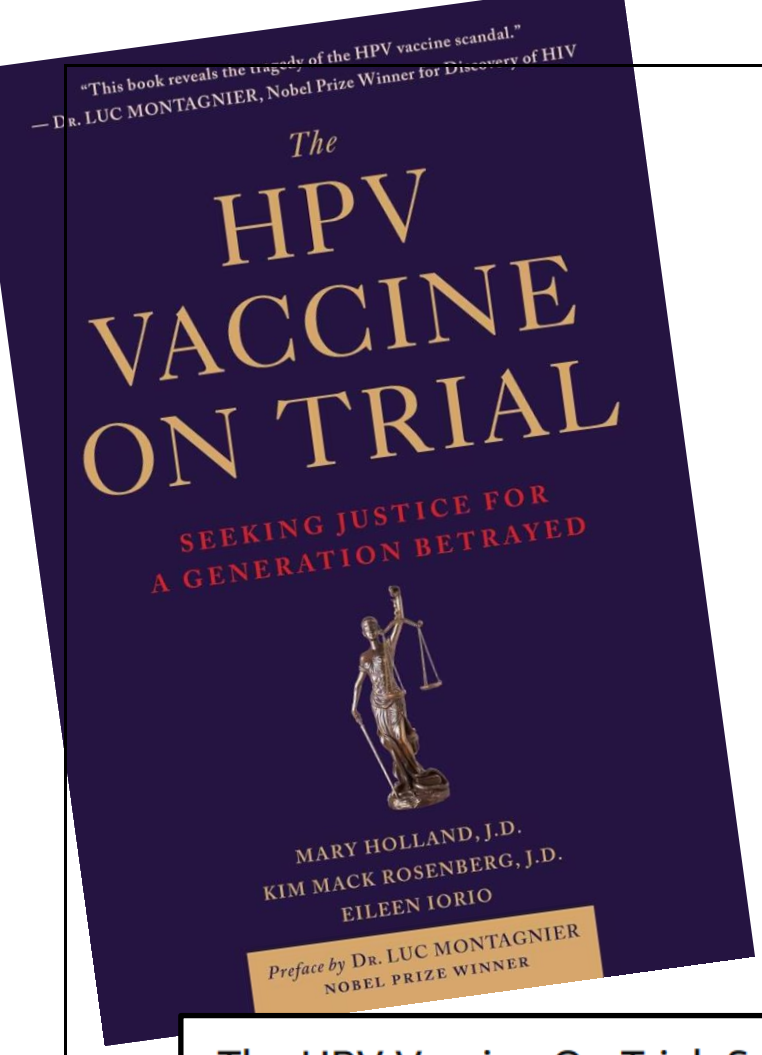

The HPV Vaccine On Trial: Seeking Justice For A Generation Betrayed Paperback – September 25, 2018

by Mary Holland (Author), Kim Mack Rosenberg (Author), Eileen Iorio (Author)

4.9 ★★★★★ 242 ratings

The HPV Vaccine on Trial

Seeking Justice for a Generation Betrayed

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Kim Mack Rosenberg, J.D.

Eileen Iorio

Book Summary by **Lies are Unbekoming**

unbekoming.substack.com

November 2023 - v1.0

Contents

Cover letter

Hello there

If you are reading this, I suspect that you have either concerns or curiosity about the HPV story and its Vaccine. You are not wrong to be either curious or concerned.

I have written several times about this vaccine and although I regret all the vaccines we allowed our children to get, I regret this one the most when I reflect the zombie like manner in which we sleep walked our children into getting it.

HPV "Vaccine": Help Pay for Vioxx - Lies are Unbekoming (substack.com)

Hiding HPV Injury - Lies are Unbekoming (substack.com)

Australia First - Lies are Unbekoming (substack.com)

As you read through this summary of this wonderful book, the magnitude of this lie will start to dawn on you. It is yet another of the mega, allopathic medicine, industrial constructions created and maintained by corrupt collaboration of government and industry.

We should never forget that:

> "It is difficult to get a man to understand something when his salary depends on his not understanding it"

The "man" in this case is the GP, Pediatrician, Gynecologist, Oncologist etc.

The model I have used to summarize most chapters is:

- Executive Summary
- Key takeaways
- Excerpts
- Statistics

Any errors are my own, and I still **strongly encourage you to buy the book**, as this summary is but a pale imitation, and also buy a copy for a friend, especially one about to vaccinate their young girl or boy.

With that said, I hope you enjoy this summary, and I hope you can make better decisions because of this work.

Regards

Lies are Unbekoming

November 2023

PREFACE

This book is not fiction. It is unfortunately the accurate description of facts occurring in our time: a promising vaccine against a virus involved in cervical cancer turns out to be the source of extremely grave side effects, even death, of young girls and boys.

This vaccine still has the support of official agencies—the WHO, FDA, CDC, EMA—and with the marketing and lobbying efforts of the manufacturers, it continues to be recommended in several countries, and even mandated in some US states!

The reader will see the truth: the side effects are underreported by medical personnel, while there is a growing number of parents suing manufacturers and governments for inducing lifelong handicaps, even death, of their loved ones.

In fact, this is the tragic example of various segments of our society, worldwide, placing economic interests before the health and protection of our younger generation.

I congratulate the authors of this book, who are showing the world this scandal.

What this vaccine is doing to thousands of our young worldwide is a crime.

Historically, vaccines have protected many people. Presently, over these last many years, too many vaccines, HPV and others, have harmed and killed so many people.

Let us mandate that ALL vaccines be safe for everyone. This is possible.

Our future depends on respect for medical ethics, according to the Hippocratic Oath:

FIRST DO NO HARM.

by Luc Montagnier, M.D.

Nobel Prize winner for the discovery of HIV

INTRODUCTION

Cancer strikes fear in people around the globe. So a vaccine to prevent cancer—as the human papillomavirus (HPV) vaccine is touted to do—seemed like a game changer. Since 2006, when the US approved the first HPV vaccine, over 125 countries have introduced it to prevent cervical and other HPV-related cancers. The three HPV vaccines bring in over $2.5 billion in annual sales for Merck (Gardasil, Gardasil 9) and GlaxoSmithKline (Cervarix). They have been pharmaceutical juggernauts, yet scandal has followed worldwide. The HPV vaccine is on trial—literally and figuratively—around the world in courts of law and public opinion.

No one disputes that cancer is a ravaging disease that leads to death, if uncontrolled. But the fact that cancer is a grave disease does not necessarily mean that a vaccine purporting to prevent it is safe and effective for everyone. The US Food and Drug Administration, the US Centers for Disease Control and Prevention, the European Medicines Agency, the World Health Organization, and many other public health agencies have embraced the HPV vaccine as a safe and effective way to prevent HPV-related cancers. Here are a few representative statements:

> **FDA**: Based on the review of available information by FDA and CDC, Gardasil continues to be safe and effective, and its benefits continue to outweigh its risks.
>
> **CDC**: The HPV vaccine is very safe, and it is effective at preventing HPV. Vaccines, like any medicine, can have side effects. Many people who get the HPV vaccine have no side effects at all. Some people report having very mild side effects, like a sore arm, from the shot. The most common side effects are usually mild.
>
> **WHO**: The WHO's Vaccine Safety Committee considers HPV vaccines to be extremely safe.
>
> **EMA**: The benefits of HPV vaccines continue to outweigh the known side effects.

These official statements contrast starkly with the reports of devastating injuries and death that we recount in this book. You'll get to know these and other children and young adults.

> **Christina Tarsell, 21 years old.**
>
> Chris was an undergrad at Bard College, New York. A talented athlete, artist, and honor student, she received three Gardasil doses when she was twenty-one. Shortly after the third dose, she died in her sleep. After eight years of hard-fought litigation in the only judicial forum available, Chris's mom "won"—the Court of Federal Claims finally acknowledged that Gardasil more likely than not caused the heart attack that led to Chris's untimely death. You can see Chris, and a memorial to her, in the photo insert.
>
> **Alexis Wolf, 13 years old.**
>
> In 2007, when Alexis was in 7th grade, she began the Gardasil series. After the second dose, her health deteriorated. After the third, she could no longer focus, sleep, eat, or behave normally. She started to have many seizures every day. She was put in psychiatric hospitals. A year and a half after her symptoms began, Alexis tested at a 4th grade level. Today, at 25, Alexis still suffers from severe neurological injury, including daily seizures. You can see pictures of Alexis both before and after receiving the vaccine in the photo insert.
>
> **Joel Gomez, 14 years old.**
>
> Joel was an athletic, healthy teenager when he got two Gardasil doses in 2013. Without warning, Joel died in his sleep after the second dose. Joel's family sued for

compensation in the Court of Federal Claims. The family's expert witness, Dr. Sin Hang Lee, testified that Gardasil likely caused his heart attack. The Department of Justice settled the case, awarding the family almost the full statutory death benefit.

Abbey Colohan, 12 years old.

In a small town in Western Ireland, Abbey received the first dose of Gardasil at school. Abbey fainted immediately and then had seizures for more than an hour. Two days later, she passed out again. Abbey started to have chronic pain, fatigue, and frequent fainting spells. Abbey's teen years have been consumed with illness and hardship. Ireland's health service denies that Abbey had an adverse vaccine reaction at school.

Colton Berrett, 13 years old.

Colton was an athletic, kind, helpful teenage boy. He loved all outdoor sports. Colton started the three-dose Gardasil series when he was thirteen. Shortly after the third dose, he became paralyzed from the neck down and had to use a ventilator. Through intensive physical therapy, Colton eventually recovered some mobility but remained on a round-the-clock ventilator. He committed suicide two months before his eighteenth birthday. In the photo insert, you can see pictures of Colton that convey far more than words ever can.

Lucy Hinks, 13 years old.

Lucy was a healthy English teenager when she began the Cervarix series in her school. Shortly after the third shot, Lucy's health plummeted. She could barely walk, slept 23 hours a day, and could not think straight. She could not attend school and had to be spoon-fed. Her parents described her as being in a "walking coma." Through many therapies and treatments, Lucy has substantially recovered but still suffers from chronic fatigue.

Maddie Moorman, 15 years old.

Maddie began the Gardasil series at the gynecologist's recommendation. After the second shot, Maddie became bedridden and ill. She had debilitating headaches every day and could no longer remember things. Her mom declined the third shot for her. Through conventional and holistic treatment, Maddie's health began to recover slowly, and she was able to complete high school and go to college. But some of Maddie's symptoms never abated, including a constant buzzing in her head and the inability to think the way she could before. She took her own life at twenty-one. You can see her pictures in the photo insert.

We show that the HPV vaccine clinical trials paved the way for such tragic results. Here are some of the little-known facts we'll explore:

HPV vaccines have never been proven to prevent cervical or any other cancer. Merck and GlaxoSmithKline, the manufacturers, did not have to prove that the vaccines prevent cancer. They were allowed to use precancerous lesions as "surrogate endpoints" in the clinical trials. Scientists do not know if the decline in cases of precancerous lesions will translate into fewer cases of cervical cancer in 20–30 years.

Even if they were 100 percent effective, which they are not, HPV vaccines do not prevent all cases of cervical cancer. The vaccines do not prevent infections from all HPV types associated with cancer, and not all cervical cancer is associated with HPV. HPV vaccines are not a replacement for cervical screening, yet evidence strongly suggests that young women are skipping screening in the mistaken belief that they no

longer need it. HPV vaccine marketing hype appears to have contributed to a sharp drop-off in cervical screening among young women.

None of the participants in the clinical trials received a true saline placebo. None of the clinical trials included a straightforward comparison of the effects of the vaccine against a true control. We use the term "fauxcebo" to describe the aluminum-containing adjuvants, other vaccines, and chemical mixtures that control subjects received instead of true saline placebos. These fauxcebos masked the adverse effects of the vaccines, making them appear safer than they would have if compared to true placebos.

Merck told young female clinical trial subjects that the vaccine had already been proven safe and that the placebo was saline. Both claims were false. A key purpose of the clinical trials was to establish safety, and the placebo was not saline. Clinical trial subjects suffered because of these lies.

The manufacturers never tested HPV vaccines on human fertility. Although this vaccine is given to adolescents throughout the world, the manufacturers acknowledge in their package inserts that they never tested the vaccine for fertility effects in humans—only rats. We look at the substantial evidence of severe adverse effects on fertility, including miscarriage and premature ovarian failure in girls and young women.

Evidence shows that certain ingredients in HPV vaccines, including sodium borate (also known as borax, a cleaning agent), may have negative effects on fertility. The European Chemicals Agency requires sodium borate to carry the following warning: "DANGER! May damage fertility or the unborn child." In the US, borax is banned in food but allowed in vaccines.

The manufacturers never tested HPV vaccines to discover if they might cause cancer. The package inserts acknowledge that the vaccines have never been tested for "carcinogenicity." But clinical trial data suggest that if women have HPV infections when they get the vaccines (and prescreening is not recommended), then they may be at higher risk for precancerous cervical lesions or worse. Some clinical trial participants later developed cancer, including cervical cancer.

The Gardasil clinical trials used a new metric, "New Medical Conditions," as a way to claim that serious health problems after vaccination were unrelated to the vaccine or aluminum-containing fauxcebo. More than 50 percent of all clinical trial participants reported "new medical conditions," including infections, reproductive disorders, neurological syndromes, and autoimmune conditions. The FDA did not question this novel metric or whether the vaccine itself might be contributing to these conditions.

Although 11–12-year-olds are the target population for this vaccine (and it is approved for children as young as nine), the vast majority of clinical trial subjects were considerably older. Only a small percentage of participants were aged 12 or younger, and their age cohort, or group, lacked a true saline control placebo, as did the older age groups. Preteens, on the cusp of puberty, have significant biological differences from young adults, the primary age group in the clinical trials. Thus, the target population was insufficiently studied before the vaccine received approval.

Doctors and scientists have published peer-reviewed articles on the adverse effects that many young women reported after HPV vaccination. Here is a non exhaustive list:

- Headache
- Orthostatic intolerance
- Syncope
- POTS
- Fatigue
- Cognitive dysfunction
- Disordered sleep
- Visual symptoms
- Blurring of vision
- Gastrointestinal symptoms
- Neuropathic pain
- Motor symptoms
- Skin disorders
- Voiding dysfunction
- Limb weakness
- Vascular abnormalities
- Irregular period

Despite US government assertions that the vaccine is safe, the federal compensation program for vaccine injury has paid out millions of dollars in damages for HPV vaccine injuries. Families have received compensation for death, brain injury, multiple sclerosis, complex regional pain syndrome, Guillain-Barré syndrome, ulcerative colitis, and other severe, debilitating conditions. We delve into reported HPV vaccine injuries and the pursuit of justice.

