

Apparent Egregious Ethical Misconduct by *British Medical Journal*, Brian Deer

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January 8, 2012

UK Research Integrity Office (UKRIO)
Reference No. 2011-060

Marketing drugs with tabloid science

Commentary

Editors at the *British Medical Journal* (*BMJ*) and Brian Deer, a freelance reporter with no formal training in science or medicine, alleged that Andrew Wakefield fabricated the diagnosis of colitis in a 1998 *Lancet* study involving 12 children with autistic spectrum disorder (ASD). In the study, some parents and physicians linked MMR vaccine to the children's gastrointestinal problems and rapid regression into autism. In 2010, Deer alleged in the *BMJ* that Wakefield alone made up the diagnosis by misinterpreting grading sheets from pathologists A.P. Dhillon and A. Anthony, who reviewed the children's colonic biopsy samples.

In the article, Deer wrote that, according to specialists, grading sheets "don't generate clinical diagnoses such as colitis." Grading sheets I recovered from Wakefield's files, however, show that Anthony wrote "colitis" in marginal notes on a number of his grading sheets. And, Dhillon included boxes to check for various diagnoses, such as Crohn's disease and "UC" for ulcerative colitis. Consistent with the *Lancet* article, both pathologists found that only one child showed no evidence of inflammation.

Last September, *BMJ*'s chief editor, Fiona Godlee, rejected a commentary I wrote about Wakefield's documents. In its place, she invited me to submit a *Rapid Response*, which I did. But, instead of admitting she had falsely accused Wakefield of making up the diagnosis of colitis, she and Deer simply cherry-picked the evidence to come up with a new theory involving "institutional research misconduct." The alleged fraudsters now include University College London (UCL) administrators, the Royal Free Hospital, and all 13 authors of the *Lancet* study.

Their objective, according to an editorial and feature article Godlee and Deer published with my *Rapid Response*, was to create the MMR scare so that UCL could sell its own safer measles vaccine, diagnostic kits and "autism products." In her editorial, Godlee acknowledged "the BMJ Group receives funding from the two manufacturers of MMR vaccine, Merck and GSK."

To support their new fraud theory, Godlee rewrote my *Rapid Response*, removing any evidence that undermined their allegations against Wakefield and others. Then, to prevent me from publishing this evidence on my NWC website, Deer filed a flurry of false allegations of ethical misconduct against me with the NWC. Godlee ignored my protests over Deer's behavior; and some of his false and misleading characterizations of my professional credentials and current work appeared in her editorial and Deer's feature article

When testifying before Parliament in 2011, Godlee agreed that peer-reviewed journals have become "the marketing arm of the pharmaceutical industry." Therefore, it shouldn't surprise anyone if her fraud allegations turn out to be nothing more than a scheme to protect the *BMJ*'s financial interests in companies marketing the MMR vaccine. What's frightening is that it requires one of Great Britain's leading medical journals to utterly destroy the reputation of one of the world's most prestigious academic institutions.

Apparent Egregious Ethical Misconduct by British Medical Journal, Brian Deer

Regarding Evidence from Dr. Andrew Wakefield's Personal Files

Supplement to Peer-Reviewed *BMJ Rapid Response*

<http://www.bmj.com/rapid-response/2011/11/09/re-how-case-against-mmr-vaccine-was-fixed>

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SUMMARY

In November 2011, Fiona Godlee, chief editor of the *British Medical Journal* (*BMJ*), and a reporter, Brian Deer, used newly discovered documents I obtained from Andrew Wakefield's personal files to allege that University College London (UCL) may have committed "institutional research misconduct." [1] The term, which I coined at the National Whistleblowers Center (NWC) in Washington, DC, refers to instances in which institutions, such as government agencies and universities, commit or support acts of research misconduct to protect government policies and industry practices.

According to Godlee, the misconduct may have involved UCL administrators, 13 scientists, and the Royal Free Hospital in London. It was all part of an elaborate scheme in which the *Lancet* study was intended to generate an MMR vaccine scare which, in turn, damaged vaccine sales by Merck and GlaxoSmithKline (GSK), which, in turn, opened up the market for UCL to sell safer vaccines, diagnostic kits and "autism products."

Godlee wrote that this scheme caused "enormous harm" to public health, and could reflect "the prevailing culture of Britain's academic institutions." In her editorial and other comments published in the *BMJ*, she called upon various oversight bodies to investigate, including Parliament, UK's Research Integrity Office (UKRIO), the Higher Education Funding Council for England (HEFCE), and UCL's Office of Provost.

In a previous version of their fraud scheme published in January 2011 [2, 3], and earlier in 2010 [4], Godlee and Deer alleged that Wakefield alone faked the diagnosis of colitis to profit from a patent UCL filed on a "transfer factor" he developed. Transfer factors are used to treat infections in immunocompromised patients who cannot be vaccinated with live vaccines, such as MMR vaccine. These were the first in a series of articles published by the *BMJ* in which Deer allegedly exposed "the frauds behind Wakefield's research." [5]

Copies of the pathologist grading sheets and other data from the 1998 study, which I obtained from Wakefield's personal files, however, appear to show that the diagnosis was not fabricated. After rejecting a commentary I submitted to *BMJ*, which included evidence that the *BMJ* had wrongly accused Dr. Wakefield, Dr. Godlee invited me to resubmit the documents as a "Rapid Response."

My report, which I have submitted to UCL, UKRIO and HEFCE, includes 72 emails exchanged between me and the *BMJ*'s editors. In my opinion, they clearly show that Dr. Godlee and others at the *BMJ* cherry-picked the evidence and rewrote my *Rapid Response* to support their new, wider fraud theory. Experts disagree on the clinical significance of the data. But, as a whole, the documents I provided clearly show that the diagnosis of colitis reported in the 1998 *Lancet* article was not fabricated. In addition, my report includes emails Brian Deer sent the NWC in which he demanded that evidence

exonerating Dr. Wakefield, which the *BMJ* edited out of my *Rapid Response*, be removed from the NWC website.

Apparent "cherry-picking" of the evidence

To support their new fraud theory, Godlee, Deer, and the *BMJ*'s lawyers engaged in the most reprehensible conduct I have ever witnessed involving any scientific journal [[Attachment 1](#) - *Rapid Response* emails]. To paint a dark picture of institutional fraud at UCL, it is my opinion that they used the same tactics of which they accused Dr. Wakefield, and now UCL at large.

To begin with, they cherry-picked a treasure trove of hitherto unpublished evidence from Wakefield's files, selecting the *only* set of documents they could possibly use to support their new fraud theory. This was A.P. Dhillon's grading sheets, in which I asked Dr. Wakefield to add the corresponding numbers used to identify the 12 *Lancet* children. It is evident from these grading sheets, which the *BMJ* uploaded on its website [6], that nowhere on them did Prof. Dhillon actually write out the word "colitis." He did, however, include a box labeled "UC" to indicate a diagnosis of ulcerative colitis.

Godlee's own expert, Ingvar Bjarnason, a gastroenterologist at King's College Hospital, London, however, told *Nature* that he believes Dhillon's grading sheets "don't clearly support charges that Wakefield deliberately misinterpreted the records." [7] "The data are subjective," he says, "It's different to say it's deliberate falsification."

To address my *Rapid Response*, Godlee devoted an editorial [1], two commentaries [8, 9], and a feature article by Brian Deer [10] arguing that what little evidence remains of biopsy slides that no longer exist does not support a diagnosis of colitis. But that's not the issue. The issue I raised in my *Rapid Response*, to which all of this effort was directed at overcoming, is whether Dr. Wakefield deliberately misinterpreted the grading sheets as Brian Deer claimed in his article entitled "Wakefield's 'autistic enterocolitis' under a microscope." [4]

What if there was no deception at UCL involving Wakefield's research and any potential conflicts of interests its administrators and scientists may have had? Could the *BMJ*'s conflicts of interest with manufacturers of the MMR vaccine have led to deceptions by the *BMJ*'s editors and Brian Deer? Based on what transpired between *BMJ*'s editors, Brian Deer, the NWC and me, I can now answer the last question. There is no doubt that *BMJ*'s editors and Brian Deer appear to be deeply involved in creating an elaborate deception.

Godlee's and Deer's apparent deception

The documents I submitted to the *BMJ*, which Godlee chose not to publish, clearly demonstrate that neither Andrew Wakefield nor any of his coauthors "faked" the diagnosis of colitis. For example, Godlee did not publish, or even mention,

photomicrographs of the missing biopsy slides for 11 of the 12 children, which I provided to *BMJ*'s editors [[Attachment 2](#) - Photomicrographs].

In Deer's article, "Wakefield's 'autistic enterocolitis' under a microscope," he referred to the missing biopsy slides as the "ultimate proof" of whether Wakefield faked the diagnoses in Table 1 of the *Lancet* article.[4] The photomicrographs of the missing slides, which were taken by Dhillon and Anthony, clearly illustrate all of the architectural structures described in Table 1. All that remains in question is whether Wakefield took it upon himself to intentionally misinterpret this information to mean "colitis."

Nowhere is that question settled more clearly than in Anthony's Power Point presentation, which I provided to *BMJ*'s editors [[Attachment 3](#) - Anthony's Power Point]. In this well-illustrated presentation, which Godlee chose not to publish, Anthony carefully explains the basis he used to interpret the architectural features described in Table 1 of the *Lancet* article as colitis. Obviously, not all experts would agree with his interpretations. But still, they leave no doubt that Dr. Wakefield did not make up the diagnosis of colitis as Deer alleged when he put "Wakefield's autistic enterocolitis" under a reporter's microscope.

Finally, I provided the *BMJ* with the GMC's copies of Anthony's grading sheets, almost all of which were created in September 1998, seven months after the *Lancet* article was published. Several sheets were dated in October 2001. Throughout his grading sheets, Anthony noted the various architectural features discussed in his power point presentation. In his marginal notes, he scribbled "colitis" for at least six of the eleven children. In her editorial [1], Godlee stated: "Anthony concluded that some of the children had "mild" or in one case "active" chronic colitis." But, because Anthony's grading sheets were dated after the *Lancet* paper was published, she deemed them to be irrelevant and did not send them out for external review. I also gave the *BMJ* copies of Prof. Dhillon's and Dr. Anthony's affidavits [11, 12], which confirm that they reviewed the *Lancet* article before it was published.

The children's biopsy slides and Anthony's grading sheets, which Dr. Wakefield used when he created Table 1 of the *Lancet* article, are perhaps the single most important pieces of evidence related to Brian Deer's allegations. The slides, however, disappeared from Dhillon's laboratory after the *Lancet* article was published; and the most relevant portion of Anthony's grading sheets disappeared as well. None of this evidence was available to the GMC during its deliberations.

Fortunately, Dr. Wakefield's personal files contained photomicrographs of all but one of the children's biopsy slides, Anthony's Power point presentation, and grading sheets that Anthony completed shortly after the *Lancet* article was published. These documents were available to the GMC through discovery. They make it abundantly clear that Anthony - not Wakefield - took the lead in interpreting architectural features in the biopsy slides as evidence that most of the *Lancet* children's biopsies exhibited signs of colitis.

Collectively, the documents described above establish beyond any reasonable doubt that the initial fraud theory that the *BMJ* published in 2010 is untrue. Namely, Dr. Wakefield

did not intentionally misinterpret the grading sheets provided by Prof. Dhillon and Dr. Anthony in order to fabricate the diagnosis of colitis reported in the *Lancet* study. This evidence compelled the *BMJ* to abandon its initial theory; but its editors made no admissions and gave no apologies. Instead, they cherry-picked Dhillon's grading sheets to support a new fraud theory in which UCL administrators and all of the *Lancet* authors allegedly conspired to falsely diagnose colitis in children with autism to profit from an MMR vaccine scare.

Apparent suppression of evidence

Dr. Godlee gained my cooperation last September after rejecting a commentary in which I addressed all of the relevant evidence and discussed how it applied to the wide range of allegations of research fraud leveled against Dr. Wakefield by Brian Deer and the *BMJ*. The commentary, for example, addressed the issues of consecutive referral of the *Lancet* children, a grant from attorney Richard Barr, and UCL's patent application related to Wakefield's research. In its place, she offered to publish a *Rapid Response* to Deer's article titled "Wakefield's 'autistic enterocolitis' under a microscope," and attach a revised commentary, photomicrographs of the missing slides, and the pathologists' grading sheets.

After obtaining my documents, *BMJ*'s editors had them externally peer reviewed, and provided copies to Brian Deer. Based on the peer-reviews, which *BMJ*'s editors would not provide to me, they rewrote my *Rapid Response* and dropped my attachments. In our original agreement (See, Attachment 1), Godlee agreed to publish my peer-reviewed letter as a *Rapid Response* to Deer's article titled "Wakefield's 'autistic enterocolitis' under a microscope." [4] But, after removing my comments concerning this article, she published my letter as a *Rapid Response* to a *different* article Deer wrote a year later entitled "How the case against the MMR vaccine was fixed." [5]

This change, which I never approved or was even informed about, completely diverted readers away from Deer's 2010 article where he alleged that Wakefield made up the diagnosis of colitis in most of the *Lancet* children by misinterpreting the pathologists' grading sheets. Addressing Deer's error in this article was the crux of what my *Rapid Response* was all about.

In short, the *BMJ* removed any evidence I supplied that could undermine the reiteration of their previous allegations of research fraud against Dr. Wakefield, or the presentation of their new fraud theory of institutional research misconduct. In the end, my *Rapid Response* was so devoid of substance that the *BMJ* did not even link to it as related content in its editorial, feature article and commentaries published to address it.

One of the documents I found in Dr. Wakefield's files was a 2006 report by the GMC's expert pediatric gastroenterologist, Prof. Ian Booth [13]. Booth compared routine pathology reports from the Royal Free Hospital with Table 1 of the *Lancet* article, which summarized Prof. Dhillon's and Dr. Anthony's blinded independent analysis of the

children's colonic biopsy slides. Based on mismatches between the two sets of records, Booth concluded that research fraud could not be ruled out.

Booth offered no explanation in his report as to why he used routine pathology reports, rather than Prof. Dhillon's and Dr. Anthony's grading sheets, to check the accuracy of Table 1. But, in an email to me, he explained that the GMC's solicitors specifically requested that he perform this analysis, and that it was used to prepare the GMC's case against Wakefield and two of his coauthors.[14] The GMC's solicitors never introduced Booth's report into evidence during the GMC's hearings.

Several weeks before the GMC issued its findings, Deer published his article in the *BMJ* using the same analysis to accuse Dr. Wakefield of faking most of the *Lancet* children's diagnoses.[4] In an editorial accompanying one of Deer's multiple articles on the subject, Dr. Godlee and two other editors declared Dr. Wakefield's research to be fraudulent.[2] In these writings, *BMJ*'s editors and Deer use the GMC hearings as a backdrop for their allegations of research fraud. Booth's expert report and his email to me, however, show that the GMC's solicitors carefully considered Booth's analysis, which was later used by Deer. They stopped short of introducing it as evidence, or charging Wakefield and his coauthors with faking the diagnosis of colitis.

When Deer discovered Booth's document posted on my NWC website in the Spring of 2011, he demanded that NWC director Stephen Kohn remove my documents [[Attachment 4](#) - Deer's NWC emails]. Deer claimed he never communicated with Booth, and was unaware of Booth's GMC report prior to seeing portions of it on my website.

Deer's claim of ignorance, however, has no bearing on whether the GMC's solicitors were instrumental in getting Deer and the *BMJ* to use the same analysis they crafted for Booth. Deer refused to explain to the NWC how he came up with the idea of investigating mismatches between the Royal Free Hospital's routine pathology reports and the *Lancet* article.[15]

Deer's use of Booth's analysis, whether knowingly or unknowingly, and the manner in which *BMJ*'s editors rewrote my *Rapid Response*, raise questions as to who may have actually written Brian Deer's articles published in the *BMJ*. The scientific and medical content of his articles are well beyond what any individual with no formal training in science or medicine would normally be able to write.

To prevent me from uploading my evidence on my NWC website, Deer sent misinformation concerning my professional credentials and association with Andrew Wakefield to the NWC, and included false allegations of ethical misconduct against me (*See*, Attachment 3). Dr. Godlee allowed this behavior to go unchecked even after learning that Deer's allegations were apparently completely false. She even participated in Deer's deceptions regarding my relevant professional credentials.

Without even asking me for a copy of my curriculum vitae, Deer suggested to the NWC that I have no relevant credentials with respect to the *Lancet* article in question. Then,

when rewriting my *Rapid Response*, *BMJ*'s editors inserted the following statement: "I am not qualified in medicine or histopathology"[16], which simply highlighted and amplified Deer's misrepresentations of my professional credentials.

When I referred Dr. Godlee to my extensive credentials listed in my revised commentary [[Attachment 5](#) - Revised Commentary], she replaced the false statement and identified me as "an expert in clinical studies involving the collection and examination of colonic biopsy samples." [17] But, after deleting this commentary and editing down my *Rapid Response*, she described me in her editorial as "a self employed environmental microbiologist." [1] In his feature article, Deer described me as a "self employed American environmental microbiologist working with Wakefield." [10]

I have not been employed as an environmental microbiologist, self or otherwise, since leaving the U.S. Environmental Protection Agency (EPA) in 2003. I live almost entirely on my federal retirement pension. For the past couple of decades, I have derived additional income as an expert witness in federal and state court cases involving the collection and examination of colonic biopsy samples. This is an area in which I have extensive professional credentials.

Since January 2011, I have worked full-time investigating Dr. Wakefield's records on a voluntary basis, with no pay. I approached Dr. Wakefield in my capacity as director of the NWC's research misconduct project to learn more about the *BMJ*'s and Brian Deer's allegations of research fraud. He did not solicit my help. I requested copies of his court pleadings and other documents; he did not approach me and offer up any of his documents. The misrepresentations Dr. Godlee and Mr. Deer published regarding my relationship with Dr. Wakefield and my current employment appear to be intentionally dishonest. More specifically, they appear to have intentionally misled the public as to the credibility of my conclusions concerning their allegations of research fraud against Dr. Wakefield.

Finally, Dr. Godlee and the *BMJ*'s lawyers appear to have attempted to get the NWC to intentionally violate UCL's copyrights on the grading sheets after UCL would not give them permission to publish them. [18] (*See*, Attachment 1) Godlee wrote: *The advice from our lawyers is that the risk of any challenge from UCL in relation to publication of the grading sheets is infinitesimally small ... and [UCL] would not, in my view, seek the adverse publicity that would follow if they were to take legal action.*

Dr. Godlee's excuse for not obtaining informed consent before publishing the children's medical records is even more disturbing. Admitting that the parents are more inclined to cooperate with Dr. Wakefield on such matters, Godlee wrote: "given (a) the fact that most of the families of the patients in question are known to be dedicated supporters of Andrew Wakefield and opponents of Brian Deer and his work and (b) the tenor of the articles that we were proposing to publish alongside David Lewis's letter, we reasonably believed that even if we could establish contact with the patients or their families, we would not obtain consent." [19]

Conclusions

Dr. Godlee's apparent complicity with regard to Deer's use of false allegations to prevent the NWC from publishing incriminating evidence of their wrongdoing, and her apparent unethical behavior regarding the matter of UCL's copyrights and the publication of the children's medical records, are particularly reprehensible. Moreover, the range and scale of misbehavior that I witnessed in the manner in which *BMJ*'s editors and Brian Deer interacted with me and the NWC, respectively, are extraordinary.

I welcome UCL's forthcoming investigation of the issues raised by the *BMJ*'s and Brian Deer's many allegations, including their latest ones based on the documents I submitted. Hopefully, UCL and others will begin to view the *BMJ*'s all-out assault on the embattled *Lancet* study for what it is. It is a vicious and malicious campaign aimed at punishing Dr. Wakefield, his coauthors, and their institutions for reporting the simple truth that some parents and physicians associate autism with the MMR vaccine. This assault is being waged by a journal funded by the two leading manufacturers of the MMR vaccine, and a reporter who employs the despicable tactics of which he falsely accuses Dr. Wakefield.

Ostensibly, the *BMJ*'s defamatory campaign against Dr. Wakefield and his coauthors serves to protect children around the world from money-grubbing scientists who, according to Godlee's editorial, are causing great harm to public health. In reality, the ongoing attacks on Wakefield, his coauthors, and their institutions are a major contributing factor to growing numbers of parents and physicians resorting to alternative vaccine schedules. They feel that they cannot trust government agencies and scientific journals to tell the truth when it comes to vaccine safety.

ADDITIONAL DETAILS

Government connections

From the beginning, attacks on Dr. Wakefield were a means to protect Government officials in the UK from being held accountable for their lack of proper oversight. In 1988, they approved an MMR vaccine containing live Urabe AM-9 mumps virus (Pluserix), which was withdrawn in 1992 after causing outbreaks of meningitis [20-23].

Dr. Wakefield's dean, Prof. Arie Zuckerman, was the first to use ethics rules as a means to prevent Wakefield's research from uncovering more problems with the MMR vaccine. Zuckerman wrote to the British Medical Association's Ethics Committee: "Clearly, [Dr. Wakefield's research] could lead to a case against the Government." [24] Committee Chair Dr. E. M. Armstrong replied that delaying or declining to conduct research in the public interest on such grounds "does not appear to be a sound moral argument." [25]

To bring down Dr. Wakefield and his coauthors, Brian Deer and Parliament Member Evan Harris met with *Lancet*'s editors in February of 2004. [26] Harris later cosponsored

a Motion in Parliament blaming Dr. Wakefield for illnesses and deaths associated with preventable outbreaks of measles.[27]

Lancet's chief editor, Richard Horton, helped the UK's General Medical Council (GMC) develop a strategy for prosecuting Dr. Wakefield and two of his coauthors. At a meeting with Horton, one of the Council's regulators jotted down some possible lines of investigation and suggested Horton contact him directly. "He seemed keen to pursue Dr. Wakefield," Horton later remarked, "especially given ministerial interest." [28]

The GMC issued its findings in 2010 and Deer summarized his accomplishments: "My investigation of the MMR issue exposed the frauds behind Wakefield's research. Triggering the longest ever UK General Medical Council fitness to practise hearing and forcing the *Lancet* to retract the paper ... it led to Dr. Wakefield and Walker-Smith being struck off the medical register." [5]

The editing process

In the 72 emails exchanged between me and the *BMJ's* editors, it became increasingly apparent that the *BMJ* had no intention of publishing the photomicrographs of the missing biopsy slides or any of the information in my commentary. At first, I thought that they just had very limited space available for addressing the issue. But, as the editing process drew to a close, that assumption proved wrong.

Dr. Godlee informed me that she was preparing two commentaries from outside experts, a feature article, and an editorial to give their side of the story. She never disclosed the fact that Deer was writing the feature article. The strategy of *BMJ's* editors and lawyers seems clear. They strictly limited my presentation of any evidence that could undermine their allegations of research fraud against Dr. Wakefield.

To this end, Dr. Godlee had my *Rapid Response*, including the attachments, peer-reviewed by two outside experts. Then, following the peer-reviewers' guidance, *BMJ's* editors reduced my *Rapid Response* from 5,000 to approximately 500 words containing mostly background information. I was allowed only four sentences at the end to state my views, which Dr. Godlee restricted to a single issue - histopathology. The insertion of Deer's false claims regarding my professional credentials suggests that he was also involved, directly or indirectly, in editing my *Rapid Response*.

Any effort on my part to include even a morsel of what was lost when my commentary was deleted met with resistance. For example, I tried to add just a few words referring to my view of the *Lancet* article as a whole. Godlee responded: "We are able to go with your revision except for the phrase 'or that the paper as a whole is deceptive' since the grading sheets relate only to the histopathology and not to the *Lancet* paper as a whole."

At the last minute, the *BMJ*'s lawyers removed the main content of the four sentences at the end of my letter in which I had been permitted to state my views.[29] Dr. Godlee wrote:

On closer reading of your letter we find that there are a few sentences that we cannot publish on legal advice. These are the sections that suggest that the BMJ's claim that Andrew Wakefield committed fraud was based on the histopathology. This is not true. I have therefore had to edit the letter further, as you will see in the attached version, again with and without track changes. As well as deleting the necessary sections, I have tried to strengthen the letter in other small ways, by reinstating your "could" and by strengthening the final mention of Dr. Anthony's grading sheets. I'm sorry to have to make these changes but this is the only basis on which I can offer publication of your letter in the BMJ. Please let me know if you are still happy to proceed. Best wishes, Fiona Godlee

I refused to do anything other than change a couple of words, and Dr. Godlee let it pass. It appeared that the *BMJ*'s intention all along was to discourage me to the point that I would eventually withdraw "my" *Rapid Response* (letter). I use quotation marks because the *BMJ*'s editors reversed the roles editors normally have. In my case, they considered it their role to write my letter, and my role to suggest changes.

