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Advance praise for
Turtles All The Way Down:
Vaccine Science and Myth

"We have found the book to be well written, serious, scientific and important… We sincerely recommend it as a scientific, medical, and public 'must read'. This book should be central to a scientific, rational, logical, skeptical, and critical discussion on routine vaccination… The authors should be congratulated on their vast scientific in-depth endeavor as well as on their courage to think outside the 'establishment box'."
—Nati Ronel, Professor of Criminology, and Eti Elisha, Senior Criminologist, in *Harefuah Medical Journal*, Sep. 2019

"This is a wonderful book – indeed, a masterpiece – and one that really needed to be written. Clearly written and very comprehensive, it is an invaluable source of knowledge for all truly interested individuals, parents as well as physicians. The title may seem puzzling at first, but once you read the book you'll realize it is a stroke of genius. I congratulate the authors on a work extremely well done."
—Russell L. Blaylock M.D., Neurosurgeon, Author of *The Liver Cure*

"In the complexity of the modern world, where media manipulation is ubiquitous, it can be difficult to discern fact from fiction, truth from propaganda. To truly understand an issue, we can no longer just trust what we are told, we must first verify through our own research and exploration. This is your opportunity to research and explore a topic of enormous importance to society. There is powerful truth told in this book, rigorously researched, meticulously documented, and written with impeccable integrity. History will judge *Turtles All The Way Down: Vaccine Science and Myth* as an important anchor to truth at a time when so little of what we read and watch can be trusted."
—Beth Lambert, Author of *A Compromised Generation* and *Brain Under Attack*

"I strongly recommend that you read the most important book ever written about vaccines. The book presents hundreds of facts, backed by solid scientific references, which will leave you speechless. The authors present an unprecedented analysis of the world of vaccines. The book shatters myths that we grew up on, one by one. And it does so elegantly and logically. It reads almost like a fiction thriller – when I read it, I could not put it down. It presents everything the medical establishment knows and does not want you to know. An entire world is about to be revealed to you. It is no exaggeration to say that this book is about to start a revolution."
—Gil Yosef-Shachar M.D.

"*Turtles All the Way Down: Vaccine Science and Myth* is a well-documented and persuasive guidebook to vaccination. The book could be, and should be, a game changer. I congratulate the authors on a work well done!"
—Neil Z. Miller, Medical researcher, Author of *Miller's Review of Critical Vaccine Studies*

"This impeccably researched and documented book formulates a cohesive and clear view of the vaccine science that is scattered in numerous scientific papers and government documents. It is a real

eye-opener, guaranteed to change your thinking. You may find it hard to believe what you read, but with the documentation right there, in front of your eyes, the conclusions are inescapable."
—Patricia Lemer M.Ed., Licensed Professional Counselor, Author of *Outsmarting Autism: Build Healthy Foundations for Communication, Socialization, and Behavior at All Ages*, Chair Emeritus, Epidemic Answers

"*Turtles All the Way Down: Vaccine Science and Myth* is an extraordinary book, as its name implies. This is a must-read for anyone who wants an in-depth introduction to the subject of vaccines to make informed decisions for themselves and their family.
The authors deserve many compliments for their comprehensive and thorough work, based mainly on sources from the scientific literature and the websites of health authorities. The book presents its arguments in clear and easy-to-understand language so that a medical education is not required in order to read it and benefit from it. However, I also strongly suggest that medical professionals of all fields delve into it. Personally, I learned a lot from reading the book and I highly recommend it."
—Haim Rosenthal M.D.

"While the media is saturated with messaging that vaccines are 'safe and effective,' an increasing number of parents are growing skeptical of this narrative. This book is a comprehensive and exceptionally well documented look into the 'science' behind vaccine safety, exposing the fact that most of the supporting evidence is based on shoddy research biased by vested interests. This is arguably the most thorough and persuasive book on the market on this important topic."
—Stephanie Seneff Ph.D., Senior Research Scientist, MIT, Author of *Toxic Legacy*

"*Turtles All The Way Down: Vaccine Science and Myth* is an important book, because it fills a gap that has long begged to be filled. It explains the science behind vaccines, distilling down a huge amount of litera-

ture, making a solid understanding of the science accessible to any committed reader. Until now, books on vaccines were either too technical for the average reader, or too simplified, or were not up to date on the current issues facing the vaccine enterprise. Every parent should have this book in their library."
—Meryl Nass M.D.

"If you are in the habit of quoting CDC as an authority on vaccine safety and efficacy, this book will break you of that habit. Our society is engaged in an existential battle between those willing to acknowledge the evidence on vaccine safety and those who make claims based on falsified and fraudulent data. In just over 500 pages, the exquisitely referenced 'Turtles' presents reality-based fact after fact, demolishing false claim after false claim made by vaccine proponents until the truth becomes inescapable."
—James Lyons Weiler Ph.D., IPAK-EDU.org

"This book is a phenomenal resource for parents navigating the decision-making process about whether or not to vaccinate their children or for any truth-seeker daring to journey down the rabbit hole of vaccine science. Extraordinarily well written and organized, this book is the perfect primer to quickly empower the reader with a clear understanding of how the public has been bamboozled with the scientifically meaningless claim that all vaccines recommended by the CDC are 'safe and effective'. Anyone who reads this book will come away with a firm understanding of the gross inadequacies of vaccine studies and the institutionalized corruption that enables the so-called 'public health' establishment to sustain the illusion that public vaccine policy is evidence-based."
—Jeremy R. Hammond, Independent Researcher, Journalist, Author of *The War on Informed Consent: The Persecution of Dr. Paul Thomas by the Oregon Medical Board*

"This is the book we've been waiting for."
—Lisa Joyce Goes, The Thinking Moms' Revolution

Turtles All The Way Down

Vaccine Science and Myth

Editors
Zoey O'Toole
Mary Holland

Children's Health Defense

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To MS, GK, and HB

To Asura

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FOREWORD

By MARY HOLLAND, J.D.

In January of 2020, the world began hearing rumors that a deadly virus was wreaking havoc in Wuhan, China. Shortly thereafter the virus made its way around the globe, causing the most pernicious pandemic since the influenza pandemic of the early 20th century, over 100 years earlier.

Governments around the globe invested heavily in the development of vaccines they hoped would relegate the disease named COVID-19 to a historical footnote. The FDA fast-tracked these vaccines, skipping large segments of the usual testing process before authorizing several different brands for emergency use in early 2021. Some of the new products, including those sold by Pfizer and Moderna, used technology never before applied to vaccines: Messenger RNA (mRNA) temporarily hijacks cells in the recipient's body, forcing them to make the "spike" proteins that enable the SARS-CoV-2 virus to invade human cells. Why would vaccinologists want the body to make the most problematic protein of a noxious virus? The intent was to provoke production of antibodies that would selectively bind to the spike protein, neutralizing the virus whenever it was encountered and rendering it harmless to human cells.

Never has vaccine development been followed so intently by the general public as it has for COVID vaccines. Suddenly, people who had never exhibited any prior interest in vaccine science or technology began debating the relative merits of the novel mRNA technology over conventional live-virus vaccines

and dissecting the formal stages of the vaccine approval process. Many, including some well-known vaccine proponents, expressed concern and skepticism about the safety and/or effectiveness of the rushed COVID vaccines.

Despite purportedly putting science in the driver's seat, governments and health authorities in the US and around the world enacted COVID policies that were, more often than not, anything but science-driven. This was especially true when it came to the vaccines.

Some of the most egregious actions health agencies and pharmaceutical companies collaborated on during the testing of COVID vaccines include

- Rushing to market vaccines that were insufficiently tested in clinical trials.
- Concealing and withholding crucial clinical trial data from the medical community and the public.
- Recommending vaccination of vulnerable subpopulations (pregnant women, children) although the vaccines were not adequately tested in these groups.

When it comes to monitoring the safety of COVID vaccines the same parties have been guilty of the following:

- Employing superficial and inadequate monitoring of post-marketing vaccine adverse events.
- Dismissing post-vaccination injuries out of hand as "unrelated to the vaccine".
- Providing no tools for medical personnel to identify, diagnose, or treat vaccine injury.
- Discouraging doctors from reporting vaccine injury.
- Sponsoring virtually no science seriously investigating reported vaccine injuries.

With respect to public discussion of COVID policies in general and vaccine policies in particular, these agencies and corporations colluded with mainstream media and social media moguls to

- De-legitimize criticism and open debate, labeling critique from senior scientists, doctors and the public as "misinformation" or "anti-science".
- Promote the false notion that COVID vaccines provide herd immunity in order to pressure the public into vaccinating "to protect others".
- Initiate, publish, and promote bad science to support the lucrative vaccine agenda.
- Artificially inflate the market for COVID vaccines by smearing and banning safe and effective, over-the-counter medications (such as ivermectin and hydroxychloroquine).

Seeing how ineffectively and dishonestly the COVID pandemic was handled (particularly in the US, which fared worse than any other country but Brazil), many people around the world grew disillusioned with their governments and health agencies. At this point, however, most of the disillusioned restrict their criticism to the mishandling of the COVID crisis, and relatively few extend their critical analysis to vaccines in general, or to the childhood vaccines. Perhaps the majority are unaware of the grim broader reality of vaccine science or they fear being labeled "anti-vaxxers" (which would be understandable, as that epithet is thrown at anyone who dares question any aspect of vaccine dogma). Even now, in 2022, after all that has transpired in the last two years, vaccines are still the "sacred cow" of medicine that should always be defended and never doubted.

But is such reserve justified? Was COVID just a one-off, with the all-encompassing folly we have witnessed born of the need

to do something and to do it quickly? Or did governments and their health agencies simply take their modus operandi to extremes in order to exploit a worldwide health crisis to advance their agenda and benefit their collaborators?

In the wake of the COVID fiasco, it is time for a deeper look down the larger vaccine rabbit hole: Are childhood vaccines so different from COVID vaccines? Are they safer? Were they tested any better? Are their injuries better documented and investigated? Are medical professionals (or anyone else) allowed to question them any more than they were allowed to question COVID vaccines? And the most important question of all: Can we entrust our babies to vaccines produced, tested, and marketed by the same agencies and corporations, doctors and government officials, researchers and high-tech moguls that failed us so miserably over the last two years?

You are now holding the book that answers all those questions, and answers them definitively. This book dissects the CDC's recommended childhood schedule with respect to the issues I highlighted above: the clinical trials, adverse event reporting, recognizing and treating vaccine injuries, vaccination recommendations that are not supported by science, science censored and contorted to support the vaccine agenda, mainstream media vaccine propaganda, and more. Throw in a thorough rebuttal of three foundational vaccination myths, and there you have it – everything you ever needed to know about vaccines, but were afraid to ask.

Turtles All the Way Down: Vaccine Science and Myth was first published in Israel in early 2019. Later that year, it set a worldwide precedent for a vaccine-critical book when a mainstream medical journal published a positive review of it. The article in the September 2019 issue of *Harefuah* ("*Medicine*"), the leading medical journal in Israel, was authored by a pair of senior academic criminologists, Nati Ronel and Eti Elisha. To the dismay of the Israeli medical establishment, Ronel and Elisha "found the book to be well written, serious, scientific and important", offering "a comprehensive view of the issue." Though

heavily criticized by some vaccine doctors as "only" criminologists who should stay in their lane, their appraisal of the book still stands today, unscathed: In the three years since its (Hebrew) publication, no medical or medical science professional has succeeded in refuting the book's claims. Unable to demonstrate that the book or its *Harefuah* review actually contained any errors, critics – doctors as well as lay people – chose instead to target the review's authors. The fierce personal attack on Ronel and Elisha for merely reviewing the book served to illustrate one of the major points in their article, that the science and medical establishment resorts to aggressive personal attacks to cover-up inconvenient truth: "It appears that science and medicine are becoming hostile to criticism in ways that are historically associated with the violence of fundamental religious orthodoxy or even inquisition committees similar to those of the Middle Ages. They are convinced they know the 'truth' and reject every attempt to question this 'truth' as heresy."

One academic, Daniel Mishori, Ph.D., a senior faculty member specializing in ethics and philosophy at the Department of Environmental Science at Tel Aviv University, was so disturbed by the lack of discussion of the book's arguments that he offered a cash prize ($4,000 donated to the hospital ward of choice) to anyone who could refute them. Since *Turtles* is over 500 pages and contains more than 1,200 references, Mishori declared he would settle for a proper rebuttal to the harsh conclusions drawn in the first chapter of the book. To this day no one has been able to meet his "Turtles challenge."

Clearly, the main reason no one has been able to refute the book's arguments thus far is that the authors made a very conscious effort to rely exclusively on publications available from "kosher" sources such as mainstream scientific journals and leading government agencies (CDC, FDA, WHO, etc.). The book contains virtually no references to studies, articles, or even quotes by anyone who has been painted as an "anti-vaxxer" by the media at any time, regardless of their quality or scientific validity. Thus, it has proved impossible, until now at least, for

even the most venerated vaccine experts to refute conclusions that were based upon savvy and accurate analysis of scientifically sanctioned sources.

