# Vaccines: truth, lies and controversy Peter C. Gøtzsche

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Here is Chapter 2 from the book, about measles

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# 2 Measles

For the last 20 years, measles has been the primary target in the battles between vaccine advocates and vaccine deniers. I shall demonstrate what is right and what is wrong.

It is important to understand that the difference between survival and death depends on the infectious dose. Peter Aaby's studies in Africa and elsewhere have disproved the prevailing dogma that malnourishment plays a significant role for measles mortality.<sup>1</sup> By using Danish patient files from 1915 to 1925, he confirmed his initial findings from the tropics that the more children there are in a family, the higher the death rate during measles epidemics.<sup>2</sup> He concluded that this is because overcrowding results in more intensive exposure within families, transferring greater doses of the virus. The children died before they had mounted an effective immune response. This explains why measles outbreaks can be particularly deadly in countries experiencing a natural disaster or conflict, with overcrowding in refugee camps that not only greatly increases the risk of infection,<sup>3</sup> but also the risk of dying from it.

Aaby's findings were met with great disbelief by the establishment but they are highly convincing. They are over 30 years old and have now been generally accepted, but dogmas have a life of their own, and a whole generation of doctors impregnated with false information needs to die

out before the dogmas – perhaps - disappear for good. One can still find the erroneous idea about malnourishment in articles and textbooks, e.g. in a so-called fact sheet from the WHO from 2018: "Severe measles is more likely among poorly nourished young children."<sup>3</sup>

After having studied the science, I have come to the conclusion that the measles vaccine is one of the best interventions we have in healthcare. It is very strange that it is necessary to remind people about this. But the sad fact is that some people – including physicians and other well-educated people who should know better - refuse to vaccinate their children against measles.

I have tried to understand the vaccine deniers' reasoning and will discuss their most important arguments below. Even in hard-core groups, there may be people who can be influenced by rational arguments, good science and ethical deliberations, particularly if you can demonstrate that what they have believed in is based on false information.

#### A cancelled meeting in California

It was with this hope in mind that I accepted to speak at a meeting in California on 17 March, 2019, arranged by *Physicians for Informed Consent*. My talk was: "How mandatory vaccination violates medical ethics."

However, as soon as it became known that I was coming, I was subjected to a public smear campaign. I was flabbergasted. I have often been harassed when I tried to speak truth to power, but this was close to the moral bottom of what I have endured.

Social media are a paradise for people behaving like kings or high priests feeling entitled to tell everybody what they should do and shouldn't do. The worst of them fire so many comments on Twitter and Facebook that they cannot have written all this themselves, at the same time as they have a full-time job to tend to. They have an army of trolls or they are on industry payroll and publish in their own name what the drug companies have written up for them.

One of the uncrowned kings, physician David Gorski, wrote: "Holy crap @PGtzsche1, formerly of @CochraneNordic, has gone full on antivax. Here he is scheduled to speak at a workshop for the antivax doctors group with the Orwellian name Physicians for Informed Consent."

On social media, many people show their worst sides and condemn others without even knowing what the issue is about. As I had never held such a talk before, Gorski could have no idea what I had decided to talk about, or what my motives and background were. He said that I would appear with "hard core antivaxers." This primitive trick is called guilt by association: "The bottom line is that @PGtzsche1 had become an antivaccine crank and deserves to be dismissed as such."

As I had not been informed about who the other speakers were, I reminded the organiser about this omission:

"I asked to see the full programme two weeks ago but have not seen it and I cannot find it on your home page. This is urgent as I am now attacked because I come to speak at your meeting. Some people have found out who some of the other speakers are and I am accused of being an 'antivaxxer,' which has nothing to do with my scientific and ethical position."

I received the programme the same day and wrote back:

"I am terribly sorry, but I will have to cancel my participation immediately. You had not informed me about who the other speakers are, so I did not know what I bought into, but I have now investigated a little. One of the speakers does not vaccinate anyone although she is a doctor, another exonerates Wakefield. This is so totally anti-science and shocking to me that I cannot afford to present in such company. Sorry. I will pay back the advance you sent me and will bear the costs that I have had and cannot get refunded. I have used a lot of time on preparing for my talk but that is my problem, not yours. Please delete me from the programme immediately. Many thanks." The doctor who does not vaccinate is Toni Bark. She uses homeopathy. In an interview I found on the Internet, she said: "What I notice is that children who come to me from other practices where they've been fully vaccinated often are - well they are the kids in my practice with asthma, panic disorder, OCD, pandas, autism, Asperger's. My kids who've never been vaccinated in my practice, I don't see those issues. I don't have one child who was not vaccinated who also has asthma, food allergies, or Asperger's or autism, or Crohn's or ulcerative colitis - none of these chronic, either chronic inflammatory or chronic autoimmune diseases."<sup>4</sup>

Bark had written to me that I should not let people like Gorski influence my decisions. I agree but I had other concerns. In my reply, I mentioned the interview: "What you say here worries me greatly. You indicate that vaccines can cause autism, which they don't, there is no reliable evidence for this ... Wakefield's research is clearly fraudulent ... Your last sentence is like saying: I have never seen anyone die in the traffic so there cannot be any traffic accidents. This interview really scares me because your statements are seductive and lack substance. Clinical practice is hugely misleading, which is why we do RCTs [randomised clinical trials]."

Another speaker was lawyer Mary Holland who has written that, "Dr. Wakefield has joined in a long, honorable tradition of dissidents in science and human rights. The world has benefitted profoundly from other courageous dissidents in science - Galileo, who argued that the sun is the center of the universe; Semmelweis, who reasoned that doctors must wash their hands to prevent transmission of infection ..."<sup>5</sup>

People like Holland do harm by spreading false messages about the science. Andrew Wakefield and his co-workers claimed that the combined measles, mumps and rubella (MMR) vaccine can cause autism, but a series of articles in the *British Medical Journal (BMJ)* in 2011 revealed that their research is fraudulent.<sup>6-13</sup>

The truth is that rigorous research has failed to establish any link between vaccination and autism,<sup>11</sup> but this doesn't mean anything for vaccine deniers, as they cannot be reached for a rational debate. An example of their dogmatism is the website *Autism Investigated*. On 13 April 2019, under the headline "Robert F. Kennedy Jr. wants to preserve uncle JFK's vaccine program," they wrote that Kennedy appeared in a video in 2015 where he stated that he wants "policies that encourage full vaccination for all Americans." They opined that "Vaccine programs should not exist. They are deadly," and that Kennedy "surrounds himself with idiots, opportunists, and vaccine crime apologists." Interestingly, Gorski called Kennedy an antivaxxer. How can the same person be both for and against vaccines? This is not a problem for the kings on social media who hide their lack of arguments behind colourful and derogatory nouns and adjectives.

If we turn our backs on vaccine deniers by telling them they are foolish and dangerous, it might recruit even more deniers from the undecided crowd in the middle who might see conspiracies where there are none. I therefore still considered going to the meeting in California, also because the organiser had assured me that most of the attendants were paediatricians "who give vaccines every day, they just don't want parents to be COERCED into consenting for a vaccine under threat that their child won't be able to attend school." Furthermore, she encouraged me to criticise her published statements about the measles vaccine, which I shall do below.

A week before the meeting, I chaired an international scientific meeting I had arranged in Copenhagen, which was the inaugural symposium for the Institute for Scientific Freedom, of which I am the Director. People had signed up from the whole world and my supporters were very worried that my participation in the California meeting would be used against us – guilt by association - and detract attention from what the new institute was about. One of the lectures was about vaccines, held by Peter Aaby,<sup>14</sup> and some highly vocal attendees wanted so badly the discussions after the talks to focus on vaccines that I had to stop them. They seemed to be vaccine deniers wanting to propagate their false beliefs, as if they were missionaries from a religious sect.

#### Wakefield's horrendous fraud

The vaccine deniers propagate misinformation and utter nonsense on their websites and social media, which are "liked" or copied by others acting like robots, without letting any rational thought come in the way. They gloss over Wakefield's horrendous fraud pretending it never happened and say he was right about measles causing autism.

In 2016, I incidentally discovered that my portrait appeared on the front page of the website of the US *Alliance for Human Research Protection* under the heading *Honors Exemplary Professionals*. Portraits of people of good repute came and went in slow succession, and I couldn't believe it when, at the end of gallery, which was in alphabetic order, I saw a photo of Wakefield. The Alliance calls itself a "national network of lay people and professionals dedicated to advancing responsible and ethical medical research practices." Wakefield is notorious for having done the opposite. I therefore asked to have my name and photo removed.

In an email to me, the founder and president of the alliance, Vera Sharav, defended Wakefield vigorously with arguments that I found were highly unlikely to be true. I therefore contacted the award-winning investigative journalist, Brian Deer, who exposed Wakefield's fraud in the *Sunday Times* and the *BMJ*.<sup>6-13</sup> He sent me and Sharav an account of the issues and explained that she had copied and pasted from vaccine deniers' websites without investigating the issues herself. Much of what she wrote was plain wrong.