The most unexpected surprise came when Dr. Godlee informed me that UCL holds copyrights on Prof. Dhillon's and Dr. Anthony's grading sheets, and would not grant permission for the *BMJ* to publish them. Dr. Godlee wanted me to post them on the NWC website; but I informed her that the NWC would not violate the copyright. Dr. Godlee forwarded my response to the *BMJ*'s lawyers, who tried to convince the NWC that there was little risk of getting caught.

Dr. Godlee explained [18]:

The advice from our lawyers is that the risk of any challenge from UCL in relation to publication of the grading sheets is infinitesimally small and that if there was such a challenge, one could simply take the sheets down from the website. There is no suggestion of commercial exploitation of the forms in publishing them, or of commercial loss to UCL, and a strong claim to be publishing in the public interest, which further reduces the risks, as does the fact that UCL wants nothing to do with this and would not, in my view, seek the adverse publicity that would follow if they were to take legal action. If you decide not publish them, I will look again at whether we should do so, although we are launching our new website on the day of publication and I have promised the web team not to do anything complicated on that day.

For Dr. Godlee and the *BMJ*'s lawyers to entice the NWC to intentionally violate UCL's copyright suggests that the journal's leadership apparently has lost its moral compass.

Discussion

Faced with evidence that their allegations of research fraud against Dr. Wakefield are untrue, Dr. Godlee and Brian Deer are now denying that they ever made such allegations in the first place. *Nature* quotes Deer as claiming he "never accused Dr. Wakefield of fraud over his interpretation of pathology records." [7] It is virtually inconceivable for Deer to take such a position after writing in the *BMJ* that Dr. Wakefield misinterpreted the pathologists' grading sheets in order to fake the diagnosis of colitis, and then boasting that he "exposed the frauds behind Wakefield's research."

Dr. Godlee was also quoted in *Nature*, saying: "the journal's conclusion of fraud was not based on the pathology but on a number of discrepancies between the children's records and the claims in the *Lancet* paper." The alleged research frauds put forth by Brian Deer, however, are largely based on interpretations of routine pathology reports by his unnamed experts, and Dr. Wakefield's alleged misrepresentations of histopathology data in Table 1 of the *Lancet* article. Dr. Godlee's claim that the *BMJ* never accused Dr. Wakefield of fraud regarding pathology data is nonsense.

BMJ's instructions to authors permit attachments to be included with a *Rapid Response*. And, in an email dated October 14, Dr. Godlee assured me that the *BMJ* would publish my "letter and other commentary on bmj.com" (Emphasis added). Editors incorporated numerous revisions in my commentary (Attachment 5) until Deputy Editor Tony Delamothe informed me on October 27 that it would not be included.

The section of my commentary titled "Brian Deer's other arguments" specifically dealt with Dr. Godlee's specious defense. In it, I addressed a range of points upon which Brian Deer and the *BMJ* based their allegations of research fraud. *BMJ*'s editors and lawyers eliminated approximately 90% of the text in the body of the *Rapid Response* I originally submitted to the *BMJ*. Then they deleted my attached commentary. *BMJ*'s editors and lawyers, therefore, forced my *Rapid Response* to accommodate Dr. Godlee's defense by making it appear that my only argument was over the grading sheets. To say the least, it was disingenuous for Dr. Godlee to only allow me to comment on the histopathologies described in the grading sheets, and then argue publicly that her fraud allegations are based on something else.

When Dr. Godlee called for a Parliamentary inquiry, she titled her editorial "Institutional Research Misconduct," a term she borrowed from the NWC website. I coined the term to describe the type of research misconduct that occurs "when institutions, including federal agencies, corporations or academic institutions commit or support acts of research misconduct to protect their interests." False allegations of research misconduct have become a weapon of choice when institutions suppress research that threatens their vested interests.[30] The *BMJ*'s handling of Dr. Wakefield's research and my efforts to correct

the record may represent the first time that a prestigious scientific journal has ever taken the lead in an effort involving this form of research misconduct.

Dr. Wakefield and his coauthors immediately came under attack for simply reporting that some of the children's parents and physicians observed a temporal association between MMR vaccination and autism. The ongoing campaign by the *BMJ* and Brian Deer to completely destroy Dr. Wakefield's career and reputation is contributing to a backlash among an increasing number of parents who witness their children developing severe illnesses concurrent with vaccinations. These reactions often increase in severity with subsequent vaccinations, and sometimes result in death. Parents and their sick children are being abandoned by the government agencies and the medical community. They are left to face a government-supported vaccine industry that does little to even monitor children who experience adverse reactions.

The ongoing campaign by Brian Deer and the *BMJ* to destroy Dr. Wakefield has undermined public confidence in the ability of the scientific community to resolve issues involving vaccine safety. This loss of confidence directly contributes to the current trend toward alternative vaccine schedules, which a growing number of parents and physicians see as their only hope. My experience with Deer and the *BMJ* only confirms what the public has always suspected. The *BMJ*'s attacks on Dr. Wakefield have nothing to do with protecting science.

Dr. Godlee recently testified to Parliament: "Even on the peer-reviewed side of things, it has been said that the journals are the marketing arm of the pharmaceutical industry. That is not untrue." [31] Dr. Godlee's complicity when Deer used false allegations to quash evidence is very revealing, especially given the involvement of other editors and the *BMJ*'s lawyers. It appears that the *BMJ* as an institution is deep into the business of using false allegations of research misconduct to protect the funding it receives from Merck and GSK. If true, then the *BMJ* is, by my definition, guilty of institutional research misconduct.

Disclaimer: The views expressed in this document are my own, and have not been reviewed or approved by the National Whistleblowers Center.

ATTACHMENTS

Attachment 1 - Rapid Response emails
Attachment 2 - Photomicrographs
Attachment 3 - Anthony's Power Point
Attachment 4 - Deer's NWC emails
Attachment 5 - Revised Commentary

References

1. Godlee F. Institutional research misconduct. *BMJ*. 2011 Nov 9;343:d7284. <http://www.bmj.com/content/343/bmj.d7284?tab=full> (See also, Editor's *Rapid Response* update.)
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16. Delamothe T to Lewis D. [Email] October 27, 2011. (*See, Attachment 1 - Rapid Response Emails*)
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Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer

Attachment 1 - *Rapid Response* emails

Page 1

From: lewisdavel <lewisdavel@aol.com> Hide
To: fgodlee <fgodlee@bmj.com>
Cc:
Bcc:
Date: Thu, Aug 25, 2011 11:29 pm
Lewis_DL_Environ._triggers.pdf, Nature_interview_2011.pdf

Fiona Godlee, editor in chief,
Jane Smith, deputy editor,
Harvey Marcovitch, associate editor

British Medical Journal

Dear Editors:

Earlier this year, *Nature* invited me to submit a commentary about my experiences at the U.S. Environmental Protection Agency (EPA), which tried to shut down my research documenting public health problems associated with biosolids. (See attached interview *Nature* published last week.)

At the time, I was investigating Andrew Wakefield's case on behalf of the National Whistleblowers Center in Washington, DC. Because of financial and other constraints in the U.K., he was unable to mount a sustained legal effort to defend himself in court. For my review, Dr. Wakefield provided access to all of the files shipped to him when he and his family moved to the United States.

To my surprise, these files include copies of the actual biopsy grading sheets, and photomicrographs of biopsy slides, upon which the children's histologies in his retracted *Lancet* article were based. These materials prove that Dr. Wakefield did not alter the records upon which the *Lancet* article was based, or fabricate any of the children's diagnoses.

Brian Deer, the reporter who filed various allegations against Dr. Wakefield, referred to this evidence as the "ultimate proof" of Dr. Wakefield's guilt or innocence. He believed, however, that the grading sheets and biopsy slides were either lost or irretrievable.

Last May, Harvard University's John F. Kennedy School of Government invited me to speak at a workshop on research ethics. One of *Nature's* reporters attended; and the group was very receptive to what I had to say about the similarities between Wakefield's case and my own.

Instead of just writing about my experiences, I decided to use them to introduce the Wakefield case in the commentary I prepared for *Nature*. After some time, *Nature's* editor decided she would like to cover it in a news article once it is published in another journal.

Since then, *Nature* has stayed in contact with me; and I have submitted the commentary to several other journals. Although editors speak highly of this work, none are willing to publish a commentary that in any way exonerates Dr. Wakefield. Apparently, it is anathema within the scientific community to defend Dr. Wakefield in any manner.

One editor at a prominent medical journal, for example, suggested only one minor change, which was to include an additional reference. He wrote that I was "very brave" and wished me luck. But when I wrote back and asked if he was willing to consider publishing it, he simply replied: "keep me and [my journal] out of it ... [do not] burn me."

It has become prohibitively time consuming for me to reformat my commentary for each new journal to consider. Therefore, before reformatting my commentary for yet another journal, I would very much appreciate knowing up front whether editors would even consider publishing any commentary that stands to exonerate Dr. Wakefield of research fraud.

If there is any interest on your behalf, I would be more than happy to revise it in whatever fashion suits you, and then formally submit it for further consideration. But, if at all possible, please respond promptly so that I can move on to the next journal if necessary.

Your kindness in responding to this inquiry is most greatly appreciated.

Sincerely,

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

NOTICE: This e-mail (including attachments) is covered by the Electronic Communications Privacy Act, 18 USC SS 2510-2521, is confidential, and may be legally privileged. If you are not the intended recipient, you are hereby notified that any retention, dissemination, distribution, or copying of this communication is strictly prohibited. Please reply to the sender that you have received this message in error then delete it. Thank you.

Page 3

From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: jsmith <jsmith@bmj.com> H.Marcovitch <H.Marcovitch@btinternet.com> Sharon Davies
<sdavies@bmj.com>
Bcc:
Date: Sun, Sep 4, 2011 4:11 pm

Dear Dr Lewis, Many thanks for this email and congratulations on your work on environmental protection. I have carefully read the attached material. I don't want to publish the article you have sent for consideration by the BMJ. It contains quite a few inaccuracies which will only serve to mislead and confuse our readers, and I don't find anything in it that undermines what we have so far published in the BMJ. However, you are welcome to submit a rapid response to Brian Deer's article on autistic enterocolitis published in 2010. Should you decide to do this, we may need to ask for some revisions to correct some of the factual inaccuracies in relation to the Andrew Wakefield case. You can submit a rapid response by clicking on the "respond to this article" to the left hand side of the full text on bmj.com. Letters to the editor are selected from among the rapid responses. Should you need any assistance in submitting a rapid response, our Letters editor, Sharon Davies, will be able to help and is copied in. All best wishes, Fiona Godlee

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From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc:
Bcc:
Date: Sun, Sep 4, 2011 5:42 pm

Dear Dr. Godlee,

Your time and consideration in reviewing my proposed contribution to the BMJ is greatly appreciated. I am happy to revise my proposed contribution as a rapid response for the BMJ so that it can be considered as a letter to the editor.

And, I am more than willing, of course, to correct any and all factual inaccuracies. Like everyone, I make mistakes. You will find that I am eager to correct anything once I am provided with documentation or logical arguments that support the corrections. After all, it is far better for me that I correct my mistakes rather than leave them for others to deal with. My only intention is to publish what is factual, true and helpful.

If it turns out that there are any facts in which we cannot agree on their significance or interpretation, I would appreciate an opportunity to present my opinion and state my rationale in my letter. I am optimistic, however, even confident, that once we compare notes and discuss these matters everyone will be on the same page.

It would be helpful if someone could go ahead and point out the specific inaccuracies that were noted and state why they are inaccurate. I assume that at least some of them represent instances where I simply failed to communicate clearly and accurately. Others may be sufficiently peripheral that I can simply delete them. I believe that this would expedite the revision process and benefit everyone.

Thank you again for your very quick response to my inquiry.

Yours truly,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
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Washington, DC 20007

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Page 5

From: lewisdavel <lewisdavel@aol.com>
To: sdavies <sdavies@bmj.com>
Cc:
Bcc:
Date: Wed, Sep 14, 2011 2:25 pm

Dear Ms. Davies,

One question:

No matter what I do to insert a space between paragraphs, the preview of my Rapid Response runs all the lines together. I'm inserting the material paragraph by paragraph in single file web page format. Do I need to keep trying different ways until spaces appear between paragraphs on the preview page?

Many thanks for your help,

David Lewis

Page 6

From: lewisdavel <lewisdavel@aol.com>
To: eletter-figures <eletter-figures@bmjgroup.com>
Cc:
Bcc:
Date: Thu, Sep 15, 2011 10:53 am
Lewis_Attachment_3._Photomicrographs.pdf

Dear Editor,

With this e-mail, I am transmitting Attachment 3 of four (4) attachments, which are referenced in my invited *Rapid Response* to Deer's article, "Wakefield's 'autistic enterocolitis' under the microscope. My Rapid Response is entitled:

Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case

Other attachments will be sent by separate e-mails.

Thank you very much for your assistance.

Sincerely,

David L. Lewis, Ph.D.
National Whistleblowers Center
Washington, DC

Page 7

From: lewisdavel <lewisdavel@aol.com> Hide
To: eletter-figures <eletter-figures@bmjgroup.com>
Cc:
Bcc:
Date: Thu, Sep 15, 2011 10:55 am
Lewis_Attachment_4._Brian_Deer's_Objections.pdf

Dear Editor,

With this e-mail, I am transmitting Attachment 4 of four (4) attachments, which are referenced in my invited *Rapid Response* to Deer's article, "Wakefield's 'autistic enterocolitis' under the microscope. My Rapid Response is entitled:

Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case

Other attachments will be sent by separate e-mails.

Thank you very much for your assistance.

Sincerely,

David L. Lewis, Ph.D.
National Whistleblowers Center
Washington, DC

Page 8

From: lewisdavel <lewisdavel@aol.com> Hide
To: sdavies <sdavies@bmj.com>
Cc:
Bcc:
Date: Fri, Sep 16, 2011 10:20 am

Sharon Davies, Electronic Communications Editor
BMJ Group

Dear Sharon,

Dr. Godlee noted that my original commentary contained a number of inaccuracies regarding Dr. Wakefield's case. I worked very hard at reviewing all of the related documents to make sure that I found and corrected any inaccuracies before they appeared in my Rapid Response. This is something I always do before anything I write goes to press.

There were only two minor details in my Rapid Response that I wasn't absolutely sure about. I thought Dr. Wakefield could easily resolve them. However, I did not want him to review my Rapid Response, or in any way have any influence on anything I wrote, before I submitted it.

Yesterday, I sent Dr. Wakefield a copy of my Rapid Response to read. He called this morning and said that there is only one minor inaccuracy. It has to do with one of the two details that I wasn't sure about. I wrote in my Rapid Response: "Child 11 no longer resided in the United Kingdom by the time the GMC held hearings." Dr. Wakefield pointed out that Child 11 never resided in the United Kingdom.

Dr. Godlee indicated that BMJ's editors would ask me to correct any inaccuracies they find in my Rapid Response, which is what I want more than anything else. If you would, please forward this email to Dr. Godlee. I would like to correct the one inaccuracy noted by Dr. Wakefield. Specifically, I would like for the one line to read: "Child 11 was a U.S. citizen, and therefore was not subject to the GMC's investigations."

I don't believe that the other detail that I wasn't sure about requires any changes. The line immediately preceding the one addressed above states: "They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children (2-5, 9)."

It was my impression, although I was not sure, that in addition to the digital scans of the missing biopsy slides for children 2-5 and 9, that I saw several 2X2 projector slides in Wakefield's files that did not appear to match any of the digital scans. Dr. Wakefield confirmed this morning that he does indeed have in his files two or three 2X2 slides that had not been scanned. He said that he would have them scanned and email them to me today or this weekend.

I would like to leave it up to Dr. Godlee and the other editors, including yourself, as to whether these additional scans should be included in Attachment 3 of my Rapid Response or mentioned in the text.

I wish to thank all of the editors for insisting on complete accuracy in my submission.

Sincerely,

David

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center

Page 9

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Washington, DC 20007

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From: Sharon Davies <SDavies@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Fri, Sep 16, 2011 10:33 am

Dear David,

Thank you very much for your email.

I have immediately taken in your change about child 11(see below), and I will flag up your query about the extra scans to Dr Godlee now.

Best wishes,

Sharon

Rapid Response view

Article citation:

FEATURE:

Brian Deer

Wakefield's "autistic enterocolitis" under the microscope

BMJ 2010; 340: c1127 [\[Full text\]](#)

Rapid Response ID: bmj_el;269995

Article ID: 340/apr15_2/c1127

Article Date: 15 April 2010

Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case		16 September 2011
David L. Lewis, Research Microbiologist <i>National Whistleblowers Center</i>	Brian Deer concluded that Andrew Wakefield misrepresented the results of a blinded analysis of biopsy slides by pathologists Amar Dhillon and Andrew Anthony in order to conclude in Table 1 of the Lancet article that 11 of the 12 children exhibited signs of non-specific colitis. To create Table 1, Wakefield relied on Dhillon's and Anthony's grading sheets where they recorded their observations of various architectural features in the children's colonic tissue samples and assessed inflammation levels. ^{1,2}	
Send response to journal: Re: Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case	Based on interviews with various experts, Deer concluded that pathology grading sheets "don't generate clinical diagnoses such as colitis." He argued, therefore, that Wakefield mistranslated the pathologists' inflammation scores to create the diagnosis of non-specific colitis. However, Deer wrote, the "ultimate proof" lies in the biopsy slides, which are missing. Editors at The Lancet retracted Wakefield's article in 2010 when the General Medical Council (GMC) pursued Deer's previous allegations and found Wakefield and one of his coauthors guilty of professional misconduct.	
Email David L. Lewis		
	In January of this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, West Indies, where Wakefield discussed his research. ³ I was invited as an	

outside observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, news coverage of Deer's latest allegations published in the BMJ broke in the international media. In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article, which contained key documents that have never been published. They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children (2-5, 9). Child 11 was a U.S. citizen, and therefore was not subject to the GMC's investigations.

The GMC's hearings began almost nine years after the Lancet article was published; and many of Anthony's grading sheets were no longer available. Anthony testified that he examined the children's biopsy slides both before and after the Lancet study was published;² however, the GMC's records included only his post-publication results. Almost all of these were dated in 1998, just months after the Lancet article was published.

Since Table 1 was based on the pathologists' grading sheets, and Deer alleged that Wakefield misinterpreted them, it follows that the grading sheets--not the missing slides--are the ultimate proof of whether Wakefield fabricated the diagnoses in the Lancet article. As indicated in Deer's article, scientists disagree over the significance of different architectural features and inflammation levels in colonic tissue samples. Such disagreements do not represent research fraud.

Dhillon's grading sheets (Attachment 1) included boxes to check, which characterized various conditions that are widely recognized as different forms of colitis, including Crohn's disease, ulcerative colitis ("UC"), and infectious, ischemic, and non-specific colitis. In one case (Child 7), Dhillon left the boxes blank, meaning none of these forms of colitis were present. For the remaining 11 children, he checked "non-specific."

Similarly, Anthony described various stages and types of colitis on his forms (Attachment 2). For all but Child 7, he specifically noted active, mild, or moderate "colitis" and/or indicated specific changes diagnostic of colitis, e.g. "chronic inflammation." Photomicrographs of the missing biopsy slides (Attachment 3) exhibit the architectural features described in Dhillon's and Anthony's grading sheets.

Surprisingly, Wakefield's files included a report by Professor Ian Booth, the GMC's expert pediatric gastroenterologist, which mirrors Deer's allegations of research fraud.⁴ Prior to the GMC holding hearings, Booth compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud"

could not be ruled out.

Using this same approach four years later, Deer concluded that Wakefield changed most of the diagnoses from normal to non-specific colitis. "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

Conclusions

Dhillon's and Anthony's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. Deer's results, on the other hand, are consistent with the expert report submitted by Professor Ian Booth, who concluded that most of the Lancet children exhibited no evidence of colitis. Since Booth and Deer both relied upon the same routine pathology reports, this finding was to be expected.

When I asked Booth why the GMC did not pay more attention to his analysis, given the fact that Deer's replication of it received so much attention, he replied: "My analysis of the case records of the children presented in the Lancet publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield et al by the legal team acting on behalf of the GMC."⁵

As an expert in clinical studies involving the collection and examination of colonic biopsy samples [See, Attachment 4], I would have advised against publishing the 1998 Lancet article had the children's histopathologies relied upon routine pathology reports rather than a systematic, blinded expert analysis. It is extremely unlikely that all, or even most, of the on-duty pathologists who created these reports were experts in pathological features associated with inflammatory bowel disease.

In conclusion, it should be no surprise that stringing together biopsy reports from on-duty pathologists with unknown credentials in intestinal pathology does not match a blinded analysis by Dhillon and Anthony, who systematically reviewed all of the biopsies together. Wakefield, in other words, did not fabricate the histopathologies of the 12 children reported in the Lancet article.

Final Note: Brian Deer objected to a preliminary analysis of Wakefield's documents, which I posted on the NWC website in June 2011. He asked Executive Director Stephen Kohn to remove it; and Mr. Kohn obliged. The NWC will refrain from commenting on Mr. Deer's allegations on its website until such time as funding is available for attorneys to review and approve any future postings. Among Mr. Deer's various complaints, he questioned my objectivity and whether I am qualified to comment on these matters. He also indicated that his allegations of research fraud do not rise or fall based upon mismatches in the histopathology records. These

issues are addressed separately (Attachment 4).

References

1. General Medical Council, Statement of Professor Amar Dhillon. 28 July 2006.
2. General Medical Council, Statement of Dr. Andrew Anthony. 18 October 2006.
3. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011. <http://www.vaccinesafetyconference.com/index.html>
4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.
5. Personal communication [Email]. I. Booth, University of Birmingham, to D. Lewis, University of Georgia. 10 August 2011.

Attachments:

1. Professor Amar Dhillon's grading sheets
2. Dr. Andrew Anthony's grading sheets
3. Photomicrographs of biopsy slides (Fig. 1)
4. Brian Deer's objections to the NWC website

Competing interests: None declared

Page 14

From: lewisdavel <lewisdavel@aol.com> Hide
To: sdavies <sdavies@bmj.com>
Cc:
Bcc:
Date: Sun, Sep 18, 2011 6:59 pm
Lewis_Second_Corrected_Attachment_4._Brian_Deer's_Objections.pdf

Dear Sharon,

Hope I'm not becoming a pest, but it would be great if you would consider just two final, easy-but-important changes.

- I corrected a stupid calculation error in 2nd sentence, 2nd paragraph, p. 1 of Attachment 4 to read: *Booth submitted his expert report on 8 November 2006, approximately eight months before the hearings began.*
- To honor BMJ's policy regarding "rudeness," I deleted a borderline remark re. Deer on p. 4 (paragraph 2, last sentence) of Attachment 4. It now simply reads: *Blowing the whistle on institutional research misconduct is not something a scientist should be ashamed of, or have to "own up to."*
- The 2X2 slides that Dr. Wakefield had not scanned, which I mentioned earlier, included a photomicrograph of Child 6, who was not mentioned in paragraph 4 of my Rapid Response.

Change (1) The first two changes can be taken care of by simply substituting the attached file labeled "**Lewis Second Corrected Attachment 4.**"

Change (2) The last change can be accommodated by correcting the numbers inside the parentheses in the next to last line of Paragraph 4 of my Rapid Response to include Child 6 as follows: "They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children **(2-6, 9).**"

If you can, please alert Dr. Godlee to my final two corrections. I am, of course, more than happy to take care of any inaccuracies that she and the other editors may have found as well.

Thanks a million for all of your help Sharon. I hope that you have a good week.

David

P.S. Will the reference numbers for the five references be super-scripted or bracketed in the published version? Reference "3" next to "I" looks like "31."

From: lewisdavel <lewisdavel@aol.com> Hide
To: fgodlee <fgodlee@bmj.com>
Cc: jsmith <jsmith@bmj.com> h.marcovitch <h.marcovitch@btinternet.com> sdavies
<sdavies@bmj.com>
Bcc:
Date: Mon, Sep 19, 2011 6:21 am
Nature_interview_2011.pdf

Dr. Fiona Godlee, FRCP
Editor in Chief, BMJ
BMJ Group

Dear Dr. Godlee,

I wanted to let you know that Eugenie Samuel Reich, Nature's reporter in Cambridge, MA, is wrapping up her coverage of the results of my investigation into the allegations of research fraud against Dr. Andrew Wakefield. She is awaiting some feedback that the GMC has promised, plus some information/quotes from Dr. Wakefield.

