



## THE SCIENTIFIC FRAUDS UNDERLYING THE FALSE MMR VACCINE-AUTISM LINK

Andrew Wakefield's 1998 paper purporting that the measles-mumps-rubella vaccine causes children to subsequently develop autism contained five specific frauds, and his subsequent comments on it contained another.

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With the production and distribution of the film *Vaxxed* and its successor *Vaxxed 2*, plus the notorious anti-vaccination/conspiracy video *Planedemic*, it has again become fashionable in some anti-vaccination circles to maintain that vaccines are medically ill-advised, provide little benefit given their risks, and are possibly pushed by a big government–Big Pharma cabal for the primary purpose of optimizing profits.

Of course, there are valid grounds for concerns regarding civil liberties given proposed government-mandated vaccination programs in taxpayer-funded schools. But to bolster the cabal theory, many want to claim that the original report by Dr. Andrew Wakefield of an association between autism and MMR vaccination was correct. They believe the subsequent outright retraction of that paper and its labeling as a fraud (*Lancet* editors 2010) was the work of this cabal to discredit a badly victimized Wakefield.

While Wakefield's theory is almost completely discredited within the biomedical research community, the ad-

herents of the cabal theory simply regard that as proof of the strength of the influence of Big Pharma funding on biomedical research. To help set the record straight, let's review the facts surrounding the frauds in Wakefield's 1998 paper. We will look as close to the primary sources as reasonably possible. That way, anyone can review these sources to make their own determinations regarding these frauds.

On February 28, 1998, Wakefield was the lead author on a paper in the British medical journal *Lancet* titled "Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children" (Wakefield et al. 1998), which reported an association in twelve children between treatment with the combined measles, mumps, rubella (MMR) vaccine and subsequent development of colitis and autism.

For our purposes, scientific fraud (Norwegian National Research Ethics Committees N.d.), or scientific misconduct, will be defined per the U.S. Office of Research Integrity (N.d.) as "fabrication, falsification, or plagiarism



in proposing, performing, or reviewing research, or in reporting research results." The ORI further defines "(a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record."

### Six Fabrications and Falsifications

The primary fabrications and falsifications in the paper occur in five main areas. There is a sixth form of falsification in Wakefield's response (Wakefield 1998) to criticisms of the paper, which will be discussed later. The first three areas of falsification and fabrication concern the reporting of the scientific findings in the article.

#### **Fraud 1. Findings of Non-Specific Colitis**

The paper reported in its Table 1 that eleven of the twelve children examined had "non-specific colitis." This was apparently a phrase used by Wakefield in final revisions to summarize the results of the histopathological examination of the biopsies collected during ileocolonoscopy.

These slides were originally examined by the clinical pathologists at the Royal Free Hospital in London and were determined to be essentially normal (Deer 2010). Given this result, the research team decided to have the slides reexamined by medical school faculty. In this review, specific histological findings were scored on a 0–3 scale by Dr. A.P. Dhillon (Godlee 2011) along with a checkbox at the bottom for other findings, such as "non-specific" or "normal." In eleven of the twelve children, the "non-specific" box was checked for at least one biopsy site.

Evidently the checking of these boxes was then reported as "chronic non-specific colitis" by Wakefield in making final revisions to the paper (Deer 2010). The checkbox on the form filled out by Dhillon, however, may have simply meant that the findings on the slide were of uncertain significance.

When reviewed by two independent specialists in 2011, Geboes (2011) reported that "I see no convincing evidence of 'enterocolitis,' 'colitis,' [or a] 'unique disease process.'" Bjarnason (2011) reported that he and his colleagues "came to an overwhelming and uniform opinion that these reports do not show colitis."

The direction of each of the eleven errors is consistent in tending to overstate the association, and this is unlikely to be due to chance. The errors also included technical medical terminology implying a particular condition is present when it was not in most cases, though Wakefield was a gastroenterologist who knew the meaning of these terms.

It thus appears that Wakefield falsified the results presented in Table 1 of the paper by stating these were examples of non-specific colitis when in fact the totality of the data available at that time indicated something non-specific or of uncertain significance was present.

#### **Fraud 2. Timing of MMR Vaccine Administration and First**

### Behavioral Symptoms

The paper's Table 2 lists the "Interval from exposure to first behavioral symptoms." In one case this is listed as "immediately," two cases within twenty-four hours, one case within forty-eight hours, two cases within two weeks, one case within one month, and one case within two months. These reported temporal associations were used in the paper to bolster the case that there was an association between vaccine administration and subsequent development of behavioral problems, such as autism.

