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Birthing Vaccine Skepticism

Andrew Wakefield, the child of two physicians, graduated from medical school in England in 1981 and embarked upon a research career in gastroenterology. He was particularly interested in the causes of Crohn's disease, an inflammatory bowel disease. After a fellowship at the University of Toronto, Wakefield became a lab researcher at the Royal Free Hospital in London in 1988.

Wakefield developed a theory that the measles virus caused Crohn's disease and formed an "Inflammatory Bowel Disease Study Group." In May of 1995, the distraught mother of an autistic child phoned Wakefield and suggested that her son's condition had been caused by the measles virus in the MMR (measles, mumps, rubella) vaccine. Of interest to Wakefield was the fact that the child also apparently suffered from symptoms consistent with inflammatory bowel disease, which the mother suspected were also caused by the MMR vaccine. Wakefield and his team began to study the mother's hypothesis. From July 1996 to February 1997, the team solicited referral letters from doctors of children who appeared to have both autism and inflammatory bowel issues. Ultimately, the team studied twelve children.

On February 28, 1998, the "team" published an article in the prestigious medical journal, *The Lancet*. The article listed twelve co-authors but was actually solely written by Wakefield. It proposed a potential link between the MMR vaccine and a bowel-brain "syndrome" causing both "regressive autism" (where children lost abilities such as speech that they had once had) and Crohn's disease. Even before publication of the article, Wakefield had told the press that the results of his research "clearly confirm our suspicions." At a press conference following publication, Wakefield said: "I cannot support the continued use of the three vaccines given together. My concerns are that one more case of this is too many." The article attracted much publicity and had a significant effect on the public's views regarding vaccination. What was unknown at that time included:

- On February 19, 1996, Wakefield had agreed to be a well-paid consultant to attorney Richard Barr who had been awarded a contract by the British Legal Aid Board to potentially file a class action lawsuit over the MMR vaccine.
- Barr and Wakefield had developed a list of things that Wakefield's research needed to show in order to be helpful to Barr's lawsuit even before the study began.
- Barr largely funded Wakefield's research project using government funds allocated to the lawsuit.
- Many of the twelve children in the study had ties to Barr or to anti-vaccine groups; they had gone to the hospital with their parents already intent upon suing the vaccine makers.
- To gather information for the study, Wakefield and his team subjected the twelve children to endoscopies, a procedure that was "high risk,"





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even though many of the children had no medical need for the procedure. Wakefield did not disclose that his team did not have ethics committee approval to perform these risky, unnecessary procedures.

- In June 1996, Wakefield filed patent applications for:
 - A single measles vaccine
 - o A treatment for inflammatory bowel disease, and
 - A treatment for autism
- Members of Wakefield's research team often spoke giddily of the Nobel Prize they would win and Wakefield himself aspired to be the greatest gastroenterologist ever.

Wakefield had previously formed companies (1991, 1993, 1994) to commercially exploit his scientific discoveries, but none had succeeded. Nonetheless, soon after publication of *The Lancet* article, Wakefield met with potential investors to form a company to sell products (e.g., an alternative measles vaccine) that he planned to develop in this area. His projections for revenue and profit potential were aggressively optimistic, depending largely on Barr's litigation succeeding. He negotiated to give the school a piece of his projected action in return for certain benefits, including a title for himself as "professor." The school refused to give Wakefield that title.

In October of 1998, Barr filed the first court claims. Wakefield was to be Barr's primary expert witness and pretended to be an independent scientist. In 1999, when shortcomings in Wakefield's study came to light (very small number of subjects, subjects not chosen randomly, no comparison group of non-autistic children, heavy reliance on parents' memories and beliefs, etc.), his university asked him to replicate his research results with a "gold standard" scientific study. Wakefield readily agreed to do so, but never even began such a study. Ultimately, he refused additional replication requests.

In 2000, Wakefield testified in Washington D.C. before a congressional committee regarding the dangers of the MMR vaccine. Another witness was John O'Leary, an Irish pathologist. Neither disclosed that they were business partners nor that O'Leary was also being supported financially by lawyer Barr. By October 2003, the flaws in Wakefield's study were sufficiently apparent that Barr's MMR lawsuit was dismissed for lack of evidence. The government money stopped flowing, but Barr and his staff had already received \$51m in current U.S. dollars and Wakefield had received \$846,000 in today's dollars, plus expenses (roughly eight times his medical school salary).