Eugenie was put on the story in February by Nature's Comments editor in London, who solicited a commentary from me about my experiences at EPA. Eugenie attended my presentation at Harvard University last spring when I spoke about the similarities between my own case and Wakefield's.

As I mentioned before, Eugenie handled Nature's recent coverage of President Obama's initiative to have all science-related agencies in the U.S. develop policies aimed at preventing political interference with federal research as my case has come to symbolize. (A copy of her article is attached.) She is aware of the Rapid Response I submitted to BMJ.

Again, I want to thank you and the other editors at BMJ for inviting me to submit a Rapid Response. Everyone at the BMJ has been most gracious; and Sharon has been a delight to communicate with. Please do not hesitate to let me know if there is anything at all in my Rapid Response that the BMJ believes could be more accurately, or more appropriately, worded. Last night, I sent Sharon my final two minor corrections.

As you and other editors consider selecting a Rapid Response for the upcoming hard-copy issue, I hope that you will think about highlighting this one. Apart from the perspective that I've written for the BMJ, I believe that the grading sheets and photomicrographs are an important part of the history of Dr. Wakefield's case. It is fitting that they are being made available for the first time on BMJ's website. I also think it would be appropriate if my perspective and a link to these documents were included in the hard copy-issue of the BMJ to help balance out the series of articles by Brian Deer.

Thank you again.

Sincerely,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007
www.researchmisconduct.org

From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: Jane Smith <JSmith@bmj.com> Harvey Marcovitch <H.Marcovitch@btinternet.com>
Sharon Davies <SDavies@bmj.com> Tony Delamothe <tdelamothe@bmj.com>
Bcc:
Date: Mon, Sep 19, 2011 7:38 am

Dear Dr Lewis,

Thank you for this. We are peer reviewing your response and will get back to you as soon as possible.

Do you know when Nature plans to publish its piece.

All best wishes, Fiona Godlee

From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc:
Bcc:
Date: Mon, Sep 19, 2011 8:10 am

Thank you Dr. Godlee.

The reporter's editor indicated that her report would be published as soon as the GMC confirms that the grading sheets are authentic, i.e. that Dr. Wakefield didn't "fabricate" them. About all I could do in my own investigation was to compare the handwriting on the grading sheets with Anthony's and Dhillon's signatures on their affidavits submitted to the GMC. Anthony, in particular, has a very distinctive handwriting, which is recognizable a mile away.

But I have no experience at all in handwriting identification. I guess there's always a chance that Dr. Wakefield fabricated the affidavits. I did, however, get the U.K. attorney Wakefield hired for his defense against the GMC to confirm the authenticity of these documents, which I discovered as I went thru Wakefield's voluminous files at his home in Texas. I don't think there's any chance any of them are fabricated.

The GMC has given multiple assurances that it will respond to Nature soon. The reporter is anxious to, if at all possible, beat the BMJ to the punch so to speak - especially since she has put so much work into this. My feeling is that Nature will publish this week if it hears from the GMC today or tomorrow.

However, regardless of what the BMJ has to say about the documents and my opinions, I would feel that the fairest thing is for you and others at the BMJ, and Mr. Deer also, get to respond first. I just wish I had submitted it to the BMJ first. The thought crossed my mind many times. I just came to the wrong conclusion that it would be probably be a waste of time, until I finally decided it was the best thing to do regardless of whether it would be rejected outright.

I'm sure that Eugenie will let me know the moment Nature hears from the GMC. I will immediately let you know, and pass along to you the GMC's response.

Sincerely,

David Lewis

From: Sharon Davies <SDavies@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Sep 19, 2011 8:15 am
Lewis_Second_Corrected_Attachment_4._Brian_Deer's_Objections.pdf

Dear David,

Thank you for your email.

I have made the corrections (see below; I have highlighted the amendments in bold for ease of finding).

With reference to your email of 16 September 2011 ("Wakefield review") you say:

It was my impression, although I was not sure, that in addition to the digital scans of the missing biopsy slides for children 2-5 and 9, that I saw several 2X2 projector slides in Wakefield's files that did not appear to match any of the digital scans. Dr. Wakefield confirmed this morning that he does indeed have in his files two or three 2X2 slides that had not been scanned. He said that he would have them scanned and email them to me today or this weekend.

I would like to leave it up to Dr. Godlee and the other editors, including yourself, as to whether these additional scans should be included in Attachment 3 of my Rapid Response or mentioned in the text.

Are the two extra slides now included in attachment 3? We think that it would be helpful to see them if possible.

Many thanks.

Best wishes,

Sharon

Rapid Response view

Article citation:

FEATURE:

Brian Deer

Wakefield's "autistic enterocolitis" under the microscope

BMJ 2010; 340: c1127 [\[Full text\]](#)

Rapid Response ID: bmj_el;269995

Article ID: 340/apr15_2/c1127

Article Date: 15 April 2010

Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case	16 September 2011
--	-------------------------

David L. Lewis,
Research
Microbiologist

Brian Deer concluded that Andrew Wakefield misrepresented the results of a blinded analysis of biopsy slides by pathologists Amar Dhillon and Andrew Anthony in order to conclude in Table 1 of the Lancet article that

National
Whistleblowers Center

Send response to
journal:

[Re: Grading sheets,
photomicrographs of
missing biopsy slides
in Wakefield's case](#)

[Email](#) David L. Lewis

11 of the 12 children exhibited signs of non-specific colitis. To create Table 1, Wakefield relied on Dhillon's and Anthony's grading sheets where they recorded their observations of various architectural features in the children's colonic tissue samples and assessed inflammation levels.^{1,2}

Based on interviews with various experts, Deer concluded that pathology grading sheets "don't generate clinical diagnoses such as colitis." He argued, therefore, that Wakefield mistranslated the pathologists' inflammation scores to create the diagnosis of non-specific colitis. However, Deer wrote, the "ultimate proof" lies in the biopsy slides, which are missing. Editors at The Lancet retracted Wakefield's article in 2010 when the General Medical Council (GMC) pursued Deer's previous allegations and found Wakefield and one of his coauthors guilty of professional misconduct.

In January of this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, West Indies, where Wakefield discussed his research.³ I was invited as an outside observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, news coverage of Deer's latest allegations published in the BMJ broke in the international media. In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article, which contained key documents that have never been published. They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children (2-6, 9). Child 11 was a U.S. citizen, and therefore was not subject to the GMC's investigations.

The GMC's hearings began almost nine years after the Lancet article was published; and many of Anthony's grading sheets were no longer available. Anthony testified that he examined the children's biopsy slides both before and after the Lancet study was published;² however, the GMC's records included only his post-publication results. Almost all of these were dated in 1998, just months after the Lancet article was published.

Since Table 1 was based on the pathologists' grading sheets, and Deer alleged that Wakefield misinterpreted them, it follows that the grading sheets--not the missing slides--are the ultimate proof of whether Wakefield fabricated the diagnoses in the Lancet article. As indicated in Deer's article, scientists disagree over the significance of different architectural features and inflammation levels in colonic tissue samples. Such disagreements do not represent research fraud.

Dhillon's grading sheets (Attachment 1) included boxes to check, which characterized various conditions that are widely recognized as different forms of colitis, including Crohn's disease, ulcerative colitis ("UC"), and infectious, ischemic, and non-specific colitis. In one case (Child 7), Dhillon

left the boxes blank, meaning none of these forms of colitis were present. For the remaining 11 children, he checked "non-specific."

Similarly, Anthony described various stages and types of colitis on his forms (Attachment 2). For all but Child 7, he specifically noted active, mild, or moderate "colitis" and/or indicated specific changes diagnostic of colitis, e.g. "chronic inflammation." Photomicrographs of the missing biopsy slides (Attachment 3) exhibit the architectural features described in Dhillon's and Anthony's grading sheets.

Surprisingly, Wakefield's files included a report by Professor Ian Booth, the GMC's expert pediatric gastroenterologist, which mirrors Deer's allegations of research fraud.⁴ Prior to the GMC holding hearings, Booth compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded that Wakefield changed most of the diagnoses from normal to non-specific colitis. "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

Conclusions

Dhillon's and Anthony's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. Deer's results, on the other hand, are consistent with the expert report submitted by Professor Ian Booth, who concluded that most of the Lancet children exhibited no evidence of colitis. Since Booth and Deer both relied upon the same routine pathology reports, this finding was to be expected.

When I asked Booth why the GMC did not pay more attention to his analysis, given the fact that Deer's replication of it received so much attention, he replied: "My analysis of the case records of the children presented in the Lancet publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield et al by the legal team acting on behalf of the GMC."⁵

As an expert in clinical studies involving the collection and examination of colonic biopsy samples [See, Attachment 4], I would have advised against publishing the 1998 Lancet article had the children's histopathologies relied upon routine pathology reports rather than a systematic, blinded expert analysis. It is extremely unlikely that all, or even most, of the on-duty pathologists who created these reports were experts in pathological

features associated with inflammatory bowel disease.

In conclusion, it should be no surprise that stringing together biopsy reports from on-duty pathologists with unknown credentials in intestinal pathology does not match a blinded analysis by Dhillon and Anthony, who systematically reviewed all of the biopsies together. Wakefield, in other words, did not fabricate the histopathologies of the 12 children reported in the Lancet article.

Final Note: Brian Deer objected to a preliminary analysis of Wakefield's documents, which I posted on the NWC website in June 2011. He asked Executive Director Stephen Kohn to remove it; and Mr. Kohn obliged. The NWC will refrain from commenting on Mr. Deer's allegations on its website until such time as funding is available for attorneys to review and approve any future postings. Among Mr. Deer's various complaints, he questioned my objectivity and whether I am qualified to comment on these matters. He also indicated that his allegations of research fraud do not rise or fall based upon mismatches in the histopathology records. These issues are addressed separately (Attachment 4).

References

1. General Medical Council, Statement of Professor Amar Dhillon. 28 July 2006.
2. General Medical Council, Statement of Dr. Andrew Anthony. 18 October 2006.
3. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011. <http://www.vaccinesafetyconference.com/index.html>
4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.
5. Personal communication [Email]. I. Booth, University of Birmingham, to D. Lewis, University of Georgia. 10 August 2011.

Attachments:

1. Professor Amar Dhillon's grading sheets
2. Dr. Andrew Anthony's grading sheets
3. Photomicrographs of biopsy slides (Fig. 1)
4. **Lewis Second Corrected Attachment 4 Brian Deer's objections pdf**

Competing interests: None declared

Page 22

From: lewisdavel <lewisdavel@aol.com> Hide
To: SDavies <SDavies@bmj.com>
Cc:
Bcc:
Date: Mon, Sep 19, 2011 8:23 am

Thanks so much Sharon. I received the scans of the extra slides yesterday - two more for Child 4 and one for Child 6. I'll add these as a second page in Attachment 3, and sent it to you shortly.

David

Page 23

From: Sharon Davies <SDavies@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date:
Mon, Sep 19, 2011 9:57 am

Thank you. I have done that now.

Best wishes,

Sharon

From: lewisdavel <lewisdavel@aol.com> Hide
To: fgodlee <fgodlee@bmj.com>
Cc:
Bcc:
Date: Mon, Sep 19, 2011 12:53 pm

Dear Dr. Godlee,

Eugenie Reich just informed me regarding Wakefield's copies of Dhillon's and Anthony's grading sheets:

"The GMC confirmed that they consider release of this data a breach of data protection law in the UK and therefore won't verify it."

Given the GMC's position, it is apparently not a good idea for the BMJ to publish Attachments 1 and 2 of my Rapid Response. Instead, I can publish them on the National Whistleblowers Center website simultaneously with the BMJ publishing my Rapid Response.

My attorneys, who are aware of the UK's data protection law and other laws relevant to GMC documents, said that the U.S. Constitution protects my rights to publish these data in the U.S. They said this applies to Wakefield as well since he is a US resident.

David Lewis

From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Sep 19, 2011 4:32 pm

Dear Dr Lewis, many thanks for letting us know. We are still seeking peer review comments. You reference two statements by Professor Booth and one by Professor Dhillon. Could you send copies of those statements or links to them. Best wishes, Fiona Godlee

From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Wed, Sep 21, 2011 8:29 am

Dear Dr Lewis, We are still working on this matter and are grateful to you for the information you have provided. One of the peer reviewers I had hoped would be able to look at the material is unable to do so. I am therefore seeking another reviewer's opinion today. Might you be able to resend the links to the grading sheets as I am concerned that these will expire tomorrow before he has had a chance to review them. Many thanks indeed. Fiona Godlee

Dr Fiona Godlee FRCP
Editor in chief, BMJ
BMJ Group
BMA House
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London WC1H 9JR

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From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: sdavies <sdavies@bmj.com>
Bcc:
Date: Wed, Sep 21, 2011 9:27 am
FINAL_Attachment_4._Brian_Deer's_Objections.pdf

Dear Dr. Godlee,

I am happy to upload the grading sheets to new temporary files and send you the new links shortly. The process takes approximately an hour.

I let Eugenie Reich know that my Rapid Response is being peer-reviewed. She sent the following response: Dear David, I'll also be really interested to see what happens in the peer review process, please keep me posted. I have several stories going through at the moment (and always) and feel bad that I can't allocate more time to this but I feel it needs to build up some of its own momentum before we weigh in. I'll be slowly continuing to contact some of the others when I can.

I'm glad it worked out that way. Now you don't have to be concerned about Nature putting anything out before you have time to gather whatever information you need. I'm very happy that you are having my Response and associated materials peer-viewed. Please let me know if you need anything else at all.

I noticed just this morning in reading through Attachment 4 that the first sentence of the last paragraph at the very end (p.8) does not mesh with the last sentence of that paragraph. The "Final Attachment 4" file is attached. I would appreciate it very much if Sharon would substitute it. (She is copied on this email.)

Many thanks for the careful attention you are giving to the materials I substituted. Regardless of what the reviewers have to say about my conclusions, it was well worth my time to provide some of the key missing documents for the BMJ to address, and help complete the record in this important story.

David Lewis

From: Sharon Davies <SDavies@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Wed, Sep 21, 2011 9:49 am
FINAL_Attachment_4._Brian_Deer's_Objections.pdf

Dear David,

Thank you for copying me in on your correspondence with my editor. Please would you mark on the copy of your rapid response below (perhaps in bold) the correction I should make to your rapid response.

To confirm, Is FINAL Attachment 4 to be used over Corrected Attachment 4 of your email of 16 September?

Thank you for your help.

Best wishes,

Sharon

Rapid Response view

Article citation:

FEATURE:

Brian Deer

Wakefield's "autistic enterocolitis" under the microscope

BMJ 2010; 340: c1127 [\[Full text\]](#)

Rapid Response ID: bmj_el;269995

Article ID: 340/apr15_2/c1127

Article Date: 15 April 2010

Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case		16 September 2011
David L. Lewis, Research Microbiologist <i>National Whistleblowers Center</i>	Brian Deer concluded that Andrew Wakefield misrepresented the results of a blinded analysis of biopsy slides by pathologists Amar Dhillon and Andrew Anthony in order to conclude in Table 1 of the Lancet article that 11 of the 12 children exhibited signs of non-specific colitis. To create Table 1, Wakefield relied on Dhillon's and Anthony's grading sheets where they recorded their observations of various architectural features in the children's colonic tissue samples and assessed inflammation levels. ^{1,2}	
Send response to journal: Re: Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case	Based on interviews with various experts, Deer concluded that pathology grading sheets "don't generate clinical diagnoses such as colitis." He argued, therefore, that Wakefield mistranslated the pathologists' inflammation scores to create the diagnosis of non-specific colitis. However, Deer wrote, the "ultimate proof" lies in the biopsy slides, which are missing. Editors at The Lancet retracted Wakefield's article in 2010 when the General Medical Council (GMC) pursued Deer's previous allegations and found Wakefield and one of his coauthors guilty of	
Email David L. Lewis		

professional misconduct.

In January of this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, West Indies, where Wakefield discussed his research.³ I was invited as an outside observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, news coverage of Deer's latest allegations published in the BMJ broke in the international media. In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article, which contained key documents that have never been published. They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children (2-6, 9). Child 11 was a U.S. citizen, and therefore was not subject to the GMC's investigations.

The GMC's hearings began almost nine years after the Lancet article was published; and many of Anthony's grading sheets were no longer available. Anthony testified that he examined the children's biopsy slides both before and after the Lancet study was published;² however, the GMC's records included only his post-publication results. Almost all of these were dated in 1998, just months after the Lancet article was published.

Since Table 1 was based on the pathologists' grading sheets, and Deer alleged that Wakefield misinterpreted them, it follows that the grading sheets--not the missing slides--are the ultimate proof of whether Wakefield fabricated the diagnoses in the Lancet article. As indicated in Deer's article, scientists disagree over the significance of different architectural features and inflammation levels in colonic tissue samples. Such disagreements do not represent research fraud.

Dhillon's grading sheets (Attachment 1) included boxes to check, which characterized various conditions that are widely recognized as different forms of colitis, including Crohn's disease, ulcerative colitis ("UC"), and infectious, ischemic, and non-specific colitis. In one case (Child 7), Dhillon left the boxes blank, meaning none of these forms of colitis were present. For the remaining 11 children, he checked "non-specific."

Similarly, Anthony described various stages and types of colitis on his forms (Attachment 2). For all but Child 7, he specifically noted active, mild, or moderate "colitis" and/or indicated specific changes diagnostic of colitis, e.g. "chronic inflammation." Photomicrographs of the missing biopsy slides (Attachment 3) exhibit the architectural features described in Dhillon's and Anthony's grading sheets.

Surprisingly, Wakefield's files included a report by Professor Ian Booth, the GMC's expert pediatric gastroenterologist, which mirrors Deer's allegations of research fraud.⁴ Prior to the GMC holding hearings, Booth compared routine pathology reports from the Royal Free Hospital with

Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded that Wakefield changed most of the diagnoses from normal to non-specific colitis. "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

Conclusions

Dhillon's and Anthony's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. Deer's results, on the other hand, are consistent with the expert report submitted by Professor Ian Booth, who concluded that most of the Lancet children exhibited no evidence of colitis. Since Booth and Deer both relied upon the same routine pathology reports, this finding was to be expected.

When I asked Booth why the GMC did not pay more attention to his analysis, given the fact that Deer's replication of it received so much attention, he replied: "My analysis of the case records of the children presented in the Lancet publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield et al by the legal team acting on behalf of the GMC."⁵

As an expert in clinical studies involving the collection and examination of colonic biopsy samples [See, Attachment 4], I would have advised against publishing the 1998 Lancet article had the children's histopathologies relied upon routine pathology reports rather than a systematic, blinded expert analysis. It is extremely unlikely that all, or even most, of the on-duty pathologists who created these reports were experts in pathological features associated with inflammatory bowel disease.

In conclusion, it should be no surprise that stringing together biopsy reports from on-duty pathologists with unknown credentials in intestinal pathology does not match a blinded analysis by Dhillon and Anthony, who systematically reviewed all of the biopsies together. Wakefield, in other words, did not fabricate the histopathologies of the 12 children reported in the Lancet article.

Final Note: Brian Deer objected to a preliminary analysis of Wakefield's documents, which I posted on the NWC website in June 2011. He asked Executive Director Stephen Kohn to remove it; and Mr. Kohn obliged. The NWC will refrain from commenting on Mr. Deer's allegations on its website until such time as funding is available for attorneys to review and approve any future postings. Among Mr. Deer's various complaints, he

questioned my objectivity and whether I am qualified to comment on these matters. He also indicated that his allegations of research fraud do not rise or fall based upon mismatches in the histopathology records. These issues are addressed separately (Attachment 4).

References

1. General Medical Council, Statement of Professor Amar Dhillon. 28 July 2006.
2. General Medical Council, Statement of Dr. Andrew Anthony. 18 October 2006.
3. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011. <http://www.vaccinesafetyconference.com/index.html>
4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.
5. Personal communication [Email]. I. Booth, University of Birmingham, to D. Lewis, University of Georgia. 10 August 2011.

Attachments:

1. Professor Amar Dhillon's grading sheets
2. Dr. Andrew Anthony's grading sheets
3. Photomicrographs of biopsy slides (Fig. 1)
4. Brian Deer's Objections to NWC website

Competing interests: None declared

Page 32

From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: Sharon Davies <sdavies@bmj.com>
Bcc:
Date: Wed, Sep 21, 2011 10:00 am

Many thanks. We will be in touch once we have heard from the reviewer. Best wishes, Fiona Godlee

Page 33

From: lewisdavel <lewisdavel@aol.com> Hide
To: SDavies <SDavies@bmj.com>
Cc:
Bcc:
Date:
Wed, Sep 21, 2011 10:29 am

Thanks very much Sharon. There are no changes in my Rapid Response. All you need to do is trash the previous PDF file labeled "Lewis Second Corrected Attachment 4. Brian Deer's Objections" and, in its place, use the corrected file I sent to Dr. Godlee (and copied you) labeled "FINAL Attachment 4. Brian Deer's Objections."

I assume that when my Rapid Response is published, the four Attachments will be posted on the BMJ.com page for Rapid Responses and internally linked to my Rapid Response where readers can click on each Attachment to view it.

Best always,

David

Page 34

From: Sharon Davies <SDavies@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Wed, Sep 21, 2011 10:34 am

Dear David,

Thank you! The links to the attachments is something to work out when we come to post your response (note to self). Not for you to worry, and I will enlist the help of colleagues when the time comes.

Best wishes,

Sharon

From: lewisdavel <lewisdavel@aol.com> Hide
To: fgodlee <fgodlee@bmj.com>
Cc:
Bcc:
Date: Wed, Sep 21, 2011 10:56 am

Dear Dr. Godlee,

The new temporary (5-day) URL's are:

Dhillon's Grading Sheets:

<https://rcpt.yousendit.com/1231218406/6fee4883539e9ccb68f540ab2213bb2a>

Anthony's Grading Sheets:

<https://rcpt.yousendit.com/1231271512/76720e83831646f64c14170f6fc5729e>

I'll be traveling the rest of the day thru Friday night, but am taking a thumb drive containing my Rapid Response files in case you need anything else.

Best always,
David Lewis

From: lewisdavel <lewisdavel@aol.com>
To: fgodlee <fgodlee@bmj.com>
Cc:
Bcc:
Date: Thu, Oct 13, 2011 8:13 am

Dear Dr. Godlee,

Dr. Wakefield forwarded to me his communications with his former attorneys who represented him before the GMC (below). As you may recall, *Nature's* reporter, Eugenie Reich, wants a copy of the GMC's cover letter transmitting the GMC's copies of Dhillon's and Anthony's original grading sheets to Wakefield's attorneys during the GMC's hearings. Below, the attorneys' office replies that they are having to manually search 172 boxes of documents, which may take some time.

Do you have any idea when the reviews of my Rapid Response will be in, and when my Rapid Response will be published?

Thank you again for inviting me to submit my materials to the *BMJ*.

Best always,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

[Forwarded to David Lewis by Andrew Wakefield]

From: Andy Wakefield
To: [Redacted]
Date: Wed, Oct 12, 2011 7:32 am

Many thanks. I realize that this is a big task and your help is much appreciated.
Andy

Subject: RE: schedule
Date: Tue, 11 Oct 2011 18:11:26 +0100
From: [Redacted]
To: [Andy Wakefield]

Andy,

My trainee looked but could not find the schedule electronically. We have 172 boxes of papers and although the contents are scheduled, that is done compendiously. It may take a little time.

From: Andy Wakefield
Sent: 11 October 2011 13:38 PM

Page 37

To: [Redacted]
Subject: schedule

Dear [Redacted],

Any news on the schedule confirming the provision, by GMC/FFW, of the original histopathology scoring sheets of Drs Anthony and Dhillon? [Redacted]
Andy

[Redacted]

From: lewisdavel <lewisdavel@aol.com> Hide
To: SDavies <SDavies@bmj.com>
Cc:
Bcc:
Date:
Fri, Oct 14, 2011 9:24 am

Dear Sharon,

I tried reaching Dr. Godlee this week regarding my peer-reviewed letter. Do you happen to know whether she is away from her office and, if so, when she will return? Hope you have a great weekend.

David

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

-----Original Message-----

From: Sharon Davies <SDavies@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Sent: Wed, Sep 21, 2011 10:34 am
Subject: Re: GMC response

Dear David,

Thank you! The links to the attachments is something to work out when we come to post your response (note to self). Not for you to worry, and I will enlist the help of colleagues when the time comes.