Brian Deer reviewed the hospital admission notes (Deer 2011) and the Medical Research Council (MRC) hearing transcripts (MRC Transcripts N.d.) and reported that of the eight of twelve cases that were reported as having first behavioral symptoms within one week, only two could be confirmed in the records. In some cases, such as Child 11, where Table 2 of the paper stated behavioral symptoms developed one week after vaccine administration, the hospital discharge note stated that behavioral symptoms began one month *before* administration of the MMR vaccine.

**It is unlikely that this was simply accidental copying errors. It indicates that the authors falsified the temporal associations between MMR vaccine administration and development of behavioral symptoms.**

The direction of all eight of these errors is consistent in tending to indicate a temporal association. It is unlikely that these were simply accidental copying errors. It indicates that the authors falsified the temporal associations between MMR vaccine administration and development of behavioral symptoms.

#### **Fraud 3. Findings of Regressive Autism**

Table 2 in the paper also lists for all twelve children their "Behavioral Diagnosis." This table lists nine of the twelve children as having autism and one additional child as possibly having autism.

Per reports reviewed by Deer (2011), including the MRC hearing transcripts (MRC Transcripts N.d.), only one child clearly had a diagnosis of regressive autism. Six of the nine listed as having regressive autism did not have this diagnosis, and five of the nine so listed had uncertain behavioral diagnoses.

The lack of underlying documentation of most of the children listed in Table 2 of the Wakefield paper as having regressive autism, when this is one of the main points of the paper, arguably rises to the level of fabrication of these results, insofar as documentation is just missing. Certainly it points to



Table 2 Neuropsychiatric diagnosis

Child	Behavioural diagnosis	Exposure identified by parents or doctor	Interval from exposure to first behavioural symptom	Features associated with exposure	Age at onset of first symptom	
					Behaviour	Bowel
1	Autism	MMR	1 week	Fever/delirium	12 months	Not known
2	Autism	MMR	2 weeks	Self injury	13 months	20 months
3	Autism	MMR	48 h	Rash and fever	14 months	Not known
4	Autism? Disintegrative disorder?	MMR	Measles vaccine at 15 months followed by slowing in development. Dramatic deterioration in behaviour immediately after MMR at 4-5 years	Repetitive behaviour, self injury, loss of self-help	4-5 years	18 months
5	Autism	None—MMR at 16 months	Self-injurious behaviour started at 18 months		4 years	

MMR=measles, mumps, and rubella vaccine.

The data presented in Table 2 of the 1998 Wakefield paper [above] lack documentation, which points to possible falsification.

falsification of the data presented in Table 2.

Two additional areas of fraudulent representations within the 1998 Wakefield et al. paper are not in the scientific findings but have to do with other scientific publication issues.

#### Fraud 4. Ethics Consent Statement

The paper stated that “Ethical approval and consent investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent.” A statement of this type is required for all medical and scientific publications to help prevent abuse of subjects in human subject research studies.

After questions were first raised by Deer (Horton 2004) and others regarding the nature of the investigations and whether they had been approved by the appropriate ethical practices committee, Murch (2004), one of the coauthors, stated that “The protocol for the 1998 *Lancet* paper was submitted on September 16, 1996” and “This protocol formed the basis for all children investigated in the 1998 *Lancet* paper, and all were investigated.” Hodgson (2004) stated, “The investigation of these children was properly submitted to and fully discussed by the Ethical Practices Committee at the Royal Free Hampstead in 1996.”

This issue was the focus of much investigation in the MRC hearings (MRC Transcripts N.d.), because many of the subjects in the paper were admitted to the hospital for studies prior to December 18, 1996, the date on which that research protocol was approved. On the basis of this and other ethical

and practice violations, the General Medical Council struck (or revoked) the medical licenses of both Dr. Andrew Wakefield and Dr. John Walker-Smith. While both initially appealed these findings to the Administrative Court (England and Wales) High Court of Justice Administrative Court, Wakefield dropped out of the appeal. The primary argument in Walker-Smith’s defense on appeal was that no such ethics committee approval was required because the investigations

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were for the clinical benefit of the children and were covered by a prior study approval for his work (Mitting 2012, #91, #93). This defense directly contradicts the statements of both Murch and Hodgson in 2004. Nonetheless, based on other evidence, Mr. Justice Mitting determined on appeal that it was not proven to the requisite criminal standard of proof that Walker-Smith had carried out the investigations without ethics board approval (Mitting 2012 #186, pp. 60–61). Re-



garding the ethics approval statement in the paper, however, Mr. Justice Mitting found, "This statement was untrue and should not have been included in the paper" (Mitting 2012, #153, p. 47).