All participants in the Gardasil clinical trials who received a "placebo" rather than the vaccine were encouraged to receive HPV vaccines at the end of the clinical trial period. By doing this, Merck destroyed any opportunity for large-scale, long-term safety and efficacy studies of vaccinated versus the original control subjects.

Lawsuits have been filed against Merck, GlaxoSmithKline, and government health agencies around world, including in the US, India, Colombia, Japan, Spain, and France. Families want treatment for their injured children and young adults. They also want to hold the manufacturers accountable and to prevent future injuries to other children.

National and international health agencies are working hand in glove with the HPV vaccine manufacturers to promote, advertise, finance, recommend, and even compel children to get HPV vaccines. We have included examples of CDC and UK National Health Service ads for HPV vaccines in the photo insert.

The US government earns royalties from Merck and GSK for licensing HPV vaccine technology. Scientists at the National Institutes of Health, with others, participated in the invention of HPV vaccines. While receiving millions of dollars in annual royalty income from these corporations, the US government ostensibly holds the upper hand in regulating them. The conflict of interest is obvious.

The HPV vaccine saga began just as Merck was trying to turn the page on its criminal conduct with Vioxx, its failed painkiller drug. Just as Vioxx was raking in $2.5 billion in annual revenue—almost the same amount Gardasil and Gardasil 9 are now bringing in—Merck withdrew it from the market because it was causing heart attacks, strokes, and death. Merck had not disclosed known heart attack risk in its clinical trial data. In 2005, Merck paid multimillion-dollar civil and criminal penalties and entered into a $4.85 billion settlement with injured plaintiffs. Congress, the Department of Justice, and the media investigated Merck for falsifying data, making false statements to regulators, making false marketing claims, failing to disclose material information to consumers, and more. In 2006, the FDA approved Gardasil, leading some to dub the HPV vaccine "Help Pay for Vioxx." History repeats itself in the Merck Vioxx and Gardasil sagas.

In researching and writing this book, we spoke with more than a hundred people who shared with us their time, expertise, and deeply personal stories. We also spoke with many injured young people and their parents, as well as with parents whose children died. We are humbled that they trusted us with their stories and have done our best to give them voice.

We also reached out to doctors, scientists, and medical researchers. We met with advocates fighting for those who have been injured. We met personally with women who were subjects in the clinical trials and spoke with doctors who were principal trial investigators. We also contacted HPV vaccine proponents, including the FDA, and are grateful for their assistance. We reached out to Merck with a long list of questions on two occasions but received no replies.

We bring legal and financial backgrounds to this task. While we are not doctors or scientists, we believe that our perspective is critical to this debate. For too long, those with real and potential conflicts of interest in industry and government have dominated public discourse about vaccine safety.

Part I examines the clinical trials and the race to develop the vaccine. It analyzes surprising data that have received little attention to date. We also provide a primer on cervical cancer to explain its real risk factors. While we focus on the Gardasil clinical trials, we also look at Cervarix, GlaxoSmithKline's version, and at Gardasil 9, the only currently available HPV vaccine in the US. (GSK took Cervarix off the US market, likely because of low sales. Merck replaced Gardasil with Gardasil 9, the new HPV vaccine against a broader range of HPV viruses.) We use official documents and the accounts of two young women injured in the clinical trials to examine their many flaws. We close Part I with a look at India, where clinical trials led to national outrage and a legal battle against the pharmaceutical industry and its partners.

Part II covers what happened after the vaccines hit the market. How do you sell a vaccine for an infection that clears almost all the time? We look at the marketing magic and "disease branding" that created a market out of thin air. We also share heartbreaking stories of injury and death. We follow several families' fights for justice. We look closely at the US and Australia, powerhouses in HPV vaccine development, whose governments are leading the charge toward universal HPV vaccine uptake.

Part III is a deeper dive into the latest research on aluminum-containing adjuvants and other ingredients of concern, including DNA fragments. We discuss HPV transmission, the

potential threat of "type replacement," cervical screening in both high and low resource countries, and more. If you don't need the deep science dive, skip ahead.

Finally, Part IV takes readers around the world to Japan, Denmark, Ireland, the UK, and Colombia. Each of these countries is a unique case study regarding the HPV vaccine, and the role that governments, media, and the law play. You'll get a close look at the latest developments in each country yet also see the global threads in common.

We strongly advocate for informed consent and hope that this book will help people to make truly informed decisions about this vaccine. Only you can be the ultimate judge for yourself or your loved one.

This story is ever-evolving, so inevitably there will be new developments before and after this book goes to print. We anticipate future editions, but in the meanwhile, for additional information or to contact us, please go to www.hpvvaccineontrial.org.

We include a glossary below to help with the "alphabet soup" of agencies and organizations that this topic requires.

GLOSSARY OF TERMS

AAHS Amorphous Aluminum Hydroxyphosphate Sulphate, the adjuvant used in Merck's Gardasil and Gardasil 9 vaccines

ACIP Advisory Committee on Immunization Practices

ACOG American College of Obstetricians and Gynecologists

Adjuvant Immune stimulating vaccine ingredient, most often an aluminum compound

AE Adverse Event

AMA American Medical Association

Antibody An immunoglobulin, a specialized immune protein, produced because of the introduction of an antigen into the body

Antigen A toxin or other foreign substance that induces an immune response in the body

ASIA Autoimmune Syndrome Induced by Adjuvants

AS04 GlaxoSmithKline adjuvant system consisting of aluminum hydroxide and monophosphoryl lipid (MPL) used in the Cervarix vaccine

CBER Center for Biologics Evaluation and Research at the US FDA

CDC US Centers for Disease Control and Prevention

Cervarix™ GlaxoSmithKline's bivalent HPV vaccine

CIN 1, 2, 3 Cervical Intraepithelial Neoplasia (1, 2, or 3)

CRPS Complex Regional Pain Syndrome

DTC Direct-To-Consumer (marketing)

EDC Estimated Date of Conception

E6 and E7 Oncoproteins in human papillomavirus that are involved in cancer or tumor initiation and progression

EMA European Medicines Agency

FDA Food and Drug Administration (US)

FUTURE I/II Females United to Unilaterally Reduce Ecocervical Disease I/II, two of the Gardasil Phase III clinical trials

GACVS Global Advisory Committee on Vaccine Safety

Gardasil™ Merck's first generation quadrivalent HPV vaccine

Gardasil 9™ Merck's second generation 9-valent HPV vaccine

GAVI Global Alliance for Vaccines and Immunization

GSK GlaxoSmithKline, manufacturer of Cervarix HPV vaccine

HBV Hepatitis B vaccine

HHS Health and Human Services (US)

HPRA Health Products Regulatory Agency (Ireland)

HPV Human Papillomavirus

HSE Health Services Executive (Ireland)

IARC International Agency for Research on Cancer of the World Health Organization

IND Investigational New Drug Application with the FDA

L1 A major capsid protein of the human papillomavirus used to make the virus-like particles (VLPs) used in HPV vaccines

L2 A major capsid protein of the human papillomavirus considered but ultimately not used to make the virus-like particles (VLPs) used in HPV vaccines

MHRA Medicines and Healthcare Products Regulatory Agency (UK)

MITT Modified Intent To Treat (study population)

MPL Monophosphoryl lipid A, a lipopolysaccharide extracted bacterium Salmonellas Minnesota strain R595 and used as part of GSK's AS04 adjuvant system in Cervarix

NCI National Cancer Institute

NCVIA National Childhood Vaccine Injury Act

NHS National Health Service (UK)

NIH National Institutes of Health (US)

NMC New Medical Condition

NSAE Non-Serious Adverse Event

NVIC National Vaccine Information Center

OTT Office of Technology Transfer (US)

PATH Program for Appropriate Technology in Health

PATRICIA Papilloma Trial against Cancer in Young Adults, part of the Cervarix clinical trials

PCR negative A result indicating the absence of the DNA sequence targeted by a specific test (for example, a specific strain of HPV), here obtained from cell samples

PCR positive A result indicating the presence of the DNA sequence targeted by a specific test

POF Premature Ovarian Failure

POTS Postural Orthostatic Tachycardia Syndrome

SAE Serious Adverse Event

Seronegative No active infection and no antibody titers at a determined measurable level

Seropositive Antibodies present above a determined measurable level, likely indicative of past exposure or infection

TGA Therapeutic Goods Association (Australia)

VAERS Vaccine Adverse Event Reporting System

VFC Vaccines For Children

VICP Vaccine Injury Compensation Program

VLP Virus-Like Particle

VRBPAC Vaccines and Related Biological Products Advisory Committee of the FDA

WHO World Health Organization

WIG Women In Government

Chapter 1: Rewarding The Inventors

In September 2017, luminaries in the healthcare field gathered at the New York Plaza Hotel to celebrate an extraordinary achievement: a vaccine to prevent cancer. Two scientists at the National Institutes of Health had created the human papillomavirus, or HPV vaccine. By 2017, it had been on the market just over ten years, although scientists had been working on it for decades. The Lasker Foundation gives awards to key leaders in the medical field.

At the ceremony, Drs. Douglas R. Lowy and John T. Schiller received Lasker Awards for their groundbreaking innovation. The Foundation celebrates scientists, clinicians, and public servants for advances in research and health. Albert and Mary Lasker, the Foundation's namesakes, created the Awards in 1945, drawing on Albert's advertising fortune, which he amassed through selling cigarettes and other products. These prestigious awards, sometimes called "American Nobel" prizes, carry not just acclaim, but $250,000 for each winner.

Drs. Lowy and Schiller, cancer biologists at the National Cancer Institute, had attained a dream—a vaccine to prevent cervical cancer, a killer for women, particularly in the developing world. In 1950, cervical cancer had also been the Lasker Foundation's theme: Dr. George Papanicolaou won a prize for his Pap test, which could identify abnormal cervical cell growth. Pap tests have saved countless lives over the past 70 years. But Drs. Lowy and Schiller's work promised something even better: to prevent cancer in the first place. This is what the Lasker Foundation sought to honor.

Dr. Craig Thompson, head of the world-renowned Memorial Sloan-Kettering Cancer Center, presided at the gala. He called the HPV clinical trials "stunningly successful." Because of Lowy and Schiller's pioneering work, the FDA approved the HPV vaccine for females in 2006 and for males in 2011. By 2015, nearly 60 million people around the globe, mostly children, had received at least one dose. Dr. Thompson proclaimed that HPV vaccines had already prevented 400,000 cases of cervical cancer.[1] A Lasker Award video went further, saying that over the next 50–60 years, the vaccine would prevent 19 million cases of cervical cancer and 10 million deaths: "The HPV vaccine is like an immunological grand slam. It prevents most cervical cancer as well as other HPV-linked cancers."[2]

In his acceptance remarks, Dr. Lowy acknowledged that he and Dr. Schiller would not have been able to develop the vaccine without public investment. For the pharmaceutical industry, the incentives to prevent disease are not as great as those to treat it. Publicly financed NIH research had been essential. He also thanked the key manufacturers, Merck and GlaxoSmithKline, for taking big risks. The vaccines have "exceeded even our most optimistic expectations, while also highlighting the value of public-private partnerships in health and disease. Amazingly, eliminating cervical cancer and other HPV-associated cancers as a major public health problem is now a realistic goal."[3]

The HPV vaccine sounded miraculous, promising to safely prevent cancer with only a few shots. It sounded almost too good to be true.

Chapter 2: Injured in the Trials: Testimony from Denmark

Executive summary:

The chapter recounts the harrowing experiences of Kesia Lyng and Sesilje, two Danish women who participated in clinical trials for the HPV vaccine, Gardasil, in 2002. Initially, Kesia and Sesilje were motivated by a desire to contribute to cancer prevention, unaware of the potential risks. However, their health deteriorated significantly after receiving the vaccine, leading to chronic and unexplained symptoms. Both women discovered that the placebo in the trial was not saline, as they were told, but an aluminum-based adjuvant, AAHS, raising serious questions about informed consent and safety testing. This revelation has prompted them to seek answers and support, shedding light on the need for transparency and accountability in vaccine trials.

Key takeaways:

1. Kesia Lyng and Sesilje participated in the Gardasil clinical trials in Denmark in 2002, believing they were contributing to cervical cancer prevention.
2. The clinical trial led by Merck used an aluminum-based adjuvant, AAHS, as the control group, not saline as participants were informed, raising questions about transparency and informed consent.
3. Both Kesia and Sesilje experienced a range of adverse symptoms, including flu-like symptoms, headaches, and fatigue, after receiving the vaccine, but their concerns were dismissed by trial staff.
4. The clinical trial protocol omitted important information about the vaccine's ingredients, potentially leaving both participants and clinicians in the dark about potential risks.
5. Despite their health struggles, Kesia and Sesilje continued to advocate for the vaccine, unaware that their symptoms might be related to the vaccine itself.
6. In 2007, when the trial was unblinded, Kesia learned she had received the vaccine, while Sesilje received the placebo. This revelation raised concerns about the safety of the vaccine.
7. Kesia and Sesilje's ongoing health problems led them to research the clinical trials, revealing inconsistencies and raising questions about the trial's integrity.
8. Both women connected with other trial participants who had similar experiences, forming a support network.
9. Questions arise about the conduct of vaccine trials globally, as Merck's FUTURE 2 trials were conducted in multiple countries.
10. This suggests that a pattern of controversy and concern surrounds the HPV vaccine Gardasil in various regions.

Statistics:

1. In 2007, when the clinical trial was unblinded, Kesia learned that she had received the vaccine after all.
2. Kesia received around $500 for participating in the clinical trial.
3. The chapter mentions that 10 percent of participants in the US received a "vaccination report card" to record adverse effects in the first fifteen days after each vaccination, but it's unclear how many Danish girls received this report card, as it is not mentioned in the Danish trial protocol.

Chapter 3: Racing toward the Vaccine

Executive Summary:

The chapter explores the development of the HPV (Human Papillomavirus) vaccine, shedding light on its historical roots and the scientific challenges faced in creating it. It discusses the pivotal role of researchers like Harald zur Hausen, who isolated HPV types associated with cervical cancer, and the race to develop an anticancer vaccine in the backdrop of President Nixon's "war on cancer." The narrative delves into the science behind HPV vaccines, emphasizing the use of virus-like particles (VLPs) to stimulate the immune system without causing infection. It also touches upon the patent wars and the US government's involvement in HPV vaccine development, leading to potential conflicts of interest.