Sharav preferred to let me go and keep Wakefield on the honours list where he still is. Without implying guilt by association, I don't understand why the people in Wakefield's company didn't ask to be removed. I wrote to several of them and drew their attention to Wakefield's fraud. At least two of the honourable people cannot request to be removed because they are dead; one of them, Florence Nightingale, already in 1910. As I had never given my permission to be on Sharav's list, I felt abused. My credibility had been used to shine a good light on Wakefield.

Wakefield published his research fraud in the *Lancet* in 1998<sup>15</sup> and Deer's revelations of it are second to none. The fraud and Wakefield's subsequent public relations campaigns have been immensely harmful. Since many people deny the facts, or don't know about them, and depict Wakefield as a hero, it is crucial in a book about vaccines to provide detail about the events.<sup>6-12</sup>

Wakefield's research was rigged right from the start. He claimed he had discovered a new syndrome, which he dubbed "autistic enterocolitis" in a paper later retracted by the *American Journal of Gastroenterology*. Wakefield claimed that the live measles vaccine caused both autism and inflammatory bowel disease, which was a result he never found but badly needed to bring his secret grand business plans to fruition.

Contrary to the rules, Wakefield did not reveal his financial conflicts of interest. While he held himself out to be a dispassionate scientist, two years before the *Lancet* paper was published – and before any of the 12 children in his study were even referred to the hospital – he had been hired to attack the MMR vaccine by a lawyer, Richard Barr, who hoped to raise a class action lawsuit against the manufacturers.

Unlike expert witnesses in court cases, Wakefield had negotiated an unprecedented contract with Barr to conduct clinical and basic research. The goal was to find evidence of what the two men claimed to be a new syndrome intended to be the centrepiece of (later failed) litigation on behalf of an eventual 1,600 British families, recruited through media stories. When Deer exposed this in 2004, it led to public uproar in Britain and the longest-ever professional misconduct hearing by the UK's General Medical Council (GMC).

Barr paid Wakefield with money from the UK legal aid fund run by the government to give poor people access to justice. Wakefield charged an extraordinary amount of about \$750,000, plus

expenses, for generic work alone. In addition, he was awarded an initial £55,000 to conduct the research later submitted to *Lancet*.

The chief executive at the hospital where Wakefield worked wrote to him that a grant would be established for the purpose, given his written confirmation that there was no conflict of interest involved. However, when the *Lancet* paper was published, and the vaccine scare was launched at a televised press conference, nobody was aware that Wakefield was receiving substantial personal payments from Barr. Because of the expected panic, extra phone lines and answering machines had been installed, and a 23-minute video news release showcasing Wakefield's claims was distributed to broadcasters. In the video, Wakefield said that the MMR vaccine should be suspended in favour of the single vaccines.

Wakefield had filed a single vaccine patent eight months before the press conference arguing for a "safer" single measles shot. His incentive for launching a vaccine scare and to keep it going for as long as possible was huge. A 35-page "private and confidential" prospectus noted that the initial market for a diagnostic test based on a patent Wakefield had filed in 1995 would be litigation driven testing of patients with "autistic enterocolitis" from both the UK and the USA. The patent claimed that "Crohn's disease or ulcerative colitis may be diagnosed by detecting measles virus in bowel tissue, bowel products or body fluids." It was estimated that by year three, income from this testing could be about £3.3m rising to £28m.

Wakefield's start-up funding was part of a staggering £26m of taxpayers' money (more than \$56m at 2014 prices) eventually shared among a small group of doctors and lawyers, working under Barr's and Wakefield's direction, trying to prove that MMR caused the previously unheard-of "syndrome." It is remarkable that Wakefield had asserted the existence of such a syndrome *before* he performed the research which purportedly discovered it. Six months before the *Lancet* report, the lawyer reminded the doctor in a confidential letter: "I have mentioned to you before that the prime objective is to produce unassailable evidence in court so as to convince a court that these vaccines are dangerous."

The Barr-Wakefield deal was the foundation of the vaccine crisis throughout the world. Even as the *Lancet* paper was being prepared, behind the scenes Wakefield was negotiating extraordinary plans to exploit the public alarm with secret schemes that would line his pockets. Although Wakefield denied any such plans, confidential documents set out his proposed shot, and a network of companies intended to raise venture capital for purported inventions, including a replacement for attenuated viral vaccines, commercial testing kits and what he claimed to be a possible complete cure for autism.

Deer discovered that nearly all the 12 children had been pre-selected through MMR campaign groups, and that, at the time of their admission, most of their parents were clients and contacts of the lawyer, Barr. It is the most bizarre set-up for "research" I have ever heard about. It is like stating the verdict in a criminal case before any evidence has been collected and without even knowing what this evidence would show or if a crime had ever been committed.

The *Lancet* paper's incredible purported finding – of a sudden onset of autism within days of vaccination – was a total sham built on unverified, vague, and sometimes altered, memories and assertions of a group of unnamed parents who, unknown to the journal and its readers, were bound to blame the vaccine when they came to the hospital because that was why they had been brought there. Wakefield, a former trainee gut surgeon, denied this.

There was also widespread falsification of patient selection criteria, clinical histories, and neuropsychiatric diagnoses. In not one case in the series of 12 children could the *Lancet* paper be reconciled with National Health Service records, and in not one case could the purported diagnosis of inflammatory bowel disease be confirmed. When the results of the pathological examinations were shown to others, they said that they were overwhelmingly normal and might be

found in almost anybody's gut. The original slides were said to have been lost, which is the standard excuse when people face trouble in fraud cases: "Sorry, the termites ate my data!"

Unsurprisingly, the GMC panel ruled that key elements of the *Lancet* paper were intentionally dishonest. The authors had omitted from the paper the children's principal gastroenterological problem. Almost all had severe constipation, and standard blood tests for inflammation were normal, but this was also unreported. Some children were a cause for concern before vaccination. Some were deemed normal months afterwards. Some did not have autism.

Wakefield said he had nothing to do with the pathological findings, although the paper stated that he assessed the biopsy specimens with the pathologist and a trainee: "All tissues were assessed by three other clinical and experimental pathologists (APD, AA, AJW)"<sup>15</sup> (the *Lancet* paper can still be read, on *Lancet's* website for free; on every page is written RETRACTED in big, bold and red letters). Wakefield has since claimed that the statement is wrong – pretty curious, as he is first author of the paper and has the ultimate responsibility of ensuring that everything is correct, not least his own role.

No reputable research ethics committee would have endorsed the kind of fishing expedition Wakefield embarked on for Barr, and without that endorsement, no reputable medical journal would have published any resulting paper. Wakefield falsely reported that a gruelling five-day battery of invasive and distressing procedures performed on the kids – including anaesthesia, ileocolonoscopies, lumbar punctures, MRI brain scans, EEGs, radioactive drinks and x-rays – proposed for the lawsuit, was approved by the Royal Free's ethics committee.

Deer revealed that the ethics committee was not told the truth about the project and had given no such approval. Responding to Deer in 2004, Wakefield and his key associates, paediatricians John Walker-Smith and Simon Murch, denied this explosive discovery and issued a formal statement. But, after being confronted with the proof at the GMC hearing, they changed their story and – despite clear rules – now argued they had needed no approval.

The story was much the same for Wakefield's basic science. He had planned his business ventures against a theory of his own that the culprit for both inflammatory bowel disease and autism was persistent infection with measles virus, which, in an attenuated form, is found live as a normal part of MMR. But Deer revealed that sophisticated, unreported, molecular tests carried out in Wakefield's own laboratory had found no trace of measles in the children's guts or blood. There were also critical flaws in one apparently positive study, which involved materials supplied by Wakefield. This fraud misled thousands of families affected by autism, both in the UK and the US, ensnared for years in hopeless litigation based almost entirely on his measles theory.

Two years before Deer's revelations, the American Academy of Pediatrics summarised the consensus: "Numerous studies have refuted Andrew Wakefield's theory that MMR vaccine is linked to bowel disorders and autism ... Every aspect of Dr Wakefield's theory has been disproven." In the US, the Barr-Wakefield deal was joined by allegations marshalled by American attorneys that a mercury-based vaccine preservative, thimerosal, was also at fault (see below).

In response to Deer, Wakefield supporters have denied that he took money for research, and, amid a barrage of sometimes paid-for smears and crank abuse of Deer, lauded the doctor as a "hero." Wakefield's deceits not only triggered the resurgence of sometimes fatal or brain-damaging measles outbreaks; they also plunged countless parents into the hell of believing it was their own fault for agreeing to vaccination that a son or daughter developed autism.

Wakefield denied any conflicts of interest and claimed he never said that MMR caused autism. But documents – including patents – evidenced this, and he published a string of falsified reports to undermine the vaccine. Even when he knew that his allegations had been proven baseless, he was found promoting them from a controversial business in Austin, Texas, where – after being fired from the Royal Free in October 2001 – he held a \$280,000-a-year post, spun from his campaign.