You may have noticed this book does not list an author. That is because the book's authors have chosen to remain anonymous, and they have some good reasons for doing so. If you're already familiar with the vaccine debate, you are probably aware that whenever someone questions any part of the official narrative surrounding vaccines, no matter how minor the point or reasonable the argument, that person is immediately attacked – to the point that well known, dedicated scientists in numerous countries have lost their careers for challenging vaccine dogma. The authors of *Turtles* are from Israel, a small country where, if someone were deemed enough of a threat to the powers that be, it would be quite simple to make their lives, as well as those of their family members, a living nightmare. This abysmal state of affairs was not lost on Ronel and Elisha, who found it disturbing that such a worthy scientific book had to be published anonymously, noting "The fact that the authors chose anonymity invokes criminological questions on the decision making processes by the medical establishment and on the issue of medical ethics surrounding the heated debate over vaccines."

Another good reason the authors chose anonymity, and perhaps the more important one from your perspective as a reader, is to "immunize" the book against ad hominem attacks, a favorite tactic employed by the pharmaceutical industry and the medical establishment. When they can't disprove an argument scientifically, vaccine loyalists typically resort to personal attacks against the people making it, following the notorious PR motto of "smear the authors – kill the book." However, this "shoot the messenger" tactic only works if there is someone to shoot. Thus, *Turtles*' authors artfully disarmed their antagonists, taking the smear campaign option off the table.

Personally, I sympathize with the authors and fully understand their motives. I have witnessed many smear campaigns targeting advocates of vaccine safety. One noteworthy example

is my colleague Robert F. Kennedy, who was a well-known environmental lawyer, when he looked into the long-term negative effects of repeatedly injecting mercury into infants' bodies. Before he published *Thimerosal: Let the Science Speak*, about a mercury-based preservative that was present in many childhood vaccines until someone in the FDA actually added up how much mercury infants were receiving, his media connections made it easy to get on television to talk about whatever he wanted. He could present the dangers of environmental mercury in any other context and the media would cheer him on, but mention the word *vaccines* and suddenly no one in mainstream media wanted anything to do with him. Despite the fact that he made it clear he was steadfastly in favor of vaccines as long as they weren't laced with a neurotoxic metal, he was increasingly vilified in the media, called everything from "anti-vaxxer" to "crazy and dangerous." But if his arguments were simply "misinformation," as the media implies, why would they need a smear campaign? Wouldn't it be better from their point of view to invite him to a public debate where their hand-picked "experts" could crush him into a fine powder? When it comes to *Turtles*, a scholarly analysis with no author to attack, the so-called experts' only options are to debate the book's content or be silent.

While character assassination can be an effective public relations strategy, it has no place in the search for scientific truth. When it comes to science, it shouldn't matter who is making the argument. All that should matter is whether or not the argument is valid. In other words, good arguments should stand – or not – on their own merits, not on the credentials or popularity of the person making the argument. Albert Einstein was a patent clerk when he published the Theory of Relativity, but his dull job and lack of academic standing obviously didn't stop him from having brilliant insights in physics. If the more established scientists of his day were allowed to shout down his theory because its originator lacked credentials, science would have lost one of its brightest lights.

The information on vaccine science contained in this magnif-

icent book is far too important to be allowed to be co-opted in this way. Our children's lives depend on getting this right. The authors of *Turtles* don't want you to take their word for anything. They want you to read the arguments in this book and verify the references and quotes they are based on (which the authors went out of their way to make accessible). And they want you to think about what you read – not about who wrote it. In this day and age, it seems that the only way to keep the focus on *what* is said in a vaccine-critical book, and not on *who* is saying it, is to say it anonymously.

So that is what they did.

With that, I challenge every physician and scientist to read *Turtles All the Way Down: Vaccine Science and Myth* and make your best effort to shoot holes in the arguments it makes. I suspect that for the vast majority it will be an eye-opening experience. If you choose not to take the challenge because you don't have the guts, then you have no place in the vaccine debate. In other words, speak now or forever hold your peace.

INTRODUCTION

"I can only show you the door. You're the one that has to walk through it."

Morpheus, The Matrix

If you are reading this introduction, we can safely assume that you are aware, at least to some extent, of the controversy surrounding vaccines. On one side of this prominent public debate stands the health establishment with its many representatives repeatedly assuring us that vaccines are safe and effective. Opposing them is a large and growing group of parents claiming that vaccines can, and do, cause severe side effects, and even their efficacy is exaggerated.

Due to the inherent complexity of its underlying subject, the vaccine debate challenges medical professionals and scientists alike – and, to an even greater extent, the average parent. In order to attain even a moderate level of expertise on this topic, one needs to have at least a basic understanding of numerous and varied medical and scientific disciplines, which are described and noted in parentheses below.

To begin with, one has to have a good grasp of vaccine-preventable diseases (expertise in *infectious diseases*). Some of these illnesses are specific to infants and children (expertise in *pediatrics*), while others are common to all age groups (*family medicine*). Next, one has to understand how vaccines for these diseases are developed (*vaccinology*): First, one must identify the

causative agent (pathogen) – typically a bacterium (*bacteriology*) or a virus (*virology*) – and study its interaction with the body's immune system (*immunology*). Furthermore, researchers need to investigate the pattern of disease in various populations and how a vaccine may affect disease dissemination and severity (*epidemiology*).

Along with any potential health benefits, vaccines are also liable to have undesirable side effects. Vaccines are composed of a multitude of diverse biological and chemical compounds, some of which are considered toxic (*toxicology*). To diagnose adverse side effects, assess their severity, and find suitable treatments, one needs considerable knowledge of clinical medicine, with the specific fields depending on which organs are affected and the level of harm sustained (*neurology, gastroenterology, dermatology, allergology, rheumatology, autoimmune diseases*, etc.)

The above is by no means an exhaustive list. Vitally important aspects of the vaccine debate lie outside the domain of medical science, and one must also devote time to those as well in order to truly understand this complex issue. One must learn how vaccine research is conducted and vaccine policy is formed in the real world – where power, money, and politics shape the rules. Vaccines are manufactured by corporations intent on maximizing their profits. As is the case for every other business sector, vaccine company executives are first and foremost obligated to their shareholders, rather than to the health and well-being of the general public. Licensing, regulation, and marketing of vaccines are all carried out by governmental entities, which are influenced by political and financial considerations. Supposedly objective and impartial, scientific research dedicated to vaccines and vaccination practices is mostly funded by these same governmental entities and vaccine manufacturers whose considerations and interests may be at odds with the interests of the general public.

Vaccine research is published in scientific and medical journals which are, in every sense, also commercial enterprises endeavoring to maximize profits for their shareholders. Physi-

cians and researchers working in the field of vaccines (or related areas) operate inside a confined system with strict rules, both formal and informal, that limit their freedom of investigation and expression. Media coverage of vaccines is also not immune to bias and conflicts of interest. Media outlets have financial relationships with some of the entities mentioned above, and these relationships shape their reporting on the subject of vaccination.

Legal and constitutional matters, especially with regard to severe vaccine side effects, occasionally crop up in courts across the globe. And ethical questions arise from legislative initiatives to compel immunization by law. Every one of these aspects (and this is still just a partial list) is an essential piece of the intricate tapestry that is the world of vaccines. It is impossible to grasp the whole picture without understanding how each of its diverse parts fits into it.

Thus, some knowledge in all the aforementioned academic and non-academic disciplines is required if one is to gain a comprehensive understanding of all the issues surrounding vaccines. Vaccination, then, has to be one of the most complex issues – if not *the* most complex – to be publicly debated over the last few decades. It's safe to assume there isn't a single person on Earth with expertise in all of these fields, even among those celebrated as "experts" on vaccination and those responsible for shaping vaccine policy. Despite the extreme complexity of this wide-ranging topic, at the end of the day it is you, the parents, who have to make vaccination decisions: Get vaccinated or not? Vaccinate your children or not? Vaccinate on schedule or space them out? Skip some of the shots or get them all?

Like everyone else nowadays, when you need information in order to make important decisions, you go to the Web, launch Google, and type in some relevant search terms, hoping the results will help you make an informed decision. But after surfing the Web in search of the answer to the to-vaccinate-or-not-to-vaccinate dilemma, you realize in short order that nailing this one will be anything but easy. A vaccine war is raging out

there: Proponents and critics, parents and doctors, authorities and executives – all are stirring an enormous cauldron of… controversy soup. You'll find a dizzying variety of material – photographs, videos, testimony, articles, quotes, opinions, arguments, explanations, proofs, and rebuttals – an endless assortment of information, interpretations, and conflicting opinions being published 24/7. And, as you delve deeper, it just gets more and more confusing.

So, where do you start? How do you put all this chaos in some kind of order? How do you collate all the seemingly random pieces of information floating around the Web into a logical and coherent mental image? How do you reconcile the contradictions between the different positions? Do you really have to spend years diligently reading in WhatsApp or Facebook groups and carefully analyzing multitudes of scientific papers in order to make decisions about a procedure that, up until a few years ago, wasn't questioned by the vast majority of parents? Is it even possible to make informed decisions without proper medical training? And who should one believe – the parents who warn against the harms vaccinations inflicted upon their children or public health experts staunchly asserting that vaccines are proven safe and effective?

Who in heaven's name is right?! Come on, we have to make this @#$& decision!

Take a breath. You can relax. You have come to the right place.

After spending a few days reading this book, your question – Who is right? – will be answered. The answer to this question that troubles millions of parents around the world is out there, its pieces scattered across hundreds of cyberspace locations – visible to all, yet hidden in plain sight for the vast majority of the public.

The purpose of this book is to reveal that answer and shine a spotlight on it for everyone to see.

Who Is This Book For?

This book is intended, first and foremost, for parents, those who are taking their first steps into the confusing world of vaccines and those who want to deepen their understanding of the field. Please note: This book does not provide comprehensive information regarding vaccine-preventable diseases, nor does it directly discuss questions concerning vaccination, such as *Should I vaccinate? Which vaccines should I give?* and *When should I vaccinate?* Instead, the book focuses on decisively answering the all-important question at hand: Who is right in the vaccine debate – vaccine proponents or their opponents?

In addition to parents, the book is intended for medical professionals, as well as medical researchers, who are interested in approaching the hot topic of vaccines from an unconventional, non-dogmatic, perspective. (Pro tip: You might want to think twice before taking this book to the office.)

Finally, the book is also intended for all those professionals whose work sometimes touches on vaccine-related topics – reporters, politicians, government officials, lawyers, teachers, social workers, therapists – and anyone else who cares about the health of their country, most notably, its children.

How to Read This Book

The book is replete with citations and references backing up its claims. The referenced documents are drawn almost entirely from mainstream sources, with a handful of exceptions. These sources include medical journals, publications and websites of health authorities (such as the US Centers for Disease Control and Prevention and the World Health Organization), vaccine manufacturers' publications, news stories and articles from mainstream media, and history and science books.

References are marked in the body of the text by a superscript number (like so[1]). For each reference, the exact quote to which the text refers is provided (if possible or relevant), includ-

ing the page number (if applicable), the document name, its main author, year of publication, and a link to the original text on the internet.[a] Since there are more than 1,200 references, in order to reduce costs and avoid unnecessary waste of resources, we chose not to include a "References" section in the printed version of the book. An electronic PDF document that includes all the references, arranged by chapter, can be downloaded for free from the internet (see the link and QR code on the book's back cover or first pages). For convenient access to the references while reading, we recommended that you read the book with your favorite screen display by your side and the reference document open to your current chapter.

Whether you are a medical professional, medical science researcher, or a parent who wants to make the best choices for your child's health, we urge you to spend some time browsing through the references, at least reading the specific quotes the text alludes to or cites. In addition, we encourage you to read as many of the original documents as you can. Since it is unlikely that you'll have enough spare time to fully explore all the book's references, we advise starting with those references that apply to any claims that seem particularly far-fetched to you. For each such reference, you might want to verify where it was published and who its authors are, making sure that the quotations used are accurate and that they faithfully represent the spirit of the original document (that is, are not taken out of context). Moreover, you are more than welcome to challenge your contacts in the medical profession – your family doctor, pediatrician, friends working in medical sciences, etc. – with the claims made in this book (making sure to attach the relevant references). Ask them to provide you with evidence that contradicts the book's assertions, but make sure they cite proper references from credible sources.

[a] Some of the papers in scientific journals are not accessible to the general public (access to the full text requires payment of a fee, which is usually quite high).

In addition to numbered references, the book also includes footnotes, denoted by superscripts of lower-case English letters ([a], [b], [c]…), that usually provide a little more detail. Unlike the references, you can find the footnotes at the bottom of the page where each appears.

And Finally: A Warning and a Recommendation

There are two possible answers to the central question in this book. If the answer is the one you'd expect, that vaccine authorities are right, you will just go on with your week somewhat better informed. If, on the other hand, the answer is that the parents are right, the earth beneath your feet may start to tremble.

Thus, you are now standing on the verge of an intellectual adventure that has the potential to violently rock your world. Once you pass through the gate, there will be no going back. You won't be able to "un-know" what you already know.