Key Takeaways:

1. Scientists have been researching the link between viruses and cervical cancer since the 1800s, with the pursuit of an anticancer vaccine gaining momentum in the 1970s.
2. HPV research was challenging due to the virus's replication in epithelial cells, but advances in DNA technology and molecular cloning, led by Harald zur Hausen, were game changers.
3. zur Hausen's team isolated HPV types associated with cancer, particularly HPV-16 and HPV-18, paving the way for vaccine development.
4. The race to create an HPV vaccine involved genetic modification of the virus into noninfectious VLPs to stimulate the immune system.
5. Epidemiological evidence, particularly from Dr. Nubia Muñoz's work, established HPV as a primary cause of cervical cancer, justifying further vaccine development.
6. The US government's involvement in HPV vaccine development raises concerns about conflicts of interest, especially given its role as an investor, patent holder, regulator, and safety monitor.
7. Pharmaceutical companies' funding of clinical trials and FDA fees create potential conflicts of interest in drug approval processes.
8. The revolving door between government agencies and the pharmaceutical industry further complicates conflicts of interest.
9. Financial incentives and the alignment of stakeholders with industry interests are prevalent in vaccine research, raising questions about the reliability of research outcomes.

Excerpts:

1. "Simultaneously, during the 1990s, scientists were gathering epidemiological evidence to justify the high cost of developing the vaccine."
2. "The US government's role in HPV vaccine development, as investor, patent holder, regulator, and safety monitor, suggests obvious conflicts of interest."

Statistics:

1. In 2012, available data estimated that licensing fees to the US government for HPV vaccines were about $15–$20 million annually.
2. HPV-related technologies have consistently ranked first or second among the "Top 20 Commercially Successful Inventions" based on annual product sale royalties since 2008.

Chapter 4: Who's Really At Risk for Cervical Cancer?

Executive Summary:

The chapter critically examines the marketing and scientific basis behind HPV (Human Papillomavirus) vaccines, particularly focusing on whether the science truly supports the marketing tactics used to promote them as cancer prevention tools. It delves into the prevalence of HPV infections and cervical cancer worldwide, highlighting that most HPV infections resolve on their own without causing cancer. The article underscores that while cervical cancer is a significant global issue, the risk factors are multifaceted, with persistent, long-term HPV infection being just one of several contributing factors. It emphasizes that the benefits of HPV vaccines must be carefully weighed against their potential risks, especially for young girls.

Key Takeaways:

1. Marketing HPV vaccines has centered around the fear of cancer, although most HPV infections resolve naturally, and cervical cancer is relatively rare in high-resource countries.
2. HPV infections are widespread, with millions of people contracting them annually, but the vast majority of these infections resolve on their own within two years.
3. Globally, cervical cancer accounts for a small percentage of all cancer cases in high-resource countries but is more prevalent in lower-resource nations, especially in Eastern Africa.
4. The effectiveness of HPV vaccines in preventing cervical cancer in the long term remains uncertain, and questions persist about their durability, especially in sexually active individuals in their twenties and thirties.
5. This raises concerns about declining screening rates, particularly among young women who have received the HPV vaccine.
6. The relationship between HPV vaccines and cervical cancer rates is complex, with confounding factors like declining screening rates making it challenging to assess their true impact.
7. This emphasizes that the effectiveness of HPV vaccines in low-resource countries, where malnutrition and poor health are common, remains uncertain.
8. Long-term effectiveness and the potential need for booster shots for HPV vaccines are areas of ongoing research and concern.
9. Addressing known risk factors for cervical cancer, including improved nutrition, access to healthcare, and comprehensive screening programs, has been effective in reducing cervical cancer rates in some countries, without relying solely on HPV vaccination.

Excerpts:

1. "Selling a product to prevent an infection that almost always resolves without treatment is a herculean task. Selling a treatment to prevent cancer is a winning market strategy, however."
2. "HPV vaccine advocates often point to the low-resource world where women die from cervical cancer because Pap tests are largely unavailable. One has to wonder whether these vaccines will offer real protection there, where people often suffer from malnutrition and poor health."

Statistics:

1. Globally, the WHO estimates that 291 million women are infected with HPV at any given time, with approximately 528,000 cervical cancer diagnoses each year, suggesting that approximately 0.18 percent of infections progress to cervical cancer.
2. In high-resource countries, cervical cancer is rare, accounting for only 0.8 percent of all new cancer cases in the US, with a median age at diagnosis of 50. The 5-year survival rate is over 90 percent when the cancer is caught early enough.
3. Based on data from the Gardasil clinical trials, the rate of serious adverse reactions following vaccination was 81.49 per 10,000 participants, and the death rate was 13.3 per 10,000 participants. In comparison, cervical cancer rates are 4.27 per 10,000, and death rates from cervical cancer are 2.76 per 10,000 in East Africa, where rates are the highest in the world.

Chapter 5: Clinical Trials: The Foundation for the HPV Vaccine

Executive Summary:

This chapter critically examines the clinical trials that served as the foundation for HPV (Human Papillomavirus) vaccines, particularly focusing on whether informed consent was truly obtained and whether the trials provided comprehensive safety and efficacy data. It questions the assertion that these vaccines are safe and effective, challenging the selective use of trial data. It highlights issues such as incomplete analysis of clinical trial results, the exclusion of potential allergens from trial documentation, and the influence of manufacturers on the trials' outcomes. It also underscores the importance of informed consent in medical trials, drawing parallels with the Nuremberg Code's principles.

Key Takeaways:

1. Independent studies have revealed that health regulators like the FDA and European Medicines Agency did not consider all available clinical trial results when approving HPV vaccines, raising questions about the thoroughness of the approval process.
2. The Cochrane Collaboration, in a review of HPV vaccine clinical trials, relied on only a subset of the available studies, with the majority funded by vaccine manufacturers. This limited scope has implications for assessing vaccine safety.
3. Critics argue that the use of active comparators in trials may have masked potential harms caused by HPV vaccines, contributing to a false sense of safety.
4. The trials for Gardasil, one of the HPV vaccines, overlapped phases and included subjects who were extremely healthy and had limited prior exposure to HPVs, potentially biasing the results.
5. The exclusion criteria for some trials were broad, allowing investigators to exclude participants based on any condition that might interfere with the study's objectives, providing wide discretion.
6. It raises questions about the failure to disclose all potential allergens in the vaccine and whether participants were adequately informed about allergens.
7. It also highlights the ethical significance of informed consent, drawing parallels with the Nuremberg Code's principles, which emphasize the essential nature of voluntary consent.

Excerpts:

1. "Vaccine proponents, including the WHO, the CDC, and industry spokespeople, trumpet the HPV vaccine clinical trial data, arguing that they unequivocally demonstrate safety and efficacy."
2. "In July 2018, things heated up further. Jørgensen, Gøtzsche, and Jefferson published an article in BMJ Evidence-Based Medicine highly critical of the Cochrane May 2018 review."

Statistics:

1. Merck began the Gardasil Phase I trials in 1997, and by 2000, before completing Phase I studies, they began Phase IIb, testing vaccines with four HPV types.
2. The Danish Cancer Society's informed consent form from 2002 for the FUTURE II trial referred to the placebo as "a vaccine without an active substance." A later form in September 2004 clearly called the placebo "saltvand," or saline, indicating that informed consent may not have been accurately obtained.

Chapter 6: Rushing Results: Surrogate Endpoints and Fast-Tracking

Executive Summary:

This chapter delves into the clinical trials of HPV (Human Papillomavirus) vaccines, specifically focusing on the use of surrogate endpoints like CIN (Cervical Intraepithelial Neoplasia) lesions instead of directly testing the prevention of cervical or other cancers. The author questions the validity of these surrogate endpoints and their suitability for fast-tracking vaccine approvals. It highlights the complexity of HPV infection progression and the uncertainty surrounding the effectiveness of these vaccines in preventing cancer. Additionally, the article scrutinizes the FDA's decision to fast-track and prioritize the review of HPV vaccines, pointing out discrepancies in the criteria used to justify these decisions.

Key Takeaways:

1. HPV vaccines, such as Gardasil and Gardasil 9, were tested in clinical trials using surrogate endpoints like CIN2 and CIN3 lesions instead of directly assessing their efficacy in preventing cervical or other cancers.
2. Surrogate endpoints allowed manufacturers like Merck and GSK to shorten clinical trials to a few years, but questions arise about the appropriateness of these endpoints in measuring vaccine effectiveness.
3. The FDA and Merck chose to use surrogate endpoints because cervical cancer is rare, has a long latency period, and would require a massive and extended trial to measure vaccine efficacy.
4. This raises doubts about whether CIN lesions, particularly CIN2 and CIN3, are suitable surrogates for cervical cancer, as not all cases progress to cancer.
5. The FDA fast-tracked Gardasil, citing the vaccine's potential to treat a "serious or life-threatening condition" and address "unmet medical needs."
6. However, the chapter highlights that most HPV infections are short-lived and not associated with cervical cancer, challenging the notion of unmet medical needs.
7. HPV vaccines have been marketed aggressively despite questions about their efficacy in reducing cervical cancer rates, especially in high-resource countries.
8. The approval process for HPV vaccines has raised concerns about whether they truly fulfill the criteria for fast-tracking and priority review set by the FDA.

Excerpts:

1. "The clinical trials did not test whether HPV vaccines prevent cervical or any other cancer. Instead, they tested the vaccines against the development of certain cervical lesions, i.e., abnormal tissue called CIN2 and CIN3 and similar lesions for other genital and anal cancers."
2. "Merck’s graph potentially leaves the incorrect impression that once an HPV infection has progressed to a CIN2 lesion or worse, the march to cervical cancer is inevitable."
3. "Merck and FDA agreed that cancer as the clinical trial endpoint 'disadvantages too many women.'"

Statistics:

1. The NCI reports that 50 percent or less, and perhaps as low as 30 percent, of CIN3 lesions progress to cervical cancer.
2. Cochrane Collaboration recently assessed the probability of CIN3 progression to cervical cancer to be as low as 12 percent.

Chapter 7: “Fauxcebos” and Placebos

Executive Summary:

This chapter delves into the critical role of placebos, or the lack thereof, in vaccine clinical trials, focusing on HPV (Human Papillomavirus) vaccines such as Gardasil and Cervarix. The traditional gold standard for clinical trials involves a "randomized double-blind placebo-controlled trial," which helps establish the true efficacy and safety of a new product. However, HPV vaccine trials have often deviated from this standard, using what the author terms "fauxcebos" or false placebos, raising concerns about the reliability of the results. The article emphasizes that a lack of true saline placebos in these trials may have obscured safety signals and highlights the potential health risks associated with adjuvants like aluminum used as controls.

Key Takeaways:

1. Placebos play a crucial role in clinical trials by helping establish the truth about a new intervention's effectiveness and safety, benefiting both trial subjects and society as a whole.
2. HPV vaccine trials, unlike traditional clinical trials, often lack true saline placebos. Instead, they typically use other vaccines or chemical solutions as controls, justifying this by claiming it would be unethical to deprive the control group of vaccine benefits.
3. Merck and GSK, the manufacturers of Gardasil and Cervarix, did not use true saline placebos in their clinical trials. Instead, they employed various adjuvants, other vaccines, and chemical solutions as controls, leading to concerns about the validity of the results.
4. Merck used aluminum-containing adjuvants, termed "fauxcebos," as controls in Gardasil trials. This raised questions about the masking of adverse effects and the accuracy of safety data.
5. Aluminum expert Dr. Christopher Exley and others believe that using a placebo known to result in side effects lacks scientific justification.
6. Federal regulations suggest that manufacturers should not include adjuvants in vaccines if they pose safety risks, but the FDA continues to presume the safety of aluminum-based adjuvants.
7. The FDA justifies using aluminum adjuvants as controls by stating it helps "blind" the study, even though the control groups received a carrier solution that did not resemble the vaccine.
8. The use of fauxcebos in HPV vaccine trials has led to questions about the integrity of the trials and the accuracy of safety and efficacy claims surrounding these vaccines.

Excerpts:

1. "Merck used 'fauxcebos'—or false placebos—as controls in the Gardasil trials, with the FDA’s blessing. These fauxcebos appear to have masked Gardasil’s ill effects."
2. "In Protocol 018, the control group received the carrier solution, which did not look like the vaccine. That study had a work-around, using staff who did not otherwise work with trial participants to prepare and administer injections."

Chapter 8: Protocol 018: Hiding in Plain Sight?

Executive Summary:

Chapter 8 of the book investigates Protocol 018 of the Gardasil clinical trial, focusing on a significant dose anomaly hidden in plain sight. It reveals that the vaccinated 9-to-15-year-olds in this study received only half the usual amount of AAHS adjuvant, a crucial component in the vaccine formulation. This anomaly raises questions about the accuracy of the dosing and its potential implications. The chapter also discusses the implications of this dosing discrepancy on safety and why the FDA may have missed this critical signal.

Key Takeaways:

1. Protocol 018 of the Gardasil clinical trial revealed a hidden dose anomaly where the vaccine administered to 9-to-15-year-olds contained only half the standard amount of AAHS adjuvant, as evident in an FDA document.
2. The way Merck presented the formulation in Protocol 018 was unnecessarily confusing and did not disclose the substantial difference in AAHS dose. This raised questions about why this dosing discrepancy existed.
3. The chapter highlights the unique nature of Protocol 018 as the only study in the preteen target population comparing Gardasil to a non-aluminum-containing control (the carrier solution), emphasizing the importance of this cohort.
4. Data suggests that the lower AAHS dose in Protocol 018 elicited similar antibody responses in preteens compared to a group with the full AAHS dose. This raises questions about the necessity of the higher AAHS dose.
5. The chapter discusses the safety concerns associated with aluminum-based adjuvants and their potential to trigger autoimmune and other serious conditions.
6. Safety data comparisons between Protocol 018 and other trial protocols show that a lower percentage of children in Protocol 018 reported new illnesses, but the data are inconclusive due to limitations.
7. Follow-up studies of Protocol 018, cited by the CDC and American Academy of Pediatrics to support Gardasil's safety and efficacy, do not address the AAHS dose anomaly.
8. The chapter emphasizes the need for accurate information and potential retractions of articles relying on Protocol 018 data if the AAHS dose anomaly is confirmed.

Excerpts:

1. "In this chapter, we shift our focus to that study's vaccine formulation, given to 9-to-15-year-olds. Hidden in plain sight in an FDA document is evidence that the vaccinated children in Protocol 018 received just half the AAHS adjuvant than in the licensed vaccine."
2. "If Merck used a half AAHS dose, the data from that Protocol do not support safety of the standard Gardasil formulation."