Throughout the investigation, Wakefield refused to co-operate, filed baseless complaints and issued statements denying every aspect. He also initiated, sought to stall and then abandoned with some £1.3m (\$2m) costs, a two-year "gagging" libel lawsuit, financed by the *Medical Protection Society*, which defends doctors against their patients. In reply, Deer and Channel 4 pressed for a speedy trial, publicly accusing Wakefield of being "unremittingly evasive and dishonest." His conduct in the litigation was also damned by a High Court judge, who said that Wakefield wished to extract whatever advantage he could from the existence of the proceedings while not wishing to progress them, and that he was using the lawsuit as a weapon in his attempts to close down discussion and debate over an important public issue.

Faced with overwhelming proof of misconduct, Wakefield concocted a preposterous conspiracy theory to account for his exposure and to explain why he could not reveal what he called vaccine secrets. He also denied rigging his results. "The notion that any researcher can cook such data in any fashion that can be slipped past the medical community for his personal benefit is patent nonsense," he argued in a March 2009 statement. "Mr Deer's implications of fraud against me are claims that a trained physician and researcher of good standing had suddenly decided he was going to fake data for his own enrichment."

On 28 January 2010 – after 197 days of evidence, submissions and deliberations – a panel of three doctors and two lay members hearing the GMC case handed down verdicts which wholly vindicated Deer. Branding Wakefield "dishonest," "unethical" and "callous," they found him guilty (against a criminal standard of proof) of some three dozen charges, including four of counts of dishonesty and 12 involving the abuse of developmentally challenged children. His research was found to be dishonest and performed without ethical approval. Five days later, *Lancet* retracted the paper as "utterly false," prompting international media interest and further retractions.

Three weeks later, on 17 February 2010, Wakefield was ousted by the directors of his Texas business, and he was later erased from the UK doctors' register, ending his career in medicine.

*Lancet's* editor, Richard Horton, protected Wakefield. In 2004, after four months of investigations, Deer briefed *Lancet's* senior staff for five hours. Later the same day, he discussed the affair with Horton and five other editors. Deer had expected Horton to say that an investigation was needed to untangle the complex matters, including possible research fraud, unethical treatment of vulnerable children, and Wakefield's conflict of interest through the lawyer. But within 48 hours, and working with the paper's three senior authors, the journal produced an avalanche of denials in statements they never retracted.

Wakefield arrived at the *Lancet* before Deer left the building. All three senior authors were former Royal Free staff, as was Horton - a fellow in the late 1980s. A decade before Wakefield's publication, Horton had done research in hepatology, on the same corridor as Wakefield in gastroenterology.

"I do not regret publishing the original Wakefield paper," Horton said in a 2003 book, at the height of the UK vaccine scare. "Progress in medicine depends on the free expression of new ideas. In science, it was only this commitment to free expression that shook free the tight grip of religion on the way human beings understood their world."

Horton developed his position in March 2010, after the GMC panel's findings fully endorsed what Deer had told him:

"We asked the institution where the work was conducted - the Royal Free hospital - to complete an investigation ... They did, and they cleared Wakefield of wrongdoing." But documents, emails, and replies obtained under the Freedom of Information Act revealed no formal investigation. What emerged was merely a scramble to discredit Deer's claims during the 48 hours after he disclosed the information. The documents showed that Horton, the paper's senior authors, and the Royal Free medical school, frantically mobilised against Deer. Were it not for the GMC case, which cost a rumoured  $\pounds 6m$  (\$9m), Wakefield's fraud would likely forever have been denied and covered up.

The denial began as soon as Deer left the *Lancet* on 18 February 2004. In Horton's private office, the doctors shared their thoughts and devised a strategy. Wakefield admitted only being retained for a lawsuit and denied receiving money himself, and the paediatric gastroenterologists Walker-Smith and Murch also denied impropriety. They also denied that some children were solicited, rather than spontaneously referred, and that there was no ethical approval. In short, the accused were investigating themselves, an investigation that Horton said, "cleared Wakefield."

However, only 17 days later, on 6 March 2004, 10 of Wakefield's 11 co-authors (they were unable to get in contact with one of them), including Walker-Smith and Murch, published what they called a *Retraction of an interpretation*:<sup>16</sup>

"We wish to make it clear that in this paper no causal link was established between MMR vaccine and autism as the data were insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract the interpretation placed upon these findings in the paper, according to precedent."

It took the *Lancet* six more years, or 12 years in total, to retract the fraudulent paper. When Wakefield refused to carry out the replication research requested of him by his employers, they fired him.

In January 2011, *BMJ*'s editor-in-chief called Wakefield's research "an elaborate fraud" and accused the Royal Free medical school and *Lancet* of "institutional and editorial misconduct."<sup>11,12</sup> Although the GMC had found Wakefield guilty of some three dozen charges, the *Lancet* continued to cover up for him. The *BMJ* editors wrote about this:<sup>11</sup>

"The *Lancet* paper has of course been retracted, but for far narrower misconduct than is now apparent. The retraction statement cites the GMC's findings that the patients were not consecutively referred and the study did not have ethical approval, leaving the door open for those who want to continue to believe that the science, flawed though it always was, still stands. We hope that declaring the paper a fraud will close that door for good."

Wakefield's fraud had both immediate and long-term consequences. In England, parents refused the MMR vaccine for their children, and the vaccination rates dropped from 91% in1998 to below 80% in 2003.<sup>17</sup>

There were measles outbreaks in London, which quickly spread to Scotland and Ireland. In 2002, 100 children in Ireland were hospitalized with measles-associated bronchopneumonia or acute encephalitis, and three children died from measles encephalitis. Another child died of measles complications in England during a 2006 outbreak.

## "Vaxxed: From cover-up to catastrophe," a catastrophically bad film directed by Wakefield

Is Wakefield still around and still being harmful? Very much so. By 2009, one in five parents in the US believed that vaccines cause autism.<sup>17</sup>

In 2016, the film *Vaxxed: From cover-up to catastrophe*, was released. This is the information about the film on its homepage, vaxxedthemovie.com:

"In 2013, biologist Dr. Brian Hooker received a call from a Senior Scientist at the U.S. Centers for Disease Control and Prevention (CDC) who led the agency's 2004 study on the Measles-Mumps-Rubella (MMR) vaccine and its link to autism.

The scientist, Dr. William Thompson, confessed that the CDC had omitted crucial data in their final report that revealed a causal relationship between the MMR vaccine and autism. Over several months, Dr. Hooker records the phone calls made to him by Dr. Thompson who provides the confidential data destroyed by his colleagues at the CDC.

Dr. Hooker enlists the help of Dr. Andrew Wakefield, the British gastroenterologist falsely accused of starting the anti-vax movement when he first reported in 1998 that the MMR vaccine may cause autism. In his ongoing effort to advocate for children's health, Wakefield directs this documentary examining the evidence behind an appalling cover-up committed by the government agency charged with protecting the health of American citizens.

Interviews with pharmaceutical insiders, doctors, politicians, and parents of vaccine-injured children reveal an alarming deception that has contributed to the skyrocketing increase of autism and potentially the most catastrophic epidemic of our lifetime."

The film's two main claims are that the MMR vaccine causes autism and that the CDC committed fraud to avoid revealing that their own study had shown this. If this had been true, it would have been a good film that would have won many prizes. But as both premises are wrong, it can best be described as an anti-vaccine propaganda film.

As noted earlier, it is understandable that parents to severely autistic children who were healthy before they developed autism are looking for an explanation. Autism can be totally devastating. The most well-known symptoms are extreme difficulty coping with unexpected change to routine or the environment and narrow interests in very specific topics. The restrictive behaviours tend to distance the patients from the world around them, with very limited desire to participate in social interactions. There are also repetitive behaviours, which may consist of repetitive body movements like hand flapping, rocking, spinning, moving constantly, obsessive attachment to unusual objects like rubber bands and light switches, speaking the same phrase again and again, and great distress or difficulty with changing focus. There can be abnormal body posturing or facial expressions, abnormal tone of voice, flat or monotonous speech, avoidance of eye contact, deficits in language comprehension, and delay in learning to speak. The most severely affected patients require substantial support.

I assume that the film's producer, medical journalist Del Bigtree, believed in what he was doing, but this is no excuse, as a journalist has an obligation to be objective and impartial and to check his sources. His account on the film's homepage of why he made it is telling about the drivers of the "anti-vaxx" movement:

"... people have asked why I would choose to leave my career as a respected producer on the medical talk show, The Doctors, to make a movie with Dr. Andrew Wakefield, arguably the most controversial figure in modern medicine. The answer is I had no choice.

'Vaccines are safe.' That is the stated fact from a highly vocal subset of the medical community ... I was alerted that a senior scientist ... had confessed on the internet that he and five of his colleagues had committed fraud on their 2004 Measles, Mumps, and Rubella (MMR) vaccine study when they covered-up the fact that the vaccine was causally associated with autism.