Best wishes,

Sharon

[Note from D. Lewis: Beginning on this date, AOL began forwarding all of my emails to my spam folder. I discovered and corrected the problem on Oct 17.]

Re: GMC cover letter status
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: Sharon Davies <sdavies@bmj.com>
Bcc:
Date: Fri, Oct 14, 2011 6:08 am
Dear Dr Lewis.

Thank you for your patience. I have been rather tied up with various things but we have now received comments from peer reviewers. We will edit your letter taking in their suggested changes and shortening it to fit our word limit for letters (300 - 400 words). We will send you the edited version for you to check.

Meanwhile we are also seeking permission from UCL to publish the grading sheets alongside your letter and other commentary on bmj.com. Getting their permission is necessary in UK law as UCL owns the copyright. However, if we don't succeed we can link to the grading sheets on your website.

I hope to be in touch next week with the edited version of your letter and a date for publication.

Best wishes, Fiona Godlee

Subject: NWC Board Meeting
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com> jsmith <jsmith@bmj.com> H.Marcovitch
<H.Marcovitch@btinternet.com> sdavies <sdavies@bmj.com>
Cc:
Bcc:
Date: Fri, Oct 14, 2011 10:23 am

Dear Editors,

The Board of Directors of the National Whistleblowers Center in Washington, DC (www.whistleblowers.org) is meeting in several hours (1PM EST). During the Board Meeting, I have to orally report on the status of my analysis of Brian Deer's article published by the BMJ. The analysis was invited as a Rapid Response, which was typeset on 16 September 2011 (below) and scheduled to be published as a peer-reviewed letter.

I would appreciate it very much if someone could let me know its status before the Board Meeting begins.

Regards,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

Rapid Response view Article citation: FEATURE: Brian Deer Wakefield's "autistic enterocolitis" under the microscope BMJ 2010; 340: c1127 [Full text] Rapid Response ID: bmj_el;269995
Article ID: 340/apr15_2/c1127 Article Date: 15 April 2010
Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case
16 September 2011

David L. Lewis, Research Microbiologist National Whistleblowers Center Send response to journal: Re: Grading sheets, photomicrographs of missing biopsy slides in Wakefield's case
EmailDavid L. Lewis

Brian Deer concluded that Andrew Wakefield misrepresented the results of a blinded analysis of biopsy slides by pathologists Amar Dhillon and Andrew Anthony in order to conclude in Table 1 of the Lancet article that 11 of the 12 children exhibited signs of non-specific colitis. To create Table 1, Wakefield relied on Dhillon's and Anthony's grading sheets where they recorded their observations of various architectural features in the children's colonic tissue samples and assessed inflammation levels.^{1,2}

Based on interviews with various experts, Deer concluded that pathology grading sheets "don't generate clinical diagnoses such as colitis." He argued, therefore, that Wakefield mistranslated the pathologists' inflammation scores to create the diagnosis of non-specific colitis. However, Deer wrote, the "ultimate proof" lies in the biopsy slides, which are missing. Editors at The Lancet retracted Wakefield's article in 2010 when the General Medical Council (GMC) pursued Deer's previous allegations and found Wakefield and one of his coauthors guilty of professional misconduct.

In January of this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, West Indies, where Wakefield discussed his research.³ I

was invited as an outside observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, news coverage of Deer's latest allegations published in the BMJ broke in the international media. In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article, which contained key documents that have never been published. They included the GMC's copies of Dhillon's grading sheets for all but Child 11, plus photomicrographs of the missing slides for some of the children (2-6, 9). Child 11 was a U.S. citizen, and therefore was not subject to the GMC's investigations.

The GMC's hearings began almost nine years after the Lancet article was published; and many of Anthony's grading sheets were no longer available. Anthony testified that he examined the children's biopsy slides both before and after the Lancet study was published;² however, the GMC's records included only his post-publication results. Almost all of these were dated in 1998, just months after the Lancet article was published.

Since Table 1 was based on the pathologists' grading sheets, and Deer alleged that Wakefield misinterpreted them, it follows that the grading sheets--not the missing slides--are the ultimate proof of whether Wakefield fabricated the diagnoses in the Lancet article. As indicated in Deer's article, scientists disagree over the significance of different architectural features and inflammation levels in colonic tissue samples. Such disagreements do not represent research fraud.

Dhillon's grading sheets (Attachment 1) included boxes to check, which characterized various conditions that are widely recognized as different forms of colitis, including Crohn's disease, ulcerative colitis ("UC"), and infectious, ischemic, and non-specific colitis. In one case (Child 7), Dhillon left the boxes blank, meaning none of these forms of colitis were present. For the remaining 11 children, he checked "non-specific."

Similarly, Anthony described various stages and types of colitis on his forms (Attachment 2). For all but Child 7, he specifically noted active, mild, or moderate "colitis" and/or indicated specific changes diagnostic of colitis, e.g. "chronic inflammation." Photomicrographs of the missing biopsy slides (Attachment 3) exhibit the architectural features described in Dhillon's and Anthony's grading sheets.

Surprisingly, Wakefield's files included a report by Professor Ian Booth, the GMC's expert pediatric gastroenterologist, which mirrors Deer's allegations of research fraud.⁴ Prior to the GMC holding hearings, Booth compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded that Wakefield changed most of the diagnoses from normal to non-specific colitis. "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

Conclusions

Dhillon's and Anthony's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. Deer's results, on the other hand, are consistent with the expert report submitted by Professor Ian Booth, who concluded that most of the Lancet children exhibited no evidence of colitis. Since Booth and Deer both relied upon the same routine pathology reports, this finding was to be expected.

When I asked Booth why the GMC did not pay more attention to his analysis, given the fact that Deer's replication of it received so much attention, he replied: "My analysis of the case records of the children presented in the Lancet publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield et al by the legal team acting on behalf of the GMC."⁵

As an expert in clinical studies involving the collection and examination of colonic biopsy samples

[See, Attachment 4], I would have advised against publishing the 1998 Lancet article had the children's histopathologies relied upon routine pathology reports rather than a systematic, blinded expert analysis. It is extremely unlikely that all, or even most, of the on-duty pathologists who created these reports were experts in 2

pathological features associated with inflammatory bowel disease.

In conclusion, it should be no surprise that stringing together biopsy reports from on-duty pathologists with unknown credentials in intestinal pathology does not match a blinded analysis by Dhillon and Anthony, who systematically reviewed all of the biopsies together. Wakefield, in other words, did not fabricate the histopathologies of the 12 children reported in the Lancet article.

Final Note: Brian Deer objected to a preliminary analysis of Wakefield's documents, which I posted on the NWC website in June 2011. He asked Executive Director Stephen Kohn to remove it; and Mr. Kohn obliged. The NWC will refrain from commenting on Mr. Deer's allegations on its website until such time as funding is available for attorneys to review and approve any future postings. Among Mr. Deer's various complaints, he questioned my objectivity and whether I am qualified to comment on these matters. He also indicated that his allegations of research fraud do not rise or fall based upon mismatches in the histopathology records. These issues are addressed separately (Attachment 4).

References

1. General Medical Council, Statement of Professor Amar Dhillon. 28 July 2006. 2. General Medical Council, Statement of Dr. Andrew Anthony. 18 October 2006. 3. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011. <http://www.vaccinesafetyconference.com/index.html> 4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006. 5. Personal communication [Email]. I. Booth, University of Birmingham, to D. Lewis, University of Georgia. 10 August 2011.

Attachments:

1. Professor Amar Dhillon's grading sheets 2. Dr. Andrew Anthony's grading sheets 3. Photomicrographs of biopsy slides (Fig. 1) 4. Brian Deer's Objections to NWC website
Competing interests: None declared

Subject: Re: NWC Board Meeting
From: HARVEY MARCOVITCH <h.marcovitch@btinternet.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Fri, Oct 14, 2011 11:15 am

Dear Dr Lewis,

I no longer have any association with BMJ Publishing Group so cannot assist with your query.

Harvey Marcovitch

Subject: Publishing on Internet
From: lewisdavel <lewisdavel@aol.com> Hide
To: fgodlee <fgodlee@bmj.com>
Cc: jsmith <jsmith@bmj.com> h.marcovitch <h.marcovitch@btinternet.com> sdavies
<sdavies@bmj.com>
Bcc:
Date: Sun, Oct 16, 2011 5:53 pm

Dr. Fiona Godlee, Editor-in-Chief
The BMJ

Dear Dr. Godlee,

Since I have received no responses to the inquiries I sent last week, I assume that you have decided not to publish my *Rapid Response*.

I feel that if the *BMJ* will not publish even a *Rapid Response*, I would be wasting my time revising my materials for another journal.

Therefore, I have arranged for the National Whistleblowers Center to post my submission to the *BMJ*, and all related documents, on the Internet this week -- unless, of course, I hear otherwise from the *BMJ* by sometime tomorrow.

I appreciate all of the consideration you and the other editors at the *BMJ* have given my work. I am confident that if there were any way for you to publish it, you would have done so.

Best always,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

Subject: Re: Publishing on Internet
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: Jane Smith <JSmith@bmj.com> Harvey Marcovitch <H.Marcovitch@btinternet.com>
Sharon Davies <SDavies@bmj.com> Julia Burrell <jburrell@bmj.com>
Bcc:
Date: Sun, Oct 16, 2011 6:07 pm

Dear Dr Lewis, we have emailed you at this email address several times over the past week to give a progress report on your rapid response, which we plan to publish an edited version shortly, once we have passed this by you. I fear that the Blackberry breakdown may have affected these communications. I will resend my previous message in hopes of it reaching you. I will also ask my assistant to call you tomorrow to check that you have received the message. Best wishes, Fiona Godlee

Subject: Re: GMC cover letter status
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: Sharon Davies <sdavies@bmj.com> Julia Burrell <jburrell@bmj.com>
Bcc:
Date: Sun, Oct 16, 2011 6:15 pm

Dear Dr Lewis. I am sending this again - see below, sent to you on Friday - as it does not seem to have reached you. Sharon Davies or my assistant Julia Burrell will call you tomorrow (Monday) to check that it has reached you, and I will send you the edited version of your rapid response on Tuesday for you to check before publication. Best wishes, Fiona Godlee

Subject: Fw: GMC cover letter status
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Oct 17, 2011 8:15 am

Dear Dr Lewis

I am forwarding again in case it didn't arrive. Best wishes.

Julia

----- Forwarded by Julia Burrell/BMJ on 17/10/2011 13:14 -----

From: Fiona Godlee/BMJ
To: "lewisdavel" <lewisdavel@aol.com>
Cc: "Sharon Davies" <sdavies@bmj.com>, "Julia Burrell" <jburrell@bmj.com>
Date: 16/10/2011 23:15
Subject: Re: GMC cover letter status

Dear Dr Lewis. I am sending this again - see below, sent to you on Friday - as it does not seem to have reached you. Sharon Davies or my assistant Julia Burrell will call you tomorrow (Monday) to check that it has reached you, and I will send you the edited version of your rapid response on Tuesday for you to check before publication. Best wishes, Fiona Godlee

From: Fiona Godlee
Sent: 14/10/2011 11:08 GDT
To: "lewisdavel" <lewisdavel@aol.com>
Cc: Sharon Davies
Subject: Re: GMC cover letter status

Dear Dr Lewis.

Thank you for your patience. I have been rather tied up with various things but we have now received comments from peer reviewers. We will edit your letter taking in their suggested changes and shortening it to fit our word limit for letters (300 - 400 words). We will send you the edited version for you to check.

Meanwhile we are also seeking permission from UCL to publish the grading sheets alongside your letter and other commentary on bmj.com. Getting their permission is necessary in UK law as UCL owns the copyright. However, if we don't succeed we can link to the grading sheets on your website.

I hope to be in touch next week with the edited version of your letter and a date for publication.

Best wishes, Fiona Godlee

Subject: Re: GMC cover letter status
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: sdavies <sdavies@bmj.com> jburrell <jburrell@bmj.com>
Bcc:
Date: Mon, Oct 17, 2011 8:30 am

Dear Dr. Godlee, I greatly appreciate you having Julia call me.

I had checked my spam folder several times last week before leaving town. AOL thereafter began inexplicably dumping mail from a number of important senders.

Things sometimes happen at the worst time. I would not have caught this problem in time had Julia not called this morning. I apologize for all of the trouble.

Everything is back on track now, and I look forward to receiving the edited version of my submission.

Yours truly,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

Subject: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: Fiona Godlee <fgodlee@bmj.com> Sharon Davies <SDavies@bmj.com> Jane Smith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 9:44 am
MMR_Lewis_rapid_response_revised.docx

Dear Dr Lewis

I work with Dr Fiona Godlee and Sharon Davies and I've been trying to work out whether you've seen, and approved, this edited version of your rapid response.

As far as I can tell it's been emailed to you at least once. Faxes to the number you've provided were bounced back. I've tried to phone you on your mobile number but after a few rings it cut off.

I telephoned the National Whistleblowers Center just now, who said they'd try to communicate with you my need to make contact.

If you get this message please email me about whether you're happy for us to publish the attachment on our website.

It's preferable for us to communicate via email. I'll be leaving the office at about noon your time but will see emails overnight.

Tony Delamothe
deputy editor

The BMJ Group is one of the world's most trusted providers of medical information for doctors, researchers, health care workers and patients group.bmj.com. This email and any attachments are confidential. If you have received this email in error, please delete it and kindly notify us. If the email contains personal views then the BMJ Group accepts no responsibility for these statements. The recipient should check this email and attachments for viruses because the BMJ Group accepts no liability for any damage caused by viruses. Emails sent or received by the BMJ Group may be monitored for size, traffic, distribution and content. BMJ Publishing Group Limited trading as BMJ Group. A private limited company, registered in England and Wales under registration number 03102371. Registered office: BMA House, Tavistock Square, London WC1H 9JR, UK.

ATTACHMENT:

Revised rapid response from David Lewis

In January this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, where Andrew Wakefield discussed his research.[1] I was invited as an observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, the news broke of Brian Deer's BMJ article on the MMR scare [2] and the BMJ's conclusion that Wakefield was guilty of research fraud.[3] In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article.

Among them were copies of histopathological grading sheets, which Wakefield told me had been created and filled in by one of his co-authors, the pathologist Amar Dhillon. Wakefield said that the grading sheets related to all but one of the 12 children, Child 11, and had been passed to him by the General Medical Council along with all documents collated for its investigation. Child 11 is a US citizen and therefore not subject to the GMC's investigations.

Each grading sheets comprised check boxes to indicate the presence of Crohn's disease or ulcerative colitis, plus a list of other headings: "infectious," "ischemic," "non-specific," and "normal." In one case (Child 7), Dhillon left the boxes blank. For the remaining 10 children, he checked "non-specific." For all but Child 7, he noted active, mild, or moderate "colitis" and/or indicated specific changes such as "chronic inflammation."

Wakefield's files also included a report by Professor Ian Booth, the GMC's expert paediatric gastroenterologist.[4] Booth had compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded: "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." [5] Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

I am not qualified in medicine or histopathology but in my opinion, Dhillon's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. In other words, Wakefield did not alter the histopathologies of the 12 children reported in the Lancet article.

1. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011.
<http://www.vaccinesafetyconference.com/index.html>

2. Deer B. BMJ 2011

3. Godlee et al. BMJ 2011

4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.

5. Deer B. BMJ 2010

Competing interests: None declared

Page 51

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com>
To: TDelamothe <TDelamothe@bmj.com>
Cc:
Bcc:
Date: Thu, Oct 27, 2011 9:50 am

Thank you very much. I'll give it a quick review and get right back to you.

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com>
To: TDelamothe <TDelamothe@bmj.com>
Cc: fgodlee <fgodlee@bmj.com> SDavies <SDavies@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 10:17 am
Lewis_Corrected_Short_BMJ_Letter.doc, Lewis_Reference_6._Brian_Deer's_Objections.doc

Dear Tony:

The shortened letter with corrections is attached. It is particularly important that it links to my response to Brian Deer concerning my qualifications for interpreting medical records and other issues he raised directly related to my response to the BMJ. I included this document at Reference 6. It is attached to this email as a Word format file. Please feel free to suggest any changes that it needs.

Thank you for your help.

Sincerely,

David Lewis

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

Subject: Re: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: Fiona Godlee <fgodlee@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 10:50 am
Lewis_Corrected_Short_BMJ_Letter.doc, Lewis_Reference_6._Brian_Deer's_Objections.doc

Dear David

Thanks for your speedy response, and thanks, particularly for not rewriting your response from scratch.

I have only further suggestion:

Instead of "As a research microbiologist who is called upon to interpret clinical records [6], Dhillon's grading sheets are consistent with the results..."

I think it is better English to say:

"As a research microbiologist who is called upon to interpret clinical records, I believe that Dhillon's grading sheets are consistent with the results..."

**

Which gets us on to the thorny question of your request that we link it to your "response to Brian Deer concerning my qualifications for interpreting medical records and other issues he raised directly related to my response to the BMJ."

It seems to be continuing a battle that has been taking place elsewhere and as far as the BMJ is concerned that's where it should stay. If Brian Deer impugns your qualifications and objectivity in the pages of the BMJ then we would feel a responsibility to let you defend yourself. But, so far, that hasn't happened.

The problems of getting your 3500 word attachment past our lawyers would be gargantuan - and not worth the effort, in our view.

We care about getting your opinion on the interpretation of the biopsies into the journal, but nothing more.

I hope after reflection that you will accept our point of view, so that we can press on with publishing your piece.

Tony Delamothe
deputy editor

Page 54

Subject: Re: Shortened version of your rapid response

From: lewisdavel <lewisdavel@aol.com>

To: TDelamothe <TDelamothe@bmj.com>

Cc: fgodlee <fgodlee@bmj.com>

Bcc:

Date: Thu, Oct 27, 2011 10:53 am

Your rewording is an improvement over what I jotted down.

Thanks very much.

Subject: Re: Shortened version of your rapid response

From: lewisdavel <lewisdavel@aol.com>

To: TDelamothe <TDelamothe@bmj.com>

Cc: fgodlee <fgodlee@bmj.com>

Bcc:

Date: Thu, Oct 27, 2011 10:56 am

RE not posting my attachment is something I will consider. However, my intention is not to publish anything with some form of the attachment. I will let you know by tomorrow.

Thanks again.

David

Subject: Re: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: fgodlee <fgodlee@bmj.com> Jane Smith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 11:00 am

Dear David

Thank you.

We look forward to hearing from you about the attachment - please no later than tomorrow morning.

Tony D

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com>
To: TDelamothe <TDelamothe@bmj.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 12:47 pm

Dear Tony,

Thank you for your patience. Please go ahead and publish the shortened letter with my corrections, including your rewording, without my attachment.

I greatly appreciate everyone's consideration, and the effort put into addressing the issues I raise in my letter.

Best always,

David L.

Subject: Re: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com> Sharon Davies
<SDavies@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 12:58 pm

Dear David

This is great news. We'll proceed with publication as soon as we can.

Tony Delamothe

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com>
To: TDelamothe <TDelamothe@bmj.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 1:25 pm
Revised_Lewis_Rapid_Response.doc

Dear Tony,

I assume everyone caught the typo - "two" and not "tow": "Among them were copies of histopathological grading sheets, which Wakefield told me had been created and filled in by **two** of his co-authors, pathologists Amar Dhillon and Andrew Anthony."

Attached, for your convenience, is the shortened letter with all of the agreed upon changes, including not publishing my attachment referring to Brian Deer's communications with the NWC.

Best wishes,

David

David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

www.researchmisconduct.org

ATTACHMENT:

Revised rapid response from David Lewis

In January this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, where Andrew Wakefield discussed his research.[1] I was invited as an observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, the news broke of Brian Deer's BMJ article on the MMR **controversy** [2] and the BMJ's conclusion that Wakefield was guilty of research fraud.[3] In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article. Among them were copies of histopathological grading sheets, which Wakefield told me had been created and filled in by **two of** his co-authors, pathologists Amar Dhillon **and Andrew Anthony**. Wakefield said that the grading sheets related to all but one of the 12 children, Child 11, and had been passed to him by the General Medical Council along with **other** documents collated for its investigation. Child 11 is a US citizen and therefore not subject to the GMC's investigations.

The grading sheets comprised check boxes to indicate the presence of Crohn's disease or ulcerative colitis, plus a list of other headings: "infectious," "ischemic," "non-specific," and "normal." In one case (Child 7), Dhillon left the boxes blank. For the remaining 10 children, he checked "non-specific." For all but Child 7, **Anthony** noted active, mild, or moderate "colitis" and/or indicated specific changes such as "chronic inflammation."

Wakefield's files also included a report by Professor Ian Booth, the GMC's expert paediatric gastroenterologist.[4]. Booth had compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded: "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." [5] Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

As a research microbiologist who is called upon to interpret clinical records, I believe Dhillon's grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. Namely, Child 7 was the only child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. In other words, Wakefield did not alter the histopathologies of the 12 children reported in the Lancet article.

1. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011.
<http://www.vaccinesafetyconference.com/index.html>
2. Deer B. BMJ 2011
3. Godlee et al. BMJ 2011
4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.
5. Deer B. BMJ 2010

Competing interests: None declared

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com>
To: TDelamothe <TDelamothe@bmj.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 1:35 pm

Thanks Tony. Could you give me a publication date?

I plan to reformat the attachment we dropped and publish it elsewhere. It would be helpful if I could have a copy of the peer reviews obtained by the BMJ to incorporate any suggestions of address any criticisms they made.

Finally, if it's not problematic, please include the URL for my NWC project somewhere in my letter
- www.researchmisconduct.org

Thanks a million for your help.

David

Page 62

Subject: Re: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Thu, Oct 27, 2011 1:30 pm

My eagle eye had spotted this, but thank you.

Tony D

Subject: Brian Deer's Complaint
From: lewisdavel <lewisdavel@aol.com>
To: fgodlee <fgodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> jsmith <jsmith@bmj.com> i.w.booth
<i.w.booth@bham.ac.uk> e.reich <e.reich@us.nature.com>
Bcc:
Date: Sat, Oct 29, 2011 1:43 pm
B._Deer's_Complaint_Re._BMJ_Submission.pdf

Dear Dr. Godlee,

I want to make you aware that Brian Deer has formally complained to the National Whistleblowers Center (NWC) in Washington, DC about my Rapid Response schedule for publication in the BMJ. He alleges that there are "numerous" deceptions in my correspondence with Professor Ian Booth, and requests that the matter be taken up by the Board of Directors of which I am a member.

Mr. Deer provided the following three specific examples of deception: (1) I indicated that a Nature reporter prompted me to write to Professor Booth; (2) I improperly exploited a university email account; and (3) I falsely claimed that Deer expanded upon Booth's expert report submitted to the GMC.

Attached to this email is a PDF file that includes (1) Mr. Deer's latest correspondence with the NWC (pp. 1-2); the chain of emails between me, Professor Booth, and Nature reporter Eugenie Reich (pp.3-4); and my approval from the University of Georgia (pp. 5-6).

Ms. Reich specifically suggested that I write Professor Booth to verify the authenticity of his expert report. She also suggested that I ask Drs. Dhillon and Anthony to verify the authenticity of their grading sheets. The attached email chain supports my account of these events, and includes Ms. Reich's email address. Please feel free to contact her if you have any questions.

I am associated with the University of Georgia School of Ecology, which has allowed me to continue both my environmental research and my investigations regarding institutional research misconduct. Since 2008, UGA has been loaning me computer equipment and providing free email services to continue these efforts. The attached email chain includes the property administrator's email address. Please feel free to contact her if you have any questions.

I have used both my personal and UGA email accounts to correspond with Eugenie Reich. To avoid my emails being automatically deleted as spam, I prefer to initially use my UGA email whenever corresponding with others in academia, and within the scientific community in general.

In one of the attachments I submitted to the BMJ, which you no longer intend to publish, I did refer to Deer's work as "expanding" on Booth's expert report. The source of this statement comes from Mr. Deer's previous complaints submitted to the NWC in which he argued that his allegations against Wakefield go beyond the comparison of histopathology records, which he and Professor Booth used. In my attachment, I made it clear: "To my knowledge, there is no evidence that Deer ever conspired with anyone to help with the job that the GMC's solicitors gave Booth."

I copied this email to Ms. Reich and Professor Booth so that they can contact you if they have any input, good or bad, regarding my account of the events involving them, which are the subject of Mr. Deer's latest allegations.