Statistics:

1. It compares safety data between Protocol 018 and other trial protocols, noting that 29 percent of children in Protocol 018 reported new illnesses compared to 49.6 percent in the pooled group, though the data's significance is limited.

Chapter 9: Enhancing Risk: “Negative Efficacy”

Executive Summary:

Chapter 9 delves into the concept of "negative efficacy" within the context of HPV vaccines like Gardasil and Cervarix. While efficacy typically measures a vaccine's effectiveness in preventing disease, "negative efficacy" suggests that the vaccine might actually contribute to the very condition it aims to prevent, in this case, cervical cancer. The chapter highlights troubling findings from clinical trials that indicate a potential increased risk of cervical disease among vaccinated individuals who had prior exposure to HPV. It questions the lack of pre-screening recommendations and explores the implications of this phenomenon.

Key Takeaways:

1. "Negative efficacy" is a term used in the context of clinical trials to describe a situation where a vaccine may enhance the risk of the disease it's designed to prevent, rather than offering protection.
2. The chapter focuses on the Gardasil and Cervarix clinical trials, which raise concerns about the possibility that some vaccinated girls who had prior HPV exposure may be at a higher risk of developing cervical intraepithelial neoplasia (CIN) or even cancer.
3. Clinical trial results indicate that women with current HPV infections or evidence of prior exposure to specific HPV types had an increased risk of developing CIN2 or CIN3 lesions after vaccination, challenging the assumption that the vaccines universally protect against HPV-related diseases.
4. The FDA and CDC do not recommend pre-screening for HPV before vaccination, despite the concerning findings from clinical trials.
5. The American College of Obstetricians and Gynecologists advises against HPV DNA testing before vaccination, even for patients with a history of HPV-related issues, raising questions about the rationale behind this recommendation.
6. Merck has sought FDA approval to expand the use of Gardasil 9 to adults aged 27 to 45, potentially exposing more individuals with enhanced risk factors to the vaccine.
7. Some children in clinical trials showed positive markers for HPV, even without sexual exposure, highlighting the uncertainty regarding whether individuals with enhanced risk factors are at a higher risk for cancer.
8. The chapter explores the logical implication that if positive efficacy indicates enhanced protection, negative efficacy suggests enhanced risk, potentially challenging the perception of vaccine safety.

Statistics:

1. The chapter provides statistics from the Gardasil clinical trials, showing that women with a current HPV 16 or 18 infection and prior exposure had a 44.6 percent increased risk of developing CIN2 or CIN3 lesions compared to the control group.
2. It also presents statistics from the Cervarix clinical trials, indicating enhanced risk for women who received Cervarix compared to controls, ranging from negative 31.2 percent to negative 48.1 percent, depending on their HPV status.
3. The chapter mentions that in the Cervarix trial for women aged 26 and over, two cases of cervical cancer occurred among vaccine recipients, although these results were not considered statistically significant by the FDA.

Chapter 10: Fertility Effects—Trial Signals Missed?

Executive Summary:

Chapter 10 delves into the critical aspect of fertility effects associated with HPV vaccines, particularly Gardasil and Cervarix. The vaccine manufacturers did not conduct human fertility studies, relying solely on rat studies, a notable omission for vaccines targeting a sexually transmitted virus. The chapter highlights alarming findings related to pregnancy outcomes, including miscarriages and birth defects, during clinical trials and their potential implications for fertility. It raises questions about the regulatory response, especially concerning miscarriage rates that exceeded the norm, and the lack of explicit warnings regarding vaccine safety during pregnancy.

Key Takeaways:

1. HPV vaccine manufacturers did not conduct human fertility studies, relying on rat studies to assess fertility safety, a surprising gap given the vaccine's target population.
2. Clinical trial data revealed alarming rates of miscarriages during the vaccine trials, with miscarriage rates in some cases far exceeding those typically observed in healthy young women.
3. The FDA did not raise concerns about miscarriage rates, despite significant deviations from the norm, and the agency did not compare the trial data to background miscarriage rates in the US or other countries.
4. The chapter notes that the European Medicines Agency did express concerns about the higher miscarriage rates in some trials but ultimately approved the vaccines without addressing the issue explicitly.
5. Congenital abnormalities in babies conceived within a 30-day window after vaccination were observed, particularly in the Gardasil trials, which raised safety concerns.
6. The chapter highlights the lack of explicit warnings on vaccine safety during pregnancy in the US package inserts, despite the absence of adequate and well-controlled studies on pregnant women.
7. Research suggests a potential link between the HPV vaccine and premature ovarian failure (POF) based on rodent studies and case reports of POF in young women following vaccination.
8. Studies indicate a decline in teen pregnancy rates in countries with high HPV vaccine uptake, raising questions about potential environmental factors, including the vaccine's impact on fertility.
9. The declining teen pregnancy rates have been reported in several high-resource countries, including the UK, the US, Canada, Ireland, Denmark, Norway, and Australia.
10. The possibility of a link between the high miscarriage rates observed in vaccine trials and declining teen pregnancy rates warrants further scientific investigation.
11. The target population for HPV vaccines, prepubescent girls, may mask potential reproductive harm due to their minimal menstrual history, making causation challenging to establish.
12. Experts remain uncertain about the exact reasons for the dramatic decline in teen pregnancy rates, citing factors like changes in media and access to contraception.

13. While there is no concrete evidence of a causal link between falling teen pregnancy rates and the vaccine, the potential association demands rigorous scientific inquiry.

Excerpts:

1. "The vaccine manufacturers state in their package inserts that they have not tested the vaccines' effect on human fertility. One would expect that a vaccine targeting a sexually transmitted virus would at least have some studies on fertility. This is not the case."
2. "When Merck combined all clinical trial data, the average miscarriage rate was similar in both the Gardasil and AAHS control groups at around 25 percent. The FDA accepted that overall, because the groups had similar rates, there was no cause for concern."
3. "Unlike the FDA, the European Medicines Agency did raise this miscarriage signal as a concern in its preapproval process."

Statistics:

1. The miscarriage rate in the Gardasil 9 trials was 27.4 percent, more than double the rate in the control group, which was 12.7 percent.
2. Data from the Cervarix clinical trial review showed higher early miscarriage rates in those who received the vaccine versus the controls, at 13.5 percent versus 8.3 percent.
3. In the Gardasil trials, there was a higher rate of miscarriage in women aged 23 to 26, at 40 percent, compared to 18.9 percent in 16-to-22-year-olds.

Chapter 11: Clinical Trial Malfeasance

Executive Summary:

In this chapter, the focus is on clinical trial malfeasance surrounding HPV (Human Papillomavirus) vaccines, particularly Gardasil. The FDA and EMA (European Medicines Agency) concluded that these vaccines are generally safe after reviewing extensive clinical trial data, which primarily revealed short-term side effects like injection site reactions, fainting, and headaches. However, the chapter delves into the complexities of safety monitoring during these trials, highlighting issues with placebos, subjective data collection, and the discretion of investigators in reporting adverse events. It also raises concerns about the labeling of "new medical conditions" and the lack of clarity regarding this category in the trial design.

Key Takeaways:

1. HPV vaccines, including Gardasil, were deemed safe by the FDA and EMA based on clinical trial data, which primarily reported short-term side effects.
2. The reliability of safety monitoring in these trials depends on unbiased monitoring and appropriate placebos.
3. Clinical trial investigators faced challenges due to significant duties, low compensation, and onerous paperwork, which could impact their reporting of adverse events.
4. The chapter questions the labeling of "new medical conditions" in trial data and its absence in the initial trial design.
5. In Gardasil 9 trials, almost 52 percent of participants reported "new medical conditions," leading to regulatory concerns.
6. The chapter discusses cases of acute leukemia in the trials and regulatory inquiries into these cases.
7. It highlights the underreporting of deaths in the trials, particularly the investigation of deaths due to motor vehicle accidents and other causes.
8. The death rates in both the vaccine and control groups were relatively high, raising questions about their association with the vaccine.

Excerpts:

1. "The Slate article that featured Kesia brought to light the safety gaps in the Gardasil trials, and in particular in reporting 'new medical conditions.'"
2. "The EMA eventually approved Gardasil 9, so the reviewers must have ultimately been satisfied with the data."

Statistics:

1. In the initial Gardasil trials, the rate of death in the Gardasil groups was 8.5 per 10,000 (10 deaths out of 11,778), almost double the background death rate in the US for young women.
2. Protocol 019, involving older women, reported seven deaths in the Gardasil group and one in the AAHS group.
3. Protocol 020, an all-male trial, had thirteen deaths out of 4,065 study participants, with a notably high death rate in the fauxcebo group.

Chapter 12: India: A Clinical Trial Scandal

Executive summary:

The chapter delves into a controversial episode in India's healthcare system, focusing on the Human Papillomavirus (HPV) vaccine scandal. India, a country with a high burden of cervical cancer cases, saw the introduction of the HPV vaccine through "demonstration projects" by organizations like PATH, funded by the Bill and Melinda Gates Foundation and supplied by Merck and GSK. However, these projects raised ethical and safety concerns, leading to a parliamentary investigation, allegations of commercial exploitation, and litigation against vaccine manufacturers. The chapter discusses the appropriateness of mass HPV vaccination in India, emphasizing the need for strong epidemiological evidence, monitoring, and safety considerations.

Key takeaways:

1. India has a significant burden of cervical cancer, with approximately 74,000 annual deaths, making it the second-leading cause of cancer death in women globally.
2. "Demonstration projects" involving HPV vaccines were initiated by organizations like PATH in India, aiming to assess safety and efficacy. However, these projects faced allegations of unethical conduct.
3. The Indian Parliamentary Committee's report accused PATH of exploiting the situation for commercial gain, jeopardizing the health of vulnerable girls, and violating clinical trial laws.
4. Consent issues were prevalent, with many minors being enrolled without proper informed consent, raising concerns about the ethical conduct of the trials.
5. Some girls experienced adverse events, such as menstrual cycle disruption and psychological changes, leading to further safety concerns.
6. The HPV vaccine controversy prompted litigation in the Indian Supreme Court, alleging unethical trials and lack of follow-up.
7. Questions were raised about the appropriateness of mass HPV vaccination in India due to incomplete cancer surveillance, changing cervical cancer rates, and the vaccine's high cost.
8. Safety concerns arose, as healthy individuals faced small but real risks from the vaccine.
9. The debate continued on whether HPV vaccination was justified when cervical screening programs were considered more cost-effective.
10. The Indian government restricted clinical trials, suspended drug approvals, and imposed new guidelines for informed consent following the controversy.
11. The Bill and Melinda Gates Foundation's involvement in funding HPV vaccination programs sparked debates about conflicts of interest in India's immunization program.
12. Foreign funding for nongovernmental organizations, including PHFI, faced scrutiny, leading to restrictions on funding from foreign entities.
13. The debate over a national HPV vaccination program in India remains ongoing, with the Supreme Court's judgment pending, while the controversy led to improved laws regarding informed consent in clinical trials.

Excerpts:

1. "The choice of countries and population groups; the monopolistic nature... of the product being pushed; the unlimited market potential and opportunities in the universal immunization programmes of the respective countries are all pointers to a well-planned scheme to commercially exploit a situation."
2. "The safety and rights of the children in this vaccination project were highly compromised and violated."
3. "[T]here is genuine cause for concerns regarding mass vaccination in this country."

Statistics:

1. Over 25 percent of all newly diagnosed cases of cervical cancer in the world occur in India.
2. Seven girls allegedly died during the HPV vaccine trials in 2009–10.
3. In 2017, the Indian government blocked the Gates Foundation and other foreign entities from further funding PHFI and other nongovernmental organizations.

Chapter 13: A Market out of Thin Air

Executive Summary:

The chapter explores the intriguing story of how pharmaceutical giants Merck and GSK created a thriving market for HPV (Human Papillomavirus) vaccines, focusing on Gardasil. It delves into the financial significance of these vaccines for the companies and the circumstances that led to their aggressive marketing. The chapter also examines the historical backdrop, including Merck's previous drug Vioxx and its withdrawal, which influenced the urgency to market Gardasil.

Key Takeaways:

1. **Financial Success:** Merck and GSK's HPV vaccines, Gardasil and Cervarix, have been substantial revenue sources for the pharmaceutical giants, with Merck's Gardasil earning $2.3 billion in 2017 alone.
2. **Financial Dependency:** Gardasil's success is so vital to Merck that it's listed as a "Key Company Product," making any negative changes in its sales a significant concern for the company's financial health.
3. **Vioxx Controversy:** Merck's aggressive marketing of Gardasil can be traced back to the Vioxx scandal, where the company faced severe criticism and legal consequences for its drug's undisclosed cardiovascular risks.
4. **FDA's Role:** The FDA's approval and oversight of Vioxx came under scrutiny, highlighting issues within the FDA's relationship with pharmaceutical companies and the need for regulatory reform.
5. **Marketing Strategies:** Merck's marketing of Gardasil involved creating a fear of cervical cancer, using tactics like "disease branding" and direct-to-consumer advertising.
6. **Gender-Neutral Marketing:** Over time, Merck expanded its marketing to include boys, focusing on preventing various HPV-related cancers, which sparked debate about its cost-effectiveness.
7. **ACIP Recommendation:** The Advisory Committee on Immunization Practices (ACIP) played a pivotal role in recommending Gardasil for both girls and boys, setting a new standard for pediatric medical care.
8. **Efficacy and Cost-Benefit:** Questions about the vaccine's efficacy against various cancers, the need for booster shots, and cost-effectiveness were raised, leading to ongoing debates.
9. **Emotional Advertising:** Merck's advertising campaign tugged at emotions by implying that vaccination could have prevented cancer, targeting both young women and men.
10. **Financial Success of HPV Vaccines:** HPV vaccines have become highly profitable for pharmaceutical companies, with potential for further expansion into new markets.

Excerpts:

1. "How is it that these corporations, some of the world's largest, now depend for their survival on HPV vaccines? How did Merck and GSK create a market out of thin air?"
2. "The FDA had serious concerns about Vioxx before its approval. When it approved Vioxx, the FDA stated that it lacked 'complete certainty' that the drug increased cardiovascular risk."
3. "Merck's sales efforts employed sophisticated marketing messages to girls and their moms, playing on a kind of consumption feminism to suggest that smart, independent girls and women choose to vaccinate with Gardasil."

Statistics:

1. In 2017, Merck made $2.3 billion in revenue worldwide from Gardasil and Gardasil 9, up from $2.2 billion in 2016.
2. GSK earned 134 million pounds (roughly $186 million) globally from Cervarix in the same year.
3. Over 270 million doses of HPV vaccines have been distributed worldwide by pharmaceutical giants like Merck and GSK.