More shocking than the accusation that a U.S. government agency was knowingly poisoning millions of its own children with a flawed vaccine was the fact that not a single mainstream newspaper, television or radio show covered the story ... If it weren't for Andrew Wakefield (whom I'll refer to as Andy), this story would have never been exposed ...

I was haunted by all of the headlines that preceded him, 'Baby Killer,' 'Father of the antivax movement,' 'The fraudulent doctor who created a fake paper linking vaccines to autism,' 'The doctor who performed unnecessary experiments on innocent children,' the list went on and on. But when Andy showed me the documentary film he was making about Dr. William Thompson, the CDC whistleblower, I was blown away. The evidence was undeniable. The CDC appeared to have lied to the world. It was the biggest story of my lifetime. As an Emmy Award-winning medical producer I knew I had the skill set to guide Andy through the challenges of making a documentary about complicated science, but before I could jump in I had to investigate Andy himself ...

I realized that I had been repeating a lot of bumper sticker slogans about his story that weren't actually true. To begin with I was shocked to discover that Andy never came out against vaccines ... More alarming was the realization that the Lancet paper in question clearly states that it does not prove a link between the MMR vaccine and autism ...

I was surprised to find that the allegations against Andy were not initiated by a medical investigator or scientific institution, but by a freelance journalist named Brian Deer who wrote a Sunday Times article for Rupert Murdoch that was as scientifically accurate as a gossip column. The General Medical Council in the U.K. then used Brian's imaginative retelling of the story behind the Lancet paper as grounds for a medical trial that ultimately stripped Andy of his medical license ... there were twelve other co-authors on the paper. The claim that Andy used fake data to create a fraudulent paper is absurd when you realize that among his co-authors were top scientists in their fields who were responsible for performing the tests, outputting the data, and ultimately verifying that it was correctly represented in the paper before signing their names to it. So why is Andy the only one of the 13 co-authors to be barred from practicing medicine? Maybe because he was the only doctor brave enough to ignore pressure from the vaccine manufacturers and the Ministry of Health to begin larger, more in depth studies investigating the hypothesis that the MMR was causing autism in our children; studies that he never got to finish.

Then there is the assertion that the Lancet study had been paid for by a biased outside source, which is easily refuted by following the paper trail that shows all financial contributions for the study were accepted by the Royal Free Hospital after the study had been completed. Lastly the most disturbing accusation for me was the claim that Andy performed unnecessary procedures on innocent children. That sounds horrible until you discover that the parents had brought their children to the hospital because their children were suffering from agonizing gastrointestinal pain and bowel issues in addition to their autism. The 'unnecessary procedures' refers to the colonoscopies and intestinal biopsies that were performed by Andy's colleagues. I don't know how a gastroenterologist is supposed to investigate possible intestinal disease without performing these standard tests, but then again, I am not a doctor. And neither is the journalist who concocted this unfortunate obstruction of medical advancement.

... people like Galileo ... are often persecuted ... In Andy's case we may be responsible for a civilization-ending epidemic of autism that has skyrocketed from 1 in 10,000 to 1 in 45 children in less than forty years. And still the CDC attempts to set our minds at ease with their official statement 'we do not know what's causing autism.'

Dr. William Thompson has come forward with physical documents and data that strongly indicate the CDC illegally manipulated the data on the MMR study. He has alleged that during the study highly significant increases in the risk of autism were found in several distinct populations and the CDC did everything from kicking children off the study to throwing data out in order to cover it up. Approximately one million children have developed autism since this fraudulent study claimed that the MMR was not responsible. Mathematicians who have plotted the increase of autism on a graph have discovered that it is a perfect exponential curve. If something is not done to stop the trend, by the year 2032 1 in 2 children born will be on the autism spectrum. This is an emergency of epic proportions.

By the time you read this there will probably be an outcry funded by the pharmaceutical industry warning people not to see this movie because it is full of lies ... They will brush the dust off the manifesto on the Wakefield fraud and send their army of bloggers to shout their sermon on every street corner of the World Wide Web ... Once you sit down in this theatre you will have

crossed the point of no return and you will find that you are in the same predicament as me. Because as Einstein said, 'Those who have the privilege to know have a duty to act.'"

If Bigtree had read Brian Deer's many revelations in the *BMJ* and the support he got from its editors and the *General Medical Council*,<sup>6-12</sup> it would seem impossible to write as he did on the film's homepage unless willful ignorance was involved. It is outrageous that Bigtree likens Deer's groundbreaking investigative work to a gossip column and says that he "concocted" this unfortunate obstruction of medical advancement.

Bigtree says it is absurd to think that top scientists used fake data to create a fraudulent paper. Being a producer on a medical talk show he should know that this has happened many times, also recently. Furthermore, it is common that top scientists lend their name to papers they know little about and that one person in a team of authors committed the fraud, often without the others' knowledge.

Bigtree talks about a civilization-ending epidemic of autism. It is of course worrying that the incidence of autism is increasing but it is nowhere near the 200-fold increase Bigtree postulates. The diagnostic criteria for autism and autism spectrum disorders have been broadened substantially over these forty years, and it is therefore impossible to claim a 200-fold increase for something that is not the same. According to the CDC, the incidence increased only 2.5 times from 2000 to 2014, and the true increase is likely much smaller because media campaigns and increased public attention also among doctors can increase psychiatric diagnoses considerably. It would be more interesting to know if there has been any increase in the most severe cases, which will always be diagnosed.

The film makes much of a prediction done by a computer scientist who says that if the current exponential growth in the number of diagnoses continues, then 80% of the boys will be autistic by 2032. Any higher bets? Why not extrapolate a few years more and arrive at 100%?

Contrary to Bigtree's prediction, the drug industry has not organised an army of bloggers to defend the vaccine. It is the vaccine deniers that have polluted the Internet.

#### The so-called CDC whistleblower was not a smoking gun

Bigtree says that Thompson found highly significant increases in the risk of autism in several distinct populations. The whole film builds on this theme, which is apparent even in its last acknowledgment: "Deepest gratitude to Dr. William Thompson. An Autism Media Channel Film 2016."

The film would collapse entirely if Thompson's claim wasn't true. And it isn't true. I searched for his so-called whistleblowing on Google but did not find anything important. No facts, only opinions by vaccine deniers, which increased my suspicion that the storytelling was wrong. On psychiatrist Kelly Brogan's website, I found this:<sup>18</sup>

"As parents around the world have known for 7 decades [sic; 70 years], and basic science has supported, **vaccines do cause autism** [sic; in bold] ... After Dr. Brian Hooker's requests through the Freedom of Information Act for original MMR study documentation, a CDC Immunization Safety Researcher, Dr. William Thompson has buckled under the pressure of his conscience and come forth as a whistleblower. These documents demonstrated a 3.4-fold increase in the incidence of autism in African American boys, expunged from the final study results in a violent act of scientific fraud ... Dr. Hooker has published the unadulterated finding here."

"Here" was a link to Hooker's study. Brogan did not mention that it had been retracted and was labelled as such!

It is difficult to understand all the fuss about the CDC study. It is not particularly interesting, but the way in which it was abused in the film is interesting. After having seen the film and read the

paper about the study, I must say that the whole edifice for the film collapsed. The study was well done. The researchers did a case-control study in Atlanta where they matched 624 children with autism to 1824 control children without autism.<sup>19</sup> The assumption for their study was that, if the MMR vaccine increases the risk of autism, which usually develops before 24 months of age, then children who are vaccinated at younger ages would have a higher risk of developing autism. They did not find this. The overall distributions of ages at first MMR vaccination were similar for case and control children (p = 0.22). The researchers analysed their data in different ways, and I find their results very convincing.

So, what did Hooker do? He got access to the study data from Thompson and went on a fishing expedition, guided by Thompson. In research, this is considered a forbidden exploration in the data when the overall result is negative. If anything is found, it is extremely likely to be spurious.

Hooker reported in 2014 that there was a relationship between MMR timing and autism incidence among African American children "exclusively found in boys," with a risk ratio (also called the relative risk) of 1.73 (95% confidence interval 1.09 to 2.77) at 24 months and 3.36 (1.50 to 7.51) at 36 months.<sup>20</sup> This research is utterly hopeless.

First, there cannot be risk ratios in a case-control study, only odds ratios, which is also what the CDC had reported on.<sup>19</sup>

Second, black boys are a subgroup of a subgroup, which is fishing to the extreme.

Third, the confidence intervals are wide, and the lower limit is close to one. One means that there is no relation between time of vaccination and development of autism. A 95% confidence interval of 1.09 to 2.77 means that we are 95% certain that the true odds ratio is between 1.09 to 2.77.

Fourth, case-control studies are fraught with bias, which is why many respected epidemiologists have stated that, because of how easy it is to be fooled, anything less than stunning results are almost impossible to believe.<sup>21</sup> Some of them do not consider an increase in an odds ratio persuasive unless the lower end of the confidence interval is at least 3, which was not the case here.