Soon thereafter, journalist Brian Deer -- whose book *The Doctor Who Fooled the World* provides virtually all the material for this case study -- began thoroughly investigating Wakefield and his research. As litigation involving Wakefield and his colleagues proceeded, documents related to Wakefield's study in *The Lancet* came to light, showing that the article inaccurately described the conditions of every single one of the twelve subjects. Some were described as having autism when medical records showed that they did not. Some were described as having Crohn's disease, when medical records showed that they did not. Others were described as having developed autism soon



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after having received the MMR vaccine, while medical records showed that they had manifested signs of autism *before* being vaccinated. And so on.

Although the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* clearly require that third-party funding and expert witness work must be disclosed as conflicts of interest, Wakefield said that he did not agree. On May 3, 2004, 10 of 12 co-authors on *The Lancet* article repudiated the paper's conclusions. Ultimately, after a long hearing, the General Medical Council canceled Wakefield's medical registration.

None of this prevented Wakefield from becoming the darling of the anti-vaccine set and creating significant vaccine hesitancy regarding the MMR vaccine (and others). The result has been a rise in measles deaths around the world. As of 2022, Wakefield maintains his discredited theory and paints himself as the victim in all this.



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Discussion Questions

- 1. The Ethics Unwrapped video on conflicts of interest states, in part, that "sometimes, individuals have incentives that conflict with their professional responsibilities, often in ways that are not transparent to the public or even in their own minds. These conflicts of interest produce serious economic and social problems." How are the facts in this case study relevant to this statement?
- 2. At the end of the day, are the factors described in this case study (wealth, fame, promotion, etc.) unique to Wakefield's situation or do these factors commonly impact the decision-making of academic researchers? If so, how?
- 3. The Ethics Unwrapped video on the self-serving bias points out that because of this bias, people have a tendency to gather, process, and even remember information in ways that advance their self-interest and support their pre-existing views. What facts in the case study might cause Andrew Wakefield to be impacted by the self-serving bias?
- 4. As mentioned, the self-serving bias inclines people to process information in a self-serving way. One relevant influence is the confirmation bias, which is the tendency of people's minds to seek out information that supports views they already hold and to interpret evidence in ways that support those views. The Ethics Unwrapped video on the confirmation bias gives this example: when physicians have an idea about a patient's diagnosis, they may focus on evidence that supports their theory while undervaluing evidence that supports an equally plausible alternative diagnosis. Do you see evidence of the confirmation bias in the facts spelled out in the case study? Explain.
- 5. Nick Chadwick was a researcher on Wakefield's team. When Chadwick applied tests the team had developed for amplifying measles DNA, he was unable to find the virus where Wakefield's theories indicated it should be found. This did not please Wakefield. As Chadwick said: "He tended to believe, you know, positive data that fitted with his hypothesis and then disregard the negative data." Does this quotation provide evidence that Wakefield was affected by the confirmation bias? Explain. Consider these quotations from Deer's book:
 - a. Wakefield's mother said: "He's very like my father. If he believed in something, he would have gone to the ends of the earth to go on believing."
 - b. John March, a veterinary vaccine specialist who was part of Barr's team to analyze the evidence, found that there was no viable legal case. March said that he was asked to sign a confidentiality agreement to ensure that the evidence would never be published, adding: "It was almost like it had become a religion. And if you got a result that you didn't like, you ignored that result and carried on."
 - c. Scientist Hugh Fudenberg turned away Wakefield's attempt to form a joint business, later saying that he didn't like Wakefield's priorities: "He wanted to prove he was right. That was his main motive. To prove he was right. He kept at it through thick and thin. He was about just money too much."
- 6. In one study of the confirmation bias done by Professors Ditto and Lopez, subjects were given a strip of paper and told they could use it to test to see whether they had a particular fictitious



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medical condition. Some subjects were told that if they put their saliva on the paper and it did not change color, then they *did not* have the condition (which portended pancreatic issues later in life). These people generally would touch the paper to their saliva, see that it didn't change color (because, unknown to them, it was just a strip of plain yellow construction paper) and go on their way happy with the result. Other subjects were told that if they touched the paper to their saliva and it did not change color, that meant that they *did* have the unfortunate condition. These subjects tended to touch the paper to their saliva, see that it didn't change color and then, not being happy with this result, would typically touch the paper to their saliva several more times, hoping for a different result. In the course of your work (maybe as a researcher, maybe in another role) you may face a situation where a particular outcome of an experiment (or a program or a plan) will be a good development for your career. How will you guard against a subconscious desire to interpret ambiguous evidence in a one-sided manner that benefits you?

