

Vaccine Risks, Benefits, and Compensation

James T. O'Reilly
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This book's cover features a 1788 portrait by Jacques Louis David. The full painting depicts the French chemist Antoine Laurent Lavoisier and his wife Marie Anne Pierrette Paulze. The couple worked together to discover oxygen and the chemical composition of water. Antoine was executed in the French Revolution, but Marie Anne was able to save his work and later published it, securing her husband's scientific legacy. The image is provided courtesy of The Metropolitan Museum of Art, New York's Open Access project, where it can be viewed in full at <https://www.metmuseum.org/art/collection/search/436106>.

*This Book Is Dedicated
To the Memory of Terry Abaray,
Whose Smiles & Energy
Encouraged Us All*

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Preface

The healthcare field is full of strange and little-noticed episodes that did not seem important at the time but later came to be of significant interest. The history of vaccines is full of odd stories of eccentric inventors, like Jenner's cowpox cure in the late 1700s, and of unusual circumstances, sometimes emerging from a quiet need for cures, and sometimes responding to public alarm about plague risks. The speech given on the Senate floor by then-Senator Joe Biden in the last days of the 2005 U.S. Senate session warned that drug industry lobbyists had created a "must-pass" legislative enactment that was tacked on to hurricane relief and military appropriations bills, without Senate Judiciary Committee hearings. Like the remarks of Senator Ted Kennedy and others, the Biden wisdom was a cautionary tale, that individuals who might be harmed by a vaccine would someday be blocked from recovering damages because of the last-minute addition of this formidable shield for the benefit of the pharmaceutical lobby. In doing so, the lobbyists had cast their fate with a majority Republican caucus, avoided public hearings, and wedged their changes in before the deadline for closing that year's Senate business. The concerns proved prescient; by the time that vaccine issues had become front-page news for Biden, the forty-sixth president of the United States, adverse events had begun to be noticed, but many compensation claims were doomed by the legislative barricades.

Beyond the COVID-19 barriers, there are compensation opportunities for parents and children who experienced serious harm from older, more familiar vaccine immunizations. We say "opportunities" rather than "rewards," for the skilled counsel must follow a tight set of twists and turns to achieve fair compensation, as more than 5,000 have done since 1986. This book maps out the turns and twisting paths are required for success in achieving compensation. Vaccines are safe, but some vaccines in the arms of some recipients generate adverse responses. A compensation system with barricades and twists that prevents compensation does not serve the public health needs of the populace.

The authors greatly appreciate the wise assistance of Jessica Powell and her colleagues at the Burg Simpson law firm office in Cincinnati, Ohio. Ms. Powell has a bright career ahead as a skilled litigator in pharmaceutical liability litigation.

Professor O'Reilly thanks his excellent team of student researchers, including Angel Ehrenschwender, Danya Shah, Selena Kanetkar, Celeste Tio, and

Zander Hary. Their energetic pursuit of knowledge marks their progress toward exceptional careers. The skilled professional librarian assistance of Susan Boland and Edith Starbuck at the University of Cincinnati was very helpful to the project's timely completion.

We thank the numerous legal advocates who tirelessly pursue these claims for their clients, especially the Vaccine Injured Petitioners Bar Association, and the public servants of the National Vaccine Injury Compensation Program (VICP) and the Justice Department, who shared their insights informally without attribution. When Professor O'Reilly testified in the May 2020 public hearing on VICP proposed changes, it was most helpful to listen to claimants and their counsel interact with VICP leadership.

My faculty colleagues and students at the College of Medicine, University of Cincinnati, provided many helpful perspectives and opportunities. My family, especially my wife Carol O'Reilly, were patient, encouraging, and inspirational. I thank them all for their fortitude over the weeks of research. We welcome comments and suggestions for future editions, at joreilly@fuse.net.

Prof. James O'Reilly

Introduction

This is a story of the law and politics of fighting infections. If you are an attorney who chooses to become involved with a client whose injury, infection, or other harm resulted from the injection of a vaccine, your decision to accept that case will have costs and consequences that we discuss in this book.

So it is most prudent for counsel to understand the legal issues and also the history, biochemistry, and biology of the vaccine development process. It is especially important whether the injured client received a vaccine for COVID-19 or for one of a dozen childhood or adult vaccines. That is because Congress in 1986 chose to give vaccine makers special status, a form of legal immunity from liability, and Congress agreed in 2005 to expand that protection to erect a broad shield from liability for those who make or market vaccines that are designated by the federal government as “countermeasures” for certain infections that carry a high risk of serious illness or death. COVID-19 was so designated on March 17, 2020, and its vaccines became legally protected as “countermeasures.” The 2020-2022 risks of COVID-19 are being closely studied, but the legal and policy fallout from the earlier vaccine legislation is not yet fully appreciated. This text is aimed at what we know now, and how it can be handled. We recognize that “hindsight will be 20/20.”

Please do not waste your effort and the client’s money by mistakenly treating compensation claims for vaccine harms as just another subset of state court tort litigation. If you wish to represent the client’s best interests, this text will support your effort to “do your homework” and to target your efforts appropriately. Tort cases against most vaccines, including COVID, would be barred by the legislative shield. We emphasize in this text the ways in which your client’s needs may be protected. There are ways to win compensation awards for your injured clients, but they are not achieved by following the conventional paths of classical tort law; instead, the winning path leads into the remarkable jungle of federal vaccine laws and regulations that were created by industry lobbyists to thwart their clients’ tort accountability. This is, by its nature, an unfinished symphony, awaiting future studies about the fallout of the coronavirus pandemic and its public costs.