Fifth, in science, one study cannot stand alone as if it were the only documentation in the universe. There are usually other studies, and in this case, some of these are much stronger. The CDC researchers refer in their discussion to six observational studies that failed to find an association between MMR vaccination and autism and consider a cohort study from Denmark particularly persuasive.<sup>22</sup> I agree and shall discuss it in the next section. If we want to find out if vaccination causes autism, the strongest research design is not to look at children who, with very few exceptions, all got vaccinated, as the CDC did, but to compare vaccinated with unvaccinated children and follow them up, which the Danish study did.

Although Bigtree and Wakefield were familiar with the CDC study and appear extensively in the film, none of them mention that much stronger studies failed to find a relation between the vaccine and autism. This is characteristic for the film, which is extremely one-sided. Its mission is to vindicate Wakefield and to tell the world how dangerous the MMR vaccine is. It is not a documentary but sheer propaganda, which is best forgotten.

Hooker's study should also be forgotten, which quickly dawned on the editors. Only one month after publication, they retracted it, which cannot be ignored by anyone who reads it because "Retracted" is written across the abstract with big letters, and there is also a link to a note mentioning the retraction below Hooker's name:<sup>20</sup>

"The Editor and Publisher regretfully retract the article as there were undeclared competing interests on the part of the author which compromised the peer review process. Furthermore, postpublication peer review raised concerns about the validity of the methods and statistical analysis, therefore the Editors no longer have confidence in the soundness of the findings. We apologise to all affected parties for the inconvenience caused."

The film did not mention that Hooker's study has been retracted. If it had, there wouldn't have been a story to tell. Instead, the film blew Hooker's findings out of proportion, which is like raising your voice if you are short of arguments. Hooker said that the risk for African Americans to get a diagnosis of autism after vaccination was "astronomical" and highly statistically significant and that it was 8 on the Richter scale for earthquakes. No understatements here.

I tried my best to follow the arguments in the film that led to the conclusion that the CDC researchers had committed fraud but there were no sound arguments. *VAXXED* asked: Did the CDC commit fraud? The film tries to convince the viewers that it did, with four so-called exhibits, like in a court case: deviation from the analysis plan; omission of data; destruction of documents; and obstruction of justice. Let's take these claims one by one.

Wakefield said that the researchers deviated from their analysis plan when confronted with the risk in African Americans, and he also criticised that they used data on race not from the school records but from the birth certificates, which only half of the children had because the others were born in another state. The researchers reported that this allowed them to obtain additional information, such as birth weight and gestational age and the mother's parity, age, race, and education.<sup>19</sup>

Were data omitted and was this a problem? No. The film tuned in on the age groups, and there was a table, apparently from Thompson's internal report, that showed results for six rather narrow age groups separately whereas the published paper operated with three age groups. I cannot see that this would make any difference to the results and the three chosen age groups in the paper were highly reasonable, given the study's hypothesis. Researchers collapse groups all the time for clarity. The film showed what was called handwritten notes by Coleen Boyle from the CDC, something about reformatting and collapsing 19-23 with 24-35 months. Wakefield said that she tried new age groups, 0-11, 12-18, and 19-36 months, but that this failed, so in the end they dismissed the data altogether. Wakefield's criticism is inappropriate. The researchers showed their results using these age groups and explained why: <18 month was an indicator of "on-time" vaccination according to the recommended vaccination schedule; <24 months was the age range by which autistic characteristics must have developed to meet DSM-IV criteria for autism.

Were documents destroyed? According to Hooker they were, because they showed a very strong statistically significant effect, and only Thompson retained them and gave them to Hooker who filed an apparently groundless complaint with the *Office of Research Integrity*. According to the film, all other people than Thompson denied that there was a meeting where the documents were destroyed, and they called him a liar.

Thomson was scheduled to present the results of the CDC study and he announced that he would say there was a causal association. The first author of the report, DeStefano,<sup>19</sup> took over and, according to the film, he reported falsely to the Institute of Medicine that there was no association. I must say I have sympathy with the CDC decision not to let Thompson present the results, as the study did not find any causal association. It even seems that Thompson accepted this conclusion because he co-authored the CDC paper.<sup>19</sup>

More than a decade later, Thompson delivered all the documents to Republican congressman Bill Posey who commented on them in congress on 29 July 2015. He recommended a thorough investigation be carried out and asked congress to subpoena Thompson because he might face jail if he spoke up without being subpoenaed. Wakefield lamented that, seven months later, congress had done nothing. I fully understand why. There is nothing to be found.

Was there obstruction of justice? No. The film claimed that the CDC's fraudulent study had been used to deny the claims that children got autism from the vaccine. But there is no basis for such claims.

The film is highly manipulative in a multitude of other ways. A young boy had been instructed to say that isolated autism is a big problem because all healthy children are at risk. Using the same logic, flying is a big problem because we are all at risk for going down with the plane. He says that his sister is 18 months old, supposed to get the MMR vaccine, and that it is seven times more likely she will get autism than if the parents wait till she has become three years old. Bigtree refers to the CDC data as evidence for "up to seven times" increased risk. But the children were white, not African American! And the confidence intervals were so wide that Bigtree might as well have said "down to almost no increased risk."<sup>20</sup> As a child, I once won a prize worth 200 DKK for a photo I took with the shutter speed at 1/250 second. So, I could say: "Already as a child, I earned a lot of money, up to 180 million Danish crowns per hour." I could also say that I earned down to 2 crowns per hour by picking strawberries.

The film shows many heart-breaking interviews with parents who believe that vaccines made their child autistic, interspersed with home video footage of their low functioning autistic children contrasted with earlier videos showing the same children looking happy and normal before the vaccination. At times, the parents tear up as they tell their story, which is a plea to make viewers believe the anecdotal evidence over the science.<sup>23</sup> I am not against using strongly emotive film sequences to convince people that they need to act, but only if the premises are correct, which they are not in this case.

The film's characters are carefully selected to compose the false narrative. Luc Montagnier won the Nobel Prize for discovery of the virus that causes AIDS, and the film shows bits of the ceremony in Stockholm. In the film, Montagnier supports the autism theory, mentions that autism is more prominent in African Americans and says that, "this fraud, of course, ranks very high."

A specialist in autism, Doreen Granpeesheh, talks about its causes and mentions a so-called inability to detoxify what you are supposed to detoxify (which is a language normally only used by quacks). The poisons come from vaccines, from GMO products (I don't think there are any toxic problems with these), and the pesticides in our food (no relation to autism has ever been documented). Worst of all, she compares the 2014 Disneyland outbreak with 644 cases of measles with the number of autism cases, listed as 1,082,353.

The parents in the film are also carefully selected. Polly Tommey has an autistic son whose autism she blames on the MMR. She is the editor of the *Autism File Magazine*, which peddles anti-vaccine pseudoscience and quack treatments for autism,<sup>23</sup> and she describes her mother as a "homeopathic hippie." She has worked closely with Wakefield on the *Autism Media Channel*.

I have observed that many people who are against vaccines are wedded to alternative medicine, even though none of it works.<sup>24</sup> If it did, doctors would no longer call it alternative medicine but simply use it.

Much of the movie features Wakefield repeating the same lies he's been repeating for two decades about how he came to want to investigate vaccines and autism, with no mention of his acceptance of large sums of money from a barrister looking to sue vaccine manufacturers. He sends the clear message that the "CDC whistleblower" vindicates him and recounts how he recommended the monovalent measles vaccine instead of the trivalent MMR, neglecting to mention his patent on this vaccine.

The movie doesn't mention Brian Deer whose articles left Wakefield stark naked, as in the Emperor's New Clothes.

Wakefield directed the film and says about this:

"For the last 20 years I have had to watch the suffering of those affected by autism as the problem multiplies year on year. What started with hope for a new understanding, new and effective treatments, and even prevention, turned to despair as special interests exploited their influence over the media to crush the science and the scientists." Quite a remark considering that the special interests that distorted the whole thing were his own. And he continues:

"And then, two decades and a million damaged children later, one man, Dr. William Thompson – a CDC insider – decided to tell the truth and the embers of that early hope glow once more. Several years ago, I decided that to take on the media you had to become the media. The best medium for this story is film. Our aim with this movie was to take this complex, high-level fraud and to give it context, and weave through it the tragic street-level narratives of ordinary families affected by autism. This film brings to the public a dark and uncomfortable truth. To ignore it would be most unwise."

Wakefield doesn't see the irony. The complex, high-level fraud is his own, and the film brings to the public not a dark and uncomfortable truth but a dark and uncomfortable lie.

The film was withdrawn from New York's 2016 Tribeca Film Festival after a public outcry.<sup>23</sup> Festival co-founder Robert de Niro, who has a child with autism, had bypassed the selection process in order to get *VAXXED* a showing there. He needed to reverse his decision, which Wakefield called an act of censorship.

In 2018, the *Guardian* noted that Wakefield, under the anti-establishment presidency of Donald Trump, had become a leading light in the US and frighteningly influential worldwide.<sup>25</sup> Wakefield and his supporters insist mainstream science is wrong and will not be persuaded otherwise. The conspiracy theories of the anti-vax movement, which *Vaxxed* exemplifies, are all over the Internet, and the apparent acceptance of Wakefield into the upper echelons of American society can only boost them further.