- 7. What special qualities might immunize you from the self-serving bias? Does this buffer seem a realistic one to you? Explain.
- 8. Wakefield had visions of a Nobel Prize and a dream of being the world's leading gastroenterologist. Yet, as Brian Deer points out, as Wakefield started his infamous study that was ultimately published in *The Lancet:*

...he'd been nobody: a doctor without patients at a third-rate London hospital and medical school. He'd been a laboratory gastroenterologist, a former trainee gut surgeon, most relevantly defined by what he wasn't. He wasn't a virologist, immunologist, or epidemiologist. He wasn't a neurologist, psychologist, or psychiatrist. He wasn't a pediatrician or clinician.

How might the overconfidence bias have played a role in the chaos that Wakefield created with his "study"? How does that square with what Deer says about Wakefield above? Explain.

- 9. Cain, Loewenstein, and Moore hypothesized that disclosure of conflicts of interest could worsen rather than improve financial advisors' performance in two ways. First, while having to disclose conflicts of interest might incentivize financial advisors to consciously try to improve the accuracy of their recommendations, they might also be tempted to provide even more biased advice knowing that their clients would perhaps discount their advice somewhat due to the disclosure of the conflict (this is called "strategic exaggeration"). Second, after doing a good thing (disclosing conflicts of interest), financial advisors might unconsciously grant themselves permission to lower their normal standards by providing even more biased advice (this is called "moral licensing"). Cain and colleagues tested their theory experimentally and found just such a result. If you are a researcher, describe how you will guard against strategic exaggeration and moral licensing after you disclose your conflicts of interest. If you are in another role (in your career or as a student), how might strategic exaggeration and moral licensing impact you?
- 10. How might researchers who wrongly, but perhaps sincerely, believe that they are on the trail of the true cause of the recent rise in autism diagnoses give themselves moral license to stretch



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the truth and to relax research protocols in order to convince the world of the accuracy of their findings that they so strongly believe? What rationalizations might these researchers use to justify their actions?

11. Once Wakefield had held a couple of press conferences announcing that his findings supported the theory he was touting, would it have been difficult for him to later admit error? Deer thought so. Do you agree with the implications of his statement below? Explain.

[Wakefield] was being paid at hourly rates to advance his "syndrome" in Barr's lawsuit. If he didn't find fault with the solicitor's target product, his lavish personal fees would stop. He'd filed for two patents claiming single measles shots. And, with [his mentor Dr. Roy] Pounder, he already announced to the world, in *Pulse* [a magazine for doctors], evidence that "confirm our suspicions."

- 12. People can be unconsciously impacted by factors such as the self-serving bias, the confirmation bias, the overconfidence bias, and the like. But sometimes, wrongdoing can be conscious and intentional. Which is it with Wakefield? Do you believe Wakefield was influenced by subtle psychological factors (as well all are), or do you think his actions were more intentional? Consider the comments below, and support your reasoning.
 - a. The Lancet's editorial board concluded:

Who perpetrated this fraud? There is no doubt that it was Wakefield. Is it possible that he was wrong, but not dishonest: that he was so incompetent that he was unable to fairly describe the project, or to report even one of the 12 children's cases accurately? No. A great deal of thought and effort must have gone into drafting the paper to achieve the results he wanted: the discrepancies all led in one direction; misreporting was gross.

- b. And journalist Brian Deer, who found Wakefield to be "incapable of embarrassment" and possessing "no conscience."
- 13. How could Wakefield have possibly believed that the disclosure rules of the "Uniform Requirements" did not apply to him? How could he have not joined ten of his eleven co-authors in retracting the article in *The Lancet?* Are these decisions indications that he is an intentional fraud, or that he is just more susceptible to these various biases than most of the rest of us? Explain.





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Resources:

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Matthew Motta & Dominik Stecula, "Quantifying the Effect of Wakefield et al. (1998) on Skepticism about MMR Vaccine Safety in the U.S.," <u>PLOS ONE</u>, Aug. 19, 2021, at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0256395.

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Moises Velasquez-Manoff, "The Anti-Vaccine Movement's New Frontier," New York Times Magazine, May 29, 2022, at https://www.nytimes.com/2022/05/25/magazine/anti-vaccine-movement.html?searchResultPosition=1

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