Nair, 167–168.
- 21 Vidor et al., 1.
- 22 Paradiso and Kohberger, 96.
- 23 Vaccine package inserts available for all FDA-licensed vaccines at www.immunize.org/fda/.

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CONTRIBUTORS

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Robert Krakow, JD is an attorney in private practice in New York and represents individuals in a variety of legal matters, including injuries from environmental toxins and vaccines. After receiving a JD from George Washington University School of Law in 1980, he began his career in public service as an attorney with the New York Public Interest Research Group (NYPIRG), a consumer advocacy group. From 1981 to 1989, Bob served as an assistant district attorney with the New York County District Attorney's Office, and as Bureau Chief in the special narcotics prosecution division. He founded his law firm in 1989, specializing in the litigation of criminal and civil matters. Krakow has a long history of vigorously advocating for the rights of children with autism and other disabilities. He is a cofounder of the Elizabeth Birt Center for Autism Law and Advocacy. He has served as Chairman of the Board of Directors of Lifespire, Inc., a

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Amy Pingel is a single mother of four children from Lake Station, Indiana. Her thirteen-year-old daughter Zeda sustained two seizures and lost the ability to eat, walk, and communicate three weeks after receiving her first dose of human papillomavirus (HPV) quadrivalent vaccine, known as Gardasil. Caring for her daughter, who remains on life support, Pingel had to quit her job as the manager of a local gas station. Recovery of quality of life for Zeda remains her top priority. Pingel is part of a growing advocacy movement of parents committed to telling the truth about their children's injuries caused by the HPV vaccine.

Richard Rovet, RN, BSN, B-C (USAF, ret) is a decorated veteran who honorably served in the United States Air Force for over twenty-four years. As a registered nurse in the military, he has served in leadership positions for most of his career, has treated patients in both emergency and trauma settings, and was competitively selected as "Best Officer" several times. Rovet served as a fighter aircraft inspector and mechanic, a flight medic, a clinical nurse and healthcare integrator, Charge Nurse, and manager of the largest internal medicine specialty clinic in the U.S. Air Force. Rovet witnessed, recorded, treated, and interviewed hundreds of individuals with Gulf War Illness and anthrax vaccine reactions on three separate air force bases. He is now retired from active duty. Rovet received his nurse training at Excelsior College. Rovet has testified before Congress on illnesses associated with the military's mandatory anthrax vaccination program. His advocacy on behalf of these veterans continues to this day.

Vera Hassner Sharav, MLS is a public advocate for human rights. She is the founder and President of the Alliance for Human Research Protection (AHRP), an information resource and catalyst for debate, committed to accountability in biomedical research. AHRP Infomails are followed by healthcare professionals, FDA officials, journalists, lawyers, and patient advocates. Sharav's achievements include opening public debate about the ethics of psychosis-inducing experiments. Her testimony and the testimonies of victims of unethical experiments catalyzed a prize-winning Boston Globe series, which prompted the National Institute of Mental Health to

suspend twenty-nine clinical trials. AHRP-filed complaints led to the suspension of a pediatric pesticide experiment, federal investigations on the use of foster-care children in experimental AIDS drug and vaccine trials, suspension of a pediatric smallpox vaccine trial, and Congressional hearings about a “violence prediction” experiment conducted on inner city pre-adolescent boys. Sharav has testified before numerous academic and government-sponsored public policy advisory forums, including the World Congress of Science Journalists. Sharav holds a Master of Library Science from the Pratt Institute. She is a child survivor of the Holocaust and witnessed the death of her father from typhus because he did not have access to penicillin. More information is available at www.ahrp.org.

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Allen Tate is a New York University student majoring in philosophy. He has two younger siblings who were both adversely affected by vaccine-induced injuries and have been diagnosed with regressive autism. Born in 1989, Tate was vaccinated according to the CDC’s 1983 schedule and has remained healthy while his siblings, born in 1992 and 1996 respectively, have suffered the severe consequences of the increased vaccination schedules of the 1990s. His family resides in the suburbs of Philadelphia. Tate is committed to vaccination choice activism and

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Andrew Wakefield, MB, BS, FRCS, FRCPath is an academic gastroenterologist from the United Kingdom and was the lead author of the 1998 *The Lancet* paper, a small case study series that was one of the first to posit a possible link between vaccines, intestinal inflammation and neurologic injury in children. Wakefield received his medical degree from St. Mary’s Hospital Medical School (University of London). He pursued a career in gastrointestinal surgery with a particular interest in inflammatory bowel disease, for which he has received numerous honors and has published over 140 original scientific articles, book chapters and invited scientific commentaries. As a result of his groundbreaking work concerning vaccines and neurologic injury, Wakefield lost his job, his country, his career and his medical license. He is author of the best-selling book *Callous Disregard: Autism and Vaccines—The Truth Behind a Tragedy*.

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