This reminds me of a famous Danish businessman who said it doesn't matter if you get bad press; it is better than no press.

Wakefield is the prime reason why many parents refuse having their children vaccinated spawning every kind of concern, not only about MMR, but over vaccinations in general, which have had disastrous consequences for some of them.

In America, a ferocious anti-vaccine movement took off after Wakefield toured US autism conferences and after he, in November 2000, had appeared on the CBS network's 60 Minutes programme linking MMR with what he called an epidemic of autism. This was followed by campaigners' claims that all vaccines are suspect.

Wakefield's false claims provide a foundation for continued fundraising from parents of autistic children, many of whom have been led to believe that Wakefield is their champion.

## Alliance for Human Research Protection calls Wakefield a hero

In 2016, when I asked to have my name removed from the Alliance's website, the bio for Wakefield was of 2 pages. When I checked it in 2019, it was of 12 pages. In both versions, Wakefield is quoted for saying:

"I was not responsible for their clinical care - that was performed by an outstanding group of gastroenterologists who confirmed, beyond a shadow of a doubt, that these children have an inflammatory bowel disease and that has now been replicated around the world."

None of Wakefield's 12 children in the *Lancet* paper had inflammatory bowel disease, and it has not been replicated. The bio is full of other grave errors, derogatory comments, colourful

adjectives and conspiracy postulates, typical for vaccine deniers. It is also a smear campaign against Brian Deer, and it sanctifies Wakefield.

Wakefield's "notoriety" (sic, in inverted commas) is said to have been generated by a relentless series of sensationalist articles and re-ignited by the editor-in-chief of the *BMJ*: "The *BMJ* embarked on a smear campaign calculated to cause the greatest damage to Dr. Wakefield." I wonder how Vera Sharav, the President of the Alliance, can know what motives people have?

In the most recent version of Wakefield's bio, this sentence had been removed: "A concerted effort has been to divert attention from regulatory failure to protect children. Instead, mainstream media has followed Brian Deer's attack dog tactics and conducted a relentless crusade to destroy Dr. Wakefield's reputation and character." Wakefield destroyed himself by his dishonesty; no conspiracy (concerted effort), crusade or dog fight was needed for this.

This is also not true: "The parents of the children in the *Lancet* study sought Dr. Wakefield's help for their children, based on his previous publications." Sharav does not mention anything about Wakefield's involvement with the planned litigation being the incentive for fishing for these parents.

"The case against Andrew Wakefield is driven by corporations whose financial interests collide with independent medical investigations that identify troublesome safety issues." It wasn't. It was one courageous man's work: Brian Deer. In 2011, Deer was named specialist journalist of the year in the British newspaper industry's annual Pulitzer-style press awards. Judges for the Society of Editors praised his "outstanding perseverance, stamina and revelation on a story of major importance."

Sharav writes about a culture of intimidation, which the pharmaceutical industry has subjected Wakefield to, but the drug industry had nothing to do with Wakefield's self-inflicted demise, and the intimidation was the other way around. Wakefield launched frivolous lawsuits against Deer. Sharav says nothing about this and we are supposed to pity the villain: "Wakefield has been vilified and subjected to false accusations orchestrated by the interconnected shadows who control the dissemination of medical information. They were determined to destroy his reputation, his credibility, his professional integrity and his career."

Wakefield's assertion about the measles vaccine being the cause of his new syndrome, autistic enterocolitis, has never been replicated by others but Sharav writes: "Read our compilation of 'Scientific reports validate "controversial" findings reported in The Lancet'."

Sharav mentions that Thomas Verstraeten assessed the risk of thimerosal, the mercury preservative in some vaccines, using a large US database, and found that exposure to thimerosal during the first month of life increased the relative risk of autism by 7.6%. She misrepresents an abstract from 1999 that noted that the risk ratio was 7.6 (1.8 to 31.5).<sup>26</sup> Thus, the risk was increased 7.6 times, which is far more than 7.6%, but the result is highly uncertain, as indicated by the wide confidence interval. Furthermore, register studies are bias prone, and results published only in abstracts are often misleading. I could not find any publication of Verstraeten's study, but he published another large database study in 2003.<sup>27</sup> In this study, the positive findings were so small that they should be ignored. There was an increased risk of tics, risk ratio 1.89 (1.05 to 3.38) and language delay, risk ratio 1.13 (1.01 to 1.27). None of the analyses found significantly increased risks for autism or attention-deficit disorder. Verstraeten concluded that no consistent associations were found between thimerosal-containing vaccines and neurodevelopmental outcomes.

Sharav does not mention this study but three studies<sup>22,28,29</sup> that did not find any link between thimerosal-containing vaccines and autism. She dismisses them with the claim that others have shown that these influential studies are fraudulent. If claiming that important studies are fraudulent, one must always give the references, but Sharav keeps her readers in total darkness.

The three studies were published in prestigious journals: *New England Journal of Medicine*,<sup>22</sup> *Pediatrics*,<sup>28</sup> and *Journal of the American Medical Association (JAMA)*.<sup>29</sup> All were from Denmark. We are world famous for our meticulous register studies and we have some of the best registers in the world. All three studies are highly convincing and as they are very large, it is not likely they overlooked anything.

In the first study, from 2002, 82% of 537,303 children in the cohort had received the MMR vaccine.<sup>22</sup> The authors identified 316 children with autism and 422 with autism spectrum disorders. After adjustment for potential confounders, the risk ratio for autism among vaccinated children, as compared with the unvaccinated ones, was 0.92 (0.68 to 1.24), and the risk ratio for autistic spectrum disorder was 0.83 (0.65 to 1.07). There was no association between the age at time of vaccination, the time since vaccination, or the date of vaccination and the development of autistic disorder. The authors concluded that their study provides strong evidence against the hypothesis that MMR vaccination causes autism. I agree. It is a very strong study, which the CDC researchers also concluded, much stronger than their own study,<sup>19</sup> and yet Del Bigtree and Andrew Wakefield made a whole film about the CDC study and ignored the Danish one!

The second study included 956 children diagnosed with autism during 1971–2000.<sup>28</sup> There was no increase in the incidence of autism during the period when thimerosal was used in Denmark, till 1990. From 1991, the incidence increased, but also among children born *after* the discontinuation of thimerosal.

In the third study, of a cohort of 467,450 children, the researchers compared those vaccinated with a thimerosal-containing vaccine with those vaccinated with another formulation of the same vaccine.<sup>29</sup> There were 440 autism cases and 787 cases of other autism spectrum disorders. The risk was similar for the two groups, risk ratio 0.85 (0.60 to 1.20) for autism and 1.12 (0.88 to 1.43) for other autism spectrum disorders. Furthermore, there was no dose-response relationship: The increase in risk ratio per 25  $\mu$ g of ethylmercury was non-existing, namely 0.98 (0.90 to 1.06) for autism and 1.03 (0.98 for 1.09) for other autism spectrum disorders.

Sharav does not say a word about these three highly convincing studies apart from postulating with no evidence that they are fraudulent. Instead, she tells us Dr. Wakefield has harmed no child whereas the medical journals and the media turn a blind eye to the catastrophic harms that hundreds of thousands of children and their families experience.

Sharav briefly mentions William Thompson's "whistleblowing" and says that the data concealed a fourfold increased rate of autism in black baby boys. Sharav goes on and on like this. The GMC process against Wakefield she calls a "kangaroo court," and her views are that the case was concocted, that he had no conflicts of interest, and that he is an honest scientist.

Deer's ground-breaking research she calls "flame-throwing style of irresponsible journalism" and BMJ's editorial<sup>11</sup> is "defamatory." But facts cannot be defamatory. It is a fact that Wakefield falsified the data.

Sharav writes that the British High Court overturned the GMC panel's verdict and exonerated one of Wakefield's co-authors, John Walker-Smith, who had appealed the GMC's action. Wakefield apologists abuse this verdict to also exonerate Wakefield, but the judgment had nothing to do with him. According to Deer, Walker-Smith and Wakefield were both financially supported by the *Medical Protection Society* that had agreed to Walker-Smith appealing, but rejected Wakefield, on advice from his own legal team. Had he appealed, the GMC would have reconvened the panel and struck him off again from the licence to practice register. That was their right, and they could have done it to Walker-Smith, but didn't, because he was about 73 and to prolong the nightmare Wakefield had put him through might have seriously impacted on his health.

Sharav claims that the High Court decision invalidates the GMC process and its charge of fraud against Wakefield and that there was no fraud in the *Lancet* study. It is unbelievable how

manipulative she is. In her letter to me, she wrote that the GMC proceedings had been discredited. They have not. They are valid and all the material was gathered by the GMC's own lawyers.