Chapter 14: The United States: Selling and Compelling

Executive Summary:

The chapter delves into the strategies employed by pharmaceutical companies, primarily focusing on Merck, to secure government mandates for their vaccines, specifically the HPV vaccine, Gardasil. It emphasizes the immense financial incentives created by such mandates and explores the intricate lobbying and political maneuvers undertaken to achieve them. The chapter also discusses the role of the CDC's Advisory Committee on Immunization Practices (ACIP) in recommending vaccines and highlights the importance of the Vaccines for Children program in ensuring the financial success of Gardasil.

Key Takeaways:

1. Government mandates for vaccines represent a lucrative opportunity for pharmaceutical companies, as they guarantee a massive market without the need for marketing efforts or liability.
2. Lobbying plays a crucial role in securing vaccine mandates, with an emphasis on indirect and health-focused pitches.
3. The CDC's Advisory Committee on Immunization Practices (ACIP) holds significant influence in recommending vaccines to the public, and its recommendations are pivotal for vaccine success.
4. The ACIP's recommendation of Gardasil for routine administration to 11- and 12-year-old girls in 2006 was a critical turning point in the vaccine's adoption.
5. Despite concerns about safety and efficacy, ACIP members have rarely discussed these issues and have focused on increasing vaccine uptake.
6. The Holy Grail for vaccine manufacturers in the US is to secure state mandates, which create substantial revenue streams.
7. Merck's efforts to pursue mandates faced roadblocks in some states, but it succeeded in several, such as Virginia and Washington, D.C.
8. State mandates for HPV vaccines have sparked controversy and raised questions about equal treatment, especially among minority populations.
9. The CDC and various medical organizations actively promote HPV vaccination, with a focus on adolescents.
10. Some states allow minors to consent to HPV vaccination without parental knowledge or consent, leading to concerns about informed consent.
11. Immigrant women seeking visas or immigration status adjustment were once required to receive the HPV vaccine, highlighting the potential for mandates based on age.
12. The military and juvenile detention facilities have recommended or offered the HPV vaccine to their populations, albeit with varying uptake rates.
13. Pharmaceutical companies employ sales techniques involving third-party endorsements, institutional support, and eventual universal mandates to promote vaccines.

Excerpts:

1. "The Holy Grail for vaccine manufacturers is to have governments mandate their products. People generally obey; the vast majority of parents comply with childhood vaccination mandates."
2. "Essential to Gardasil's financial success would be the ACIP recommendation and approval for the Vaccines for Children program."
3. "The CDC recommends many ways to increase uptake, including PR campaigns, emails and robocalls, as well as physician and parent trainings."

Statistics:

1. "As of 2016, the CDC reported that 65 percent of teenage girls and 56 percent of teenage boys had received at least one dose of an HPV vaccine."
2. "In 2007, over 50 percent of parents reported that they were not likely to have their children vaccinated."
3. "The 69 centers include most major US university medical centers, including Harvard, Yale, Stanford, NYU, Johns Hopkins, and UCLA, as well as other hospital medical centers, such as the Mayo Clinic."

Chapter 15: Injury Reports Flood In

Executive Summary:

Chapter 15 of the book unveils the distressing consequences of the Gardasil vaccine, focusing on the stories of Alexis and Christina, who faced severe health issues after vaccination. This raises crucial concerns about Gardasil's safety, demanding comprehensive research.

The chapter highlights determined individuals like Emily and Norma, who, after tragic losses, initiated campaigns for awareness and research. A network of families who lost daughters to the vaccine forms, revealing inconsistencies in vaccine quality.

Legal challenges against vaccine manufacturer Merck and the role of media are discussed. The Vaccine Adverse Event Reporting System (VAERS) data from 2006 to 2017 shows 57,000 reports linked to HPV vaccine, emphasizing the need for research and transparency.

Tragic cases of Joel Gomez, Maddie Moorman, and Colton Berrett further underscore the urgency of investigating HPV vaccine safety.

Key Takeaways:

1. Norma Erickson, a freelance reporter, initiated an investigation into cases of teenage girls experiencing adverse reactions to the Gardasil vaccine.
2. Alexis, a previously healthy 13-year-old, suffered severe health issues, including seizures and behavioral changes, after receiving Gardasil.
3. Despite her deteriorating condition, Alexis received additional doses of Gardasil as recommended by her pediatrician.
4. Christina, a talented and healthy young woman, also experienced adverse effects after receiving Gardasil and tragically passed away.
5. The CDC's investigation into these cases was limited, and discrepancies in reporting by Merck, the vaccine manufacturer, were observed.
6. Emily Tarsell, Christina's mother, embarked on a quest for answers and support from various organizations and advocates following her daughter's death.
7. Emily's unwavering pursuit of answers and justice for her daughter led her to investigate the HPV vaccine, Gardasil, and launch a campaign for further research.
8. Families affected by alleged HPV vaccine injuries formed a support network, sharing information and experiences, revealing inconsistencies in vaccine purity and content.
9. Legal challenges arose as families sought justice against Merck, with some law firms initially representing Gardasil cases withdrawing from the cases.
10. Emily's partnership with her attorney and expert witnesses played a pivotal role in her ongoing battle for justice.
11. Media attention brought both visibility and harsh criticism to advocates questioning Gardasil's safety.
12. VAERS, established in 1986, is a database tracking vaccine injuries, including those related to the HPV vaccine.
13. As of May 2018, VAERS had received 57,620 reports related to the HPV vaccine, including 420 deaths.

Excerpts:

1. "Norma Erickson, a freelance reporter, had been writing about health for Examiner.com and began to come across inexplicable stories about perfectly healthy teenage girls receiving the Gardasil vaccine and then suffering bizarre and terrible symptoms."
2. "Alexis, a happy and well-adjusted 13-year-old, experienced a dramatic change in her behavior and health after receiving the Gardasil vaccine. She developed seizures, panic attacks, and other troubling symptoms."
3. "Christina, a talented and accomplished young woman, received the Gardasil vaccine and subsequently experienced health issues that ultimately led to her untimely death."
4. "The symptoms from the survey results were consistent with those Chris had experienced. Emily now knew in her heart that Gardasil had caused Chris's death."
5. "There was a special bond among the six other mothers Emily knew that had, at about the same time, lost their daughters: Megan Hild, Jessica Ericzon, Santana Valdez, Amber Kaufman, Jenny Tetlock, and Annabelle Morin."

Statistics:

1. According to an analysis of NVIC questionnaires, a dose-response relationship was found for various reported symptoms, including chronic fatigue, headache, dizziness, joint/muscle pain, chest pain, skin disorders, heart disorders, problems concentrating, menstrual problems, and seizures.
2. The FDA allows a fairly wide range of acceptable contamination in vaccine lots, leading to variability in vaccine purity.
3. As of May 2018, VAERS had received 57,620 reports related to the HPV vaccine.
4. Among these reports, 420 deaths were associated with the HPV vaccine.
5. Joel Gomez's family received $200,000 in compensation from the National Vaccine Injury Compensation Program.

Chapter 16: Seeking Justice

Executive Summary:

This chapter explores vaccine liability and compensation in the United States, tracing the historical development of vaccines and the challenges they pose. It discusses the National Childhood Vaccine Injury Act of 1986, which aimed to ensure vaccine supply, compensate the injured, and enhance safety but also provided substantial liability protection to the vaccine industry.

The chapter focuses on Emily Tarsell's pursuit of justice after her daughter's death following a Gardasil HPV vaccination, resulting in a $250,000 compensation award. It also highlights Jasmyne Gramza's case, where her claim for vaccine-related injuries was denied. This chapter underscores the complexities of vaccine injury compensation and potential legal challenges for vaccine manufacturers.

Key Takeaways:

1. Vaccines have played a crucial role in public health since the 18th century, with Edward Jenner's smallpox vaccine being a milestone.
2. The 1980s saw a rise in vaccine-related injuries, leading to legal actions against vaccine manufacturers and healthcare providers.
3. The National Childhood Vaccine Injury Act of 1986 aimed to stabilize vaccine supply, compensate the injured, and enhance vaccine safety.
4. This Act provided substantial liability protection to vaccine manufacturers, unlike the pharmaceutical drug industry.
5. The recommended vaccines for children in the US have significantly increased since 1986, creating a profitable vaccine market.
6. The compensation process for vaccine injuries operates through a federal program, making it challenging to pursue legal action in regular courts.
7. A "Table of Injuries" is used to determine compensation for certain vaccine-related injuries, but most cases must prove causation, which is complex.
8. HPV vaccine compensation cases exemplify the challenges faced by those seeking compensation for off-Table injuries, requiring them to establish a vaccine-injury connection.
9. Special Masters are appointed to adjudicate vaccine injury cases, raising concerns about their impartiality.
10. While numerous HPV vaccine injury cases have been filed, few have resulted in compensation, presenting difficulties for victims seeking justice.
11. The legal process for vaccine injury compensation can be lengthy, adversarial, and complex, posing challenges for petitioners.
12. The reliance on scientific evidence and expert testimony further complicates vaccine injury claims, given the incomplete understanding of vaccine mechanisms.
13. Emily Tarsell's case, seeking compensation for her daughter's alleged HPV vaccine-related death, illustrates the lengthy and challenging legal battle faced by vaccine injury claimants.

Excerpts:

1. "The 1986 Act made it impossible to sue vaccine manufacturers or healthcare providers for vaccine injury without first filing in a federal compensation program."
2. "Only a small fraction, less than 1 percent of the total federal vaccine budget, goes toward vaccine safety research."
3. "Special Master Moran stated that he was not requiring scientific certainty, but merely a more-likely-than-not standard."
4. "For Emily, the purpose of this legal nightmare was not the money. Congress capped the award for death at $250,000 in 1986 and has never raised it."
5. "More than seven months after the hearing, the Special Master denied compensation, finding that the timing of Jasmyne's symptoms did not fit the recognizable profile for vaccine-induced ITP."

Statistics:

1. "The market value of childhood vaccines in the US is approximately $17.4 billion in 2018."
2. "As of early 2018, there have been 280 cases filed in the Compensation Program for HPV vaccine injury, and 156 cases have been dismissed."
3. "In 2013, the Program had already paid out $5.9 million in awards and annuities to 49 HPV vaccine victims."
4. Emily Tarsell was awarded $250,000 for her daughter's death and $60,000 for her past pain and suffering.
5. Jasmyne Gramza's platelet level dropped to 23,000 after developing idiopathic thrombocytopenic purpura (ITP) following HPV vaccination.

Chapter 17: Controlling the Message

Executive Summary:

This chapter delves into the striking similarities between Big Tobacco and the pharmaceutical industry, particularly in the context of HPV vaccine marketing. It explores how both industries use public relations framing, influence over government regulators, silencing of dissenting science, and marketing tactics that often target youth. The chapter presents instances of efforts to control the narrative around HPV vaccines, highlighting the suppression of scientific studies, media backlash against vaccine critics, and questionable actions by regulatory bodies like the European Medicines Agency (EMA). This chapter raises concerns about the pharmaceutical industry's tactics in shaping public perception of vaccine safety.

Key Takeaways:

1. Big Pharma's marketing of HPV vaccines shares similarities with Big Tobacco's tactics, including framing the narrative and silencing dissent.
2. Pharmaceutical companies have been accused of discrediting and silencing critics who raise concerns about HPV vaccine safety.
3. The chapter discusses the Toronto Star's retracted exposé on HPV vaccines and the subsequent backlash from physicians.
4. It highlights Katie Couric's efforts to explore the HPV vaccine controversy on her show, which led to criticism and a subsequent apology.
5. The suppression of scientific studies, such as the retraction of a study on HPV vaccines in mice, is a cause for concern.
6. Dr. Sin Hang Lee's open letter to the WHO alleges deliberate misleading on HPV vaccine safety by the Global Advisory Committee on Vaccine Safety (GACVS).
7. The EMA's dismissal of safety concerns regarding HPV vaccines, despite internal disagreements, raises questions about regulatory practices.
8. The Nordic Cochrane Centre's complaint about the EMA's handling of the HPV vaccine issue highlights potential conflicts of interest and scientific misconduct.
9. The chapter discusses Heidi Larson's assertion that HPV vaccines are safe and questions the dismissal of children's adverse reactions as psychosomatic.
10. The chapter draws parallels between Big Pharma and Big Tobacco, raising ethical questions about putting profits above public health.

Excerpts:

1. "Big Pharma’s vaccine marketing parallels Big Tobacco’s marketing in several ways: (1) significant public relations framing; (2) influence over government regulators; (3) silencing or discrediting any science that suggests harm; and (4) marketing products, particularly to youth."
2. "Over the years, Big Pharma has silenced or discredited HPV vaccine critics on many specific occasions. By sowing doubts about injuries as 'anecdotes' and 'psychogenic' stories of hysterical girls, Big Pharma has cynically followed Big Tobacco’s footsteps."
3. "In July 2015, Denmark requested the European Medicines Agency to investigate HPV vaccine adverse effects based on reported cases of postural orthostatic tachycardia syndrome (POTS) following vaccination."

Statistics:

1. The global expenditure on HPV vaccines can be roughly estimated at 25 billion Euros.
2. The EMA's report dismissed safety concerns and reports of suspected HPV-related complex regional pain syndrome (CRPS) and POTS, concluding that the data "do not suggest a causal link" between these conditions and the vaccines.
3. The ABC website received 12,000 comments in response to Katie Couric's program on the HPV vaccine, indicating significant public interest and concern.

Chapter 18: Australia: First to Inject

Executive summary:

Australia occupies a central role in the realm of HPV vaccines, having conducted clinical trials for both HPV vaccines and recommending them for girls in 2007 and later for boys in 2013. Cervical cancer is remarkably rare in Australia, with mortality rates lower than in the United States. Indigenous communities, with low screening rates, face higher cervical cancer risks. The HPV vaccine itself is an Australian invention, pioneered by Professor Ian Frazer and Dr. Ian Zhou, and it enjoys widespread recognition. However, its introduction faced hurdles, with initial rejection by Australia's drug approval board based on cost and efficacy concerns. Prime Minister Howard's intervention eventually led to its approval, making Australia the first country to incorporate it into a national school immunization program.

Despite the vaccine's success and adoption in Australia, it has not been without controversy. Reports of adverse reactions stirred public concern and led to a temporary drop in the vaccine's manufacturer's share price. Australia, like other countries, reported adverse events but denied a causal link to the vaccine, raising questions about conflicts of interest due to industry funding. Critics, including Steve Tunley and Judy Wilyman, raised concerns about the vaccine's safety and efficacy, often facing backlash from media and pro-vaccine entities. Despite these controversies, Australia continued to promote the vaccine as a lifesaving tool, even introducing Gardasil 9 to replace the original vaccine in schools in 2018.