So far as I'm concerned, Deer's allegations of a shocking campaign of deception on my part only makes me wonder whether there is any truth behind the "elaborate fraud" of which he accuses Wakefield of perpetrating.

Sincerely,

David Lewis

ATTACHMENT:

EMAIL: Brian Deer to National Whistleblowers Center Re. BMJ Submission

From: Brian Deer [mailto:bd@briandeer.com]

To: contact@whistleblowers.org

Cc: ek@whistleblowers.org

Sent: Fri, 28 Oct 2011 08:15:00 -0400

Subject: To: Dr Stephen Kohn

To Dr Stephen Kohn,
Kohn Kohn & Colapinto/National Whistleblowers Center

Dear Dr Kohn,

On June 2, 20 and 22 2011, I wrote to you concerning the conduct of the National Whistleblowers Center in relation to the activities of your board member David Lewis. You didn't respond to or acknowledge my concerns. However, out-of-office autoresponders evidence your organisation's receipt.

Plainly as a consequence, on August 10, Lewis wrote an email to one Professor Ian Booth of the University of Birmingham, England. I have never had any dealings or communications with Professor Booth, and have never seen any article, letter, report or document of any kind authored by him, apart from an extract from a statement concerning Andrew Wakefield published this year at your website.

I attach Lewis's email to Booth. It contains numerous deceptions. For example:

(1) That Lewis was writing on the business of the University of Georgia (improperly exploiting a university email account, rather than using those he publishes at your website and elsewhere)
(2) That he had been prompted to write to Booth by a question from a Nature reporter (3) That "someone had passed along" Booth's report in the Wakefield matter He also plants in the letter the claim that I "expanded" on Booth's report when, as already made crystal clear to Lewis and to you, I had never seen it prior to your publication, let alone expanded upon it.

As we all know, Lewis is pursuing a bitter and malicious campaign of abuse against me. This has intensified following his defeat in the Georgia court of appeal over his sewage sludge grievance. Scrutiny of that grievance would, I think, raise further questions about Lewis, and hence perhaps about some of your organisation's other clients. His allegations against me, recently submitted to the BMJ, the British Medical Journal, include those to the effect that I'm part of a conspiracy with government and industry to conceal possible evidence of horrific injuries purportedly caused to children by vaccines. They are so shocking that any right-minded person would be appalled.

Lewis pursues this campaign in collaboration with the charlatan Wakefield, and could have no honest reason for misleading Booth, or for failing to be straightforward about who Lewis is and the nature of his agenda, set out at your website. The degree of of guileful intent is extraordinary. I think that this whole shocking affair should now be placed before the board of the National Whistleblowers Center, as it goes to the question of whether you - in this instance now outside your previous attorney-client relationship with Lewis - or your organisation could have any honest belief in his integrity.

Yours sincerely,
Brian Deer

<http://briandeer.com>

[Attachment]

From: DavidL@uga.edu
To: i.w.booth@bham.ac.uk
Date: Wed Aug 10, 2011 5:24PM
Professor Ian Booth, Dean of Medicine
School of Clinical and Experimental Medicine
College of Medical and Dental Sciences
University of Birmingham

Dear Professor Booth:
Nature's reporter in Cambridge, Massachusetts is interviewing me pursuant to a presentation I recently gave at Harvard University concerning research misconduct.

I mentioned that someone had passed along to me an expert report that you submitted to the General Medical Council hearings in the matter of Andrew Wakefield and his coauthors. It appears that you were the first person to actually perform the analysis of documents that reporter Brian Deer later expanded upon and wrote about in the British Medical Journal and elsewhere.

This is an interesting bit of history, if the expert report (attached) is authentic. It would be most helpful if you could confirm that you did indeed submit this early analysis. If this is the case, the why didn't the GMC pay it more attention?

Yours sincerely,
David L. Lewis, Ph.D.
Director, Research Misconduct Project
EMAIL SERIES: David Lewis - Ian Booth - Eugenie Reich

From: David Lewis Sent: Thursday, August 11, 2011 4:14 PM To: e.reich@us.nature.com Cc: lewisdavel@aol.com Subject: FW: GMC Expert Report
FYI Thanks, David

From: David Lewis Sent: Thursday, August 11, 2011 4:19 PM
To: Ian Booth [i.w.booth@bham.ac.uk]
Cc:
Subject: RE: GMC Expert Report

Dear Professor Booth Thank you very much for your immediate response. It is very helpful.
Wishing you the best always,
David L. Lewis, Ph.D., Director
Research Misconduct Project
National Whistleblowers Center
3238 P Street, NW
Washington, DC 20007

From: Ian Booth [i.w.booth@bham.ac.uk] Sent: Wednesday, August 10, 2011 11:49 PM To: David Lewis Subject: RE: GMC Expert Report
Dear Dr Lewis

Thank you for your enquiry. Yes, this is my document, although my understanding is that its contents remain confidential between myself and the GMC's solicitors to whom I submitted it. My analysis of the case records of the children presented in the Lancet publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield et al by the legal team acting on behalf of the GMC. I am not aware of

any delay between the submission of my analysis and its incorporation into the arguments brought against Wakefield.

I hope this is helpful.

Yours sincerely

Ian Booth

Professor Ian Booth

Leonard Parsons Professor of Paediatrics and Child Health

The Medical School

University of Birmingham

Birmingham

B15 2TT

Tel +44 (0) 121 414 3687

Fax +44 (0) 121 414 7149

From: David Lewis [mailto:davidl@uga.edu] Sent: 10 August 2011 22:24 To: boothiw@adf.bham.ac.uk Cc: lewisdavel@aol.com Subject: GMC Expert Report

Professor Ian Booth, Dean of Medicine

School of Clinical and Experimental Medicine

College of Medical and Dental Sciences

University of Birmingham

Dear Professor Booth:

Nature's reporter in Cambridge, Massachusetts is interviewing me pursuant to a presentation I recently gave at Harvard University concerning research misconduct.

I mentioned that someone had passed along to me an expert report that you submitted to the General Medical Council hearings in the matter of Andrew Wakefield and his coauthors. It appears that you were the first person to actually perform the analysis of documents that reporter Brian Deer later expanded upon and wrote about in the British Medical Journal and elsewhere. This is an interesting bit of history, if the expert report (attached) is authentic. It would be most helpful if you could confirm that you did indeed submit this early analysis. If this is the case, the why didn't the GMC pay it more attention?

Yours sincerely,

David L. Lewis, Ph.D.

Director, Research Misconduct Project

EMAIL SERIES: David Lewis - UGA

From: LewisDaveL@aol.com [LewisDaveL@aol.com]

Sent: Sunday, November 22, 2009 8:51 PM

To: Bonita A Wagers

Cc: David Lewis

Subject: Re: Authorization for off campus use of Ecology equipment

Bonita Wagers

Administrative Assistant

Odum School of Ecology

RE: Dell Optiplex GX520 control number 590773 and Lenovo Thinkpad Z60M control number 591338

Dear Bonita:

I still need to use these computers off-campus. I purchased them under a grant when I had an office in the Department of Marine Sciences.

There was no place in Ecology for me to set up a desk and computer when Marine Sciences needed my office there last year. So Brenda Maddox had me sign some paperwork to keep these items at home (1310 Saxon Road, Watkinsville) for the time being.

However, if there is any space in Ecology where I could keep these computers and use them there, I would be happy to set them up there. Just let me know what I need to do. I should be in town for the next couple of weeks and can stop by your office at any time, either to sign new paperwork or set up the computers there.

Thanks again,

-David

David L. Lewis, Ph.D.

Director, International Center for Research on Public Health and the Environment

www.researchcenter.uga.edu

DavidL@uga.edu

In a message dated 11/18/2009 1:00:25 PM Eastern Standard Time, bwagers@uga.edu writes:

Hello,

It's that time of year again. I have received notice that the authorization is expiring soon for the following equipment assigned to you:

Dell Computer Optiplex, Inv. #590773

Lenovo Computer Thinkpad, Inv. #591338

I have 2 questions:

1. Do you need to continue off campus use of this equipment?

2. What justification can you give for using it off campus?

As soon as I can get this information, I will fill out the form for you. When I have it ready, I'll let you know so you can come in and sign it. Thanks, Bonita

--

Bonita Wagers

Administrative Assistant

Odum School of Ecology

Ph: 706-542-2968

Subject: Re: Shortened version of your rapid response
From: Tony Delamothe <TDelamothe@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Mon, Oct 31, 2011 5:06 am

Dear David

Thanks for your latest two emails.

We're discussing everything to do with your rapid response tomorrow (Tuesday) and I'll get back to you after that.

Tony Delamothe

Page 69

Subject: Re: Shortened version of your rapid response
From: lewisdavel <lewisdavel@aol.com> Hide
To: TDelamothe <TDelamothe@bmj.com>
Cc: fgodlee <fgodlee@bmj.com> jsmith <jsmith@bmj.com>
Bcc:
Date: Mon, Oct 31, 2011 6:46 am

Great! Thanks for letting me know.

David

Subject: RE: Brian Deer's Complaint
From: Reich, Eugenie Samuel <E.Reich@us.nature.com>
To: lewisdavel <lewisdavel@aol.com> fgodlee <fgodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> jsmith <jsmith@bmj.com> i.w.booth
<i.w.booth@bham.ac.uk>
Bcc:
Date: Mon, Oct 31, 2011 11:31 am

I am not working today so have only looked through this email that I was copied on briefly, but in case it's helpful, I did see David Lewis speak at a Harvard event and I did interview him. I also did ask questions about how the information he has come to him and suggested checking any leaked documents with original sources. This would be a pretty standard practice for a reporter thinking about relying on a leaked document so it was a natural idea from my perspective and I therefore wasn't surprised to see he did that.

A final word is that I haven't decided yet whether/what to write about this. If I did I'd obviously be contacting anyone who might be relevant both in regard to leaked documents and more generally, and I really hope for everyone's help doing a fair accurate story if that happens.

=====
nature
Eugenie Samuel Reich, Reporter
e.reich@us.nature.com
25 First Street, Cambridge, MA 02141
+1.617.475.9243 (Office) +1.617.821.1538 (Cell)

Subject: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: Tony Delamothe <tdelamothe@bmj.com> Sharon Davies <sdavies@bmj.com> Rebecca Coombes <rcoombes@bmj.com>
Bcc:
Date: Wed, Nov 2, 2011 3:29 pm
MMR_Lewis_letter_edited_November_2_2011.doc,
MMR_Lewis_letter_edited_with_track_changes_November_2_2011.doc

Dear Dr Lewis,

Once again I must apologise for the delay in getting back to you. I have been away but I am pleased that my deputy Tony Delamothe has been in touch and has progressed things in my absence. As he explained, we had a meeting yesterday to finalise our plans for publication and I am now able to share these with you.

First I should say that our expert reviewers do not agree with your interpretation of the grading sheets. They conclude that the grading sheets indicate largely normal bowel. However, we think that the grading sheets are important and that the wider medical public should be given an opportunity to consider what they say. We also think that their provenance through you and interpretation by you are important parts of the story.

Secondly, I am afraid that despite my best efforts we find ourselves unable to publish the grading sheets themselves. UCL has not given permission and our lawyers say that without this we cannot publish them on bmj.com.

Given these two issues, our plan is as follows. We would like to publish your letter (once finalised - see further edits and queries below) alongside two commentaries from our expert reviewers, plus a feature article and an editorial explaining where the grading sheets fit into the story.

We would like to do this online at midnight on Wednesday 9 November, with print publication after that.

We do not think it is essential that the grading sheets themselves are made available to readers, but if you decide you would like to place them on the National Whistleblower Center website and were to send us the url by Monday 7 November, we could include that as a link in your letter. If you do decide to do this, we would ask that you do not actually open them up to the public or publicise them in advance of our publication of your letter.

Assuming you are happy with these arrangements, let me now move on to the text of your letter, which we have edited further based on additional comments and yesterday's editorial discussion. Two versions are attached - one with track changes, the other without in order to make it easier to read. The important changes are:

- 1) we have changed "infectious" to "infection" and "ischemic" to "ischaemia" because that's what appears on Dhillon's grading sheets
- 2) we have reintroduced Anthony's results. However it strikes us as odd that he "noted active, mild, or moderate 'colitis' and/or indicated specific changes such as 'chronic inflammation' " as these aren't options appearing on Dhillon's grading sheets - and one assumes Anthony was using the same sheets as his boss rather than something of his own devising. I have queried this in the text
- 3) we have decided to do away with all mention of Child 1, Child 2 etc because the general points can be made just as strongly without that amount of identifying detail
- 4) given the account of your relevant qualifications that you sent us last week, we're happy to reinstate your original: "As an expert in clinical studies involving the collection and examination of

colonic biopsy samples...."

I look forward to hearing from you.

Best wishes, Fiona Godlee

Dr Fiona Godlee FRCP
Editor in chief, BMJ
BMJ Group
BMA House
Tavistock Square
London WC1H 9JR

Tel: +44 (0)207 383 6002/+44 (0)1223 872084
Fax: +44 (0)207 383 6418
BMJ Group: <http://group.bmj.com>

Personal Assistant, Julia Burrell
jburrell@bmj.com
Tel: +44 (0)207 383 6102

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ATTACHMENT:

Letter to the BMJ from David Lewis

In January this year, National Whistleblowers Center (NWC) director Stephen Kohn spoke at a vaccine safety conference in Jamaica, where Andrew Wakefield discussed his research.[1] I was invited as an observer. My responsibilities at the NWC include investigating "institutional research misconduct" in which government, industry and academic institutions use false allegations of research misconduct and other means to suppress scientific research to protect certain government policies and industry practices.

During the conference, the news broke of Brian Deer's BMJ article on the MMR controversy [2] and the BMJ's conclusion that Wakefield was guilty of research fraud.[3] In response to my request for more information, Wakefield allowed me to review his personal files concerning the Lancet article. Among them were copies of histopathological grading sheets, which Wakefield told me had been created and filled in by two of his co-authors, pathologists Amar Dhillon and Andrew Anthony. Wakefield said that the grading sheets related to all but one of the 12 children, who as a US citizen was not subject to the GMC's investigations. Wakefield told me that the GMC had passed the grading sheets on to him along with other documents collated for its investigation.

The grading sheets comprised check boxes for the pathologist to indicate the presence and severity of Crohn's disease or ulcerative colitis, plus a list of other headings: "infection," "ischaemia," "non-specific," and "normal." In one case Dhillon left the boxes blank. For the remaining 10 children, he checked either "non-specific" or "normal", with "non-specific" being checked for at least one of each child's biopsies. For the same 10 children, Anthony noted active, mild, or moderate "colitis" [Could you explain how Anthony did this, since the forms do not mention the word colitis. Did he note this in words on the forms in each case?]and/or indicated specific changes such as "chronic inflammation." [What level of chronic inflammation did he indicate. If only scoring 1 on most occasions, it would be more accurate to say "changes such as "occasional lamina propria polymorphs" or "slight increase in lamina propria mononuclear cells." "] Wakefield's files also included a report by Professor Ian Booth, the GMC's expert paediatric gastroenterologist.[4]. Booth had compared routine pathology reports from the Royal Free Hospital with Table 1 of the Lancet article and found that on-duty pathologists had indicated that most of the children's biopsies were normal. He reported to the GMC that the "altered" diagnoses in the Lancet article suggested "an exaggerated view of the histology," and concluded that "scientific fraud" could not be ruled out.

Using this same approach four years later, Deer concluded: "These changes--from normal to abnormal, or from healthy to diseased--had also raised concern in the mind of at least one of the paper's authors [histopathologist Susan Davies]." [5] Davies, as Deer noted, testified at the GMC's hearings that her concerns were allayed when she discussed them with Dhillon and others.

As an expert in clinical studies involving the collection and examination of colonic biopsy samples, , I believe Dhillon's [and Anthony's?] grading sheets are consistent with the results Wakefield reported for the children's histologies in Table 1 of the Lancet article. [Do you have any views on whether the grading sheets are consistent with what was reported in the Lancet article as a whole, including the claim that these children were exhibiting a "unique disease process"?] Namely, there was only one child whose biopsies showed no evidence of colitis in Dhillon's blinded expert analysis. In other words, Wakefield did not alter the histopathologies of the 12 children reported in the Lancet article.

1. Vaccine Safety: Evaluating the Science. Jamaica, West Indies. 3-8 January 2011.
<http://www.vaccinesafetyconference.com/index.html>

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

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

4. Booth I. General Medical Council, Fitness To Practice Panel (Misconduct). Wakefield, Walker-Smith, Murch. Second Addendum to Overview Statement. 8 November 2006.

5. Deer B. Wakefield's "autistic enterocolitis" under the microscope. BMJ 2010;340:c1127.

Competing interests: None declared

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> sdavies <sdavies@bmj.com> rcoombes
<rcoombes@bmj.com>
Bcc:
Date: Wed, Nov 2, 2011 4:52 pm

Dear Dr. Godlee,

Thank you for your email. I am happy with all of the arrangements made by the BMJ. I should be able to respond to all of the issues you raised by late tonight or early tomorrow morning.

Regards,

David Lewis

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> sdavies <sdavies@bmj.com> rcoombes <rcoombes@bmj.com>
Bcc:
Date: Wed, Nov 2, 2011 11:59 pm
Anthony_Power_Point.ppt, Lewis_Revised_BMJ_LETTER_Nov_2_2011.doc,
Lewis_Revised_BMJ_LETTER_Nov_2_2011.doc

Dear Dr. Godlee,

My revised Nov. 2 letter is attached in two files (with and without changes tracked). In the file where changes are not tracked, places where changes were made are highlighted in red.

Since two commentaries by experts who disagree with my conclusions are to be published with my letter, I want to make sure that my conclusions are clearly and accurately stated. My original attachments along with the majority of my full Rapid Response where I discussed my conclusions and the basis for them were cut out.

I deleted some of the non-critically important text in the Nov 2 version, then replaced the last paragraph with two short paragraphs to ensure that my conclusions are absolutely clear. This, plus adding a few words to address your queries, increased the word length by about 35 words. If you like, I can find more words to remove to accommodate the two short paragraphs I used to supplant the last paragraph in the earlier version.

I feel that this is a reasonable compromise, given that the BMJ is publishing two opposing commentaries, a feature article and an editorial with my letter.

I have contacted the NWC about providing you a non-public URL for the grading sheets by Monday Nov 7, which will be embargoed until midnight Wed Nov 9.

Regarding the queries inserted in the Nov 2 version, I have the following comments:

[Could you explain how Anthony did this, since the forms do not mention the word colitis. Did he note this in words on the forms in each case?]

Anthony and Dillion used different forms when the Lancet article was written. They discussed the grading sheets in their sworn Statements submitted to the GMC. [References 1, 2 of my Rapid Response before it was shortened. Sharon should have these.]

[What level of chronic inflammation did he indicate. If only scoring 1 on most occasions, it would be more accurate to say "changes such as "occasional lamina propria polymorphs" or "slight increase in lamina propria mononuclear cells." "]

Attached is Anthony's PPT presentation, where he discussed his approach for grading levels of inflammation.

[Do you have any views on whether the grading sheets are consistent with what was reported in the Lancet article as a whole, including the claim that these children were exhibiting a "unique disease process"?]

No.

Thank you again for all the work everyone has put into this. I look forward to reading everything next week.

Best always,

David Lewis

Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> sdavies <sdavies@bmj.com> rcoombes <rcoombes@bmj.com>
Bcc:
Date: Thu, Nov 3, 2011 12:19 am
Lewis_Revisions_MMR_Lewis_letter_edited_November_2_2011.doc

Looks like the previous email below is missing the tracked changes, which are attached to this email.

From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> sdavies <sdavies@bmj.com> rcoombes <rcoombes@bmj.com>
Bcc:
Date: Wed, Nov 2, 2011 11:59 pm
Anthony_Power_Point.ppt, Lewis_Revised_BMJ_LETTER_Nov_2_2011.doc,
Lewis_Revised_BMJ_LETTER_Nov_2_2011.doc

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[Do you have any views on whether the grading sheets are consistent with what was reported in the Lancet article as a whole, including the claim that these children were exhibiting a “unique disease process”?]

No.

Thank you again for all the work everyone has put into this. I look forward to reading everything next week.

Best always,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date: Thu, Nov 3, 2011 5:26 pm
MMR_Lewis_letter_revised_with_track_changes_Nov_3_2011.doc,
MMR_Lewis_letter_revised_Nov_3_2011.doc
Dear Dr Lewis,

Many thanks indeed. Much of this is fine and I think we are nearly there. However there are a couple of sections of the letter that require some changes. I have made the changes in the attached version, again with and without track changes. In the version without track changes I have indicated in red the two sections that have been edited.

1. End of paragraph 3: Your text said that Anthony's grading sheets indicated colitis for all but one child. However, on checking the grading sheets the word colitis appears in relation to only one child. We have therefore re-worded this section to simply report what Anthony wrote. I hope you think this is an accurate, if necessarily brief, reflection of what is on the forms. Let me know if not.

2. Penultimate and final paragraphs: We have deleted your final sentence as it was defamatory. However, I think it was also unnecessary as you make the point well without it. This section also required a change to the way you had reported Anthony's comments. Again, I hope you will find these changes fair and accurate.

I look forward to hearing from you.

Best wishes, Fiona Godlee

Dr Fiona Godlee FRCP
Editor in chief, BMJ
BMJ Group
BMA House
Tavistock Square
London WC1H 9JR

Tel: +44 (0)207 383 6002/+44 (0)1223 872084
Fax: +44 (0)207 383 6418
BMJ Group: <http://group.bmj.com>

Personal Assistant, Julia Burrell
jburrell@bmj.com
Tel: +44 (0)207 383 6102

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date:
Thu, Nov 3, 2011 6:33 pm
LEWIS_CHANGES_MMR_Lewis_letter_revised_Nov_3_2011.doc

Dear Dr. Godlee,

I am very appreciative of the meticulous review that BMJ is giving my letter. It is to everyone's benefit.

I agree that my statement that Anthony's grading sheets "indicated colitis for all but one child" could be misleading. I consider chronic inflammation of the colon to at least be indicative of colitis, if not definitive. The problem is wording it in a way so that no one is led to believe that Anthony *wrote* "colitis" on grading sheets for all but one child.

This is particularly important if the NWC cannot post the grading sheets. Steve Kohn said that the UCL may have common law rights, and that he is unsure whether it would be legal for the NWC to post them in the U.S. The fact that the documents are copyrighted was news to us. We thought we were only dealing with legal issues associated with the GMC. If BMJ's attorneys could provide any legal documents that may shed light on this issue, please let me know.

I rechecked Anthony's forms. There are actually two children in which he wrote some form of "chronic colitis" on his grading sheets. This includes the ileal biopsy for Child 5 (Slide 96-13543) where he wrote "mild chronic colitis." For Child 6 (Slide 96-11992), he wrote "active chronic enteritis + colitis" for the ileal biopsy, "Mild active chronic colitis" for the sigmoid biopsy, and "active chronic colitis" for the rectal biopsy.

My suggestion, as indicated in the attached, tracked changes, is to just state "For two children, he noted 'chronic colitis'. The rest of your changes are fine as is.

Many thanks,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Fri, Nov 4, 2011 12:57 pm

Dear Dr Lewis,

Dear Dr Lewis. Just to reply in relation to the legal issues (I will reply with the final text of your letter shortly).

The advice from our lawyers is that the risk of any challenge from UCL in relation to publication of the grading sheets is infinitesimally small and that if there was such a challenge, one could simply take the sheets down from the website.

There is no suggestion of commercial exploitation of the forms in publishing them, or of commercial loss to UCL, and a strong claim to be publishing in the public interest, which further reduces the risks, as does the fact that UCL wants nothing to do with this and would not, in my view, seek the adverse publicity that would follow if they were to take legal action.

If you decide not publish them, I will look again at whether we should do so, although we are launching our new website on the day of publication and I have promised the web team not to do anything complicated on that day. So much for promises!

I would be very grateful if you could let me know your decision on this as soon as possible.

Best wishes, Fiona Godlee

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc:
Bcc:
Date: Fri, Nov 4, 2011 1:05 pm

Dear Dr. Godlee.

This is very helpful.

My impression from Steve Kohn early this morning is that - after looking into the matter - he is inclined to post the grading sheets. I forwarded your email, and will urge him to decide one way or the other today.

Many thanks,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date: Sat, Nov 5, 2011 10:40 am
MMR_Lewis_letter_revised_Nov_5_2011.doc

Dear Dr Lewis,

Apologies for not getting back to you yesterday. We have now had a chance to review again the Anthony grading sheets and think we should increase the number of children for whom he notes "colitis" from two to six. I have made this change in the attached revised version of the letter.