If you choose to continue reading, you will have to gather the courage required for a journey to the other side of reality, courage to face new facts and examine them objectively, courage to ask hard questions when you are expected to merely obey, and courage to stand your ground in the face of pressure from family, friends, doctors, government officials, and what will probably feel like everyone else.

If you aren't brave enough to get through this book, you might want to put it down, at least for now. Give it to someone else that you think is ready for the challenge. Come back to it in the future, when the time is right.

If, however, you choose to accompany us on this journey, you might want to make yourself a cup of coffee, get a smartphone or tablet and download the reference document so you have it next to you, and get comfy before we embark on our odyssey to the godforsaken corners of the vaccine version of Wonderland, where nothing is quite as it seems.

PART I

VACCINE SAFETY

Vaccine safety lies at the heart of the public debate on vaccines. Although prominent in many discussions, vaccine efficacy is only of secondary importance. The chief motivation driving vaccine-awareness advocates is the conviction that vaccination causes serious health harms in some recipients, and that this grim truth is largely concealed from the public. Had vaccines been perceived as completely safe, like health authorities claim, the animated public debate about them would never have gained traction. A vaccine with side effects that are mild and transient, that only causes serious or permanent damage extremely rarely (the proverbial "one in a million"), is unlikely to make any parent climb a virtual soapbox and preach to the cyber masses – even if its efficacy is less than ideal.

The public entities that promote vaccines – health authorities, physicians, researchers, medical societies and organizations – all echo a unified message: Vaccines have been tested more than any other medical intervention and are completely safe. This categorical claim, however, stands in stark contrast to the firsthand experience of thousands of parents who insist that their children suffered serious vaccine-related health harms. With the exception of a very small number of cases compensated by the government, the health establishment's response to parental claims of vaccine injury is utter dismissal and complete denial. Parents are told that they got it all wrong, that their child couldn't have been harmed by vaccination. Any temporal association between vaccine administration and subsequent deterioration in health is merely an unfortunate coincidence. The safety of each vaccine, they are told, was thoroughly vetted before it received marketing approval and is constantly monitored thereafter. Science has spoken – and science must prevail. Any negative impressions about vaccines are false and should be discarded; any misgivings should be put to rest. Vaccines are safe! Vaccines are effective!

The medical establishment's claim that [all] vaccines are

completely safe is based on activity in three distinct domains: a) clinical trials every new vaccine must undergo before it is approved for general use; b) computerized vaccine adverse event reporting systems that monitor post-marketing vaccine safety on an ongoing basis, and c) ad hoc epidemiological (population) studies that explore various aspects of vaccine safety. All of these will be scrutinized in the chapters that follow.

The first part of the book will thus explore the critical question of vaccine safety, examining in detail the institutional claims that vaccines are extremely safe and that their safety has been established by rock-solid science.

1

TURTLES ALL THE WAY DOWN: VACCINE CLINICAL TRIALS

According to a well-known story in the scientific community, an elderly woman approached a famous scientist shortly after he concluded his lecture on cosmology and the structure of the solar system:

"Your beautiful theory about the earth being round, and rotating around the sun, is very interesting, young man. Unfortunately, it is also very wrong. I have a better theory," the woman told him.

"And what would that theory be, madam?" the scientist responded.

"Well, what you call 'planet Earth' is not round at all. Actually, it is kind of a large, flat disk that rests on the shoulders of four giant elephants."

"And what do these four elephants stand on?" the scientist inquired.

"They stand on the back of a giant turtle," the elderly woman answered.

"And what does that turtle stand on?" the scientist asked with an inquisitive grin.

"On another, bigger, turtle."

"And what does the second turtle stand on?"

"Well, my dear man," said the elderly woman with a victorious smile, "it's turtles all the way down!"

Even today, approximately 150 years after it first appeared, the story of the scientist, the elderly woman, and the turtles remains quite popular in scientific circles. Its appeal appears to be due not only to the paradoxical punchline, but also to the way it portrays the relationship between scientists and laypeople: On the one hand, the wise scientist, rational and calm, and on the other the simple-minded elderly woman confusing scientific knowledge and reality with myth. By emphasizing the wide intellectual chasm between expert and layperson, this amusing anecdote reinforces scientists' deep-seated expectation that science be unanimously recognized as the arbiter of objective Truth. Standing on their high pedestal, scientists, at least in their own eyes, are both worthy and capable of making final judgments on matters of public interest related to their expertise.

This paternalistic tendency is evident in long-standing attempts by scientific and medical entities to portray the public conversation on vaccines as a lopsided dispute. On one side of the debate, we are told, stand doctors and researchers who draw their moral authority from years of academic training and work experience and whose arguments are backed by solid scientific evidence and validated by the medical establishment worldwide. On the other side, they tell us, stand a multitude of parents and activists, who lack formal training, follow charlatans and quack doctors, and feed on fake news spread through social media.

Yet, as will become clear in the following pages, the surprising truth – which becomes self-evident when one devotes enough time and energy to researching vaccines – is that the roles are reversed: The elderly woman (the parents in this case) anchors her claims on bedrock science and displays a deep understanding of scientific methodology, while the medical establishment bases its position on… "turtles all the way down".

Vaccine safety lies at the heart of the long-lasting and intense clash between those that support universal vaccination and those that oppose it. Health authorities' argument that *Vaccines are safe!* is based, first and foremost, on the presumption that each new vaccine undergoes a meticulous process of testing and

approval. This process includes a series of clinical trials, which purportedly utilize the most advanced scientific tools and techniques available and adhere to the highest safety standards. Once a new vaccine successfully passes these hurdles, it is considered safe by all relevant medical bodies.

This chapter, then, examines the methodology used for testing vaccines' safety as part of their pre-licensing approval process. Are new vaccines really rigorously scrutinized, as the public is routinely promised, in keeping with an uncompromising commitment to the highest possible safety standards?

Not only is the answer a flat "no", by the end of this chapter you will learn the inconceivable secret the medical establishment has concealed from the public eye for decades: **Clinical trials of vaccines are rigged to hide their true (and high) rate of side effects,** which means the medical establishment's long-standing claim that vaccines are safe has no scientific merit.

It sounds improbable, doesn't it? Impossible to believe!

By the time you finish reading this chapter you will know it's true.

Before we explore the methods employed by medical authorities to conceal vaccines' inadequate safety testing, we must familiarize ourselves with their pre-licensing approval process and its principal tool – the randomized controlled trial. Armed with this knowledge, we can then peel off, one by one, the protective layers that enfold the hidden, abhorrent, and nearly unbelievable truth.

The Vaccine Approval Process

Medical "biologics" (such as vaccines) undergo a lengthy and tedious approval process, replete with bureaucratic forms, documents, and reviews. The process is determined by the authorizing body – most commonly the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) – and includes, in addition to endless paperwork, a

requirement to conduct a series of clinical trials[a] that demonstrate the effectiveness and safety of the product submitted for approval. This required series of clinical trials is divided into three *phases*, with each phase commencing only when and if the preceding phase has been successfully concluded. If the product does not prove safe or effective in any one of the phases, it will not win the coveted approval. Consequently, its development is likely to terminate, and the (usually considerable) funds invested in it will go down the drain.[1]

The first hurdle a new vaccine must leap is the "pre-clinical phase", in which the product goes through a multitude of laboratory[b] and animal experiments.

The next step in the series is a *Phase 1 Clinical Trial,* in which a small trial group (typically dozens of subjects) is given the new vaccine in order to determine how the human body responds to it. The underlying assumption is that, despite its success in animal experiments during the pre-clinical phase, the vaccine could still prove to be harmful to humans.[2] Therefore, in this stage, researchers attempt to identify particularly salient or severe side effects, such as severe allergic reactions, disability, early symptoms of a chronic problem, severe illness, or death. Due to the limited number of subjects, a Phase 1 trial cannot provide a complete picture of the extent and variety of side effects (adverse events) that could potentially be caused by the vaccine.

If the vaccine successfully passes Phase 1, the next experimental phase – the *Phase 2 Clinical Trial* – is performed on a larger group, typically several hundred people, and the vaccine's

[a] A clinical trial is a research study with human subjects (as opposed to animal studies). The word *trial* indicates artificial (deliberate) conditions specifically designed for the study's purpose (unlike studies that do not interfere with subjects' daily lives). The word *clinical* implies that the study involves some kind of intervention (for example, vaccination of subjects), as opposed to observational studies which only collect and analyze information. More on this topic in chapter 4.

[b] A laboratory experiment is an experiment made with specialized equipment outside the living organism (e.g. in a test tube or Petri dish). It is termed *in vitro*.

effectiveness is evaluated in its designated population (e.g., adults over 65 or diabetic patients under 18). This stage is also when the effects of varying the vaccine's dosage and delivery timing on efficacy and safety are examined. However, the absence of a control group (see the *Randomized Controlled Trial* section below) and the relatively small number of subjects in Phase 2 trials, preclude the attainment of definite or final answers regarding the vaccine's efficacy and safety. Those await the next testing phase.

Phase 3 Clinical Trials are conducted in several thousand subjects, sometimes even tens of thousands. These trials are designed to assess and validate the vaccine's effectiveness, to compare the new treatment with existing treatments (if any), and to collect information that will allow the vaccine to be used safely. This is the final experimental phase before the approval for commercial use, and it is of paramount importance in determining the efficacy and safety of the experimental vaccine. Phase 3 results will be published in the manufacturer's package insert and will serve as key evidence for the vaccine's safety and efficacy for years to come.

Subjects in a Phase 3 trial are randomly divided into one of two groups: the *trial group*, which receives the test vaccine over a specified period of time, and the *control group*, which receives a placebo (dummy) or some other compound (see the detailed explanation in the next section). Throughout the study period, researchers monitor trial participants' health and collect information that will be used to evaluate the vaccine's efficacy and safety. The large quantity of subjects, as well as their separation into trial and control groups, affords a deeper probe into the vaccine's safety and its potential side effects, including those that occur relatively infrequently (i.e. one case in hundreds or thousands of subjects).

Successful completion of a Phase 3 trial paves the way for the long-awaited approval for commercial production and marketing of the new vaccine. However, even after the vaccine has been in general use for a while, additional trials are sometimes called for.

These "post-marketing" trials may be required to investigate unexpected adverse events reported after licensing or negative effects that have emerged in a specific population segment. This type of trial is called a *Phase 4 Clinical Trial*.

As mentioned above, after the vaccine successfully passes Phase 3 trials, the doors open for commercial use. However, for new vaccines, receiving approval from the authorizing body is not sufficient. The product must also receive the approval of the authority responsible for distribution of vaccines. In the US, the FDA is in charge of licensing new vaccines, while the Centers for Disease Control and Prevention (CDC) is responsible for making recommendations for their actual use, including who should receive them (their ages and health status), the timing and number of doses to be received, and which vaccines can be given concurrently. The final step in the long process of marketing a new vaccine is its integration into the national vaccine programs of the US and other countries around the globe. Adding a vaccine to the American schedule recommended by the CDC instantly guarantees sales of millions of units per year in the US alone, thus assuring its manufacturer a handsome return on its initial investment.[3]

The Randomized Controlled Trial (RCT)

In a "simple" vaccine clinical trial (one without a control group, as is the case for trials in Phases 1 and 2), researchers face an inherent difficulty in determining whether a specific condition reported during the trial period is actually caused by the experimental compound or not. If a trial subject experiences a severe and immediate phenomenon following the receipt of the test vaccine, such as fainting or cardiac arrest, it could be reasonably assumed that the recently consumed vaccine was the culprit. When the side effect is less pronounced, or appears days or weeks following vaccine administration, however, the researchers' decision is less obvious. For example, if the subject's temperature rises to 103°F less than 48 hours after administration

of the test vaccine, the researchers do not have enough information to decide whether this is a true side effect or merely an unfortunate coincidence. One option is to have every participant who experiences a health-related condition during the trial undergo a series of in-depth medical examinations in order to uncover possible links to the experimental vaccine. This strategy is not feasible or economical, however, if only because the vaccine is new and its specific effect on the human body is virtually unknown. Consequently, such an investigation could prove lengthy, costly, and unlikely to yield conclusive results.

A better option is to conduct an "enhanced" clinical trial – a controlled, randomized, and blinded trial (also known as a *randomized controlled trial* – RCT). In an RCT, subjects are divided into two groups:[c] the *trial group*, receiving the test compound, and a *control group*, receiving a dummy or existing compound (whose efficacy and safety profile is well known). Subjects are randomly assigned to the two groups prior to the start of the trial to ensure that the groups are virtually alike in every relevant characteristic (age, gender, area of residence, demographic status, and so on). The term *blinded* (or *blinding*), means that the trial subjects do not know which group they are in and thus do not know whether they received the test or dummy compound. In a *double blind* trial, the researchers also do not know which subjects belong to which group. Thus, prior knowledge of which compound a participant received is not likely to influence either subjects or researchers and skew the results of the trial. In a non-blinded trial, subjects who receive the test compound, rather than the dummy one, may complain more about side effects, since they expect them to occur.[d] Similarly, a researcher who knows a particular subject belongs to the control group also knows that any reported side effects are not

[c] Sometimes the experiment may include three groups, or more. For example, a trial might consist of two trial groups and a control group.