Key takeaways:

1. Australia played a pivotal role in the development and adoption of HPV vaccines, conducting clinical trials and recommending them for girls in 2007 and boys in 2013.
2. Indigenous communities in Australia face higher cervical cancer risks due to low screening rates.
3. The HPV vaccine was invented by Professor Ian Frazer and Dr. Ian Zhou, gaining international recognition.
4. Initially, Australia's drug approval board rejected the vaccine due to cost and efficacy concerns, but it was eventually approved following Prime Minister Howard's intervention.
5. Australia became the first country to implement a national school immunization program for HPV vaccines.
6. Reports of adverse reactions to the vaccine sparked controversy and temporarily affected the manufacturer's share price.
7. The Therapeutic Goods Association (TGA) in Australia denied a causal link between adverse events and the vaccine, despite receiving industry funding.
8. Critics, including Steve Tunley and Judy Wilyman, questioned the vaccine's safety and efficacy, facing media backlash.
9. In 2018, Gardasil 9 replaced the original vaccine in Australian schools, with the government promoting it as a lifesaving tool.

Excerpts:

1. "Australia conducted clinical trials for both HPV vaccines and was one of the first countries to recommend it for girls in 2007."
2. "The HPV vaccine is an Australian invention, at least based on the 1990s patent wars."
3. "In a surprising turn of events, however, Australia's drug approval board, the Pharmaceutical Benefits Advisory Committee, rejected the Gardasil application in November 2006."

Statistics:

1. Cervical cancer mortality rate in Australia: 1.8 deaths per 100,000 women.
2. Over 70 percent uptake of HPV vaccine in Australian schools since 2007.
3. Around 4,300 reported adverse events related to HPV vaccines in Australia from April 2007 to March 2018, including one death.

Chapter 19: Challenging the Scientific Consensus: The Mavericks

Executive Summary:

This chapter delves into the controversy surrounding the HPV (human papillomavirus) vaccine and the efforts of organizations like SaneVax to challenge its safety claims. Norma Erickson, the founder of SaneVax, joined forces with medical maverick Dr. Sin Hang Lee to investigate the vaccine's safety. Dr. Lee's expertise in pathology and cervical screening techniques became instrumental in their quest for answers. They uncovered the presence of HPV DNA fragments in the vaccine, which raised concerns about its safety and efficacy.

Furthermore, the chapter explores the possibility that the vaccine contains an undisclosed adjuvant, a Toll-Like Receptor (TLR) agonist, which could enhance its immune response. Dr. Lee's research suggests that the HPV vaccine may require this undisclosed component to be effective. This discovery raises questions about transparency and the potential link between the vaccine and autoimmune illnesses. The chapter sheds light on the complex and contentious issues surrounding HPV vaccination.

Key Takeaways:

1. SaneVax, led by Norma Erickson, challenges the safety claims of the HPV vaccine and aims to promote only safe, affordable, necessary, and effective vaccines.
2. Dr. Sin Hang Lee, a pathologist, collaborates with SaneVax to investigate the HPV vaccine's safety.
3. HPV DNA fragments were discovered in Gardasil, the HPV vaccine, raising concerns about its safety.
4. The HPV vaccine may contain an undisclosed adjuvant, a Toll-Like Receptor (TLR) agonist, which could enhance its immune response.
5. The presence of HPV DNA fragments and the undisclosed adjuvant in the vaccine raise questions about transparency and potential links to autoimmune illnesses.

Excerpts:

1. "Dr. Lee's approach to pathology fit perfectly with SaneVax's objective to provide the public with solid science."
2. "Dr. Lee believed that there was a real risk that the vaccine itself might trigger a dangerous reaction in HPV-infected girls and women that could accelerate abnormal cervical cell growth."
3. "Dr. Lee's research suggests that the HPV vaccine may require this undisclosed component to be effective."

Statistics:

1. By 2013, people in 157 countries had visited SaneVax's website for information on the HPV vaccine.
2. Dr. Lee found HPV DNA contamination from HPV 18 or HPV 11 in 16 sealed Gardasil vials collected from various countries.
3. The FDA acknowledged the presence of DNA fragments in Gardasil but asserted they were not harmful, based on VAERS data.

Chapter 20: Aluminum-Containing Adjuvants: Fueling the Fire?

Executive Summary:

This chapter explores the contentious issue of aluminum-containing adjuvants in vaccines, examining their potential health implications. It questions the safety of aluminum adjuvants, given the limited understanding of their mechanisms and potential risks. The chapter highlights concerns raised by experts about aluminum's toxicity, its potential links to various health issues, and the absence of comprehensive safety studies. Additionally, it criticizes a 2004 review that discouraged further research into aluminum-adjuvanted vaccines and anticipates a forthcoming Cochrane review on this topic, particularly concerning HPV vaccines. Overall, the chapter emphasizes the need to prioritize safety concerns in vaccine development and administration.

Key Takeaways:

1. Aluminum is abundant in our environment but becomes biologically active when extracted from the earth's crust, raising concerns about its safety.
2. Aluminum has no known biological benefit and can potentially cause adverse effects in humans and other organisms.
3. Aluminum-containing adjuvants are used in vaccines to boost immune responses, but their mechanisms and safety are not fully understood.
4. Research indicates potential associations between aluminum and health issues such as autoimmune diseases, breast cancer, and Alzheimer's disease.
5. Injected aluminum in vaccines can be more efficiently absorbed by the body compared to ingested aluminum, potentially leading to higher exposure levels.
6. Premature infants and individuals with reduced kidney clearance are particularly vulnerable to aluminum toxicity.
7. Despite historical awareness of the potential harm of injected aluminum, it continues to be used in vaccines.
8. Claims of safety for aluminum-containing adjuvants lack comprehensive studies against placebos.
9. The FDA's upper limit for aluminum in vaccines focuses on enhancing vaccine effectiveness rather than safety.
10. Safety assessments for newer aluminum adjuvants are inadequate.
11. Recent research challenges the assumption that "the dose makes the poison," suggesting that even low doses of aluminum adjuvants may be toxic.
12. Studies raise concerns about aluminum adjuvants' potential neurotoxicity, warranting reevaluation.
13. Regulatory agencies have yet to take decisive action to address concerns about aluminum adjuvant safety.

Excerpts:

1. "Aluminum accumulates in the environment and does not return to the earth's crust. We are exposed to 'an ever-increasing burden of potentially biologically available aluminium.'"
2. "Injected aluminum bypasses the protective processes of the gut, and we essentially absorb 100 percent."
3. "Dr. Christopher Exley, criticizing this review, pointed out more than a decade ago that it should be obvious that the mere fact that aluminum has been in longtime use in vaccines does not necessarily prove that it is safe."
4. "Both the 2004 review and the protocol for the forthcoming review highlight real-world implications for vaccine manufacturers and public health authorities if some or all aluminum adjuvants are determined to be unsafe."
5. "The long-term health consequences of aluminum—and particularly of aluminum-containing adjuvants—are potentially devastating."

Statistics:

1. According to Dr. Exley, "aluminum adjuvants have the potential to do great harm."
2. The FDA's upper limit for aluminum in vaccines is 0.85 mg per dose.
3. Researchers injected mice with dosages of 200, 400, and 800 mcg/kg of aluminum adjuvant, equivalent to 2, 4, and 8 human doses, respectively.
4. In the 2004 Cochrane review, researchers expressed doubts about the safety of aluminum adjuvants in vaccines, despite the limited evidence available.
5. A 2013 study by Dr. Exley and other experts raised concerns about the neurotoxic potential of aluminum adjuvants.

Chapter 21: What Else Is in the Vial?

Executive Summary:

The chapter delves into the ingredients of HPV vaccines, particularly Gardasil and Gardasil 9, shedding light on components beyond aluminum-containing adjuvants. It raises concerns about the lack of comprehensive safety research on these ingredients when used in vaccines. The chapter explores Polysorbate 80, Sodium Borate, L-Histidine, yeast, and an enzyme called Benzonase™, all of which are present in HPV vaccines, emphasizing their potential risks and implications for public health.

Key Takeaways:

1. **Ingredients Beyond Aluminum**: HPV vaccines contain various other ingredients, including Polysorbate 80, Sodium Borate, L-Histidine, yeast, and Benzonase™, alongside aluminum-containing adjuvants.
2. **Lack of Comprehensive Safety Research**: There is insufficient research on the safety of these ingredients when injected into humans, particularly in vaccines. Regulatory agencies have not imposed stringent safety requirements for these components.
3. **Polysorbate 80**: Polysorbate 80 is a common ingredient in food, cosmetics, and pharmaceuticals, but its safety in vaccines is uncertain. It can breach the blood-brain barrier, potentially allowing harmful substances into the brain.
4. **Sodium Borate (Borax)**: Sodium Borate, present in Gardasil and Gardasil 9, is used as a pH buffer. It is banned as a food additive in the United States due to potential reproductive harm, raising questions about its safety in vaccines.
5. **L-Histidine**: L-Histidine, a vasodilator, is included in Gardasil. Its role in the vaccine and potential immune system implications remain unclear.
6. **Yeast**: HPV vaccines are fermented in genetically modified yeast, raising concerns about potential allergic reactions and autoimmune issues.
7. **Benzonase™**: Benzonase™, an enzyme used to remove residual nucleic acids from vaccines, is mentioned in clinical trial protocols but not in package inserts. Its safety profile is unknown.
8. **Genetically Modified Vaccines**: HPV vaccines are genetically modified, and their long-term effects on health are not yet understood. Concerns exist about the behavior of recombinant DNA in the human body.
9. **Need for Further Research**: Given the limited data on the safety of these ingredients in vaccines, regulators and manufacturers should prioritize additional research to ensure the safety of vaccines as a whole.

Excerpts:

1. "In assessing the safety of vaccines, we must consider the potential health risks of all components of the vaccine."
2. "The bottom line is that polysorbate 80 is not well studied for toxicity or other harms in humans..."
3. "So the FDA says we can inject borax without evaluating its safety, but we cannot eat borax without evaluation."

Statistics:

1. Sodium Borate (Borax) is banned as a food additive in the United States.
2. The Material Data Safety Sheet for Sodium Borate states that data concerning carcinogenic effects, mutagenic effects, teratogenic effects, and developmental toxicity data are unavailable.
3. HPV vaccines are genetically modified, and their long-term effects on health are unknown, with concerns about the behavior of recombinant DNA in the human body.

Chapter 22: HPV Vaccines, Autoimmunity, and Molecular Mimicry

Executive Summary:

The chapter explores the relationship between HPV vaccines, autoimmunity, and molecular mimicry. It highlights concerns about autoimmune diseases emerging in individuals following HPV vaccination and investigates the potential role of aluminum-containing adjuvants in triggering these adverse reactions. The chapter delves into the work of researchers like Dr. Romain Gherardi and Dr. Yehuda Shoenfeld, who have studied the link between aluminum-containing adjuvants and autoimmune conditions. It also examines the concept of molecular mimicry, where similarities between viral proteins and human proteins may confuse the immune system, potentially leading to autoimmunity.

Key Takeaways:

1. HPV vaccines have raised concerns about autoimmune diseases occurring in some individuals post-vaccination, sparking debates about their safety.
2. Aluminum-containing adjuvants, like AAHS in Merck's adjuvant, have been implicated in provoking immune responses, potentially leading to chronic inflammation and autoimmune conditions.
3. Dr. Romain Gherardi and Dr. Yehuda Shoenfeld's independent research has identified a condition known as Autoimmune Inflammatory Syndrome Induced by Adjuvants (ASIA) associated with aluminum-adjuvanted vaccines, which shares symptoms with conditions reported after HPV vaccination.
4. Industry-sponsored studies on vaccine safety, such as those by GSK, have been criticized for their study design, which lacks an inert control group and may not adequately capture autoimmune signals.
5. Genetic susceptibility may play a role in determining who develops autoimmune conditions following vaccination, and environmental factors like fluoride, pesticides, and mercury may also contribute.
6. Doctors need to be aware of the potential for vaccines to trigger autoimmune diseases in genetically vulnerable individuals.
7. Some experts and clinicians recommend caution in vaccinating individuals with personal or family histories of autoimmune diseases and autonomic disorders.
8. Case reports, like an 11-year-old girl diagnosed with autonomic neuropathy following HPV vaccination, underscore the need for medical personnel to recognize potential side effects, including neurological ones, post-vaccination.
9. Possible mechanisms for vaccine-induced autoimmunity include heightened immune responses upon subsequent exposures to the virus or vaccine and bystander activation, which involves nonspecific immune responses.
10. Molecular mimicry is a prominent theory explaining autoimmunity after HPV vaccination, suggesting that similarities between viral and human proteins may lead to immune confusion and autoimmune responses.
11. Research by Drs. Tomljenovic and Shaw supports the molecular mimicry theory, showing evidence of autoimmune vasculitis triggered by cross-reactive HPV-16 antibodies.
12. Controversy surrounds the connection between molecular mimicry, autoimmune disease, and HPV vaccines, with some experts dismissing concerns and others highlighting the potential risks.

13. Researchers are exploring the development of HPV vaccines with no overlap between human and viral proteins to reduce the risk of cross-reactivity and eliminate the need for adjuvants.

Excerpts:

1. "The number of viral matches and their locations makes the occurrence of side autoimmune cross-reactions in the human host following HPV16-based vaccination almost unavoidable." - Dr. Darja Kanduc, University of Bari, Italy (2009)
2. "Many researchers believe there is a genetically vulnerable subset of people who develop autoimmune conditions following exposure to an adjuvant, causing chronic immune system stimulation."
3. "In 2017, Drs. Jill R. Schofield of the University of Colorado and Jeanne E. Hendrickson of Yale University published an important article that included a case report of an 11-year-old girl diagnosed with POTS and neurocardiogenic syncope, among other problems, following her first dose of Gardasil."

Statistics:

1. Dr. Paul Offit mentioned that the HPV vaccine had been formally studied in more than a million people and claimed it had been shown not to cause the side effects associated with autoimmune diseases.
2. Research has identified numerous matches between HPV and human proteins, including dozens of sites on the HPV 16 L1 protein alone.
3. A 2017 study investigated the potential link between HPV and the development of lupus due to molecular mimicry, providing evidence to support this hypothesis.