Sharav writes that *BMJ*'s accusation of fraud was itself a fabrication and that the mudslinging would never stand up in a court of law. Of course, it would, and the *BMJ* editors asserted that there was clear evidence of falsification.<sup>11</sup>

Sharav asserts that others have replicated Wakefield's findings. She offers a hyperlink that doesn't work, and I couldn't find the material in a Google search, so I assume it has been removed, if it ever existed. *BMJ* and I are not aware of any confirmatory studies. Apart from this, there will always be many highly flawed papers that purport to have shown something that supports popular beliefs, so it is not a matter of whether some odd papers like the retracted study by Hooker exists, it is a matter of whether there is any *reliable* research. The hypothesis about the measles vaccine causing autism should be relegated to the graveyard of discredited medical hypotheses, if there is any room left.

Sharav ends her sanctification of Wakefield with an amusing remark: "Even a cursory examination of the scientific reports validating Dr. Wakefield's controversial findings, convinces us of the scientific integrity of the much disparaged article. We have, therefore, concluded that Dr. Andrew Wakefield is indeed a hero for his courageous stand."

A cursory examination cannot validate Wakefield's findings unless it is done with the eyes closed. The vaccine deniers ignore the indisputable scientific evidence that Wakefield's research is fraudulent<sup>6-13</sup> and depict Wakefield as being the victim of a societal conspiracy that forced him to leave England and go to the United States. I say indisputable because it is indisputable. It is very rare that anything is indisputable in science but in this case it is. The evidence of fraud is so stunning in every detail of it that it cannot be questioned.

Wakefield's so-called bio has no authors. I supposed it was written by Sharav even though it says that "we" concluded Wakefield is a hero. I asked Sharav and the Board of Directors about it, and it turned out that only Sharav has concluded Wakefield is a hero.

#### Public statements by Physicians for Informed Consent (PIC)

Shira Miller, a physician, founded this organisation in 2015, after the mandatory vaccination law (SB277) for school attendance passed in California. It is an educational, non-profit organisation whose mission is to safeguard informed consent (and informed refusal) in vaccination. Miller wrote to me that the volunteer leadership of PIC is comprised of physicians, scientists, and attorneys, and that their membership includes thousands of patients, the general public and a coalition of over 100 international organisations. As already noted, when she invited me to speak at her meeting in March 2019, she encouraged me to criticise what she had written about measles, which I shall do now.

Miller wrote in  $BMJ^{30}$  that "our organization has found that it has not been proven that the MMR vaccine results in less death or permanent disability than what is expected from measles."<sup>31</sup> She argued that the risk of dying or suffering permanent injury from measles in the United States was very small, even before the measles vaccine was introduced in 1963, and that the risk of dying from measles before vaccination was only 1 in 10,000 or 0.01%.<sup>32</sup> She asserted that the official risk of 1 in 1,000, e.g. from the CDC, is that high because only 10% of measles cases are reported.

Miller quoted a large Danish study that reported 1.56 MMR-related febrile seizure cases per 1,000 vaccinated children aged 15 to 17 months within 2 weeks of the vaccination.<sup>33</sup> The researchers described this risk difference to unvaccinated children as small. It was also transient (after 2 weeks the risk was even a little lower in the vaccinated than in the unvaccinated group). Some perspective is clearly needed. Although 82% of the children were vaccinated, only 5% (973) of the seizures occurred within 2 weeks of the vaccination. Thus, instead of 973, there would have

been 624 seizures without vaccination (973/1.56). This means that only 2% (349/17,986) of the febrile seizures were caused by vaccination, and this did not lead to more cases of epilepsy. It is therefore a trivial harm, particularly if compared to the beneficial effects of the vaccine on mortality and morbidity.

Miller wrote that the risk of febrile seizures after MMR vaccination, 1 in 640,<sup>33</sup> is five-fold higher than the risk from measles, but the data she compared are not comparable. First, the Danish registries are far more complete than US registries, and the data she used for the comparison came from the CDC,<sup>34</sup> which she had just criticised for 90% underreporting. Second, Miller's estimate is indirect and highly uncertain. She argued that measles surveillance had shown 3 to 3.5 times more measles seizures than measles deaths,<sup>34</sup> and she then used her own low measles case-fatality rate of 1 in 10,000 to calculate a seizure rate from measles of 1 in 3,100. Third, seizure risk after vaccination should not be compared to seizure risk after measles. What should be compared is total mortality and morbidity (not only including seizures but also, for example, permanent brain damage), and if this is done, there is no doubt that vaccination wins by far, and that the difference in seizures is trivial.

PIC's information leaflet about the MMR vaccine is also problematic.<sup>31</sup> Miller quotes CDC when saying that serious allergic reactions occur once per one million doses. "However, other severe side effects include deafness, long-term seizures, coma, lowered consciousness, permanent brain damage, and death. While the CDC states that these side effects are rare, the precise numbers are unknown." Such information is seriously misleading and looks like a scare campaign. As MMR is an attenuated live virus vaccine, it may cause similar problems as infections with measles, mumps and rubella, but the infections are far worse than the vaccines. Millions of people would die and many more would be harmed if we did not vaccinate.

"Additionally, the manufacturer's package insert states, 'M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility." This is also seriously misleading. What about the potential for the infections to cause such harms? For example, rubella may cause miscarriage, preterm birth, or stillbirth, as well as a variety of birth defects, but Miller says nothing about such issues.

A figure in the leaflet shows that the risk of permanent injury from the MMR vaccine is 4 times higher than the risk of dying from measles in the United States.<sup>31</sup> However, it is obscure how Miller derived the risk of permanent injury, 4 in 10,000, or what the injury is. This risk is unbelievably high. It is 32 times larger than Miller's estimate for permanent injury after measles in the same leaflet, 1 in 80,000, which cannot be correct. Miller quotes another of her leaflets for this low disease risk, and it turns out that injury means permanent disability from measles encephalitis, i.e. brain damage. Well, according to Miller herself, 1 in 10,000 die due to measles (in reality, it is at least 10 in 10,000 that die, see below). Is it not "permanent disability" to be dead, which should therefore have been included?

Miller's estimates are invalid, and she compares apples and oranges. The worst blunder is that the reason that so few people die is that almost the whole population is vaccinated!

Miller criticises one of the large Danish studies, the one from *New England Journal of Medicine*,<sup>22</sup> but her discussion of this study is uninterpretable. She notes that there was a difference between the data adjusted for confounders (reported in the paper) and the raw data (which were not reported). She did not explain where she got the raw data from and what they showed, and it escapes me how she could claim that the study did not rule out the possibility that the MMR vaccine increases the risk of an adverse event that leads to permanent injury by up to 77%. She might equally well have said that the study did not rule out the possibility that the vaccine decreased the risk of an adverse event by some amount. In fact, the vaccine *does* decrease the risk of

permanently injury quite substantially. But vaccine deniers are not interested in the truth. When they see it, they distort it beyond recognition.

#### Why are measles vaccines important?

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.<sup>3</sup> Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths. Before the vaccine was introduced in 1963, major epidemics occurred causing an estimated 2.6 million deaths each year. The most serious complications to measles include blindness, encephalitis (an infection that causes brain swelling), severe diarrhoea and dehydration, ear infections, and severe respiratory infections such as bacterial pneumonia.

The WHO did not mention that the vaccine also protects against the increased risk of dying from other infections. A study in *Science* from 2015 reported that the risk of dying from other infections after a measles infection is increased during the next 2-3 years.<sup>35</sup> The authors explained that this is because measles cause immunosuppression, likely via depletion of B and T lymphocytes. However, it seems that the investigators cherry-picked their data<sup>36</sup> and at any rate, their hypothesis cannot explain Aaby's finding that vaccination against measles decreases total mortality much more than predicted by its specific effect against measles even in settings where no one got measles.<sup>37</sup> Thus, it seems likely that the measles vaccine has beneficial immune training effects and measles itself may also have such effects. The investigators confirmed Aaby's finding that the nonspecific benefits of vaccination are stronger in females than in males.

It is important to avoid getting infected because there are no antiviral treatments for measles. The WHO recommends that all children with measles should receive two doses of vitamin A, given 24 hours apart, to prevent blindness and other eye damage and because it reduces the number of deaths from measles by 50%.<sup>3</sup>

Is this correct? A Google search on *vitamin A Cochrane measles* finds the relevant Cochrane review:<sup>38</sup>

After a single dose, there was no significant reduction in mortality in the vitamin A group, risk ratio 0.70 (0.42 to 1.15). However, two doses of vitamin A (200,000 international units on consecutive days) reduced the mortality in children aged less than two years, risk ratio 0.21 (0.07 to 0.66).

We should always check the evidence behind official recommendations. Although I do not doubt that measles vaccines save millions of lives, I asked the WHO what their evidence was for the numbers of lives saved.<sup>3</sup> It was not easy to find out whom to contact because the report had no authors. On WHO's website where I found the report, I went from *Who we are* to *Contact us* that displayed an envelope, which usually means that one can submit questions via this route, but the link was dead. I was unable to find an email address I could use. There was a phone number, but I don't use the phone when I have questions about science; I need a written reply. In such situations, I often use the media option. There was something called *For general inquiries* but it sent me back to the page I came from, with the phone number!