In finalizing the paper, there was a discussion of the wording of the ethics consent statement among the authors (Mitting 2012, #153, p. 46). Following this, Wakefield evidently inserted this standard language of an ethics consent approval statement. This was a falsification of the actual record to facilitate publication of the paper.

#### **Fraud 5. Conflict of Interest Statement**

In 1998, at the time of the paper's submission, *Lancet*, like most medical journals, required that the authors sign a statement disclosing any actual conflicts of interest and any items that could be perceived as conflicts of interest. Wakefield declared no conflicts of interest with respect to the publication.

Unbeknownst to the editors or readers at the time, however, Andrew Wakefield had filed a patent for virological testing in 1995 (Wakefield 1995). He had been engaged as an expert by lawyer Richard Barr since February 1996 to work on a potential lawsuit against virus manufacturers (*Sayer et al. vs. Smithkline et al.* 2007). He was paid in total £435,643 (about \$568,700 at current exchange rates) for this work (Deer 2007). Both the editor of *Lancet* (Horton) and a vice dean of the Royal Free and University College School of Medicine (Hodgson) stated in writing that this conflict should have been disclosed. Failing to disclose such an obvious potential monetary conflict of interest in the outcome was a form of falsification of the record to facilitate publication and improve the perceived impact of the findings.

There was a last form of fraud committed by Andrew Wakefield in connection with this paper, but it was not in the paper itself.

#### **Fraud 6. Methods of Patient Referral**

Immediately after the paper was published, criticisms were raised regarding a possible strong bias in patient selection (Rouse 1998). Nearly all the patients were originally contacted through an anti-vaccine campaign and the solicitors attempting to sue the vaccine manufacturers (Deer 2011).

In the paper itself, this was described as, "We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder" and "12 children, consecutively referred to the department of paediatric gastroenterology ... ." In a subsequent response to this critique, Wakefield (1998) stated, "These children have all been seen expressly on the basis that they were referred through the normal channels (e.g., from general practitioner, child psychiatrist, or community paediatrician) on the merits of their symptoms."

When this was examined in detail during the MRC hearings (MRC Transcripts N.d., #35, p. 47), the committee found that Wakefield's statement in the response was dishonest and irresponsible. The case of referral of Child 12 was examined in detail as the mother testified and revealed that the mother was supplied with a "fact sheet" written by Wakefield prior to being seen. The levels of biasing in the findings for that child as revealed in the MRC transcripts are discussed in detail on the *lbrb* blog (Cary 2012).

This issue was also addressed with respect to Wakefield's coauthor, Dr. Walker-Smith, during the appeal of the MRC findings. In that appeal, Mr. Justice Mitting found that the finding of the MRC panel was not correct with respect to Walker-Smith's coauthorship of the paper (Mitting 2012, #158–159, pp. 62–63). It is important to note that this finding on appeal did not address the MRC finding with respect to the dishonesty of Wakefield's separate response to criticism of the paper.

The significance of the findings in the paper depended on the route of referral. The findings would be stronger if they were found in a consecutive series of children who came to





the clinic; they would be weaker if they were found in a set of children chosen to potentially have the significant findings. By claiming that the referrals were through normal channels, when in fact the cases were selected for the findings prior to referral and the parents were prompted with the desired findings, Wakefield falsified this aspect of the scientific record.

### Other Types of Fraud

Commentators often simply state that Andrew Wakefield committed fraud in the study that was published in 1998. Other than the scientific fraud discussed above, there are other common meanings of the term. *Fraud* often refers to either criminal fraud or civil fraud, a tort. Wakefield was never tried for either type with respect to the 1998 paper and study.

Criminal fraud has several elements that must be proved to support a conviction (which depend in detail on the jurisdiction in question). These are 1) misrepresentation of a material fact; 2) by someone who knows that the material fact is false; 3) with intent to defraud; 4) to a person or entity who justifiably relies on the misrepresentation; and 5) actual injury or damages result from that reliance on the false representation. In both the United States and the United Kingdom, each of these elements would have to be proven beyond a reasonable doubt (Criminal Fraud N.d.).

In the case of the 1998 paper, it is unclear who the parties would be who were injured or damaged by the scientific frauds in that paper. Assuming such parties existed, it seems it would be difficult to prove beyond a reasonable doubt the third element, that Wakefield engaged in the fraud with the intent to defraud the person injured.