Chapter 23: The Overlooked Fallout from the HPV Vaccine

Executive summary:

In this chapter, the complexities of HPV vaccines, their impact on cervical screening guidelines, and overlooked aspects of HPV infection and transmission are explored. The shift from annual Pap tests to less frequent screening and controversies surrounding newer HPV DNA and RNA testing methods are discussed. Challenges in cervical screening in low-resource countries and the possibility of nonsexual HPV transmission are highlighted. The chapter also addresses the prevalence of HPV in different populations and the need for tailored vaccine solutions. Additionally, it delves into HPV vaccines, focusing on type replacement, the concept of Original Antigenic Sin (OAS), and their link to cervical cancer. The chapter raises questions about the role of HPV in cervical cancer beyond vaccination.

Key takeaways:

1. Cervical screening guidelines have evolved, moving from annual Pap tests to less frequent screening, driven by concerns over overdiagnosis, overtreatment, and potential racial bias in recommendations.
2. Newer DNA and RNA HPV tests are replacing or being used alongside Pap tests, but their sensitivity, potential for false negatives, and the debate over screening frequency continue.
3. Eliminating Pap tests entirely may risk missing precancerous and cancerous conditions unrelated to HPV, underscoring the importance of balanced screening approaches.
4. National health regulatory bodies in various countries are advocating for HPV DNA testing as the primary cervical cancer screening tool, but concerns about sensitivity persist.
5. Low-resource countries face unique challenges in cervical screening, where innovative, low-tech options like VIA and self-collection are making a difference, especially in late-stage cancer identification.
6. Natural substances like curcumin and compounds from shiitake mushrooms show promise in treating HPV infections and cervical cancer, highlighting potential alternative treatments.
7. Poor nutrition and specific genetic changes may also impact cervical health, necessitating broader considerations in cervical cancer prevention.
8. Revaccinating with Gardasil 9 after receiving Gardasil may offer limited medical benefits and potential risks, prompting further research into vaccination strategies.
9. HPV infections can occur in non-sexually active individuals, challenging the assumption of solely sexually transmitted HPV infections.
10. Vertical transmission of HPV from infected mothers to infants during childbirth is possible but not fully understood, warranting continued investigation.
11. HPV prevalence varies by race, ethnicity, and location, raising questions about the effectiveness of one-size-fits-all HPV vaccines.
12. Concerns about type replacement, recombination of HPV within types, and the need for ongoing research underscore the complexity of HPV and vaccines.

13. Uncertainty exists regarding the extent to which HPV is the sole cause of cervical cancer, with factors like chronic inflammation and genetic mutations potentially playing significant roles.

Excerpts:

1. "Current cervical screening guidelines are in flux. Some readers will remember the days of annual Pap tests. No one liked them, but they were an accepted part of annual gynecological care."
2. "Doing away with Pap tests altogether thus seems to create the risk of missing some precancerous and cancerous conditions, particularly those not related to HPV."
3. "Because HPV vaccines protect against only limited HPV types, some scientists are concerned about 'type replacement.' This means that when a vaccine protects against infection from a particular type of the virus, infections caused by other types may become more common."
4. "In a clinical trial study in which girls who had received the full Gardasil series were revaccinated with Gardasil 9, the revaccinated girls had lower, and not necessarily protective, titers to the new HPV types in Gardasil 9 compared to girls who had not previously been vaccinated with Gardasil and received only Gardasil 9."
5. "Is the generally accepted theory of HPV infection the only plausible route for a woman to develop cervical cancer? Is it possible that other factors are at work, at least in some cases?"

Statistics:

1. "A 2015 article analyzed the screening results from over 250,000 women. It concluded that almost 20 percent of women with cervical cancer may receive false negative results from HPV DNA testing alone."
2. "Latina women are the most likely to receive cervical cancer diagnoses and to die from cervical cancer in the US, followed by African American women."
3. "Spanish researchers found that HPV 16 or 18 was present in 42.7 percent of women examined with CIN2 or CIN3, but HPV 16 and 18 types alone were present in only 28.2 percent of cases without coinfection with other high-risk or probable high-risk types."
4. According to a 2016 CDC study, the overall prevalence of HPV increased from 54.4 percent in the "prevaccine" era (2003–2006) to 58.1 percent overall (56.7 percent for those vaccinated) in the vaccine era (2009–2012), raising questions about potential type replacement.
5. Researchers found HPV in only 39.5 percent of premalignant and malignant cervical lesions in an Egyptian study, suggesting that factors beyond HPV may play a role in cervical cancer development.

Chapter 24: Japan: Pulling the Plug

Executive Summary:

The chapter delves into Japan's complex journey with the HPV vaccine and its decision to suspend the proactive recommendation of the vaccine. Japan faces challenges in combating cervical cancer, with low participation rates in cervical screening. The Ministry of Health initially promoted HPV vaccination but abruptly suspended its recommendation due to reported adverse effects. This suspension had ripple effects, including undermining confidence in the vaccine globally. Japan's cautious approach towards vaccines and its response to adverse events have sparked debates and lawsuits. Despite industry pressures, Japan remains a significant influence in the global HPV vaccine discourse.

Key Takeaways:

1. Japan has a relatively high incidence of cervical cancer, with low participation rates in cervical screening programs, contributing to a significant number of deaths.
2. The Japanese Ministry of Health initially promoted HPV vaccination but suspended its proactive recommendation due to reported adverse effects, causing a drastic drop in vaccination rates.
3. Adverse events following HPV vaccination, including complex regional pain syndrome (CRPS) and neurological symptoms, raised concerns about the vaccine's safety.
4. Japan's history includes instances of caution regarding vaccines, such as suspending the measles-mumps-rubella vaccine and other vaccines in response to safety concerns.
5. Japan hosted an International Symposium on Adverse Reactions to HPV Vaccines, facilitating dialogue between vaccine proponents and critics.
6. Dr. Shuichi Ikeda's research in Japan contributed to the understanding of adverse reactions to the HPV vaccine and challenged the psychogenic explanation.
7. The Japan Medical Association and the Japanese Association of Medical Sciences issued guidelines for managing post-vaccination symptoms, acknowledging the medical nature of reactions.
8. Japan stands alone in its cautious approach to HPV vaccination, with medical professionals recommending a "wait and see" approach.
9. Industry executives fear Japan's decision could influence other countries to reject the HPV vaccine, leading to efforts to restore its recommendation.
10. A class action lawsuit in Japan seeks damages and access to medical specialists for those injured by the HPV vaccine.
11. Japan's response to adverse events has centered on listening to patients' voices and conducting thorough examinations, challenging the psychogenic explanation.
12. The chapter highlights the power of mobilized families, engaged medical professionals, and politicians in shaping Japan's stance on the HPV vaccine.
13. Japan continues to be a significant influence in the global HPV vaccine discourse, with the world closely monitoring its actions and decisions.

Excerpts:

1. "In Japan, cervical screening usually takes place in a women's hospital setting, where women usually go only when they are pregnant or ill."
2. "The Ministry abruptly suspended its proactive recommendation on June 14, 2013, less than three months after it had added the vaccine to the immunization schedule, due to 'an undeniable causal relationship between persistent pain and the vaccination.'"
3. "Despite acknowledging this concern, the report sticks by its psychogenic explanation for injuries."

Statistics:

1. Approximately 9,400 women in Japan are diagnosed with cervical cancer each year, with about 3,600 of them succumbing to the disease.
2. By June 2013, an estimated 8.3 million Japanese girls had received the HPV vaccine, constituting around 70 percent of those born between 1994 and 1998.
3. The class action lawsuit in Japan involves 119 plaintiffs seeking damages of 15 million yen (approximately $135,000) for each injured person.

Chapter 25: Denmark: Pushing Back in Europe

Executive summary:

This chapter delves into Denmark's role as the epicenter of the HPV vaccine controversy in continental Europe. Despite the availability of the vaccine, Denmark has faced growing concerns regarding its safety and its alleged connection to various adverse health effects in young girls. Karsten Viborg's journey is highlighted as he fought to find treatment for his daughter Rikke, who experienced severe symptoms after receiving the Gardasil vaccine. This chapter also discusses the pivotal role played by doctors like Dr. Louise Brinth and Dr. Jesper Mehlsen, who conducted research and raised concerns about vaccine-related health issues. It touches upon the controversy surrounding the European Medicines Agency (EMA) and its assessment of the vaccine's safety.

Key takeaways:

1. Denmark serves as the focal point of the HPV vaccine controversy in Europe, with concerns raised about the vaccine's safety despite recommendations by health authorities.
2. Karsten Viborg's daughter, Rikke, experienced debilitating symptoms after receiving the Gardasil vaccine, prompting his quest for answers and treatment.
3. Doctors like Dr. Louise Brinth and Dr. Jesper Mehlsen played a crucial role in diagnosing and treating girls with suspected HPV vaccine-related health issues, and their research led to concerns about the vaccine.
4. The documentary "The Vaccinated Girls" brought widespread attention to the controversy, featuring the stories of affected girls and the concerns of medical professionals.
5. Denmark saw a significant increase in reported adverse events following the HPV vaccine, including conditions like POTS and CRPS.
6. Despite growing concerns, the Danish Health Authority continued to recommend the HPV vaccine, while uptake rates declined sharply.
7. The controversy led to a switch from Gardasil to Cervarix in Denmark, and efforts were made to promote the vaccine for boys as well.
8. Parent groups and doctors continued seeking answers, and Denmark remained under scrutiny for its handling of the HPV vaccine program.
9. Ongoing research by doctors like Drs. Brinth and Mehlsen, as well as studies examining biological factors, are essential to understanding the vaccine's potential adverse effects.
10. The chapter emphasizes the need for more comprehensive research beyond epidemiological studies to address the HPV vaccine controversy.

Excerpts:

1. "Karsten Viborg was a typical family man enjoying life with his wife and two teenage children. He had no idea when he and his wife consented to the Gardasil vaccine for their 12-year-old daughter in 2010 that their lives would never be the same."
2. "The documentary featured many of the girls in Karsten’s patient support group and raised the alarm about the side effects of the vaccine, in particular in athletic girls."
3. "The EMA did not agree with Dr. Chandler’s findings or the call for further investigation, however. Ignoring Dr. Chandler’s observations based on data from the

WHO database, it stated that no link existed between the HPV vaccine with POTS and CRPS."

Statistics:

1. Over 2,300 adverse events from the HPV vaccine have been officially reported in Denmark, with over 1,000 considered severe.
2. The Statens Serum Institute reported 150 adverse events per 100,000 shots sold in 2015, including POTS, CRPS, and "medically unexplained physical symptoms."
3. Uptake of the HPV vaccine in Denmark declined from 80 percent in 2009 to 15 percent in 2016, although it has been gradually increasing due to awareness campaigns.

Chapter 26: Ireland: Injected and Neglected

Executive Summary:

This chapter, delves into the controversial introduction of the HPV vaccine Gardasil in Ireland and its impact on young girls. It begins by recounting the harrowing experience of Abbey Colohan, who suffered a severe reaction after receiving the vaccine, leading to seizures and ongoing health issues. Despite compelling evidence of adverse reactions, the Irish health authorities downplayed the incidents.

The chapter highlights the political controversy surrounding the vaccine's introduction in Ireland, including concerns raised by parent advocacy group Mothers' Alliance Ireland (MAI) regarding the vaccine's safety, side effects, and potential risks. Despite these concerns, vaccination rates among preteen girls soared, partly due to the vaccine being administered directly in schools. However, parents were not provided with adequate information about potential side effects, and the Health Service actively discouraged the distribution of non-government-approved information.

The chapter also introduces the grassroots movement known as REGRET (Reactions and Effects of Gardasil Resulting in Extreme Trauma), born out of the shared experiences of parents whose daughters suffered adverse reactions to the HPV vaccine. These parents began advocating for awareness and seeking answers about the risks associated with the vaccine, ultimately aiming to prevent similar experiences for others.

The chapter "Advocacy Begins in Ireland" delves into the origins of the advocacy group REGRET and their relentless pursuit of answers regarding the adverse effects of the HPV vaccine. It highlights the challenges faced by the parents of girls who experienced health issues after receiving the vaccine and their efforts to engage with health authorities, media, and pharmaceutical companies. The chapter also reveals the changing vaccination policies, media influence, and the Irish Cancer Society's involvement in the controversy. Ultimately, it paints a picture of parents' determination and the government's steadfast support of the vaccine program.

Key Takeaways:

1. Abbey Colohan's severe reaction to the Gardasil vaccine, resulting in seizures and ongoing health issues, exemplifies the controversy surrounding HPV vaccination in Ireland.
2. Despite evidence of adverse reactions, Irish health authorities dismissed concerns and attributed severe side effects to panic attacks or unrelated issues.
3. The introduction of Gardasil in Ireland faced political and public pressure, with criticism from groups like Mothers' Alliance Ireland (MAI) regarding the vaccine's safety.
4. High vaccination rates among preteen girls were achieved, in part, by offering the vaccine directly in schools, but parents were not provided with comprehensive information about potential side effects.
5. The Health Service discouraged the distribution of non-government-approved information and downplayed the need for informed consent.
6. The grassroots movement REGRET emerged from parents' shared experiences, aiming to raise awareness and advocate for transparency regarding the HPV vaccine's risks.
7. REGRET, an advocacy group formed in Ireland in 2015, represents parents whose daughters experienced health issues after receiving the HPV vaccine.

8. The group faced difficulties in getting help for their daughters within the state-funded medical system, leading them to engage with the minister of health and other stakeholders.
9. Dr. Kevin Connolly, chairman of the National Immunisation Advisory Committee, acknowledged the possibility of the vaccine causing health issues but supported its importance in fighting cervical cancer.
10. The European Medicines Agency (EMA) conducted an investigation into the vaccine's association with Postural Orthostatic Tachycardia Syndrome (POTS) and Complex Regional Pain Syndrome (CRPS) but concluded that there was no association.
11. Merck/Sanofi Pasteur MSD changed the recommended dose schedule from three doses to two, citing a Canadian study's data to support the change.
12. The Health Service managers defended the vaccine's safety and rejected a causal link between the vaccine and the girls' illnesses.
13. A documentary titled "Cervical Cancer Vaccine, Is It Safe?" featuring REGRET members garnered public attention and increased awareness about the controversy.
14. The Irish Cancer Society initiated a campaign to endorse the HPV vaccine due to declining vaccination rates and attributed this decline to REGRET's awareness campaign and the documentary.
15. Parents within REGRET continued their advocacy efforts, using the tagline "Injected and Neglected" to draw attention to their daughters' plight.
16. Media outlets and prominent figures criticized the parents, labeling them as "antivaccine activists" and accusing them of spreading misinformation.
17. Some individuals and organizations received funding from vaccine manufacturers, raising questions about conflicts of interest.
18. Jonathan Irwin, founder of the Jack & Jill Foundation, publicly shared his daughter's adverse reaction to the vaccine, calling on the Minister for Health to take action.
19. The chapter concludes by discussing the potential vaccination of boys and the ongoing controversy surrounding the HPV vaccine in Ireland.