I was about to give up when I found an email to be used if the matter is urgent: mediainquiries@who.int. So, I needed to pretend I was a journalist and that my matter was urgent. This is a common problem with big organisations. It is usually impossible to write to a drug company's headquarters. There is no email address anywhere. Some organisations seem not to want to be contacted by anyone. In my email, I suggested that WHO linked to the evidence, which is needed if the WHO wanted to be an evidence-based organisation, so that researchers can check it. "Can you please send my suggestion to the relevant office, copying me, so that I can see the email address?"

I didn't get a reply from the WHO's press office, so I sent a reminder, which didn't help either.

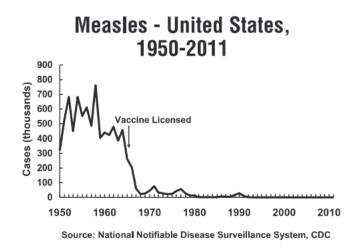
It is easy to look up the relevant Cochrane review of the MMR vaccine by googling *measles Cochrane*.<sup>39</sup> The authors included five randomised trials, one controlled clinical trial, 27 cohort studies, 17 case-control studies, five time-series trials, one case cross-over trial, two ecological studies, and six self-controlled case series studies, involving a total of about 15 million people.

One MMR vaccine dose reduced the risk of measles by 95% and the risk of secondary cases among household contacts by 92%. The risk of febrile seizures was slightly increased in one large cohort study involving half a million children, risk ratio 1.10 (1.05 to 1.15) and somewhat more in other studies, relative incidence 4.09 (3.10 to 5.33) and 5.68 (2.31 to 13.97). The risk of thrombocytopenic purpura was increased in a case-control study, odds ratio 6.3 (1.3 to 30.1).

No relation was found between the MMR vaccine and autism, asthma, leukaemia, hay fever, type 1 diabetes, gait disturbance, Crohn's disease, demyelinating diseases, bacterial or viral infections. The authors concluded that the design and reporting of safety outcomes were largely inadequate.

People who are concerned about the rising rates of autism and think it is caused by vaccines are barking up the wrong tree. If autism is caused by some external factor, it would be far more relevant to investigate the effect of brain active substances like depression pills when given to pregnant women or to pregnant experimental animals.

There were no data on deaths in the studies in the Cochrane review. However, when the vaccine is highly effective in preventing measles, it would be expected to be also highly effective in reducing mortality. Observational data on measles incidence and mortality are very convincing, and I show below a graph from the CDC, which is slightly inaccurate; the introduction of the vaccine occurred in 1963, a little earlier than the arrow shows:<sup>34</sup>



Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.<sup>40</sup> There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990.

In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.<sup>41</sup> In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.<sup>42</sup>

It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.<sup>43</sup> The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20<sup>th</sup> century, the mortality was 11% among the poorest and 0.6% among the richest.

An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.<sup>44</sup> Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.<sup>34</sup>

## References

1 Aaby P. Malnourished or overinfected. An analysis of the determinants of acute measles mortality. Dan Med Bull 1989;36:93-113.

2 Aaby P. Severe measles in Copenhagen, 1915-1925. Rev Infect Dis 1988;10:452-6.

3 World Health Organization. Measles. 2018; 29 Nov. https://www.who.int/en/news-room/fact-sheets/detail/measles.

4 Dachel A. AofA Q&A: Dr. Toni Bark Illinois MD on pediatric health and vaccination status. 2014; 3 Nov. https://www.ageofautism.com/2014/11/aofa-qa-dr-toni-bark-illinois-md-on-pediatric-health-and-vaccination-status.html.

5 Holland M. Who is Dr. Andrew Wakefield? Chapter 28. http://vaxxedthemovie.com/wp-content/uploads/2016/04/Who-is-Dr.-Andrew-Wakefield-by-Mary-Holland-JD.pdf.

6 Deer B. How the case against the MMR vaccine was fixed. BMJ 2011;342:c5347.

7 Deer B. Secrets of the MMR scare. The Lancet's two days to bury bad news. BMJ 2011;342:c7001.

8 Deer B. Secrets of the MMR scare . How the vaccine crisis was meant to make money. BMJ 2011;342:c5258.

9 Deer B. More secrets of the MMR scare. Who saw the "histological findings"? BMJ 2011;343:d7892.

10 Deer B. Pathology reports solve "new bowel disease" riddle. BMJ 2011;343:d6823.

11 Godlee F, Smith J, Marcovitch H. Wakefield's article linking MMR vaccine and autism was fraudulent. BMJ 2011;342:c7452.

12 Godlee F. Institutional and editorial misconduct in the MMR scare. BMJ 2011;342:d378.

13 Deer B. Andrew Wakefield concocts a conspiracy. Undated. http://briandeer.com/solved/tall-story.htm.

14 https://www.scientificfreedom.dk/. There is a link on the front page to presentations at the symposium 9 March 2019.

15 Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998;351:637-41.

16 Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. Lancet 2004;363:750.

17 Flaherty DK. The vaccine-autism connection: a public health crisis caused by unethical medical practices and fraudulent science. Ann Pharmacother 2011;45:1302-4.

18 Brogan K. CDC: You're fired. Autism coverup exposed. Undated; the first comment is from 2014. https://kellybroganmd.com/cdc-youre-fired-autism-coverup-exposed/.

19 DeStefano F, Bhasin TK, Thompson WW, et al. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. Pediatrics 2004;113:259-66.

20 Hooker BS. Measles-mumps-rubella vaccination timing and autism among young African American boys: a reanalysis of CDC data. Transl Neurodegener 2014;3:16. RETRACTED.

21 Taubes G. Epidemiology faces its limits. Science 1995;269:164–9.

22 Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med 2002;347:1477-82.

23 Orac. Vaxxed: From cover-up to catastrophe. 2016; 18 July. https://respectfulinsolence.com/2016/07/18/in-which-andrew-wakefield-and-del-bigtrees-antivaccine-documentary-vaxxed-is-reviewed-with-insolence/.

24 Gøtzsche PC. Survival in an overmedicated world: look up the evidence yourself. Copenhagen: People's Press; 2019.

25 Boseley S. How disgraced anti-vaxxer Andrew Wakefield was embraced by Trump's America. The Guardian 2018; 18 July.

26 Verstraeten T, Davis RL, DeStefano F. Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life. Abstract at EIS Conference; 1999.

27 Verstraeten T, Davis RL, DeStefano F, et al. Safety of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases. Pediatrics 2003;112:1039-48.

28 Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics 2003;112:604-6.

29 Hviid A, Stellfeld M, Wohlfahrt J, et al. Association between thimerosal-containing vaccine and autism. JAMA 2003;290:1763-6.

30 Miller S. Re: The unofficial vaccine educators: are CDC funded non-profits sufficiently independent? 2017; 18 Nov. https://www.bmj.com/content/359/bmj.j5104/rr-13.

31 Physicians for Informed Consent. Measles – Vaccine Risk Statement (VRS). Oct 2017. https://www.physiciansforinformedconsent.org/measles/vrs. 32 Physicians for Informed Consent. Measles – Disease Information Statement (DIS). Oct 2017. https://www.physiciansforinformedconsent.org/measles/dis.

33 Vestergaard M, Hviid A, Madsen KM, et al. MMR vaccination and febrile seizures: evaluation of susceptible subgroups and long-term prognosis. JAMA 2004;292:351-357.

34 CDC. Measles. Undated. https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html.

35 Mina MJ, Metcalf CJ, de Swart RL, et al. Long-term measles-induced immunomodulation increases overall childhood infectious disease mortality. Science 2015;348:694-9.

36 Aaby P, Benn CS. Developing the concept of beneficial nonspecific effect of live vaccines with epidemiological studies. Clin Microbiol Infect 2019;25:1459-67.

37 Benn CS, Fisker AB, Rieckmann A, et al. How to evaluate potential non-specific effects of vaccines: The quest for randomized trials or time for triangulation? Expert Rev Vaccines 2018;17:411-20.
38 Huiming Y, Chaomin W, Meng M. Vitamin A for treating measles in children. Cochrane Database Syst Rev 2005;(4):CD001479.

39 Demicheli V, Rivetti A, Debalini MG, et al. Vaccines for measles, mumps and rubella in children. Cochrane Database Syst Rev 2012;(2):CD004407.

40 Atkinson WL, Orenstein WA, Krugman S. The resurgence of measles in the United States, 1989-1990. Annu Rev Med 1992;43:451-63.

41 Centers for Disease Control and Prevention. Complications of measles. 2019; 5 Feb. https://www.cdc.gov/measles/about/complications.html.

42 Tanne JH. Measles: two US outbreaks are blamed on low vaccination rates. BMJ 2019;364:I312.

43 Larsen K. Den desperate kamp mod mæslinger. Ugeskr Læger 2019; 14 March.

44 Osborne S. Measles outbreak kills 1,200 in Madagascar. The Independent 2019; 15 April.