[d] In clinical trials with infant subjects, as many vaccine trials are, biased reporting from participants is impossible. However, if parents are aware of their child's grouping (trial or control), reporting bias is plausible.

due to the vaccine and may inadvertently (subconsciously) underreport medical conditions occurring during the trial period. Only when the trial is over, after all relevant information has been collected, is the specific compound administered to each of the study subjects revealed, and the researchers, with the complete data in hand, can begin the post-clinical data analysis.

When it comes to pre-licensure testing of drugs, vaccines, and other medical products, RCTs are widely considered the industry's "gold standard". The random distribution of subjects to trial and control groups, as well as the minimization of potential biases through the use of double-blinding, facilitates a reliable and meaningful comparison of trial and control group data.[4] As an example, in a vaccine trial in which the control group is receiving a dummy compound, one can measure the level of antibodies produced in trial group subjects and compare it to that of the control group, thus getting a measure of vaccine efficacy. Similarly, a researcher could compare the incidence of adverse events following vaccination in the two groups, thus getting an estimation of vaccine safety. The larger the number of trial participants and the better the researchers adhere to RCT standard practices, the more reliable and comprehensive the trial results will be.

Due to the high quality and reliability of RCTs, they are the method designated by regulatory agencies (and accepted by the pharmaceutical industry) for evaluating efficacy and safety of vaccines in Phase 3 clinical trials.[5]

The Control Group in a Clinical Trial

As we have seen, the use of a control group in a clinical trial allows researchers to examine the therapeutic effect of the compound (efficacy) and the rate of adverse events it causes (safety) by comparing outcomes in the trial group with those of the control group. This comparative statistical analysis, then, will be influenced by the nature of the compound the researchers give to the control group.

As a general rule, when deciding upon the type of compound given to the control group in an RCT, there are two options. For a trial of a completely new drug or vaccine, i.e. one which does not have an approved equivalent, the control group should receive an inert compound (*placebo*)[6] that does not affect the parameters measured in the trial.[e] However, if a proven treatment already exists, it may be unethical to prevent control group participants from receiving it. For example, in trials of new cancer drugs, it is considered unethical to prevent the control group's subjects from receiving an existing drug for their illness. In this scenario, then, the control group would receive the current approved treatment. This practice is also the norm for vaccines even though vaccines are used preventatively (not treatment for an existing condition) and are given to healthy individuals.[7]

If we apply the above guidelines to the clinical trials for the two generations of the Prevnar vaccine,[f] then the original Prevnar, a new vaccine that had no therapeutic alternative at the time it was developed, should have been tested in an RCT in which the control group received an inert injection as a placebo. In the trials of Prevnar-13, the next-generation vaccine, the control group should have received the (original) Prevnar vaccine, assuming that it would be unethical to deprive that group's subjects of the current Prevnar vaccine's protection, whose efficacy is already proven.

So how do researchers determine the incidence of adverse events associated with the new compound being tested in a controlled clinical trial? By comparing the rate of adverse events observed in the trial group to that of the control group. For example, if in a new vaccine's trial group of 1,000 infants there were 20 cases of high fever, and in the control group (which has

[e] In vaccine trials, the conventional placebo is usually a saline (salt water) injection that is widely accepted as having no side effects (except those related to the physical act of injection).

[f] A vaccine for preventing infection caused by the pneumococcal bacteria.

the same number of subjects) there were only 10 such cases registered, the results would imply the risk of high fever in the vaccinated is twice as high as in the unvaccinated. In absolute terms, the data shows that the vaccine increases the risk of high fever occurrence from 1 in every 100 infants to 1 in 50.[g]

When the control group's subjects are given a placebo, an inert substance not known to cause high fever, it is assumed that the incidence of high fever recorded for the group represents the *background rate* (or *baseline rate*) of the phenomenon. In other words, the background rate is the number of subjects who would experience high fever naturally, regardless of any trial intervention. In our example above, we would assume that 1 in 100 control group subjects developed high fever due to random causes (unrelated to the trial). Since the trial group would likely experience a similar background rate of high fever (1 in 100), any significant deviation from this level should be attributed to the experimental vaccine. It follows, then, that an RCT in which the control group receives an *inert placebo* is designed to answer the critical question of *How many adverse events does the new vaccine cause?* Of course, we should keep in mind that trial results are no more than a good estimation. If or when the vaccine is released to the market, the actual reported adverse event rate might deviate significantly from that observed in the clinical trial. Still, the results of RCTs are the best estimate of safety available to science during the vaccine approval process, and in many cases, throughout its lifetime.

In a trial in which the control group receives a different vaccine (as in the trial of Prevnar-13 vs. Prevnar, its predecessor), the results obtained are always relative, answering the question *How many more (or less) adverse events does the new vaccine cause compared to the current vaccine?* For example, if (out of 1,000

[g] The above calculation is intentionally simplistic and is intended to demonstrate the basic principle applied in analyzing the results of an RCT, which is the comparison of different quantitative parameters between trial and control groups. In practice, researchers apply complex mathematical calculations that utilize various statistical functions and parameters.

subjects) 24 cases of high fever were observed in the trial group, while 20 such cases were reported in the control group, the new vaccine would appear to increase the odds of high fever by 20% (relative to the current vaccine). That is an important piece of information as it reveals how the new-generation vaccine's safety fares against that of its predecessor. However, it is impossible to calculate from a trial such as this one the absolute rate of adverse events caused by the experimental vaccine – that is, the rate of adverse events from vaccinating compared to not vaccinating. The absolute rate could not be calculated because the control group received a compound (the current vaccine) which is not inert (neutral), but rather has side effects of its own. In the above example, 24 cases of high fever were observed in recipients of the new vaccine, and 20 cases in current vaccine recipients. But how many cases would have been reported in trial subjects given a true placebo? This trial cannot answer that question; therefore, the absolute rate of adverse events caused by the new vaccine cannot be calculated from trial data. The new vaccine could be said to cause 24 cases of high fever per 1,000 subjects, but this number would not represent a reliable estimate[h] as it does not take into account the background rate of the phenomenon, which was not measured in the trial.

In order to determine the true rate of adverse events of a new generation vaccine, a *three-arm trial* must be conducted, combining the two methods described above. In this kind of trial, subjects would be randomly allocated into three groups, one trial and two controls: The trial group would receive the new generation vaccine, the first control group would receive the current vaccine, and the second control group would receive an inert placebo. This trial design is considered to be of excellent quality, as it measures both the *absolute* rate of adverse events (comparing the new vaccine to the placebo) and the *relative* rate (comparing the new vaccine to the current vaccine).[8] From a

[h] The 24 per 1,000 rate represents a "ceiling" of the phenomenon, as was observed in the trial. The "floor" is, of course, zero.

public health perspective, the three-arm trial answers two important questions: (1) *How many adverse events does the new vaccine cause when compared to not vaccinating?* and (2) *How many adverse events does the new vaccine cause when compared to the existing vaccine?*[i] Continuing with our Prevnar example, if the placebo-receiving control group reported, say, 8 high fever cases per 1,000 subjects, then the study would indicate that the new vaccine – which, as we recall, had 24 cases of high fever per 1,000 subjects – increased the risk of high fever by a factor of three (or, put differently, caused 16 more cases per 1,000 subjects), compared to not vaccinating.

Another scenario in which a three-arm trial would be appropriate is re-establishing the safety of a legacy vaccine that was originally tested many years ago. The environment into which today's infants are born may differ significantly in crucial health-related aspects from the environment in which a first-generation vaccine was tested decades ago. For example, the current measles-mumps-rubella-varicella (MMRV) vaccine (ProQuad) is the "grandchild" of the original MMR vaccine, which was tested in the late 1960s. Back then, the vaccine schedule consisted of only the diphtheria-pertussis-tetanus (DPT) and polio vaccines, with the first dose administered at age two months. If ProQuad were clinically tested against the original MMR and proved to have a similar safety profile, could we assume it is safe just because its grandparent vaccine was deemed safe 50 years ago? MMR vaccines are typically administered in the second year of life, after most of the infant vaccine schedule has already been delivered. If, hypothetically, the MMR's risk of harmful side effects were related to the load of previously administered vaccines, then we could not automatically accept the present safety of the original

[i] In order to overcome ethical objections to a three-arm trial, administration of the existing vaccine to placebo group participants could be delayed for several months, so as not to prevent them from getting the protection it is supposed to provide. Alternatively, the trial could be carried out in a country where the existing vaccine was not routinely provided, so the control group would not be deprived of a treatment the subjects would otherwise receive.

MMR. Remember that the MMR was first tested when the vaccine schedule consisted of only two other vaccines. If it were tested today, with many more vaccines on the schedule, some of which are given to pregnant mothers, others to newborns and infants one month of age, would it still be proven safe? And the changing vaccine program is just one aspect of the environment that may affect the safety of a given vaccine. Other factors, such as chemical exposure, changing diets, air pollution, radiation, etc., could also play a role. Therefore, a clinical trial comparing ProQuad to MMR alone is deficient, as it would rely on the presumed safety of a vaccine (MMR) that might no longer be safe. Once more, a third group receiving a placebo is the proper solution to the problem.[j]

To summarize, in a clinical trial of an (entirely) new vaccine, the control group should receive a placebo so that the absolute rate of the vaccine's adverse events can be determined. This design does not pose an ethical problem, since the vaccine has no existing alternative. In a trial of a new-generation vaccine, one control group should receive the current vaccine and another should receive a placebo (a three-arm trial).

External Control Group

Another important point to consider is that an RCT control group cannot be replaced with data from another trial, or any other externally calculated background rate. In other words, it is not scientifically valid to draw conclusions by comparing the observed rate of any phenomenon in a randomized controlled trial to the rate reported in another trial or to a rate observed in

[j] One might claim that safety issues with a vaccine that has been in use for many years would have been discovered earlier by other surveillance means such as adverse event reporting systems and epidemiological studies. However, as will be discussed in chapters 3, 4, and 5, these measures are far less reliable than RCTs.

the general population.[k] For example, if in a particular vaccine trial the reported incidence of sudden infant death syndrome (SIDS or "crib death")[l] in the trial group were 0.5% (1 in 200), researchers could not then compare this rate to the background rate of the phenomenon in the population (say 0.8%), thus determining that the vaccine lowered the risk of SIDS. This is because trial participants comprise a subgroup which could possess specific characteristics, known or unknown, which are not representative of the entire population. This could potentially yield trial results that are not comparable to rates in the general population.[9] For example, the proportion of infants participating in a trial whose parents smoke may be much lower than the background rate in the entire population, skewing the incidence of crib death in trial participants in a downward direction. Of course, skewing in the opposite direction is equally possible.

Similarly, there is little scientific merit in comparing results from different clinical trials. For example, no significant insights could be derived from comparing the results of a Prevnar-13 trial carried out in infants from the New York area in 2010 with those of a Prevnar trial conducted in Philadelphia in 2005. This is due to the randomization principle of the Randomized Controlled Trial (RCT), which requires that the trial participants be randomly divided between the trial group and the control group. Obviously, groups whose members were selected at different times and places would not satisfy this requirement. In the above examples, any differences in trial results could be entirely due to dissimilarities between the groups, such as different socioeconomic status, environmental exposures, or behavioral characteristics.

The principle described above is well known to the pharma-

[k] Except in very specific and limited cases that are not relevant to this discussion.

[l] Crib death, formally named sudden infant death syndrome (SIDS), is the term used when an infant dies for no discernible reason.

ceutical industry and it appears in numerous vaccine manufacturers' leaflets. For example, the package insert for Glaxo-Smith-Kline's (GSK) hepatitis A vaccine (Havrix) reads: "Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice."[10]

Clinical Trials in Children

Throughout most of the 20th century, the prevailing opinion in the world of medicine was that due to the relative fragility of children (compared to adults), they should be protected from the perils of medical research. The result was a distinct lack of scientific knowledge about the effects of medical interventions (such as medication) on children. Administering medication to children, therefore, was largely a wide-ranging experiment conducted on the public. Circumstances began to change in 1977 when the American Academy of Pediatrics (AAP) published new guidelines regulating the participation of children in clinical trials. In the new guidelines, the AAP said that drugs and vaccines should be tested on the population for which they are intended – in this case, children – and that this requirement is not only ethical, but essential to their health as well.[11]

Over the following decades, various international medical organizations have formulated ethical rules governing the participation of children in clinical trials of drugs and vaccines. According to these rules, children may only be included in experiments intended to achieve an important scientific or public health objective directly related to the health and well-being of children. Children should not participate in studies that do not promote such goals, such as studies designed merely to confirm the results of other studies or studies designed to advance scientific knowledge that does not concern children.[12]

In addition, the medical code of ethics states that all parties

involved in a trial must carefully weigh the potential benefit to child participants against the potential dangers involved. If the study's participants cannot be expected to benefit from the given intervention, then the intervention's inherent risk must be "minimal", especially if the subject has not consented to participate in the trial (as is the case with infants). For example, if children assigned to the control group of a drug trial were to receive a dummy medication (placebo) and a blood test, then both the medication and the blood draw must present no more than "minimal" risk. Also, the potential benefit must be substantial enough to justify the intervention's risk.[13] For example, in a trial of a children's cough syrup, the risk associated with the new drug should be relatively low as the potential benefit would be relatively low, while the potential benefit in a trial of a child cancer medication would be significantly higher, thus the risk posed by the drug could be proportionately higher as well.