However, I have also noticed that Anthony's grading sheets are dated either September 1998 or October 2001, so they were completed after the Lancet paper was published. I have added a comment to this effect.

In view of this, I have also removed reference to Anthony's conclusions at the end of your letter.

The two sections in red again show where the changes have been made. I hope you are happy with these amendments.

One final thing. The letter says you have declared no conflicts of interest. Could you please clarify who paid for your travel and accommodation for the January 2011 vaccine safety meeting in Jamaica. We recommend to all our authors that they should declare any conflicts of interest before publication in order to avoid embarrassment afterwards.

Thank you again and all best wishes, Fiona Godlee

Dr Fiona Godlee FRCP
Editor in chief, BMJ
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Fax: +44 (0)207 383 6418
BMJ Group: <http://group.bmj.com>

Personal Assistant, Julia Burrell
jburrell@bmj.com
Tel: +44 (0)207 383 6102

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date: Sat, Nov 5, 2011 2:13 pm

Dear Dr. Godlee,

Thank you very much for bringing up the Jamaica related expenses. The conference occurred before my project at the NWC project was contemplated. But since the conference is mentioned in my letter, I should fully explain the connection and how my expenses were covered. I think it would be best for me to come up with a line to add, and then give all the details on my NWC website, which is linked in my letter.

Briefly, Claire Dwoskin -who gave a grant to NVIC to support the Jamaica conference - called me after a close friend, Gina Green, told her about my biosolids research. Gina serves with me on the National Whistleblowers Center Board of Directors.

Claire, whom I'd never met before, called me shortly before the conference began and asked if I would talk about my experiences with biosolids. I agree, but then NVIC told Claire that the conference agenda set in stone and there was no time to include me as a speaker. Claire asked me to come anyway, and just let her know what I thought about the presentations.

The Dwoskins, who have a home in Jamaica, arranged for me to stay with friends of theirs, the Hart family - which I did. I was reimbursed for my travel, which was several hundred dollars to fly coach from Atlanta to Jamaica and back.

I didn't even think to claim any of this as a "competing interest" with my NWC investigation because it all occurred before I even talked with Steve about doing an investigation on Wakefield's case something through my NWC project.

I never heard of Wakefield until all the press coverage hit during the conference. I asked Wakefield to send me a copy of his book, which I read a month or so after the conference. Then I asked him to send me some of the documents referenced in his book, which he did. After that I started asking him about things I considered important, which were not explained in his book, and I obtained other documents from him. Then I talked with Steve about doing an official investigation associated with my NWC project.

Steve flew in from Wash DC to make his presentation and left early the following morning. We had coffee together shortly before he left. He asked about the Wakefield controversy, which was in the news. I remember telling him that one of the speakers at the conference commented during a break that he believed Deer's earlier allegations were true. I asked him how he knew. It was clear he had no first-hand knowledge. There was other talk about it during breaks, and I remember telling Steve that my feeling was the conference speakers and attendees were divided over whether Wakefield was guilty.

Steve left and, at that time, it had not entered my mind to look into Wakefield's case in any depth, much less set up a NWC project on it.

I don't see how expenses to cover me making a presentation on biosolids at a conference that occurred before my research misconduct project was even conceived could be considered a competing interest with the project. But I still would like to have all of this explained in detail on my NWC web page linked in my BMJ letter, plus summarized in a line at the end of my letter if you agree.

I need to cancel plans with others today and tomorrow to address your most recent changes in my letter. I'll do my best to get something back to you late tonight or early tomorrow EST.

The issues you raise are vitally important to the accuracy of my letter. I immensely appreciate this interaction.

David Lewis

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date: Sun, Nov 6, 2011 12:01 am
Corrected_MMR_Lewis_letter_revised_Nov_5_2011.doc,
LEWIS_NWC_SUMMARY_Nov_5_Final_Draft.doc

Dear Dr. Godlee,

Thank you again for locating additional errors in my letter.

Corrections

Seems like every time I look at Anthony's handwriting, I come up with different numbers of places he wrote "colitis." Some are obvious. Others look like similar words, but once I see "colitis" it's obvious that is what he wrote. It's like taking a test for color blindness.

If it's okay with you, I would like to just go with your final count on the attached version.

My long Rapid Response contained the following information: "Anthony testified that he examined the children's biopsy slides both before and after the Lancet study was published;2 however, the GMC's records included only his post-publication results. Almost all of these were dated in 1998, just months after the Lancet article was published."

Your reintroduction of this information in the last version is very important. Thanks so much for catching this after it feel through the cracks in the editing process. Removing my statement at the end regarding Anthony's grading sheets at the end, where I forgot to consider the fact that all we have is his post-Lancet documents, is also good.

However, I still want to address Deer's statement in the article in question, which I quoted in the long version of my Rapid Response as follows: "Based on interviews with various experts, Deer concluded that pathology grading sheets "don't generate clinical diagnoses such as colitis." He argued, therefore, that Wakefield mistranslated the pathologists' inflammation scores to create the diagnosis of non-specific colitis." This is a central issue in my original letter.

In place of the statement at the end, which you removed, please consider the following statement, which I inserted: "If Anthony's grading sheets are similar to ones he completed for the Lancet article, they suggest that he used grading sheets to diagnose 'colitis.'"

In a previous version, you corrected some of my loose descriptions of Dhillon's boxes for checking "UC," "non-specific" etc. For example, you changed "infectious" to "infection." At the time, I only thought about how I had jotted them down from memory and never gone back to accurately reproduce these categories in my letter.

I should have also pointed out that the significance of "infection" for example, which is my area of expertise, depends upon what part of the intestinal tract it involves so far as colitis is concerned. In the attached version, I made the following very minor clarifications: (1)... "not when, for all but one child, Dhillon indicated "non-specific" in a box associated, **in some cases**, with other forms of colitis"; and (2) "Many if not most non-experts in histopathology, such as Wakefield and myself, may conclude that Dhillon's grading sheets **could** indicate non-specific colitis in all but one child."

It's hard to take care of everything from major errors to nuances using just a few words, but hopefully this helps improve the accuracy.

Competing interests.

I inserted the following line: "Prior to investigating Wakefield's documents, organizers of the Jamaica conference covered my travel expenses." But, I left "None declared" before it because I don't see how my attendance to a conference to talk about biosolids, which occurred before my NWC project ever entered my mind could be a competing interest with the NWC project.

This may be too confusing, but I don't know how else to handle it in a few words. I explained it in detail in a summary I plan to post on the NWC website, which will be used to link (hopefully) the grading sheets as well as other important documents.

Attached is what I consider to be the final draft of that summary. I would like for you and others to point out anything that you may want clarified or corrected in my summary to be posted by the NWC (late Nov 9), just as you have with my letter.

So long as my letter includes a link to my NWC web page, and the Jamaica travel expenses are explained in detail in my NWC summary, I really don't care how it's handled in the letter. You can leave it "None declared", or as I have it on the attached version, or remove "None declared."

Along these lines, I have tried to think of anything else at all associated with the conference that would be embarrassing to find out about after my letter is posted. There are only two things I can think of that even remotely apply.

(1) Chris Shaw, who was a speaker and emceed most of the technical presentations, offered me a job [which] would have been funded, at least partly, by the same donor who funded the Jamaica conference. I turned down the offer.

(2) UBC submitted a grant proposal to this donor, which involved funding a number of the scientists who presented at the conference. The donor was unhappy at the way the research was organized. She offered to try to raise some funding to pay me if I would take a look at the different projects and come up with an overall research agenda for the group.

I agreed to take a look at it. I sent her some ideas, but haven't charged anything for my work or come up with a final plan. Whether the UBC group and this potential donor will ever get on the same page, and whether my suggestions will be useful, on time will tell.

I know that having a grant can be a competing interest. I've never heard that applying for funding should be reported as a competing interest. I'll leave it up to you so far as me reporting that someone asked me to propose something, and if they like it, they'll try to raise some research funding, and if that happens, I'll be funded if I'm still interested when all that happens.

The area of research I would like to establish is looking at potential interactions between environmental pollutants and vaccine adjuvants. So far, the donor is cold to the idea, and scientists who presented at the conference - who the donor asked me to share my ideas with - like it even less. My guess is that I will end up getting funding for it from some other source - if I ever do the research at all.

Best always,
David Lewis

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: rcoombes <rcoombes@bmj.com> sdavies <sdavies@bmj.com> tdelamothe <tdelamothe@bmj.com>
Bcc:
Date: Sun, Nov 6, 2011 8:17 am
More_Corrected_MMR_Lewis_letter_revised_Nov_5_2011.doc,
LEWIS_NWC_SUMMARY_Nov_6_Draft.doc

Dear Dr. Godlee,

Re. my NWC summary.

After getting a little sleep, I realized that Wakefield directly observing most of the expert histopathologists' grading activities didn't so much give him insight into how they defined "non-specific colitis," but whether they considered the evidence as a whole to indicate non-specific colitis in all but one child.

I revised the attached Nov 6 NWC text to read:

When Wakefield summarized Dhillon's grading sheets, he likely would have known whether Dhillon and Anthony considered their histopathological data in the grading sheets represented evidence of non-specific colitis. Moreover, Dhillon wrote in his sworn Statement that Wakefield provided him with a copy of Table 1 to review and approve before it was published.

Re. my Letter.

A minor point. Since I inserted "in some cases":

"not when, for all but one child, Dhillon indicated "non-specific" in a box associated, in some cases, with other forms of colitis", it adds nothing to insert "could" in:

"Many if not most non-experts in histopathology, such as Wakefield and myself, may conclude that Dhillon's grading sheets could indicate non-specific colitis in all but one child."

Therefore, I removed "could" in the attached "More corrected" version of my Letter.

Sorry to keep going back and forth so much, thanks for your patience.

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc: Rebecca Coombes <RCoombes@bmj.com> Sharon Davies <SDavies@bmj.com> Tony Delamothe <TDelamothe@bmj.com>
Bcc:
Date: Sun, Nov 6, 2011 8:42 am

Many thanks for this. I am out and about this afternoon but will get back to you as soon as possible later today. Best wishes, Fiona Godlee

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc: Rebecca Coombes <RCoombes@bmj.com> Sharon Davies <SDavies@bmj.com> Tony Delamothe <TDelamothe@bmj.com>
Bcc:
Date: Sun, Nov 6, 2011 2:53 pm
MMR_Lewis_letter_revised_final_November_6_2011.doc

Dear Dr Lewis. Thank you. I have now had a chance to read your several emails and I think we are there!

I will send the attached version to Sharon Davies and Rebecca Coombes for publication.

With best wishes, Fiona Godlee

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Tel: +44 (0)207 383 6102

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Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc: RCoombes <RCoombes@bmj.com> SDavies <SDavies@bmj.com> TDelamothe <TDelamothe@bmj.com>
Bcc:
Date: Sun, Nov 6, 2011 3:01 pm

Dear Dr. Godlee,

The last version is perfect so far as I'm concerned. Everyone's input greatly contributed to ensuring its accuracy. I cannot thank everyone enough.

Best always,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Nov 7, 2011 1:52 pm
MMR_Lewis_letter_revised_final_final_November_7_2011.doc,
MMR_Lewis_letter_revised_final_final_with_track_changes_November_7_2011.doc

Dear Dr Lewis, We have hit a slight problem. On closer reading of your letter we find that there are a few sentences that we cannot publish on legal advice. These are the sections that suggest that the BMJ's claim that Andrew Wakefield committed fraud was based on the histopathology. This is not true. I have therefore had to edit the letter further, as you will see in the attached version, again with and without track changes. As well as deleting the necessary sections, I have tried to strengthen the letter in other small ways, by reinstating your "could" and by strengthening the final mention of Anthony's grading sheets. I'm sorry to have to make these changes but this is the only basis on which I can offer publication of your letter in the BMJ. Please let me know if you are still happy to proceed. Best wishes, Fiona Godlee

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Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com> Hide
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:Date:
Mon, Nov 7, 2011 2:02 pm

Dear Dr Lewis, apologies for not replying sooner. After a discussion today with our lawyers we have decided to post the gradng sheets. I hope this helps. Best wishes, Fiona Godlee

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com> Hide
To: FGodlee <FGodlee@bmj.com>
Cc:
Bcc:
Date: Mon, Nov 7, 2011 2:56 pm
LEWIS_FINAL_CHANGES_MMR_Lewis_letter_revised_final_final_with_track_changes_November_7_2011.doc

Dear Dr. Godlee,

Thank you for clarifying that part of my letter. I propose the text in the attached revision, which does away with the legal issue of fraud - without removing the heart of my letter. My simple rewording of the two sentences avoids any legal concerns while preserving the primary message for which I submitted my Rapid Response.

I hope that you and your attorneys will allow me to state my views.

Best always,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Nov 7, 2011 6:17 pm
MMR_Lewis_letter_revised_final_version_November_8_2011.doc

Dear Dr Lewis. Thank you. We are able to go with your revision except for the phrase "or that the paper as a whole is deceptive" since the grading sheets relate only to the histopathology and not to the Lancet paper as a whole. I have therefore deleted this phrase. The final paragraph now reads:

"As a research microbiologist involved with the collection and examination of colonic biopsy samples, I do not believe that Dr. Wakefield intentionally misinterpreted the grading sheets as evidence of "non-specific colitis." Dhillon indicated "non-specific" in a box associated, in some cases, with other forms of colitis. In addition, if Anthony's grading sheets are similar to ones he completed for the Lancet article, they suggest that he diagnosed "colitis" in a number of the children."

A final version of the letter is attached.

Best wishes, Fiona Godlee

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Page 96

Subject: Re: Your letter to the BMJ
From: lewisdavel <lewisdavel@aol.com>
To: FGodlee <FGodlee@bmj.com>
Cc:
Bcc:
Date: Mon, Nov 7, 2011 6:20 pm

The last version you sent is fine.

Best always,

David Lewis

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Mon, Nov 7, 2011 6:47 pm

Thank you. I'm sorry about the delay in getting back to you, and for these last minute changes. I will pass this version to my colleagues who are managing publication. Best wishes, Fiona Godlee

Subject: Re: Your letter to the BMJ
From: Fiona Godlee <FGodlee@bmj.com>
To: lewisdavel <lewisdavel@aol.com>
Cc:
Bcc:
Date: Tue, Nov 8, 2011 10:14 am

Dear Dr Lewis. Your rapid response will be published on bmj.com at 11pm UK time, along with the other material I mentioned in an earlier email - the expert commentaries, the feature article, and an editorial from me. The other material focusses as you might expect, mainly on the grading sheets, and as I have previously indicated, the total package comes to a different view of their significance for the MMR scare and Wakefield's research. The whole package of material, including your rapid response, will also appear in the BMJ's print edition published this weekend. Best wishes, Fiona Godlee

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Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer

Attachment 2 - Photomicrographs

FIGURE 2. Photomicrographs of *Lancet* study large intestinal biopsies[†]

David L. Lewis, Ph.D., Research Microbiologist

Moving from left to right and top to bottom, the photomicrographs that follow are designated (a) thru (i) and described below.

(a) [*Lancet* paper, Fig. 3 (black & white)] Biopsy from Child 3 with cryptitis (circle). Reported in the *Lancet* paper as “dense infiltration of the lamina propria crypt epithelium by neutrophils and mononuclear cells.” An expert intestinal pathologist (AP Dhillon) and his assistant (A. Anthony) translated these features as evidence of non-specific, acute, chronic and chronic active colitis. Based on reports from on-duty pathologists, GMC expert Professor Ian Booth and reporter Brian Deer disputed these findings.

(b) Child 2 biopsy indicating the same pattern of inflammation (circle) as Child 3 above. Dhillon and Anthony translated these features as evidence of acute and chronic non-specific colitis with cryptitis as reported in *The Lancet*. Booth and Deer did not dispute these findings.

(c) Child 5 biopsy exhibiting crypt architectural distortion with bifid forms typical of mucosal healing in the presence of chronic inflammation. Pathologists translated these and other features as evidence of acute and chronic non-specific colitis as reported in *The Lancet*. Booth and Deer disputed these findings.

(d, e) Child 9 biopsies indicating a marked increase in mononuclear inflammatory cells in both the lamina propria (bracket) and lining epithelium with neutrophils also in the former. (e) illustrates a marked focal increase in intraepithelial lymphocytes (IELs) (circle), which Dhillon reported and interpreted as moderate to marked increase in IEL's with increase in chronic inflammatory cells throughout the colon. Anthony missed these features, scoring the biopsy as normal. Booth and Deer disputed these findings.

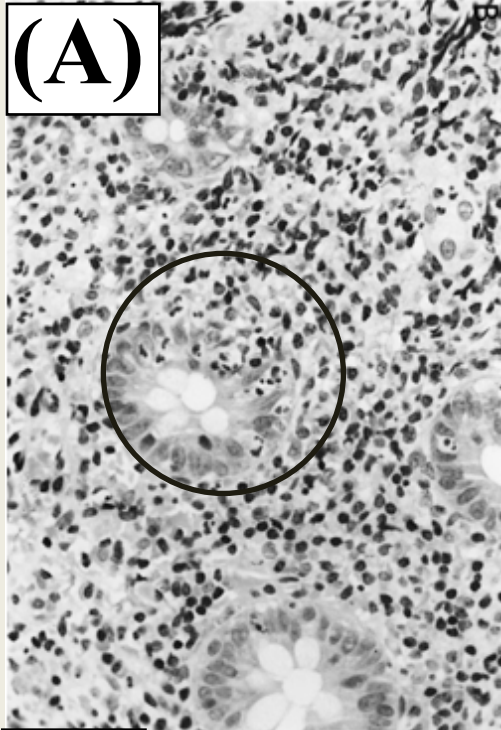
(f) Child 4 biopsy. Diffuse lymphocytic infiltration of surface and crypt epithelium in colon. Booth and Deer disputed these findings.

(g, h) Child 4 continued.

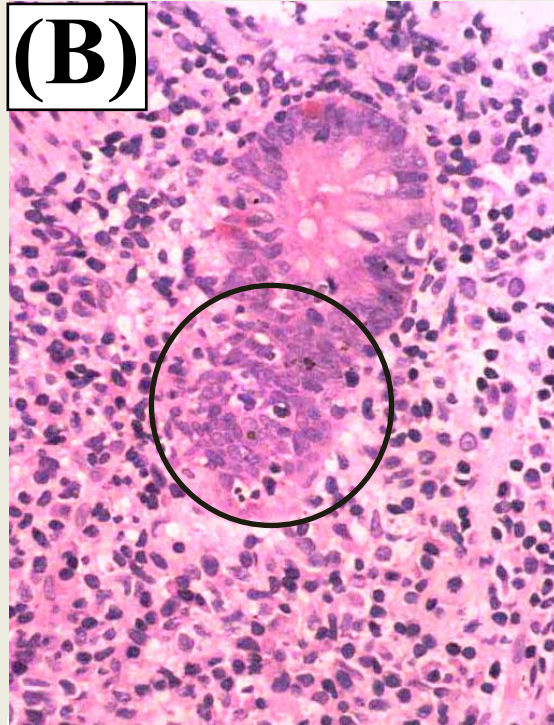
(i) Child 6 biopsy, for which the same features/diagnosis were reported as for Child 4. Booth and Deer disputed these findings.

[†] Sections stained with hematoxylin, eosin; original images were 2X2 color slides magnified 100X. Descriptions were provided by A. Wakefield (2011); except for Child 6, which D. Lewis simply noted observations published in *Lancet* Table 1.

(A)



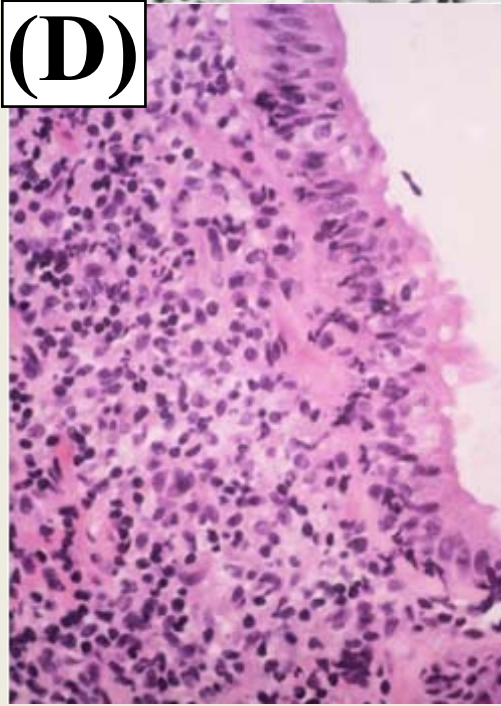
(B)



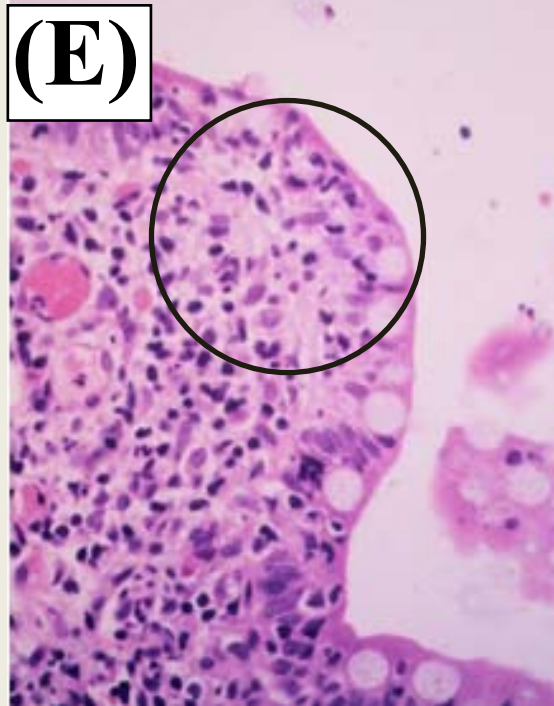
(C)



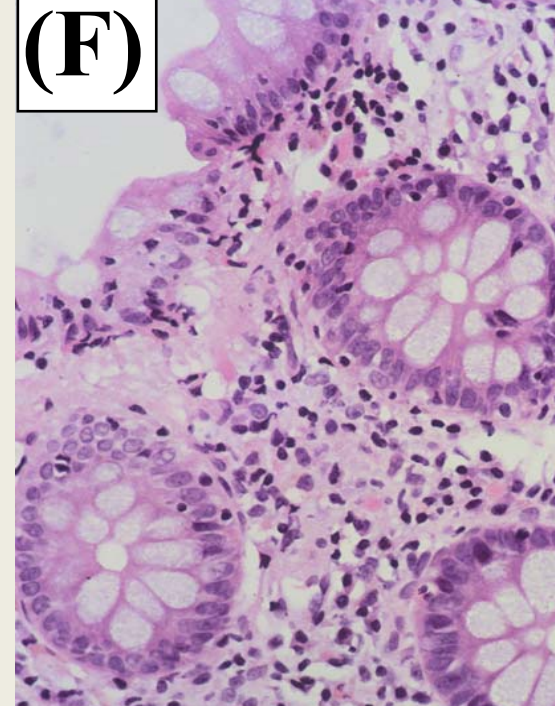
(D)



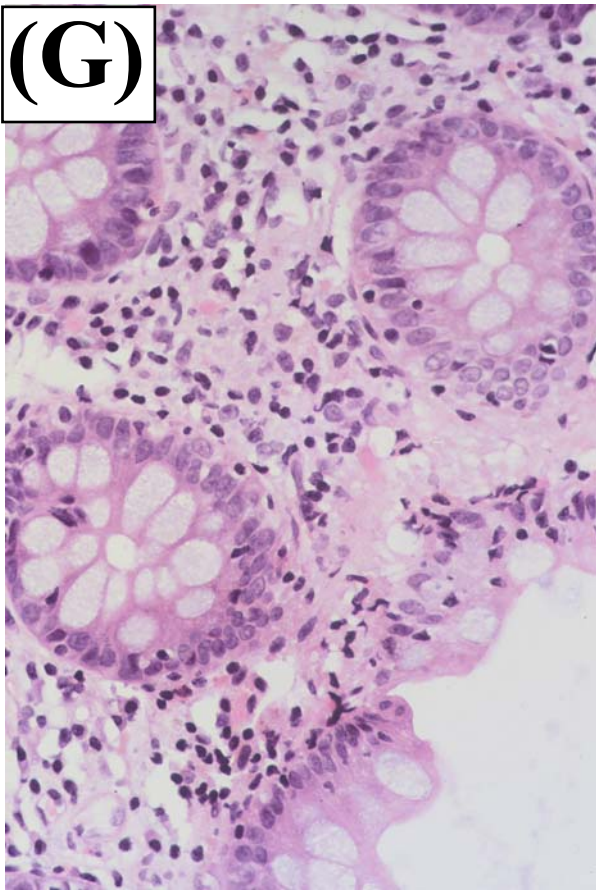
(E)