Excerpts:

1. "Some of the tactics employed [by campaigners] can only be equated to a form of emotional terrorism. As a result, the uptake of the HPV vaccine in this country has dropped to an all-time low." - Tony O'Brien, Health Service Executive Ireland, Irish Examiner, August 31, 2017.
2. "Abbey’s life has never been the same since 2014. It now revolves around doctors and specialists who are trying to ease her pain. She now suffers from recurring seizures and cannot predict when she will have a good day or a bad one." - Abbey Colohan's struggle after receiving the HPV vaccine.
3. "Kiva quickly came across other stories in Facebook groups. After describing Kelly’s symptoms, she nervously asked in one of these groups about the HPV vaccine and if other girls had experienced these symptoms shortly after getting it, too." - The formation of REGRET and parents sharing their experiences.
4. "In 2015 Merck, or Sanofi Pasteur MSD in Europe, changed its recommended dose schedule from three doses to two. It is unclear why Sanofi would rush ahead of countries like the US in recommending such a dramatic change, but it was based on some credible data."

5. "The new minister for health, Simon Harris, publicly called on doctors to 'come out fighting' against people who pass on 'uninformed nonsense' coming from 'scaremongers.'"

Statistics:

1. Approximately 90 women in Ireland lose their lives to cervical cancer each year, with around 300 cases reported annually, translating to 3.7 deaths per 100,000 women.
2. Vaccination rates among preteen girls in Ireland reached over 80 percent in the first year of the school-based HPV vaccination program.
3. The Health Service informed staff in their 2015 guidelines for immunization that 1 in 4 Irish adults have literacy problems, potentially affecting their ability to understand patient information leaflets.
4. HPV vaccine uptake rates in Ireland dropped from 87 percent to 72 percent in the previous year due to mounting adverse reports and advocacy efforts.
5. The documentary "Cervical Cancer Vaccine, Is It Safe?" aired on December 14, 2015, and led to a rapid decline in Ireland's uptake of the vaccine, as mentioned by Dr. Brenda Corcoran of the National Immunisation Office in a presentation to professionals in 2017.
6. Uptake of the HPV vaccine in Ireland increased to 62 percent from 50 percent following an aggressive campaign by the government-sponsored "HPV Vaccine Alliance."

Chapter 27: The United Kingdom: Media Magic

Executive Summary:

This chapter delves into the United Kingdom's experience with the introduction of the Cervarix vaccine to combat cervical cancer. It begins with the tragic case of reality TV celebrity Jade Goody, who became a prominent figure in the vaccine's rollout due to her battle with cervical cancer. Her story, widely covered in the media, led to increased public awareness and interest in the HPV vaccine. Despite initial success, concerns arose as reports of adverse reactions and even deaths following vaccination emerged. The chapter also highlights the advocacy efforts of parents like Steve Hinks, who fought for recognition of vaccine-related injuries. Despite challenges and controversies, the UK maintains a high vaccination rate, making it a strong supporter of HPV vaccine manufacturers.

Key Takeaways:

1. **Early Introduction**: The UK introduced the Cervarix vaccine in 2008, targeting girls aged 12 to 18 to prevent cervical cancer.
2. **Jade Goody's Impact**: Reality TV celebrity Jade Goody's battle with cervical cancer heightened public awareness about the disease and the importance of vaccination.
3. **Adverse Reactions**: Media reports highlighted adverse reactions to the vaccine, including cases like Carly Steele's, raising concerns about its safety.
4. **Natalie Morton's Death**: The tragic death of fourteen-year-old Natalie Morton, initially attributed to the vaccine but later linked to a rare tumor, stirred controversy and led to a temporary vaccine batch recall.
5. **Vaccine Injury Compensation**: The UK's vaccine injury compensation program is considered arbitrary, with strict criteria for compensation.
6. **Parent Advocacy**: Parents like Steve Hinks became advocates for HPV vaccine safety, forming groups like the UK Association of HPV Vaccine Injured Daughters (AHVID).
7. **Yellow Card Reporting System**: The Yellow Card system, established to monitor drug reactions, has received over 9,000 reports of adverse events related to the HPV vaccine since 2008.
8. **MHRA Dismissal**: Despite high adverse event reports, the Medicines and Healthcare products Regulatory Authority (MHRA) dismissed most cases as unrelated to the vaccine.
9. **Vaccination Coverage Decline**: Vaccination coverage declined from over 90 percent to around 80 percent in recent years.
10. **Boys' Vaccination Debate**: The debate over vaccinating boys was fueled by lobbying groups like HPVAction.org, with concerns about sexual discrimination and the cost-effectiveness of inclusion.
11. **Legal Challenges**: The Throat Cancer Foundation filed a high court case against the NHS, alleging sexual discrimination under the Equality Act due to the exclusion of boys.
12. **JCVI Recommendation**: The Joint Committee on Vaccination and Immunisation (JCVI) recommended expanding the vaccination program to include boys, citing potential benefits for unvaccinated girls and the MSM community.

13. **Strong Support**: Despite controversies and resistance, the UK maintains a high vaccination rate and remains a strong ally for HPV vaccine manufacturers.

Excerpts:

1. "Cervical cancer was already at the forefront of mainstream conversation in 2008 because reality TV celebrity Jade Goody was dying from the disease."
2. "In the aftermath of her death, the British Medical Council conducted a study titled 'Coverage of Jade Goody's cervical cancer in UK newspapers: a missed opportunity for health promotion?'"
3. "Like all parents who find themselves in this position, his journey had not been by his choice. He published Lucy's story on SaneVax's website, and then parents in similar situations in the UK contacted him for help and advice."

Statistics:

1. Over 9,000 Yellow Card or adverse drug reports (ADRs) related to the HPV vaccine have been reported in the UK since 2008.
2. In a written answer documented in Parliament in 2017, there were 8,835 reported reactions to Cervarix, Gardasil, and Gardasil 9, with over 34 percent of them categorized as "serious."
3. The latest figures show that 9,156 adverse event reports were filed for the HPV vaccine's first ten years, reporting 24,000 symptoms, with eight deaths reported, although none are considered related to the vaccine.

Chapter 28: Colombia: Families Fighting Back

Executive Summary:

The chapter delves into the controversy surrounding the HPV vaccine in Colombia, primarily through the eyes of Mario Lamo, an anthropologist and journalist. It discusses the historical context of cervical cancer rates in Colombia, the introduction of the HPV vaccine, concerns raised by Mario Lamo, and the alarming reactions experienced by Colombian girls, particularly in El Carmen de Bolívar. The chapter also explores the legal battles and public relations war that ensued, highlighting the struggle for recognition and justice by affected families.

Key Takeaways:

1. **Cervical Cancer in Colombia:** Colombia has historically faced high cervical cancer rates, but they have significantly decreased over the years, mainly attributed to socioeconomic improvements, reduced parity, and advances in cancer screening.
2. **Introduction of HPV Vaccine:** In 2013, Colombia announced the introduction of the HPV vaccine, sparking concerns about the lack of public debate and potential pharmaceutical lobbying behind the decision.
3. **Mario Lamo's Warnings:** Mario Lamo, a journalist, raised concerns about the HPV vaccine's safety and efficacy, publishing articles in mainstream newspapers and highlighting the risks associated with the vaccine.
4. **Adverse Reactions in El Carmen de Bolívar:** Following the administration of the HPV vaccine, girls in El Carmen de Bolívar experienced severe adverse reactions, including convulsions, fainting, and paralysis, raising alarm and gaining attention on social media.
5. **Government Denial:** The Colombian government initially dismissed these reactions as psychosomatic, attributing them to mass hysteria and refusing to investigate potential vaccine-related causes.
6. **Legal Battles:** Families of affected girls, led by figures like Monica León del Rio, initiated legal battles against the government and Merck Sharpe and Dohme, seeking compensation for injuries and justice.
7. **Public Relations War:** A public relations battle erupted, with HPV vaccine advocates defending its safety, while some experts raised concerns about the vaccine's side effects and called for transparency.
8. **Vaccine Uptake Decline:** Due to the controversy and public awareness, HPV vaccine uptake in Colombia plummeted from the target rate of 80-90% to just 5%.
9. **Class Action Lawsuit:** In August 2017, a class action lawsuit was filed on behalf of 700 affected girls against Merck Sharpe and Dohme for vaccine-related injuries, including fatalities.
10. **Constitutional Court Ruling:** The Constitutional High Court ruled that the HPV vaccine would no longer be mandatory in Colombia, acknowledged the vaccine as a possible cause of injuries, and emphasized the need for informed consent.
11. **Ongoing Battle:** The chapter concludes with the ongoing legal battle between affected families, the pharmaceutical company, and the Colombian state, as they seek answers, treatment, and compensation for vaccine-related injuries.

Excerpts:

1. "Mario spent almost two decades in the US and learned a great deal about vaccines while there."
2. "The government moved to dismiss the girls' claims immediately, declaring their reactions psychosomatic in nature, even though officials never medically examined the girls."
3. "The Constitutional Court ruled that the HPV vaccine would no longer be considered mandatory in Colombia, stating that it could not rule out the vaccine as the cause of the girls' injuries."

Statistics:

1. Cervical cancer rates in Colombia have reduced from 120 per 100,000 in the 1960s to 20 per 100,000 today.
2. Approximately 5,000 women in Colombia are affected by cervical cancer each year, with almost half of them losing their lives to the disease.
3. HPV vaccine uptake in Colombia dropped to just 5% from the target rate of 80-90% following the controversy.

Chapter 29: The Emperor Has No Clothes

Everyone in the streets and the windows said, "Oh, how fine are the Emperor's new clothes! Don't they fit him to perfection? And see his long train!" Nobody would confess that he couldn't see anything, for that would prove him either unfit for his position, or a fool. No costume the Emperor had worn before was ever such a complete success.

"But he hasn't got anything on," a little child said.

"Did you ever hear such innocent prattle?" said its father. And one person whispered to another what the child had said, "He hasn't anything on. A child says he hasn't anything on."

"But he hasn't got anything on!" the whole town cried out at last.

Hans Christian Andersen, "The Emperor's New Clothes"

If cancer has been dubbed the emperor of all maladies, then surely the HPV vaccine is the emperor of all vaccines. With cutting-edge, genetically engineered VLP technology; the promise to prevent cancer; accolades from world medical organizations; glowing endorsements from government health agencies; and soaring revenues and market penetration in more than a hundred twenty-five countries after a scant twelve years, few would cast doubt on the HPV vaccine's regal status among medicines, let alone vaccines. Yet as in the fairy tale, a child can see that the emperor has no clothes and that his regal vestments are an illusion.

In the twelve years since Gardasil gained approval, the triumphal narrative has prevailed. But the devastating narrative of harm to children worms its way into public discourse nonetheless, undermining the vaccine's international success story. We have highlighted the discrepancies and half-truths in the mainstream narrative. Just as it took time for the fairy tale crowd to catch on, so it is taking time for the world to come around to seeing the truth about the HPV vaccine.

Thus far, HPV vaccine effectiveness is showing promise in reducing the risk of cervical lesions in follow-up studies, but the vaccine is still at an experimental stage. Its effectiveness in preventing cancer remains unknown. The vaccine clinical trials were profoundly flawed for many reasons, including that no saline placebo was used as a control and that manufacturers did not adequately study the vaccines' target preteen population. Since 2006, children and young people around the world have unwittingly taken part in an uncontrolled clinical trial, without their or their parents' informed consent.

This widespread deprivation of true informed consent violates fundamental tenets of ethical medicine and human rights. It is simply unethical to put lives at risk without real informed consent, particularly when safer alternatives for cervical cancer prevention exist and the vaccine has never been proven to prevent cancer. To uphold human rights, individuals must receive full information about risks and benefits of the vaccine. It is entirely within a person's right to reject the vaccine and to defer to traditional and safe alternatives to cervical cancer prevention, such as a healthy lifestyle and Pap tests, as well as newer HPV DNA and RNA tests.

Although regulators claim the vaccine is safe, both the FDA and the WHO have received over 100,000 reports of adverse events, including deaths, from around the world. Are they all coincidences? Although scientists now recognize that symptoms from the vaccine occur in clusters, they have not yet made this a research focus. Scientists could be doing studies that might yield a deeper understanding of long-term effects if they studied cluster symptoms now. Likewise, scientists should pay attention to the many missed safety signals in the clinical trials, which the book highlights, including effects on fertility and autoimmune conditions. As

Nobel laureate Luc Montagnier reminds us in the preface, the Hippocratic Oath is “First Do No Harm.”

We urgently call for more research on ways to help the children and families now suffering from HPV vaccine injury. These people have been neglected and mistreated simply because their pleas for help discredit the dominant narrative of a flawless vaccine. The medical community’s impulse to disregard HPV vaccine injury or to discount it as psychogenic is deeply disheartening. Yet we are encouraged by the work of a growing number of doctors and scientists to help these victims of iatrogenic harm.

We also call for civility. We are dismayed that families who report HPV vaccine injuries are branded “antivaccine” and “antiscience” by media and government agencies alike. This marginalization and bullying destroys civil public discourse and discourages scientific inquiry, when we urgently need both. All media, including social media, should be a place where civil information sharing occurs.

As with Merck’s Vioxx, the truth will come out. The HPV vaccine is on trial, both in the courts of law and public opinion. The evidence is mounting, as we’ve made clear. The future of the vaccine is uncertain. But in the meantime, how many children will suffer because of a pharmaceutical nonbinding promise that in 20 to 30 years, the vaccine will prevent some HPV-related cancers?

As the vaccine enters its second decade, it continues to be the object of high praise. But accounts of scandal, lawsuits, severe injuries, and deaths grow, challenging the prevailing narrative. This book poses many questions that regulators and manufacturers have a duty to answer. Crucial questions around the clinical trials, the ingredients in the vaccines, missed safety signals, and the potential for harm in the real world remain unanswered. It is incumbent on the scientific community to seek higher standards in clinical trial safety, especially for children. Transparency and disclosure of all clinical trial data would deter some if not all clinical trial malfeasance. This book highlights how the flawed clinical trials missed key safety signals.

Through lost lives and permanent injuries, children are resoundingly telling us that the HPV vaccine is unsafe. As in the fairy tale, adults are already starting to echo the child’s truth telling. People around the world are whispering about the vaccine’s risks and harms. The question is, When will the whispers turn into a roar? When will the world proclaim that the Emperor has no clothes?