A more lenient approach holds that even if a trial procedure has no expected benefit, a "minor increase over minimal risk" is allowed if the experiment has the potential for gaining knowledge about the subjects' disorder that is considered to be of "vital importance". However, even with this approach, the risk associated with the intervention must not exceed the risk a healthy child would face in everyday life and should not cause permanent or irreparable damage. In any case, there must be prior knowledge of the level of risk inherent in the procedure. If the risk is unknown, it cannot be determined to be "a minor increase over minimal risk".[14] It is important to note that the above discussion holds equally true for both the trial and control groups of an experiment.

Now that we are familiar with the different clinical phases of the vaccine approval process, the purpose of control groups in randomized controlled trials, and the ethical limitations imposed on children's participation in medical research, we can better examine the deliberately flawed procedure the industry uses to conduct vaccine clinical trials.

A Problem and a Solution

Let's take a moment to examine a hypothetical scenario: A major pharmaceutical company has developed a new drug against a particular medical problem. Following its preliminary trials, the company realizes that the drug is associated with a relatively high incidence of serious side effects that may negatively affect its chances to win FDA approval. Let us suppose that, since the company spent hundreds of millions of dollars developing the drug and the target market segment is worth billions of dollars in sales per year, the company decides to move forward with the licensing process and start a Phase 3 clinical trial. Given all of the above, what are the company's options, legal and illegal, for ensuring that the trial demonstrates a positive safety profile, thus clearing the way for the drug's approval?

One option is to artificially lower the incidence of adverse events reported in the trial group (the group receiving the new drug), by withholding or modifying data for specific cases. The difficulty with this technique is that for the duration of the trial, because of the enforced double-blinding, researchers do not know which subjects belong to which trial group. Thus, one cannot suppress or dilute reports for a specific group (the trial group, in this case) while leaving those of the other intact. Randomly suppressing reports would not be likely to accomplish the desired effect as the ratio of adverse events in each of the two groups would probably not change much.

Another theoretical option would be to modify the results following the conclusion of the clinical stage of the trial, at which point the blinding is removed and the data becomes fully available to the researchers.[m] The difficulty with this approach is that falsifying trial data is a criminal offense, which can lead to grave consequences for the company and the researchers them-

[m] Triple-blind RCT studies prevent this kind of possibility by hiding the group identity even in the analysis stage. Studies of this type are rare and not usually part of vaccine clinical trials.

selves, making this an unattractive option.

Another option would be to use various statistical techniques (which will be discussed later in the book), to build a false safety profile for the drug being tested. The difficulty with this approach is that the RCT study design greatly reduces researchers' ability to affect the results since they gain access to the full data set at a time when the data can no longer be altered. With limited ability to control the data, it can be quite difficult to eliminate undesired signals by statistical manipulation while at the same time successfully covering one's tracks.

The last option available to the company wishing to hide their product's undesirable side effects is to design a trial in which the reported rate of adverse events in the control group would likely be very similar to that of the trial group. As described previously, the RCT's control group represents the baseline rate to which the trial group is compared. A similar proportion between the two groups would indicate that the adverse events reported in the trial group were the result of "background noise" only and not caused by the experimental drug. This technique has three distinct advantages: (1) It is 100% legal, (2) it is very effective, and, as it turns out, (3) it has the full approval of licensing authorities around the world. As we shall shortly see, this method is exactly the one vaccine manufacturers employ to deliberately obscure the real incidence of vaccine adverse events.

The entire vaccine program is founded upon this deception.

Fake Placebo

It is virtually impossible to state the bottom line of the analysis presented above mildly, so here goes: **Vaccine trials in general, and childhood vaccine trials specifically, are purposely designed to obscure the true incidence of adverse events of the vaccine being tested**.

How do they do this? By using a two-step scheme: First, a new vaccine (one which does not have a predecessor), is always

tested in a Phase 3 RCT in which the control group receives another vaccine (or a compound very similar to the experimental vaccine, see explanation below). A new pediatric vaccine is never tested during its formal approval process against a neutral solution (placebo). Comparing a trial group to a control group that was given a compound that is likely to cause a similar rate of adverse events facilitates the formation of a false safety profile. The rate of adverse events of the tested vaccine is said to be similar to the "background rate", hence it is considered safe. The researchers, and the vaccine manufacturer they work for, seem to "forget" that the compound they administered to the control group is a bioactive substance, carrying its own risks and side effects, and hardly represents the baseline or background rate that is essential to an RCT for a new vaccine.

Thus, the vaccine is approved and added to national vaccine programs throughout the world. Then, when the "next generation" vaccine comes along, its pre-licensing clinical trials will always compare the new vaccine to the current vaccine and never to a placebo. Thus, all parties involved ensure that the true rate of vaccine adverse events is never discovered – for either the original or upgraded vaccine – and that rate is never shared with the public, or even the medical world.

The practice of giving a different vaccine to the control group in an RCT of an entirely new vaccine and calling it "placebo" is a deliberate misrepresentation of the term. As explained previously, a placebo is a compound (or procedure) that does not affect the parameters measured in the trial. When testing the efficacy of a new vaccine, researchers measure the level of disease antibodies in both study groups, so the substance given to the control group must not affect that antibody level, or the comparison becomes meaningless. For example, in a hypothetical new hepatitis C vaccine trial, it would not make scientific sense to inject the control group subjects with a compound that could increase (or decrease) the subjects' hepatitis C antibodies. Doing so would preclude a valid assessment of the effect of the vaccine on the antibody level, as the substance taken by the controls

could have distorted the comparison.[n]

The above analysis holds true for safety testing as well. If the compound given to the control group has its own significant side effects, it cannot be regarded as a true placebo. If the rates of adverse events observed in the trial and control groups appear similar, is it because the experimental vaccine is safe or because the control compound is just as unsafe as the vaccine? It would be impossible to know. Giving the control group an active substance in an RCT intended to test safety would be a bad design decision, then. Yet this is exactly how new vaccine Phase 3 trials are performed: Instead of a placebo, the control group receives a different vaccine, which is certain to cause its own adverse events and can in no way be deemed a neutral substance.

This practice of administering a different vaccine to the control group in a new-vaccine trial has no bearing on efficacy testing: It is highly likely that the control vaccine, which usually targets a different disease, would have no effect on the antibody level of the disease targeted by the test vaccine. Thus, using our hepatitis C example, if the control group subjects in the vaccine trial were given the Prevnar vaccine, no change in their hepatitis C antibody level would be expected; thus, the true efficacy of the test vaccine could be determined. But this lack of effect is not the case when it comes to safety: Because the Prevnar vaccine has its own side effects, it cannot be considered neutral in this context. Therefore, the true rate of adverse events for the experimental hepatitis C vaccine cannot be determined by comparing it to the rate in the group that received Prevnar since the controls did not receive a neutral compound.

This deliberate distortion of the placebo concept in clinical trials of new vaccines is so prevalent that researchers and vaccine

[n] Thus, a positive effect (a significantly higher level of antibodies in the trial group) could be the result of the control group's compound *lowering* the antibody level rather than the vaccine *raising* it. The opposite would hold true for a negative effect: The vaccine could have done a decent job raising the antibody level, but the control substance, for some unknown reason, was almost as effective, thereby diminishing the vaccine's positive effect.

package inserts frequently refer to the bioactive compound given to a control group as "placebo", even when it's clear it is another vaccine or a similar bioactive compound, which in itself is not safety-neutral.[15] Falsely using the term "placebo" allows researchers to conclude that the new compound "was proven safe" because its rate of adverse events was similar to that of placebo – even though the substance the control group received was decidedly not a placebo. For example, in one of the DTaP[o] vaccine trials, the rate of hospital admissions in the trial group was almost 1 in every 22 subjects. The researchers did not consider this statistic alarming, however, because in the control groups that received different DTP vaccines,[p] the hospitalization rate was similar.[16] Was such a high hospitalization rate in trial participants unrelated to the vaccines used, or were they the main culprit? Only the use of a true placebo control group could answer that question.[17]

No logical explanation can be found for the ubiquitous practice of administering bioactive compounds to control groups in trials of new vaccines other than a desire to conceal the true rate of adverse events of the vaccine. Testing a new vaccine against a placebo in an RCT is the simplest, safest, cheapest and most reliable option. Saline (sterilized salt water), for example, is a safe, reliable, widely available, and inexpensive compound – certainly when compared to a vaccine. Because it does not cause significant adverse events, nor does it produce disease-specific antibodies, it provides a reliable baseline for both safety and efficacy testing and is therefore ideal for control group usage. Calculation of the true rate of adverse events of the test vaccine becomes straightforward and simple. Despite its clear benefits as a placebo, vaccine makers prefer not to use saline in vaccine trials, and the reason for this should be obvious by now.

[o] A vaccine against diphtheria, tetanus, and pertussis that contains an acellular pertussis component.

[p] The older version of the DTaP vaccine that contains a whole-cell pertussis component.

How Were Vaccines on the Schedule Tested?

Now that the groundwork has been laid, it's time to consider the vaccines on the CDC's recommended childhood vaccine schedule: How were they tested for safety before getting marketing approval? Were the clinical trials of these vaccines "cooked" in the manner described above? Were they tested against (real) placebos? Is their true rate of adverse events known?

According to the current CDC vaccination program,[18] all children routinely receive vaccines against 13 different diseases by the age of two years.[q] Let's examine each of these vaccines.

Diphtheria-Tetanus-acellular-Pertussis Vaccines (DTaP): The DTaP vaccine is administered in various combinations – with or without inactivated polio, Hib, and hepatitis B components – and is manufactured by two companies: GlaxoSmithKline (GSK) and Sanofi Pasteur.

GSK's Pediarix vaccine protects against five diseases: diphtheria, tetanus, pertussis, hepatitis B, and polio. The safety section of the vaccine's package insert mentions 14 clinical trials involving 8,088 subjects. In the largest of the trials, conducted in Germany, the trial group received the Pediarix vaccine and a Hib vaccine, while the control group received Infanrix (DTaP vaccine, see below), Hib, and oral polio vaccines. In another trial explicitly mentioned in the leaflet, Pediarix was tested against a control group receiving Infanrix, hepatitis B, and inactivated polio vaccines. The leaflet does not describe the compounds given to the control groups in the remaining 12 safety studies, other than indicating that all of them received "comparator vaccines".[19]

GSK also manufactures a 4-in-1 vaccine called Kinrix, which is identical to the above Pediarix, minus the hepatitis B component. In the vaccine's largest clinical trial, the control group received Infanrix and IPOL (polio) vaccines. All trial participants were also concomitantly administered a dose of the MMR vac-

[q] As of April 2020. Not counting the annual influenza vaccine.

cine. The leaflet does not mention any trial involving a placebo control group.[20]

And how was the aforementioned Infanrix vaccine itself tested? The vaccine, which includes diphtheria, tetanus, and acellular pertussis components, was tested for safety in one clinical trial against a control group that received the DTP vaccine (the older, whole-cell pertussis, version), and in another that had no control group.[21]

What about the older generation DTP vaccine? What safety testing did it undergo? Although this vaccine is known to have caused serious side effects in infants (and was therefore replaced by the newer DTaP vaccine in the late 1990s),[22] it was never tested in a modern clinical trial in which the control group received a true placebo.[23] The vaccine, which was developed in the first half of 20th century, underwent a series of trials in the 1930s and 1940s at a time when the concept of the randomized controlled trial was still in its infancy. Hence, in most of these trials, there was no randomized control group, and the researchers devoted little effort to gathering information on the side effects of the tested vaccine.[24]

In addition to the above, a search of the *clinicaltrials.gov* web-site, a repository of clinical trials conducted since the year 2000, yields dozens of results for GSK's Infanrix vaccine family. None of them specifies an RCT with a placebo control group.[25]

To summarize, the safety of GSK's 5-in-1 and 4-in-1 vaccines was tested against the triple vaccine (DTaP), which was tested against the older generation vaccine (DTP), whose safety was never tested in an RCT with a placebo control group. A turtle standing on the back of a turtle, standing on the back of yet another turtle – all the way down.