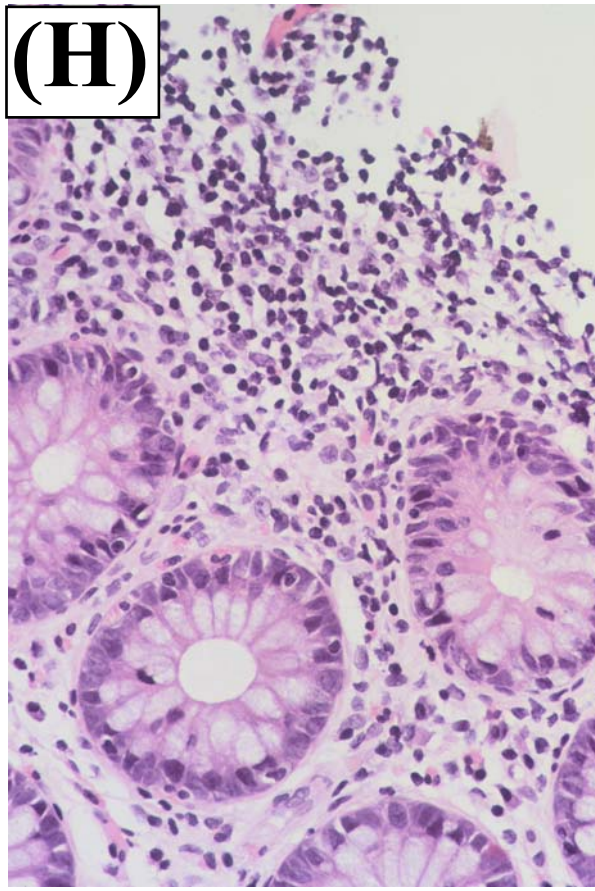
(F)



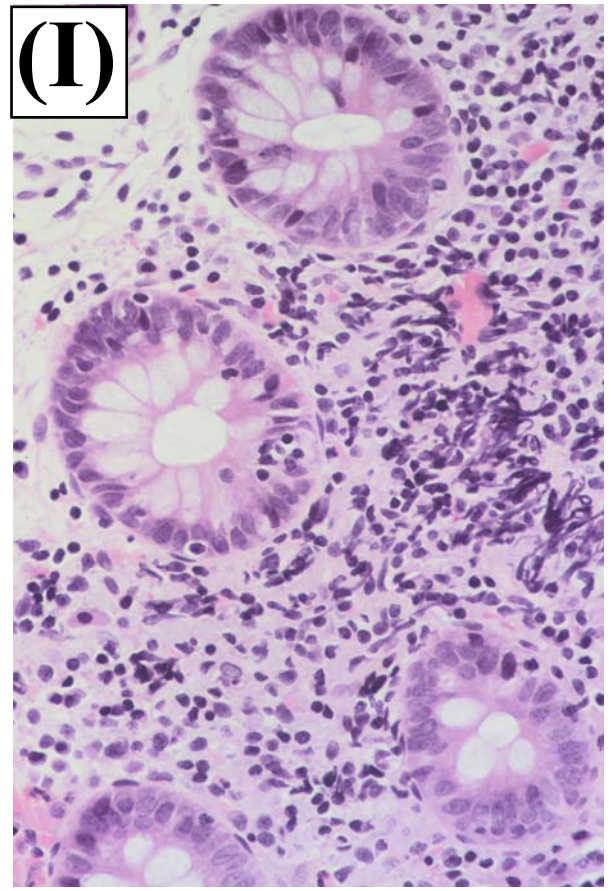
(G)



(H)



(I)



Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer

Attachment 3- Anthony's Power Point

Figure 1. Power-Point Presentation by Wakefield Coauthor Pathologist Andrew Anthony

In a series of slides circa 1998, Dr. Anthony laid out his basis for assessing levels of acute and chronic inflammation when grading colonic biopsies. Note: One patient's name, which appeared on two slides, was converted to initials [AG] by David Lewis.

Histological evaluation

1- Routine histology

- Terminal ileum (x1) and colon biopsies (x7) were taken and reported routinely by departmental histopathologists
- No formal histology proforma
- Assessments were subjective
- Formal report issued to clinicians (paediatric gastroenterologists)
- Important because difficult to promote and defend notion of a mild form of gut inflammation in autistic children if these were reported as normal here.

Histological evaluation

2- Research histology

- Original terminal ileum and colon biopsy slides were reported by research pathologists (AA)
- According to formal histology proforma
- Assessments were semi-quantitative measurement of gut injury

Histological evaluation

3- Research histology (inflammation)

- Acute inflammation
 - Grade 0 no Neutrophils
 - Grade 1 Neutrophils in lamina propria
 - Grade 2 Neutrophils in crypt epithelium
 - Grade 3 Neutrophils in crypt lumen
- Chronic inflammation
 - Grade 0 no increase in chronic inflammatory cells (CICs)
 - Grade 1 mild increase in CICs
 - Grade 2 moderate increase in CICs
 - Grade 3 severe increase in CICs

Histology Proforma

HISTOLOGY

Patient	Slide No
Other information	
Pathologist	Date

MICROSCOPY

	None	Mild	Moderate	Severe	Score (0,1,2,3)
ACUTE INFLAM.	0	1 Occasional lamina propria PMNs	2 Cryptitis	3 Crypt abscesses	
CHRONIC INFLAMM.	0	1 Slight increase in mononuclear cells	2 Moderate increase	3 Severe increase	
EPITHELIAL\ LAMINA PROPRIA	0	1 Changes to surface epithelium (lifting, lamina propria condensation)	2 Erosion	3 Ulceration	
LYMPHOID FOLLICLES	0	1 Reactive changes (prominent germinal centres, tingible body macrophages)	2 Follicular enlargement, (with confluence, hyperplasia)	3 Ulceration (aphthoid)	
CRYPTS	0	1 Bifid glands Goblet cell depletion	2 Glandular disruption, Paneth cell met.	3 Dysplasia	
APOPTOSIS	0	1 Mild increase	2 Moderate increase	3 Severe increase	

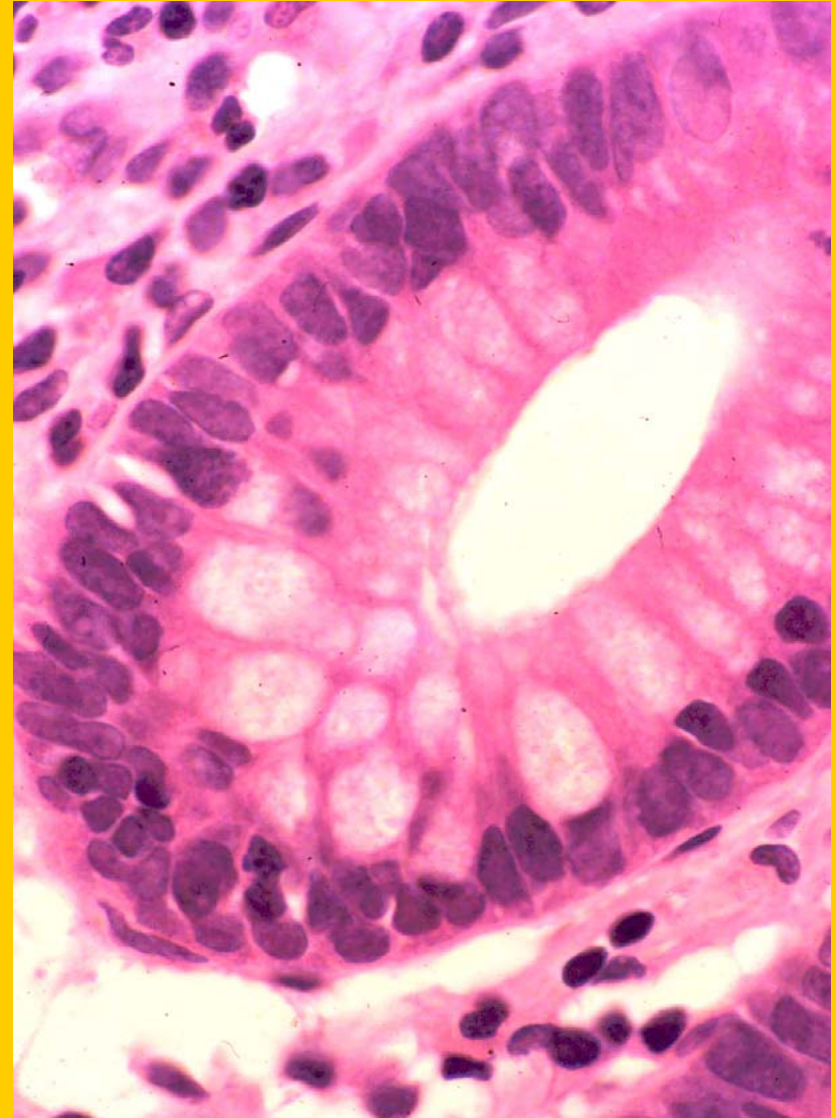
Acute inflammation -grade 0

- **No neutrophils in lamina propria or crypt epithelium**



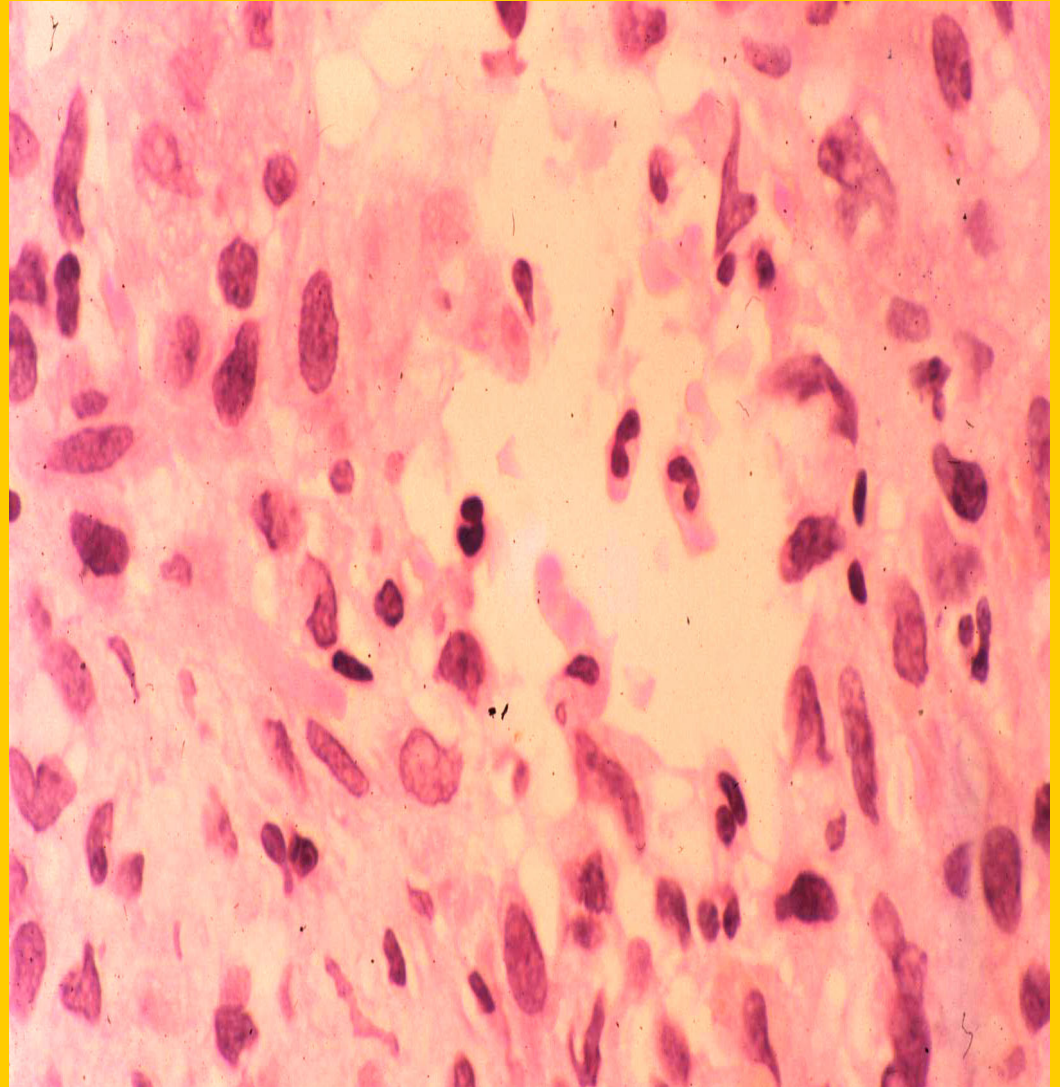
Acute inflammation -grade 0

- No neutrophils in lamina propria or crypt epithelium



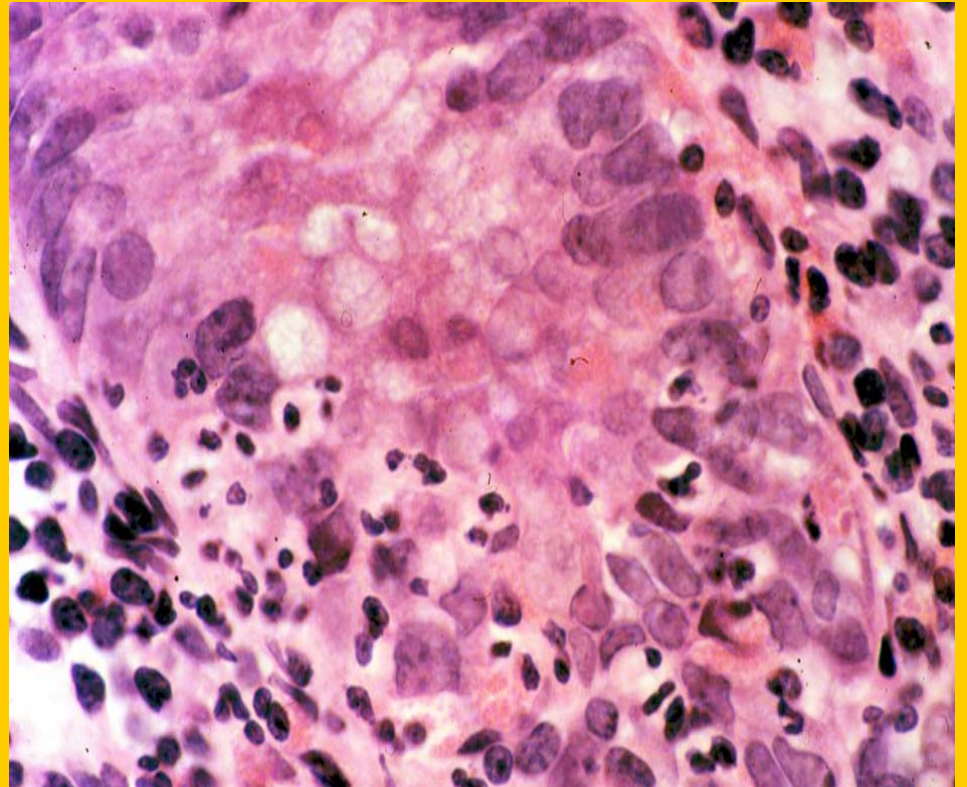
Acute inflammation grade - 1

- **Neutrophils seen in lamina propria**



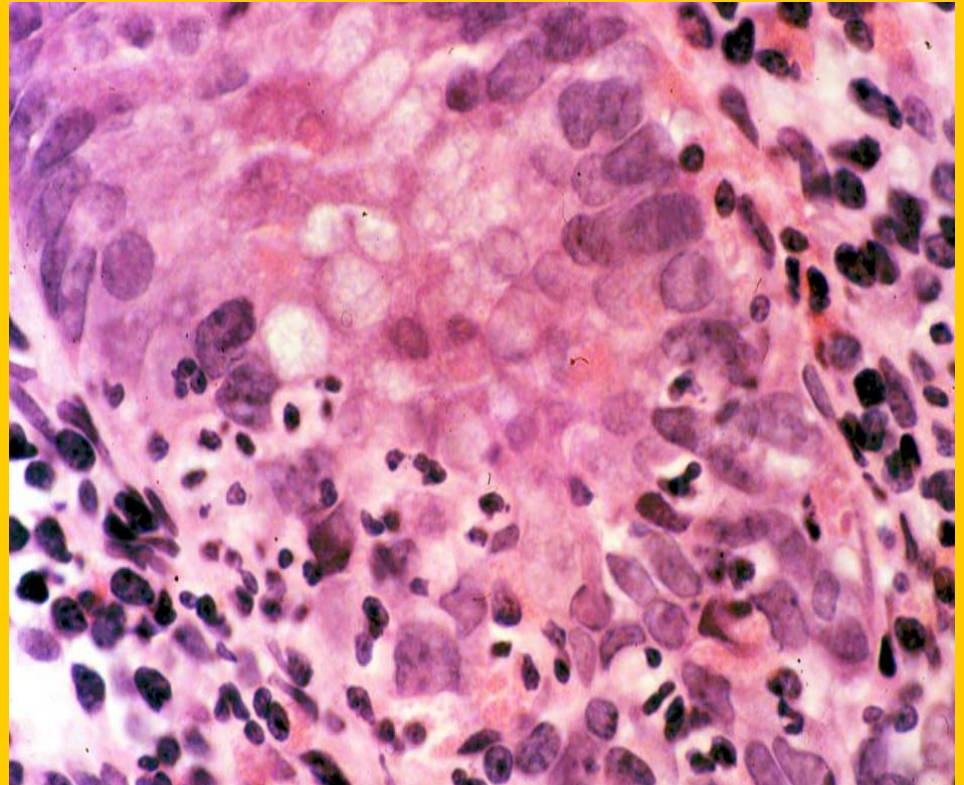
Acute inflammation grade - 2

- Neutrophils infiltrate crypt epithelium
“*cryptitis*” or
“*active inflammation*”)
seen in OL, WK, AG, JS



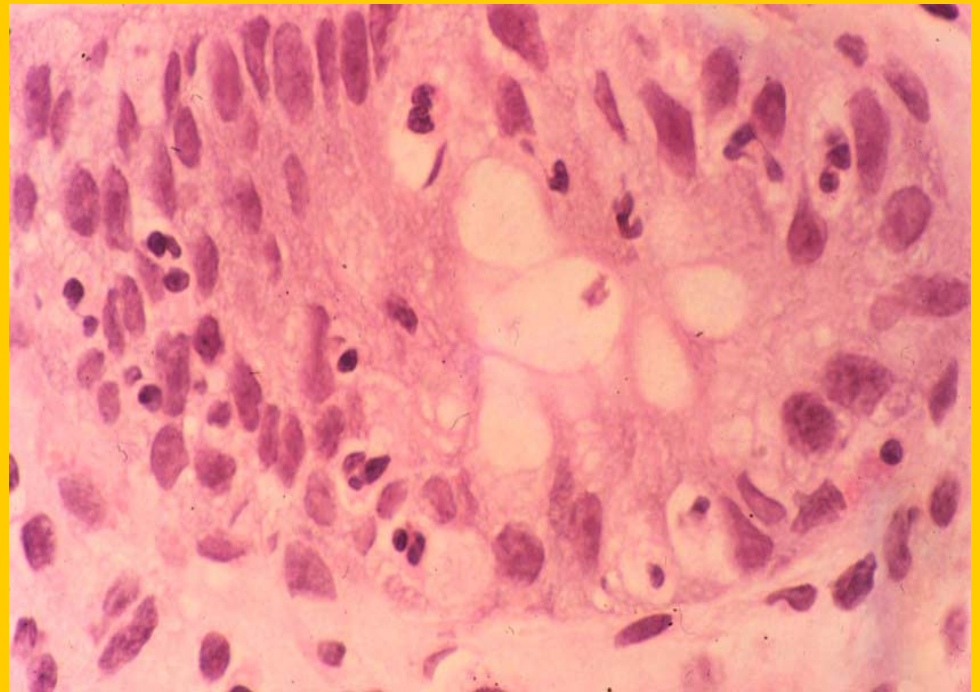
Blinded evaluation of acute inflammation grade - 2

- Patient RM 12 y
- No history given
- Active ileitis + crypt abscess reported
- Later found to have to have Asperger's syndrome



Acute inflammation grade - 2

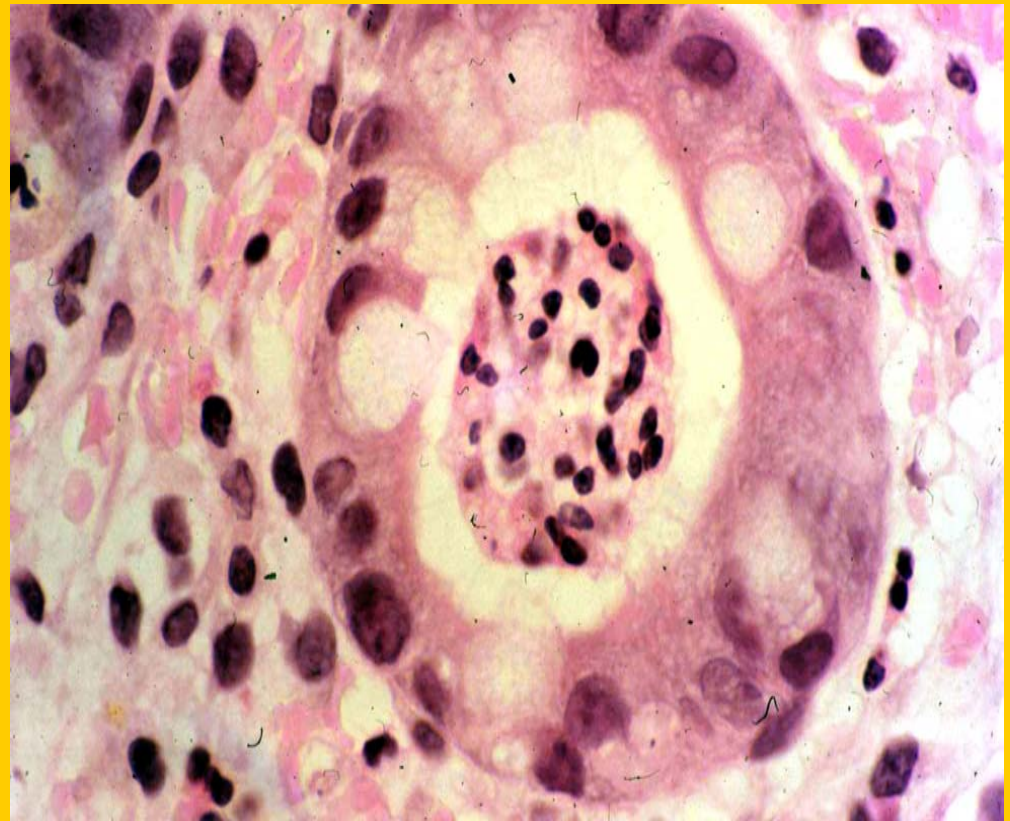
- Neutrophils infiltrate crypt epithelium
“*cryptitis*” or
“*active inflammation*”)