Civil fraud as a tort generally has as requisite elements the intentional misrepresentation or concealment of an important fact upon which the victim is meant to rely, and in fact does rely, to the harm of the victim. People who invested money in Wakefield's business proposal or the attorneys who paid him a large amount of money as a consultant for their lawsuits might have some claim for a monetary injury. Because the standard of evidence in a civil case is simply the preponderance of the evidence, the review of the scientific frauds above suggests such a lawsuit may have succeeded; however, none was ever brought.

### Conclusion

The scientific frauds in Wakefield's 1998 paper are clear from the readily available records, and it is clear why this paper was eventually retracted when the full record became available. Whether these would rise to the level of a civil or criminal fraud is unknown, as these scientific issues were never adjudicated in a court of law. While there are good reasons to consider the safety and efficacy of vaccines and for patients to be fully informed before being vaccinated, the alleged link between the MMR vaccine and autism is not one of them. ■

### References

- Bjarnason, I. 2011. Commentary: We came to an overwhelming and uniform opinion that these reports do not show colitis. *BMJ* 343: d6979. Available online at <https://www.bmj.com/content/343/bmj.d6979>.
- Cary, M. 2012. Transcripts from the GMC hearings. *lbrb* (February 2). Available online at <https://leftbrainrightbrain.co.uk/2012/02/02/transcripts-from-the-gmc-hearings>.
- Criminal Fraud. N.d. Everything you need to know about fraud crimes and fraud law. Find Law. Available online at <https://criminal.findlaw.com/criminal-charges/fraud.html>.
- Deer, B. 2007. Revealed: Undisclosed payments to Andrew Wakefield at the heart of vaccine alarm. Available online at <http://brianddeer.com/wakefield/legal-aid.htm>.
- . 2010. Wakefield's 'autistic enterocolitis' under the microscope. *BMJ* 340: c1127. Available online at <https://www.bmj.com/content/340/bmj.c1127>.
- . 2011. How the case against the MMR vaccine was fixed. *BMJ* 342: c5347. Available online at <https://www.bmj.com/content/342/bmj.c5347>.
- Geboes, K. 2011. Commentary: I see no convincing evidence of "enterocolitis," "colitis," or a "unique disease process." *BMJ* 343: d6985. Available online at <https://www.bmj.com/content/343/bmj.d6985>.
- Godlee, F. 2011. Institutional research misconduct. *BMJ* 343: d7284 (data supplement). Available online at <https://www.bmj.com/content/343/bmj.d7284>.
- Hodgson, H. 2004. A statement by the Royal Free and University College Medical School and the Royal Free Hampstead NHS Trust. *Lancet* 363(9411): 824. Available online at <https://www.thelancet.com/journals/lancet/article/PIIS0140673604157115/fulltext>.
- Horton, R. 2004. A statement by the editors of *The Lancet*. *Lancet* 363(9411): 820–821. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15699-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15699-7/fulltext).
- Lancet editors. 2010. Retraction—ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 375(9713): 445. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(10\)60175-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60175-4/fulltext).
- Mitting, J. 2012. *Walker-Smith v. General Medical Council*. Available online at <http://www.bailii.org/ew/cases/EWHC/Admin/2012/503.html>.
- MRC Transcripts 2007–2010. N.d. Casewatch. Available online at <http://steinmetz.org/peter/Medical/wakersTranscripts.zip>.
- Murch, S. 2004. A statement by Dr. Simon Murch. *Lancet* 363(9411): 821–822. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15708-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15708-5/fulltext).
- Norwegian National Research Ethics Committees. N.d. Fraud and plagiarism. Available online at <https://www.etikk.no/en/library/topics/integrity-and-collegiality/fraud-and-plagiarism/>.
- Rouse, A. 1998. Correspondence. *Lancet* 351(9112): 1356. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(05\)79082-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)79082-6/fulltext).
- Sayer et al. v. Smithkline et al. 2007. MMR and MR Vaccine Litigation Sayers and others v. Smithkline Beecham plc and others. All ER (D) 30 (Jun).
- U.S. Office of Research Integrity. N.d. Definition of research misconduct. Available online at <https://ori.hhs.gov/definition-misconduct>.
- Wakefield, A. 1995. Diagnosing Crohn's disease or ulcerative colitis by detection of measles virus. (UK patent application 2 300 259 A). UK Patent Office.
- . 1998. Autism, inflammatory bowel disease, and MMR vaccine. *Lancet* 351(9112): 1356. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(05\)79083-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)79083-8/fulltext).
- Wakefield, A. et al. 1998. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 351: 637–41. Available online at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(97\)11096-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/fulltext).



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