In addition to GSK's diphtheria-tetanus-pertussis family of vaccines reviewed above, Sanofi Pasteur's DTaP line of vaccines is also approved for use in the US. The Pentacel vaccine (DTaP, polio and Hib) was tested in four clinical trials during its licensing process. In three of the trials, the control group participants received an assortment of different vaccines.[26] The fourth trial

appears to have had a control group that received no vaccines. However, the clinical review document submitted to the FDA reveals that the trial actually had no control group.[27]

Sanofi's Quadracel 4-in-1 vaccine (DTaP and polio) was tested for safety in one large clinical trial. The control group received Sanofi's 3-in-1 (Daptacel) and polio vaccines.[28]

Daptacel, Sanofi's triple DTaP vaccine, underwent four clinical trials during its licensing process. All of the trials were randomized and controlled, and in all of them, the control group received different combinations of DTaP or DTP vaccines, sometimes concurrently with other vaccines as well.[29]

The rates of adverse events in the trials reviewed above were always compared with rates observed in control groups whose participants also received vaccines. For example, a major study conducted in Sweden in the early 1990s compared four different DTP-related vaccines and found that serious adverse events – seizures, life-threatening events, onset of chronic illness, and more – occurred in approximately 1 in 200 vaccinees. Adverse events classified as "prohibiting future vaccination" were reported for 1 in every 100 vaccinees, and about 1 in 22 subjects were admitted to a hospital.[30] However, since the rates for the new-generation-vaccine (DTaP) groups were similar to that of the old-generation-vaccine (DTP) groups, the new vaccines received the green light.

The bottom line is that none of the many products in either of the DTaP vaccine family lines routinely administered in the US has been tested for safety in a clinical trial with a placebo-controlled group.

Haemophilus Influenzae Type B (Hib) Vaccine: The vaccine protects against infection caused by the Haemophilus influenzae type b bacterium. It can be administered as a component of the 5-in-1 Pentacel vaccine, discussed above, or as a separate vaccine. At present, there are three standalone Hib vaccine brands approved for use in the United States.

Hiberix is produced by GSK. Its package insert reports a sin-

gle RCT in which the vaccine was administered concomitantly with several other vaccines (DTaP, polio, hepatitis B, and others). The two control groups received a different Hib vaccine or a DTaP-polio-Hib vaccine, along with several other vaccines. Seven other trials mentioned in the leaflet were not blinded ("open label") and apparently had no control groups.[31]

ActHIB, manufactured by Sanofi Pasteur, was clinically tested for safety in three RCTs. In the first, the vaccine was simultaneously administered with the DTP vaccine, while the control group received the DTP vaccine alone. In the other two trials, the trial groups received a combination vaccine with ActHIB as one of its components, while the control groups received the same combination vaccine (without the ActHIB component), and a separate ActHIB vaccine.[32]

PedvaxHIB, by Merck, was tested in Native American infants. The package insert states that the control group received a placebo; however, all trial participants were also given the DTP and OPV vaccines concomitantly.[33]

Polio Vaccine (IPV): Similar to the Hib vaccine, the inactivated polio vaccine is administered as either a component of DTaP combination vaccines (discussed previously) or as a standalone vaccine. The IPOL vaccine, by Sanofi Pasteur, is the only brand currently licensed and used in the United States. Its package insert does not mention any pre-licensure RCTs that were performed for the vaccine.[34] Wasn't the vaccine clinically tested before it was introduced into the US schedule in the early 1990s?

Well, no. According to a document released by the FDA in 2018 following a Freedom of Information Act (FOIA) request, the vaccine underwent two clinical trials. However, these trials did not meet the current requirements for a Phase 3 randomized controlled trial. The first trial, which was conducted in 1980-1983, consisted of only 371 subjects in the IPOL trial group and about the same number in the control group, which (and this shouldn't be surprising by now) received the oral polio vaccine (OPV). The OPV, manufactured by Lederle, was the only polio

vaccine licensed in the US at the time. In addition, all trial participants received the DPT vaccine. The trial was controlled, randomized, and possibly blinded (though the licensing documents do not state this explicitly), but obviously not placebo bound. The second study, conducted in Buffalo, New York, in the late 1980s, enrolled 114 children who underwent a series of three vaccinations with either IPOL, OPV, or a combination of both. Most of the children received the DPT vaccine as well. This trial was not controlled, randomized, or blinded.[35]

So, the inactivated polio vaccine (IPV) "safety turtle" – established in two small trials, only one of them an RCT with any sort of control group – stands on the back of Lederle's oral polio vaccine (OPV) safety turtle. And what lies below that turtle's feet? Only thin air, apparently. The Lederle vaccine, introduced in the US in the early 1960s, has no public documentation of any clinical trials performed pre-licensure, or thereafter.

Prevnar Vaccine: The Prevnar vaccine brand protects against multiple strains of the pneumococcus bacterium that can cause pneumonia. The Prevnar-13 vaccine protects against 13 bacterial strains and has been in routine use in the US since 2010.[r] The vaccine replaced the older-generation vaccine called Prevnar, which was introduced in 2000 and protected against 7 bacterial strains.

How was Prevnar-13's safety tested before approval? Browsing the vaccine's package insert reveals that it was tested against its predecessor, Prevnar.[36] In these trials, severe adverse events were reported in 1 in 12 infants receiving Prevnar-13 (8.2% of subjects) and slightly less often in Prevnar subjects (7.2%).[37] But how many babies who participated in the trial would have experienced severe medical events if not vaccinated at all? That question cannot be answered because the Prevnar-13 trials did not include a placebo control group. Unsurprisingly, the rate of

[r] The Prevnar-13 vaccine is routinely given to infants at ages 2, 4, 6, and 12 months.

adverse events in the Prevnar-13 was generally similar to, albeit slightly higher than, the rate of its predecessor; thus, the vaccine was declared "safe" and approved for use by the FDA.

The Prevnar-13 turtle stands on the back of the Prevnar turtle. And what is the Prevnar turtle standing on? The answer: On the back of another turtle, which is standing on nothing but thin air, as we shall immediately see.

Prior to its approval, the Prevnar vaccine underwent a major clinical trial in the United States. In this trial approximately 17,000 infants received Prevnar and a similar number of controls received a vaccine against the meningococcus bacterium.[38] A review of the scientific paper reporting the results of the trial reveals that about 1,000 subjects in total were hospitalized (about 1 in every 35 infants), and about 1 in 16 had emergency room (ER) visits within 30 days of receiving the vaccine.[39] In addition to the Prevnar or meningococcal vaccine, all trial subjects received concurrent DTP or DTaP vaccines. (Note that administering the trial and control vaccines concurrently with other vaccines further obscures the results, as it impossible to determine which adverse events are due to which vaccine(s).)

And what about that meningococcal vaccine received by the control group subjects? In 1998, the year its trial took place, there was no existing alternative to the Prevnar vaccine. Thus, there were no ethical reasons not to give the control group an inert saline injection. Yet the manufacturer chose to give the control group the meningococcal vaccine instead, despite the fact that it had not yet been approved by the FDA and was still "experimental".[40] Why would the manufacturer, as well as FDA and other licensing approval bodies, prefer using an experimental vaccine over the safe, economical, practical, and ethical alternative of a saline placebo? There can be only one answer: to hide the true rate of Prevnar's adverse events.

Hepatitis B Vaccine: Engerix-B is a hepatitis B vaccine manufac-

tured by GSK, which is routinely given to US infants.[s] How was it tested for safety? The vaccine package insert provides an exceptionally brief description: "The incidence of local and systemic reactions was comparable to those of plasma derived hepatitis B vaccines."[41] The package insert mentions another safety study, carried out in children aged 11 to 15 years, where both trial and control groups received the Engerix-B vaccine, though different dosing regimens were applied.[42]

Twinrix, also made by GSK, is a combined hepatitis A and B vaccine. This vaccine was tested in clinical trials against a control group receiving the company's single hepatitis A and B vaccines (Havrix and Engerix-B, respectively).[43]

Recombivax-HB is a hepatitis B vaccine produced by Merck. Surprisingly, its package insert does not mention any safety RCT in infants that was performed for this vaccine.[44]

In summary, the safety of the three hepatitis B vaccines routinely given to newborns has not been tested in a single randomized controlled clinical trial in which a control group received a placebo. As should be all too familiar by now, it's "turtles all the way down" again.

Hepatitis A Vaccine: Two hepatitis A vaccines are routinely used in the United States:[t] the GSK Havrix vaccine and Merck's Vaqta vaccine.

In a large-scale trial in Thailand with over 40,000 participants, GSK's Havrix was compared with a control group which received Engerix-B, the company's hepatitis B vaccine. In three other clinical studies, the trial groups received the Havrix vaccine concurrently with another vaccine and the control groups received several other vaccines (MMR, varicella, and more).[45]

The safety testing of Merck's vaccine, Vaqta, was not much different. According to FDA licensing documents, the vaccine

[s] Hepatitis B vaccine is typically given on the day of birth, and at the ages of 1 month and 6 months.

[t] Hepatitis A vaccine is given twice in the second year of life.

was tested in two clinical trials:[46] The first one ("Monroe") had no control group, while the second, in addition to having no control group, administered Vaqta along with two other vaccines.[u] Vaqta's package insert mentions several additional studies but none with a control group that received a placebo. It is interesting to note that contrary to the FDA licensing document, the package insert states that there was a control group in the "Monroe" study and that it received a placebo. A closer look reveals that the "placebo" used contained the vaccine's aluminum adjuvant,[v] [47] and further examination reveals that it also contained the preservative thimerosal (a mercury-based substance removed from most vaccines in the early 2000s).[48] As mercury is a potent neurotoxin and aluminum adjuvants are used because they stimulate a strong immune reaction, both of these substances are a far cry from being inert and safety-neutral.

Measles, Mumps, Rubella, and Varicella (Chickenpox) Vaccine: Merck manufactures a single-dose varicella vaccine called Varivax. The safety section of its package insert mentions a "double-blind, placebo-controlled study" of 914 healthy children and adolescents, in which only two mild symptoms, pain and redness at the injection site, "occurred at a significantly greater rate in vaccine recipients than in placebo recipients."[49] Does that mean a real placebo was used in this trial? Definitely not. The paper describing the study reveals that the so-called placebo given to the control group was actually the test vaccine from which the viral component was removed.[50] No wonder the rates of adverse events were similar between the trial and control groups.[51] Another controlled study compared the safety of two different formulations of the Varivax vaccine. According to the leaflet, the

[u] The observed adverse events in the second trial were compared to a "historical" control group, that is, to the results of another, and different, vaccine trial. As explained previously in this chapter, this technique is not scientifically valid because it conflicts with the principle of randomization, which is one of the pillars of an RCT study.

[v] Adjuvant is an immune system stimulant that is present in some vaccines.

safety profiles of the two formulations were comparable.

The two measles-mumps-rubella vaccines licensed for use in the US[w] are a 3-in-1 vaccine called MMR II, and a 4-in-1 vaccine (measles-mumps-rubella and varicella) called ProQuad. Both are manufactured by Merck.

ProQuad's safety was tested in several randomized clinical trials, most of which were not blinded ("open label" studies). The largest RCT compared ProQuad to a control group that received the older-generation MMR II and the Varivax vaccine at the same time. Another study in children 4-6 years old divided the subjects into three groups: The first received ProQuad and "placebo"; the second, MMR II and "placebo"; and the third, MMR II and Varivax. In the open label studies, the participants of both trial and control groups received additional vaccines.[52]

The package insert for MMR II does not mention any safety trials.[53] As with the polio vaccine (IPOL) described earlier, a FOIA request revealed that the vaccine was tested in the mid-1970s in eight small clinical trials.[54] The control groups in all of the trials received either the predecessor vaccine (MMR), a measles-rubella (MR) vaccine, or a single-dose of the rubella vaccine. A total of approximately 850 children received MMR II. Some of the trials seem to have been randomized, but none were blinded. These trials, considered either singly or in combination, do not meet the current requirement of a Phase 3 randomized controlled trial, which might explain their complete absence from the package insert.

Finally, let's examine how the original MMR vaccine, licensed in 1971, was tested before getting the nod from the regulator. Will we find a placebo-receiving control group in this legacy vaccine's trials? Well, almost. Similar to MMR II, the original MMR was tested in a few small-to-medium trials wherein the newer vaccine was given to a total of more than 1,000 infants and children. The control groups' subjects totaled about

[w] The MMR and MMRV vaccines are administered at the age of 12–15 months and again between the ages of 4 and 6.

one tenth that number, and most of them were siblings of the vaccinated children (which violates the randomization principle). The control group participants received no injection at all, which means the studies were not blinded; everyone knew who got the vaccine and who didn't. As with MMR II, the MMR trials fail to meet the Phase 3 RCT bar.[55]

Evidently, the safety of the MMR line of vaccines, like the rest of the vaccines in the US childhood vaccination program, was tested according to the de facto industry rule of "turtles all the way down".

Mere Coincidence or Deliberately Flawed Design?

As we've clearly illustrated in the preceding sections, not one of the vaccines the CDC recommends all American children receive was tested for safety in a Phase 3 clinical trial where the control group received an inert placebo. All the vaccines reviewed in the preceding pages – of which tens of millions of doses are administered to infants and toddlers in the US every year – were tested in trials which did not include any control group at all, or ones in which the so-called control group received at least one other vaccine.

Is it just coincidence that none of these vaccines has been tested against a true placebo, despite the fact that in many cases doing so would have been easier, cheaper, and yielded more valid results than the testing that was done? Is it just an accident of fate that the accepted methodology of all childhood vaccine trials obscures the real rate of adverse events of the new vaccine? That seems highly improbable.