Vaccine Risks, Benefits, and Compensation

Part I

The Science Background

What Is the Role of a Vaccine in Helping to Avoid Illnesses?

Immunity is defined as protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.

Vaccination is the act of introducing a vaccine into the body to stimulate the recipient's immune system to produce immunity to a specific disease, ultimately protecting the person from that disease. Vaccines are commonly given via needle injections, but can also be distributed by mouth or sprayed into the nose.

The goal of vaccination is to prevent disease. The disease comes from a "pathogen" that could enter the body via a bacteria, virus, parasite, or fungus. Each pathogen contains its own specific antigen. Once a pathogen enters the body, the immune system begins to form antibodies to protect against the pathogen's specific antigen. Antibodies are proteins made by white blood cells as an immune response, and antibodies can bind specific antigens. Once bound, the antibody destroys the antigen. Some antibodies destroy antigens directly, while others make it easier for white blood cells to destroy the antigen. When the human body is exposed to an antigen for the first time, it takes time for the immune system to respond and produce antibodies specific to that antigen.

Vaccines often contain weakened or inactive parts of a specific antigen and will trigger an immune response within the body. This weakened version will not cause the disease in the person receiving the vaccine, but it will prompt their immune system to respond much as it would have on its first reaction to the actual pathogen. Some vaccines take a different approach at the cellular level, affecting the RNA of the cells. Many vaccines can require multiple doses, given weeks or months apart. This is needed to allow for the recipient body's production of long-lived antibodies and development of memory cells. This way the body is trained to fight the specific disease-causing antigen, and it will create a memory of the pathogen so as to rapidly fight it if and when the body is exposed in the future.

Introduction to Vaccine History

Vaccination, the process of introducing weakened or inactivated material from an infectious organism or virus into a human body to train its immune response, has great importance in maintaining the public health of societies both domestically and abroad. In the past, vaccination was a hotly debated topic dominated by theories that could not fully explain how this process of immunization worked. In 1796, the British doctor Edward Jenner used the vaccinia virus (which causes cowpox) to transfer smallpox immunity to a human. Smallpox, the highly contagious and deadly disease that was eradicated in 1980 through vaccinations, was quite literally a plague on humanity for millennia. According to recent archaeological findings, smallpox may have evolved alongside humanity since the third century BCE.¹ The disease, resulting from damage caused by the variola virus, was characterized by recognizable smallpox sores or pustules and intense fevers that resulted in death for approximately three out of ten individuals who contracted the virus (30 percent mortality).²

Efforts to eliminate smallpox and poliomyelitis have saved millions of lives. In modern times, we know much more about safely designing vaccines, and most countries have adopted certain requirements known as vaccine schedules. These establish a schedule of child vaccination, because of the overall benefit to the community from vaccination that reduces the potential spread of a pathogen like smallpox. Within the United States, these schedules are implemented state-by-state, and child vaccinations are required to enroll the child in public school. While government regulatory agencies are mostly involved in enforcing and determining appropriate vaccination campaigns and schedules, public opinion toward vaccines also contributes to a large extent in the individual choices regarding vaccination. Although the great majority of Americans consider the benefits of vaccination to outweigh the potential risks, there are still opponents to vaccination recommendations.³ You will find citations throughout this book to the divergent roots of science, law, and policy that created our modern vaccine structure. We hope that immunity from the harsh effects of mistrust and hostility will help to protect you, whatever the legal system might present as risks to you and to your clients.

¹ “History of Smallpox,” Centers for Disease Control and Prevention, last reviewed August 30, 2016, <https://www.cdc.gov/smallpox/history/history.html>.

² *Id.*

³ Cary Funk, Brian Kennedy, and Meg Hefferon, “Vast Majority of Americans Say Benefits of Childhood Vaccines Outweigh Risks,” *Pew Research Center*, 42, 48 (February 2017). https://www.pewresearch.org/internet/wp-content/uploads/sites/9/2017/02/PS_2017.02.02_Vaccines_FINAL.pdf.

As hundreds of millions of people accept vaccination as a means to avoid serious and fatal illnesses like COVID-19, some small portion of that wide group may have medical side effects that are harmful. The legal process, and requisite medical knowledge, for compensating these vaccine recipients is complex and beyond the normal awareness of legal advisors. *Vaccine Risks, Benefits, and Compensation* delivers answers to the complex questions arising out of vaccine injuries with succinct and pragmatic guidance.



About the Authors

Professor James O'Reilly of the University of Cincinnati College of Medicine has authored 55 textbooks and more than 230 articles on safety, health, and medical litigation issues. He has been a frequent advisor and expert witness on liability issues, and his work has been called "The Expert" on medical issues by the U.S. Supreme Court.

Janet Abaray, Managing Partner of the Cincinnati, Ohio, office for nationwide law firm Burg Simpson, has been an active products liability litigator for decades and frequently speaks to liability and safety issues.