As explained at the start of this discussion, testing the safety of a next-generation vaccine against its predecessor is justifiable on ethical grounds: Withholding an existing and proven treatment from control group subjects would be immoral. However, there is no justification for conducting a chain of trials (turtle upon turtle upon turtle) that ultimately stands on nothing but air. Moreover, what possible rationale could justify trials for new

vaccines wherein the control groups receive other (sometimes experimental) vaccines? Would a safety trial for a new cigarette have any credibility at all if the "control" group consisted of subjects who smoked a different kind of cigarette?

Whether or not you believe this trial methodology is ethical, its consequence remains the same: The true rate of adverse events of routine childhood vaccines is virtually unknown; therefore, there is no scientific basis for claiming they're safe.

The fact that we don't know how often childhood vaccines hurt the children who receive them casts a dark shadow over the legitimacy of vaccine programs the world over. But that is not all. Even worse, as we shall shortly see, safety trials conducted for some childhood vaccines blatantly and seriously violate the medical code of ethics. In any vaccine clinical trial, a balance must be struck between the vaccine's potential benefits (disease protection) and potential risks (adverse events). When control subjects in vaccine trials receive another type of vaccine, even if it's done in order to obfuscate the real rate of adverse events of the vaccine being tested, the compound they receive is at least of some potential benefit to them. However, in the rotavirus vaccine trials this imperative ethical risk-to-benefit balance was blatantly violated.

The Clinical Trials of the Rotavirus Vaccines

Designing clinical trials for the RotaTeq and Rotarix vaccines was particularly challenging for their manufacturers, Merck and GSK, respectively. To begin with, the first rotavirus vaccine brand (RotaShield) was recalled from the market[56] after it was found to significantly increase the risk of intussusception, a highly dangerous condition in infants.[x] This meant that clinical

[x] Intussusception is a condition in which part of the intestine folds into the section immediately ahead of it. This, in turn, could cause bowel obstruction and even require surgical intervention. If left untreated, intussusception can result in death.

trials for the new rotavirus vaccines had to adhere to higher safety standards. In addition, the companies faced an equally serious problem: With RotaShield off the market, there was no suitable vaccine to give to control group subjects.

A rotavirus vaccine dose, a few drops of an opaque liquid, is consumed orally.[y] Hence, the control group in its clinical trials could not receive a vaccine administered via injection as it would violate the RCT blinding principle. If the trial group were vaccinated orally, while the control group was injected, it would be easy to tell the two groups apart. At the time the rotavirus vaccine trials began, there was no other orally ingested vaccine licensed for use. The use of the live polio vaccine (OPV), also consumed by mouth, was terminated in Western countries several years earlier.[z] As a result, there was no oral vaccine available to compare with rotavirus vaccines in clinical trials.

Another option would be to give the control group a few drops of a neutral liquid, such as a solution of sugar or salt water. These compounds are safe, inexpensive and convenient to use – ideal for the purpose of testing the vaccine's efficacy and safety. Because these were entirely new vaccines, which had no alternative, there were no ethical objections to using such a solution.

So, on the one hand, rotavirus vaccine manufacturers did not have a ready-made vaccine available for use in the control group, and on the other, there was no impediment to using a cheap, available and effective substance, such as sugar water. How, then, did they choose to conduct their Phase 3 clinical trials? A preliminary examination of the clinical trial record of the rotavirus vaccine shows that the control groups in the RotaTeq and Rotarix trials received… a placebo![57] Was this, then, the industry's first breach of the sacred tradition that vaccines never be tested against a true placebo? Were the rotavirus vaccine trials

[y] The rotavirus vaccine is routinely administered to babies at the age of 2, 4, and 6 months.

[z] This occurred after it was discovered that the vaccine could cause paralysis in a small proportion of vaccinees.

the first to provide reliable and relevant information about the rate of adverse events of a childhood vaccine?

The answer to these questions is, unfortunately, "no and no".

Examining one of the licensing documents submitted to the FDA by GSK[58] indicates that the placebo received by the control group in the main Rotarix trial (which included approximately 63,000 infants) is nothing but the tested vaccine without its antigenic component.[aa] This compound, the vaccine-sans-antigen (*sans* means *without*), is well suited for testing the efficacy of the vaccine as it does not produce rotavirus antibodies. However, when it comes to safety, it's a whole different ballgame: The vaccine-sans-antigen is a potentially potent compound whose side effects are likely to be quite similar to those of the vaccine being tested.

And what was the placebo in Merck's RotaTeq vaccine trial? That's difficult to say because Merck deleted its description from the licensing document submitted to the FDA.[59] It appears that the trial's placebo is a trade secret, which implies its contents were very similar to the vaccine's. Further examination of RotaTeq documents supports this hypothesis: In another RotaTeq clinical trial, the control group received the vaccine-sans-antigen, similar to the compound control group subjects received in the Rotarix trial.[60]

The bioactivity of the compounds given to the control groups in rotavirus vaccine trials was seemingly apparent in the rate of adverse events reported in the trials. In the Rotarix trial, about 1 in 30 control group subjects experienced a "severe" medical event (a rate which was even slightly higher than that of the trial group), and a similar proportion of participants was hospitalized. In addition, 16 infants suffered intussusception and 43 died.[61] In the RotaTeq trial, similar rates were recorded in the control group: Serious adverse events were reported in 1 of every

[aa] The antigen in the vaccine is the substance that stimulates the desired immune response. It is usually composed of attenuated or killed particles of virus or bacteria.

40 subjects, 15 suffered intussusception, and 20 infants died.[62]

Using the word placebo to describe the vaccine-sans-antigen leaves the false impression that it is a safe compound that has no side effects of its own. Formal documents, which reference the rotavirus vaccine trials, rely on the supposed biological neutrality of that "placebo". One example is the Rotarix vaccine package insert, which states in the clause discussing the rate of intussusception reported in pre-licensure trials: "No increased risk of intussusception was observed in this clinical trial following administration of ROTARIX when compared with placebo."[63] (The trial in question is the same trial referenced above. There are plenty of other examples, too).[64] Nowhere is there any reference to the actual contents of that "placebo".

The rotavirus vaccine makers were evidently able to find a creative solution to the challenge they faced. They gave their trials' control groups compounds that were very similar to their vaccines, and – as was, no doubt, expected – the resultant rates of adverse events were not significantly different from those observed in the trial groups. In future trials of next-generation rotavirus vaccines, GSK and Merck will be able to give their control groups the standard "placebo" – the currently licensed vaccine – whose safety "was already proven" in its pre-licensure trials.

But there's a fly in this sticky ointment.

Unethical Trials

As previously discussed, the ethical standards for using children as subjects in clinical trials are exceptionally high. Clinical trial designers must ensure that planned procedures are balanced with respect to the expected benefit and risk to the participating infant or child. If a child subject is likely to receive no benefit, the potential harm must be "minimal" or only "slightly above the minimum", and by no means permanent or irreparable. In addition, the risks associated with any procedures must be well-known in advance.[65]

In stark contrast to the standards above, tens of thousands of infants in the control groups of the rotavirus vaccine trials received compounds that could provide no potential benefit to the recipient yet carried significant risk. Neither GSK's nor Merck's vaccine-sans-antigen could possibly prevent rotavirus as they did not contain the antigenic particles that evoke immune reactions to the virus. On the other hand, these compounds had significant potential to cause harm, as demonstrated in the trials. (Remember, 1 in every 30 or 40 control group subjects experienced a serious adverse event). In addition, the safety profiles for the vaccines-sans-antigens were unknown (and, for all we know, still are) as they were new compounds specifically formulated for the rotavirus trials with no documentation of past safety studies. Hence, the health risks associated with administering them to infants was undetermined.

To sum up, tens of thousands of infants were given an utterly useless compound whose safety was unknown and whose side effects could be (and probably were in some cases) severe and permanent. Thus, the Phase 3 clinical trials of the rotavirus vaccine constitute blatant violations of the medical code of ethics.

This ruthless breach of ethics and morality is highlighted by the fact that there was no scientific justification for giving the vaccine-sans-antigen to the control group other than a malicious intention to conceal the experimental vaccine's true rate of adverse events. Using a real placebo that posed no health risk – a few drops of sugar or salt water – would have cost less and led to more scientifically valid conclusions by enabling straightforward calculations of the true adverse event rates as well as vaccine efficacy.

The manner in which the rotavirus vaccine trials were conducted raises grave questions which should not be directed solely toward the vaccines' manufacturers. The FDA supervises the vaccine approval process, and it is the FDA that approved these

trials.[bb] The vaccine also received CDC approval and that of other health authorities around the world, even though its pre-licensure trials unnecessarily endangered tens of thousands of children and may have caused serious harm to hundreds, as well as dozens of needless deaths.

The Declaration of Helsinki is the ethical code governing the conduct of human medical experimentation. The Declaration was formulated for the medical-scientific community by the World Medical Association and is considered the ethical cornerstone of the medical research field. It leaves no doubt as to the ethical violations perpetrated in the rotavirus trials:

> *Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed. When the risks are found to outweigh the potential benefits […] physicians must assess whether to continue, modify or immediately stop the study.*
>
> *. . . [A] potential research subject who is incapable of giving informed consent [...] must not be included in a research study that has no likelihood of benefit for them unless […] the research entails only minimal risk and minimal burden.*[66]

The *Nuremberg Code*, the medical code of ethics established in the late 1940s to bring Nazi doctors to justice, constitutes the basis of the Declaration of Helsinki. It too underlines the immorality of the rotavirus vaccine trials: "[An] experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury."[67] A similar conclusion was also reached by a World Health Organization (WHO) committee that recently examined placebo use in clinical trials.[68]

Ponder it as you will, you won't find a satisfactory explana-

[bb] A similar, though not identical, design was employed in the pre-licensure trials of the human papillomavirus (HPV) vaccine Gardasil.

tion for the way the rotavirus vaccine trials were conducted other than the malicious desire to assist the manufacturers in obscuring and concealing the vaccines' true adverse event rates. This demonstrates that the public health establishment is willing to go to great lengths to maintain the pretense of vaccine safety, casting aside medical ethics and even fundamental principles of morality in the process.

Childhood Vaccine Clinical Trials: A Summary

The table below summarizes the safety testing performed in Phase 3 clinical trials for the vaccines included in the CDC-recommended childhood vaccination program.

Table 1: The control group in Phase 3 clinical trials of CDC's routine childhood vaccines

Disease	Vaccine	The Control Group in Phase III Clinical Trials
Diphtheria-Tetanus-Pertussis (with and without Polio, Hepatitis B and Hib)	Pediarix *(Diphtheria-Tetanus-Acellular Pertussis-Hepatitis B-Polio)*	Control groups in the trials received either the Infanrix vaccine along with hepatitis B, Hib, and polio vaccines, or other, unspecified vaccines. No control group received a placebo.
	Kinrix *(Diphtheria-Tetanus-Acellular Pertussis-Polio)*	In the only trial specifically described in the package insert the control group received the Infanrix and polio vaccines. The package insert doesn't mention any trial involving a placebo control group.
	Infanrix *(Diphtheria-Tetanus-Acellular Pertussis)*	Tested against a control group that received the DTP vaccine or no control group.
	DTP *(Diphtheria-Tetanus-Pertussis)*	The older-generation vaccine was developed in the 1930s and has never been tested in an RCT against a control group receiving a real placebo.

	Pentacel *(Diphtheria-Tetanus-Acellular Pertussis-Polio-Hib)*	The control groups in 3 of the 4 trials received an assortment of different vaccines. The 4th trial's control group may have received no vaccines; however, its safety data is not presented in the package insert.
	Quadracel *(Diphtheria-Tetanus-Acellular Pertussis-Polio)*	The control group in the trial received the Daptacel and polio vaccines.
	Daptacel *(Diphtheria-Tetanus-Acellular Pertussis)*	The control groups in the trials received other vaccines.
Haemophilus Influenzae Type B	Hiberix	The only blinded RCT had two control groups receiving another Hib vaccine or a DTaP-polio-Hib, along with several other vaccines.
	ActHIB	Control groups received either the DTP vaccine or other combination DTaP-based vaccines.
	PedvaxHIB	Most of the control group subjects received DTP and OPV vaccines along with a "placebo" whose ingredients were not specified.
Polio	IPOL	The package insert does not mention any RCT performed for the vaccine.
Pneumococcal Disease	Prevnar-13	Tested against a control group receiving Prevnar (older-generation vaccine).
	Prevnar	Tested against a control group that received an experimental meningo-coccal vaccine.
Hepatitis B	Engerix	Its side effect rate was compared to that of a previous generation product (plasma vaccine).
	Twinrix	Tested in clinical trials against a control group that received separate hepatitis A and B vaccines.

	Recombivax HB	The package insert does not mention any safety RCT performed in infants.
Hepatitis A	Havrix	The control group in the main trial received the hepatitis B vaccine. In three other trials, the control group received several other vaccines (MMR, varicella vaccine, and more).
	Vaqta	In one trial, there was no control group (according to another document, the control group received a compound that included aluminum and thimerosal), and in the second trial the vaccine was given concurrently with other vaccines and without a control group.
Measles, Mumps, Rubella, Varicella (Chickenpox)	ProQuad *(Measles, Mumps, Rubella, Varicella)*	Safety was tested in several randomized clinical trials, most of which were not blinded. None of the trials contained a control group receiving only a placebo.
	MMR II *(Measles, Mumps, Rubella)*	Tested in eight small unblinded clinical trials. All of the trials had one or more control groups receiving either the predecessor MMR vaccine, a measles-rubella (MR) vaccine, or a single-dose of the rubella vaccine.
	MMR *(Measles, Mumps, Rubella)*	Tested in several small to medium unblinded and partially randomized trials. The control groups totaled about 1/10 the number of subjects in the trial groups and received no injection.
	Varivax *(Varicella)*	In one RCT the "placebo" given to the control group was actually the test vaccine from which the viral component was removed. Another trial compared two different formulations of the vaccine.
Rotavirus	RotaTeq	The control group in the trial probably received the vaccine-sans-antigen compound (the description of the control compound was intentionally

		deleted from FDA licensing documents).
	Rotarix	The control group in the trial received the vaccine-sans-antigen compound.

Counter Arguments

As summarized in the table above, the manufacturers' package inserts and FDA licensing documents indicate that none of the US routine childhood vaccines has been tested against a true placebo. It is very unlikely that new documents which attest to the opposite will suddenly appear. It is also highly improbable that a new technique for calculating the true rate of vaccine adverse events in an RCT by comparing it to population background rates or to a non-placebo control group will miraculously emerge. A moral justification for giving control group infants a compound that could seriously harm them, while providing them with no potential benefit, will also not be forthcoming anytime soon.

However, because the arguments made in this chapter undermine the very foundations of the childhood vaccine program, devout believers in the "vaccines are safe and effective" mantra try hard to refute them. Their popular arguments and suggested responses are presented below.

Important Note: When addressing alleged refutations to the content of this chapter, the first response should be to politely request scientific references backing them up. When facing the inevitable and grave consequences of the material presented in this chapter, vaccine proponents sometimes resort to baseless, even borderline imaginary, claims. In many cases, asking for a valid scientific reference that backs up a claim will quickly put the argument to rest.

"A placebo in vaccine clinical trials is only used for the purpose of testing vaccine efficacy." – This is a bizarre claim which has no

scientific basis (just ask for a scientific reference – you won't get one). A (real) placebo given to the control group in a vaccine clinical trial provides a "background rate" for both efficacy and safety. Therefore, in a trial which has a placebo group, both vaccine efficacy and the incidence of adverse events could be easily calculated by comparing results in trial vs. control groups.

"It is unethical not to give the control group another vaccine." – The practice of always testing vaccines against other vaccines gives rise to the "turtles all the way down" scenario, where the true rate of adverse events of any childhood vaccine is never determined. In fact, the opposite is true: It is unethical not to conduct at least one trial from which one can reliably estimate the rate of adverse events before a vaccine is licensed and widely used.

As reviewed in this chapter, medical ethics guidelines permit the administration of a placebo to a control group in a clinical trial of a completely new vaccine and to a control group in a three-arm trial of a next-generation vaccine.

"When testing a next-generation vaccine, it is unethical not to give the control group the current vaccine." – This argument is similar to the previous one, but focuses specifically on the next-generation vaccines. It certainly makes sense to test the safety of a next-generation vaccine against the current one, but if the current vaccine has never been previously tested against a placebo, it is "turtles all the way down" again; that is, the data collected from the vaccine's clinical trials is inadequate for establishing a true safety profile.

The solution to the above is straightforward: Conduct a three-arm trial with next-generation vaccine, current vaccine, and placebo groups. This allows the comparison of the safety of the new vaccine to the existing one, as well as obtaining an estimation of the absolute rate of the new vaccine's adverse events (by comparing it to placebo). A trial of this kind has never been conducted for any of the routine childhood vaccines.

"It is sufficient to test a new vaccine against another vaccine whose rate of adverse events was determined in a previous trial (or measured for a country/region/city population)." – As explained in the chapter, the results of one randomized controlled trial (RCT) cannot be compared to that of another RCT, nor to population "background rates" (even if those are known, which is uncommon) because it violates randomization. Known or unknown differences may exist between the studies' populations that could potentially skew the results significantly. Vaccine package inserts, which are published by the manufacturers and approved by health authorities, state this explicitly.

"It is sufficient to test a next-generation vaccine against the current vaccine, as the current vaccine has already been given to millions over many years and proven safe." – The argument implies that if we know that a certain current vaccine is safe and a control group in a next-generation vaccine trial is given that vaccine, then if adverse events are comparable between the groups, it can be concluded that the new vaccine is also safe for use.

First, this presupposes that the current vaccine is safe. But we cannot make that assumption if the current vaccine itself was tested in clinical trials designed to obfuscate its true rate of adverse events. That is, the industry's "gold standard", the RCT, was "cooked" (as was the case in this chapter's examples) in order to hide the health risks of the tested vaccine. Instead, we must base our judgment of its safety on inferior studies[cc] performed only after the vaccine has been on the market for several years.

Secondly, without a placebo control group there is no way to prove that the vaccine being tested is actually safe. For example, in one of the DTaP vaccine trials, 1 in every 22 subjects in the trial group was admitted to the hospital. A similar hospitalization rate was also reported in the control group (which received the older-generation DTP vaccine).[69] Is this a normal background

[cc] See chapter 4 for a review of types of epidemiological studies.

rate? Would nearly 5% of all infants really end up in the hospital if they didn't receive these vaccines? Should we regard both these vaccines, which appear to cause an alarmingly high rate of hospitalizations, as "safe" simply because they have similar hospitalization rates? Or is the reality that neither of them are safe? Definitive answers to these questions could only be obtained by adding a placebo group to the trial. Only then could we calculate a meaningful baseline hospitalization rate that could be put to good use in evaluating the vaccine's safety.

In any case, the above claim is irrelevant for trials of entirely new vaccines for which there are no valid reasons not to use a real placebo control.

"The safety of the [xyz] vaccine was extensively studied after it was approved for wide use and was found to be excellent." – Statistical (epidemiological) studies, which are typically conducted only after a vaccine has been in wide use, are considered inferior to RCT studies. The RCT is the industry's "gold standard", and every new vaccine must undergo such a trial before it is approved for use. It would not be acceptable or reasonable to approve a vaccine for use without adequate clinical studies, and then, after it was administered to millions of babies, retroactively endorse it based on methodologically inferior studies.

"The assertion that vaccines are never tested against a placebo is false. Here are some references to vaccine clinical trials in which the control group received a real placebo."[70] – The claim made in this chapter is not that vaccines in general are never tested against placebo in their pre-licensure process. Rather, it is childhood vaccines recommended by the CDC that were never tested against a placebo. The references provided to support the above statement do not refute this claim, as they link to trials of adult vaccines, or vaccines that are not used in the United States. In fact, these references reinforce this chapter's arguments, as they demonstrate that using a placebo control group in a vaccine RCT is valid, feasible, methodologically sound, and ethical.

"Contrary to your claim, a placebo is not mandatory in a vaccine clinical trial. Instead, the control group could be given nothing (i.e., no intervention)." – In a double-blinded randomized controlled trial (RCT), the control group must receive a compound that looks the same and is administered in the same way as the tested compound. This eliminates potential reporting bias. For example, subjects who know they received the experimental vaccine are more likely to report adverse events than control group participants who received no intervention. This rule also applies to trials with infant subjects even though it is generally believed they are not affected by this bias, because their parents, who are usually present at the time of vaccination, can certainly be affected.

In any case, there are no current childhood vaccines that were tested in clinical trials that included a no-intervention control group, which renders the above claim irrelevant.

"The vaccine-sans-antigen that was given to the control group in the rotavirus trials is a safe compound since it is made of a mixture of ingredients, each of which is generally considered to be safe." – This is yet another baseless claim that has no scientific or factual basis. Even if we presuppose that the individual ingredients in the compound given to the control group in the rotavirus trials were harmless, we cannot assume their specific mixture was harmless, too. This is a fundamental tenet of drug and vaccine testing methodology: A compound's safety is not the sum of the safety of its parts. Thus, we cannot presume its safety based on a theoretical calculation of the aggregated safety of its ingredients. It must be clinically tested before it is approved for wide use (even more so, if given to babies).

Additionally, in the case of the rotavirus vaccine trials, neither the manufacturers nor the licensing bodies claimed that the vaccine-sans-antigen that was given to the control group was considered, or proven to be, safe or that its safety profile was known. If anyone claims the opposite, they must provide the scientific references to back it up.

"Giving the control group the vaccine-sans-antigen is the proper way to test the vaccine's antigen efficacy and safety." – Once again, this is a baseless claim that has no scientific merit. A clinical trial in which the trial group receives the test vaccine and the control group the vaccine-sans-antigen compares two experimental compounds whose safety profiles are unknown. Therefore, such a trial design precludes calculation of the true rate of adverse events of the test vaccine. For a valid determination, the control group should receive a placebo, which is a compound whose rate of adverse events is known and is very close to zero. In clinical trials using vaccine-sans-antigen compounds in the control group (for example, the rotavirus vaccine trials), researchers reasoned that "no significant difference in the rate of adverse events was observed in trial and placebo groups." However, this claim is critically flawed, since the "placebo" given to the control group was not neutral (i.e., one which had zero side effects), but rather a bioactive compound whose rate of side effects was unknown.

In addition, the safety of the vaccine antigen is irrelevant as it is not administered by itself, but rather in combination with all the vaccine's other ingredients. It's the safety of the vaccine as a whole that matters, and that is not best tested by comparing it to the vaccine-sans-antigen.

In any event, the above discussion should only be considered theoretical, since administering a potentially harmful substance with no potential benefit to infants in a clinical trial violates the medical code of ethics as well as fundamental moral principles.

"It is inconceivable that every doctor and researcher in the entire world would approve, or retroactively approve, of a flawed methodology for testing vaccines' safety before they are licensed. Are all of them taking part in a huge conspiracy?" – Providing a complete and comprehensive answer to this claim goes beyond the scope of this chapter. In short, the vast majority of physicians and researchers are completely unaware of the manner in which vaccine safety trials are designed and conducted and the meth-

odological flaws inherent in that process.

Regardless, this claim is essentially irrelevant, as it does not directly answer the arguments presented in the chapter and therefore cannot refute them. A doctor or researcher who has studied vaccine safety and maintains there are no flaws in their licensing process should respond directly to the arguments made in this chapter instead of asking the public to blindly agree based on professional authority alone.

Summary

Vaccines, as opposed to drugs, are given to healthy babies and thus must meet a particularly high safety standard. Clinical trials of new vaccines must be impeccably designed and performed, thereby providing high-quality, reliable data about the products' efficacy, and more importantly, about their safety. Anything less is socially and morally unacceptable.

Vaccine manufacturers and health authorities worldwide frequently assure us, the public, that vaccines are tested at the highest possible level and that the rigorous series of clinical trials they undergo as part of the licensing process ensures that vaccines are truly safe and effective.

These assurances, however, are meaningless at best and deliberately misleading at worst.

As we have seen in this chapter, vaccine trials are designed and performed in such a way as to ensure that the true extent of adverse events is hidden from the public. There is not a single vaccine in the US routine childhood vaccination program whose true rate of adverse events is known. The assertion that vaccines cause serious side effects in "one in a million" vaccinees contradicts the results of numerous clinical trials in which serious adverse events were reported in 1 in 40, 30, or even as few as 20 vaccinated infants. After becoming acquainted with the finer details of vaccine safety trials, hearing the familiar tune of "a similar rate of adverse events was reported in the control group" (which received another vaccine or similar compound) comes off

as ludicrous, cynical, and patently immoral.

Current vaccine clinical trial methodology completely invalidates the claims that vaccines are safe and that they are thoroughly and rigorously tested. And pulling out that bogus card completely topples the childhood vaccine program's house of cards, as officials' assurances of vaccine safety rely primarily on deliberately flawed, industry-sponsored clinical trials.

Furthermore, some of the clinical trials that have been conducted for routine childhood vaccines, which were approved by relevant health authorities, blatantly violated the medical code of ethics (the Declaration of Helsinki) and fundamental principles of morality. In these trials, infants in the control groups were given completely useless compounds (an antigen-free vaccine) whose safety was unknown and which had the potential to cause serious and irreversible damage to health, including death.

Any reader looking for a quick and definitive understanding of the truth about vaccine safety – well, you can put this book down right now. You have your answer: The entire vaccine program is based on a deliberate cover-up of true vaccine adverse event rates. This seemingly mighty fortress, carefully constructed over many decades and fortified by countless officials, researchers, and physicians – actually stands on nothing but turtles all the way down.

Ask your doctor:

• Was the vaccine that you are recommending tested in a pre-licensure clinical trial with a (real) placebo control group? If not, how do you (or anyone else, for that matter) calculate its true rate of adverse events?

• Is it morally acceptable to conduct a clinical trial in infants for a new vaccine, where the "control group" receives an untested compound, i.e. the vaccine-sans-antigen, which is likely to cause irreversible side effects and has no potential benefit?