[AG] - colon

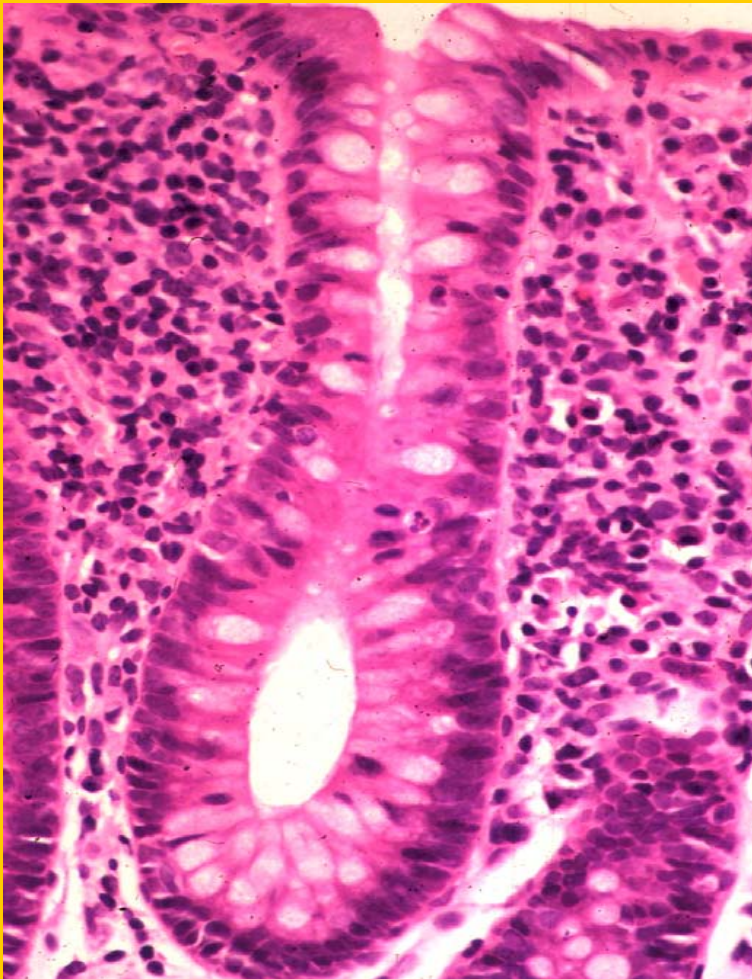
Acute inflammation grade - 3

- Neutrophils within crypt lumen
“*crypt abscesses or “active inflammation”*”)



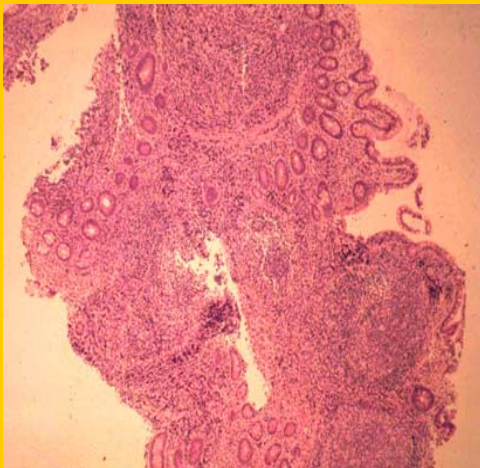
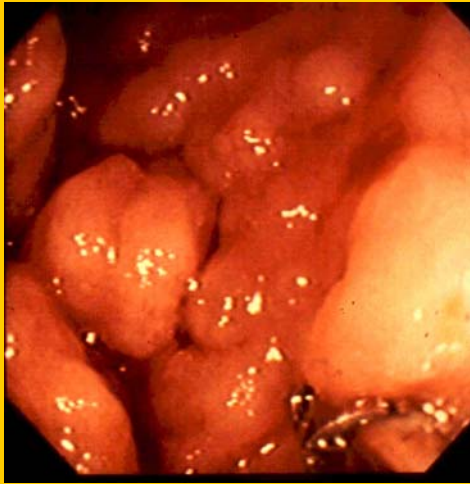
[AG] - colon

Chronic inflammation



- “Chronic in terms of time (long-standing) and type of infiltrating cells”
- Quantified by counting immuno-stained cells
- Seen in BH, DH

Lymphoid nodular hyperplasia (Inh)



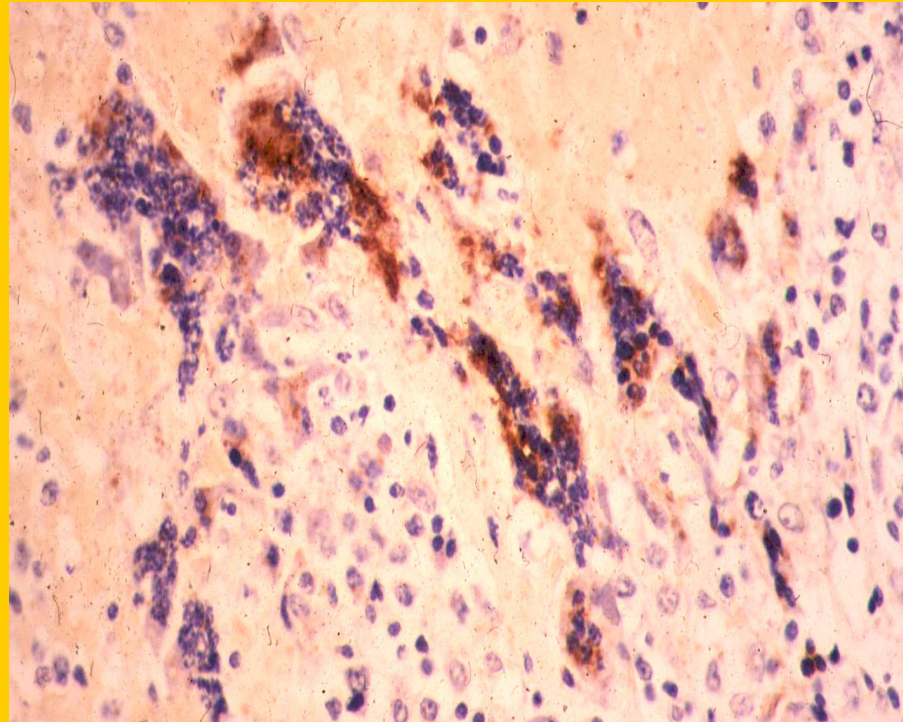
- First obvious abnormality seen in autistic children.
- Implies activation of immune system of gut
- Measles virus found in follicle

Case: Acute measles vaccine in the gut 1

- **AB 13 months - male**
- **Sudden illness a few days after his MMR vaccination and then died suddenly 5 days later in hospital.**
- **Post mortem showed severe acute inflammation of colon with Warthin-Finkeldy giant cells (these are cells seen in tissues infected with measles virus.**

Case: Acute measles vaccine inflammation of the gut 2

- Warthin-Finkeldy giant cells in colon and spleen; considered to be incidental finding.



**Warthin-Finkeldy
cells staining positive
for measles virus**

Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer

Attachment 4 - Deer's NWC emails

> From: Brian Deer [mailto:mail62@briandeer.com]

> To: contact@whistleblowers.org

> Cc: lmw@whistleblowers.org

> Sent: Thu, 02 Jun 2011 08:36:40 -0400

> Subject: To Stephen Kohn/David Lewis

>

> To Dr Stephen M Kohn

> Copy please to Dr David Lewis

>

> Dear Dr Kohn,

>

> I write to you having this morning found your website and the apparent

> project posted on it by Dr David Lewis, apparently a retired

> microbiologist. This project, evidently begun just last December (the month

> before you and he attended a "vaccine safety conference" in Montego

> Bay, Jamaica, with "MMR doctor" Andrew Wakefield and other activists in

> that area of endeavour) appears to be engaged in no activity other than an

> attempt to exonerate Wakefield of proven wrongdoing. In this activity, Dr

> Lewis accuses me of misconduct in my long and now-concluded investigations

> of Wakefield for The Sunday Times of London, and of acting in at least

> tacit collusion, if not overt conspiracy, with the pharmaceutical industry

> and government.

>

> The information on Dr Lewis's pages has been compiled in the plainest

> collaboration with Wakefield, who, you may know, was last year found guilty

> of serious professional misconduct by a UK statutory tribunal of three

> doctors and two lay members, sitting in public as a fitness to practise

> panel of the General Medical Council (GMC). The charges found proven -

> against a criminal standard of sureness - included four counts of

> dishonesty (being research and financial misconduct, and two counts of

> common lying to doctors about his research) and a dozen involving the abuse

> of vulnerable, developmentally-challenged children, contrary to the

> Helsinki declaration for the protection of humans involved in medical

> research, and probably also common law. Wakefield was entitled to appeal

> to the High Court in London, but withdrew his application, and therefore

> the verdicts are final. For his GMC case, Wakefield called no witnesses.

> He submitted that evidence given against him was offered in good faith,

> confirmed that there were no conflicts of interest in the hearing,

> explicitly with regard to the chair of the panel, and asked no questions of

> the government's senior official for vaccine policy who was called by the

> prosecution to evidence the damage caused.

>

> Dr Lewis's information at your website is false in almost all its key

> assumptions, and false in all its conclusions. In this aspect, I am not

> surprised, since Wakefield is an immensely persuasive operator and has

> inflicted extraordinary damage on past collaborators who were drawn into
> his deceptions. A Professor John Walker-Smith is one example, having been
> found guilty by the GMC panel (although not of dishonesty), as a co-author
> of the MMR research project, published in the Lancet in 1998, and about
> which I have extensively written. Another would be the former dean of the
> medical school where they worked. I could cite perhaps a dozen more
> individuals, some of considerable professional calibre, who rue the day
> they ever believed what Wakefield told them.

>

> I should say that Wakefield's allegations made on CNN while you were
> together in Montego Bay - that I am working with the drug industry - are
> utterly false and were made by Wakefield whilst knowing them to be false.
> He knows exactly how my investigation of him unfolded, and how it was
> fuelled by his own dishonest and threatening behaviour. Dr Lewis gives the
> impression that it was these allegations of Wakefield's that whetted his
> appetite for an attack on me.

>

> Although I'm not really surprised that Dr Lewis has apparently been
> suckered in this manner (particularly given the longstanding sense of
> personal grievance he harbours, and which, to his credit, he owns up to on
> his page) I am surprised that your organisation would publish this material
> without making even the slightest effort to put them to me.

>

> You might note the following statement about me, made by Dr Lewis:

>

> "We are talking about a reporter with no education or experience in
> medical practice of any kind who collected and interpreted different and
> arguably less reliable medical records than those upon which the Lancet
> article was based.

>

> "The GMC completely disregarded this argument when, as the following
> pages show, it was first posed by Ian Booth, a professor of paediatric
> gastroenterology. Now, it seems, the whole world is buying into this same
> ridiculous argument made by a reporter with no competence whatsoever in
> interpreting medical records of any kind. As a research microbiologist, I
> must say that this is completely insane."

>

> If your own CV reflects your personal calibre and integrity, you may join
> with me in expressing surprise that Dr Lewis - who himself appears to have
> no relevant professional qualifications on these matters - would express
> himself in these terms, particularly with regard to someone he has never
> met, spoken to or even emailed, and whose investigations in the field of
> medicine have twice won the UK's leading journalism prize. Those
> investigations, I might add, have extended over some 25 years, including
> seven years involvement in the Wakefield matter.

>

> Moreover, work by me on Wakefield was peer-reviewed, including in the
> fields of paediatrics and gastrointestinal pathology, and was additionally
> checked by BMJ staff and lawyers, who inspected documents. I have had the
> further benefit of advice from leading figures in relevant medical and
> scientific fields, and have devoted many months to professional study. My
> findings have since been publicly presented to experts of the highest
> standing.

>
> Finally, on this point, the information was not “interpreted” by me,
> as Dr Lewis divines. It was interpreted by at least four senior
> specialists in gastroenterology, including a professor of gastrointestinal
> pathology. Personally, I think you would find it hard to imagine many
> circumstances in which any journalist had gone to such efforts to try to
> properly understand what he was writing about: in this case on a matter of
> such public importance as the safety of children by means of vaccination.
> Dr Lewis’s tone towards me, however, is hardly short of contemptuous.

>
> I also note that, rather than linking to my reports in the BMJ, Dr Lewis
> has scraped those reports from the journal’s website and has republished
> them (possibly accurately or inaccurately, but it is impossible to readily
> tell) at yours. This is the plainest breach of copyright, and can only
> reflect poorly on Dr Lewis and your organisation. Could I ask you to
> ensure that copyright material is taken down, and that, instead, the
> material is referenced by means of hyperlinks to the published reports.
> Not least, this will allow people to read those reports in their proper
> context, including internal BMJ links to supporting documentation, and to
> be quite sure that the text is accurately what was published.

>
> I will not deal with Dr Lewis's allegations in detail here, but in
> passing I would say that the GMC panel did not reject any of my
> submissions, as Dr Lewis claims. It did not seek to rule on the issue of
> research fraud, much less reject it as Dr Lewis asserts, since this matter
> was not directly laid in the charges against Wakefield, submitted to the
> panel in July 2007. It is my understanding that, since there were already a
> range of dishonesty charges laid over the research, the prosecuting lawyers
> advised that it would be impossible to add yet more and still finish the
> case in the three years it ultimately took. Such is the thoroughness and
> fairness of proceedings involving accused doctors.

>
> Evidence of research fraud largely came to light after the first charges
> were served on the defendants, and after patient records - mostly those to
> which Wakefield had access when he contrived his paper - were carefully
> examined by experts. Indeed, a Professor Booth, who Dr Lewis mentions,
> raised the question of “fraud” in his expert report, which, as a matter
> of fact, I had not read before a portion was posted at your website.
> Nevertheless, the panel found that Wakefield had dishonestly misrepresented

> the basis of patient admissions into his study - the selection criteria -
> which is itself a finding of research fraud.

>

> Having set up the canard that the GMC had rejected research fraud
> charges, Dr Lewis then extemporises: "Unhappy with the fact that the GMC
> stopped short of finding Wakefield guilty of research fraud, editors at the
> BMJ hired Deer to dig further."

>

> Apart from the abusive quality of these allegations, the journal's
> editors were not, to my knowledge, in the least "unhappy", as he somehow
> divines, and did not hire me to "dig further". These allegations, I
> regret to tell you, have been made up. If you pause to consider, a priori,
> any possible evidential basis for Dr Lewis's purported knowledge of the
> state of mind of the BMJ's editors, in about June of last year, you may
> yourself find this sentence both unfortunate and revealing about his
> mindset. To be charitable to your colleague, however, these allegations
> were made up by Wakefield - proven to be a liar against the most stringent
> evidential and procedural standards - and Dr Lewis probably only repeats
> them without taking the trouble to verify what he writes, or even to
> carefully read the GMC charge sheet so as to understand the issues before
> the panel. Nevertheless, it is your organisation which now publishes this
> false information.

>

> Although I have made references in my journalism to general practitioner
> records, particularly for dates of birth and so forth, I did not generate
> my conclusions by tabulating mismatches between those records and the
> Wakefield Lancet paper, as alleged by Dr Lewis (repeating another
> now-familiar argument of Wakefield's).

>

> In passing, I note that Dr Lewis's position in this regard must depend,
> a priori, on the surprising acceptance that the paper falsely reported the
> children's status. Then, relying on this acceptance, Wakefield is
> purportedly exonerated on the basis that he had not looked at the primary
> care documentation and so did not know that his paper was wrong. Thus, the
> argument must go, Wakefield is innocent because, since he did not know the
> children's true status, he could not be guilty of fraud. Although, in
> passing, I might draw your attention to Wakefield's actual claims in the
> Lancet, which clearly lead readers to believe that he had consulted GP
> records, I leave that today as a mere curiosity.

>

> Despite this "wrong but not dishonest" defence, however, I should
> point out that Wakefield's claim that my work depended on a comparison
> between GP records and the Lancet paper has been published so widely on the
> web in the last few months that the BMJ's editors issued a statement which,
> among other things, correctly denies this. Dr Lewis ought to have seen
> that statement. You might think it would be obvious to even the most

> junior libel lawyer, much less to the experienced specialist defamation
> barrister who you might expect (and in fact did) deal with my BMJ reports
> pre-publication, that dishonesty entails an intent to deceive and could
> therefore not be based on matters of which Wakefield could plausibly claim
> that he had no knowledge. In short, we are not that dumb.

>

> Nor is the finding by the editors of the BMJ of research fraud against
> Wakefield critically dependent on mismatches in histopathology records, as
> alleged by Dr Lewis. Although Wakefield undoubtedly falsely reported the
> recorded gut pathology in the children, your colleague's attempt to
> retrospectively reinterpret records written in the 1990s (in a manner
> inconsistent with a large body of documentary evidence) so as to clear
> Wakefield of dishonesty over the Lancet paper, is bound to fail.

>

> I ask you to request Dr Lewis to take down his pages and to put to me
> squarely, and in writing, (a) what it is he says I have done that I should
> not have done, and/or (b) what it is he says that I should have done that I
> failed to do.

>

> If Dr Lewis seeks to critique my reports in the BMJ or The Sunday Times,
> I request that you ask him to identify the words he complains of, with
> proper referencing for third-party verification via the BMJ and/or Sunday
> Times websites, in order that any response from me is firmly based upon
> what is actually published under my name, and not upon spurious, false and
> dishonest recasting of my journalism by Wakefield. In short, tell me what
> I said, and not what Wakefield says I said.

>

> Of course, you may decide to join with Dr Lewis and proceed on the basis
> that, after your doubtlessly memorable trip together to Jamaica, you know
> better than a statutory tribunal sitting in public for much of three years,
> and have made up your mind with regard to your fellow conference
> speaker's integrity. In that case, I suppose, you will continue to
> circulate unchecked allegations against me with frank disregard for whether
> they are true or false. That must ultimately be a matter for you, for your
> personal reputation as well as Dr Lewis's, and for the reputation of the
> enterprise you lead.

>

> Yours sincerely,

>

> Brian Deer

>

> [I would be grateful if you will acknowledge receipt of this
> communication]

>

NWC to Brian Deer

> 11:41 AM 6/22/2011

> Mr. Brian Deer

> c/o

> mail62@briandeer.com

>

> Dear Mr. Deer:

>

> Thank you for your email concerning Dr. Wakefield and the ongoing review

> being conducted by Dr. David Lewis. We are carefully reviewing the information contained in your email. As you know, vaccine safety is an

> important issue, and I am sure we all share an interest in making sure that

> there is open an accurate debate on these matters.

>

> I ask that you provide answers to the following questions. We want to

> make any necessary corrections on our web page as soon as possible.

Please

> provide these answers within ten days.

>

> Thank you for your interest.

>

> Sincerely yours,

>

> THE NATIONAL WHISTLEBLOWERS CENTER

>

> QUESTIONS:

>

>

> 1. You state: "at least four senior specialists in gastroenterology,

> including a professor of gastrointestinal pathology" provided the interpretations of medical records upon which your allegations of research

> fraud against Dr. Wakefield are based. So that we can assess their qualifications, please give us their names and current affiliations.

>

> 2. Why were these specialists, who provided the interpretations of

> medical records upon which your allegations of research fraud against Dr.

> Wakefield are based, not listed as coauthors of your articles published by

> the BMJ, or at least acknowledged?

>

> 3. Were any of these specialists funded by pharmaceutical companies

> within the past three years?

>

> 4. Were any of your articles published by the BMJ, or any portions

> of them, ghostwritten by any of these specialists or other individuals?

>

> 5. Have you investigated whether any of these specialists have any
> other potential conflicts of interest?
>
> 6. You state that your "work on Wakefield" was reviewed by medical
> experts, BMJ staff, lawyers and leading figures in science and medicine who
> inspected your documents and vouched for the veracity of your conclusions.
> Please provide their names and current affiliations.
>
> 7. Were any of these experts funded by pharmaceutical companies
> within the past three years?
>
> 8. Have you investigated whether any of these experts have any other
> potential conflicts of interest?
>
> 9. You state that Dr. Lewis accuses you of "wrongdoing." Please
> quote the specific statements by Dr. Lewis to which you are referring, and
> explain what specific acts of wrongdoing you believe that Dr. Lewis has
> accused you of.
>
> 10. You apparently allude to certain potential conflicts of interest
> by the GMC Chairman, to which Dr. Wakefield did not object. What specific
> potential conflicts are you referring to?
>
> 11. You praised Dr. Lewis for "owning up" to his past whistleblower
> activities. What specifically did Dr. Lewis do to which he needed to own up
> to or fess up, so to speak.
>
> 12. You state that you did not compare any of the general
> practitioners' records with Wakefield's article published in The Lancet.
> Therefore, please tell us if you compared any of the following categories
> of medical records with the Lancet article: general practitioners' notes,
> routine pathology laboratory reports retained by the general practitioners,
> Royal Free Hospital clinical records, and Prof. Paul Dhillion's analysis of
> biopsy samples.
>
> 13. Did you compare any medical records other than those listed above
> with the Lancet article. If so, which records?
>

> 14. Please list the sources from which you obtained each of the
> categories of the medical records you compared with the Lancet
article.
>
> 15. What submissions did you make to the GMC, which you say
Dr. Lewis
> claims the panel rejected?
>
> 16. Which statement, or statements, by Dr. Lewis do you
believe
> represents a claim that the GMC rejected your submission(s)?
>
> 17. You state that the BMJ did not hire you to "dig
> further" into the allegations against Wakefield. What specifically
did
> the BMJ hire you to do?
>
> 18. Would you provide us with a copy of your contract with the
BMJ
> and any other documents supporting your answer to the question above
> regarding your employment by the BMJ?
>
> 19. How much were you paid by the BMJ?
>
> 20. You state that you did not generate your conclusions by
> tabulating mismatches between general practitioner records and the
> Wakefield Lancet paper. From what, specifically, did you generate
your
> conclusions of data manipulation or research fraud from?
>
> 21. Which specific records do you allege that Dr. Wakefield
> manipulated or misrepresented in his Lancet article?
>
> 22. Which statements did Dr. Wakefield publish in the Lancet
article
> that "clearly lead readers to believe that he had consulted GP
records"?
>
> 23. Please provide a reference to the BMJ's statement you
alluded to
> regarding what you call Dr. Wakefield's "wrong but not dishonest"
> defense.

> From: Brian Deer [<mailto:mail62@briandeer.com>]
> To: contact@whistleblowers.org
> Cc: lmw@whistleblowers.org
> Sent: Wed, 22 Jun 2011 13:03:19 -0400
> Subject: Re: To Stephen Kohn/David Lewis
>
> Dear "contact@whistleblowers.org",
>
> Please will you convey to your executive director, Dr Kohn, my
comment
> that I have seldom, in almost 30 years of national news journalism,
> received a communication so oozing with malice and foolishness as
that
> below. I realize that anybody can set up a website and call
themselves
> what they like, but I would assume that anybody of even modest
professional
> calibre wouldn't want this kind of material to see the light of day.
>
> I don't believe that anybody would enter dialogue with an
individual who
> expresses themselves in this manner from behind the veil of
anonymity. As
> a journalist, I might sometimes accept anonymity from a person
offering
> information - for example as a whistleblower - but the idea of me
> responding substantively to this deeply offensive anonymous material
is
> absurd, and I can assure you that virtually anybody at all with any
> knowledge of public affairs, business practise or media ethics will
tell
> you the same.
>
> Obviously, I know who wrote this list, and it only serves to
confirm that
> Dr Lewis is incapable of any kind of independent or objective
review.
> However, if you wish to identify yourself and give me your landline
number
> I will happily arrange to telephone you and we can discuss these
matters.
>
> Again, please pass this to Dr Kohn, so that he is fully in the
picture as
> to what is going on.
>
> Yours sincerely,
>
>
> Brian Deer

From: Brian Deer [mailto:bd@briandeer.com]
To: contact@whistleblowers.org
Cc: ek@whistleblowers.org
Sent: Fri, 28 Oct 2011 08:15:00 -0400
Subject: To: Dr Stephen Kohn

To Dr Stephen Kohn,
Kohn Kohn & Colapinto/National Whistleblowers Center

Dear Dr Kohn,

On June 2, 20 and 22 2011, I wrote to you concerning the conduct of the National Whistleblowers Center in relation to the activities of your board member David Lewis. You didn't respond to or acknowledge my concerns. However, out-of-office autoresponders evidence your organisation's receipt.

Plainly as a consequence, on August 10, Lewis wrote an email to one Professor Ian Booth of the University of Birmingham, England. I have never had any dealings or communications with Professor Booth, and have never seen any article, letter, report or document of any kind authored by him, apart from an extract from a statement concerning Andrew Wakefield published this year at your website.

I attach Lewis's email to Booth. It contains numerous deceptions. For example:

(1) That Lewis was writing on the business of the University of Georgia (improperly exploiting a university email account, rather than using those he publishes at your website and elsewhere)
(2) That he had been prompted to write to Booth by a question from a Nature reporter (3) That "someone had passed along" Booth's report in the Wakefield matter He also plants in the letter the claim that I "expanded" on Booth's report when, as already made crystal clear to Lewis and to you, I had never seen it prior to your publication, let alone expanded upon it.

As we all know, Lewis is pursuing a bitter and malicious campaign of abuse against me. This has intensified following his defeat in the Georgia court of appeal over his sewage sludge grievance. Scrutiny of that grievance would, I think, raise further questions about Lewis, and hence perhaps about some of your organisation's other clients. His allegations against me, recently submitted to the BMJ, the British Medical Journal, include those to the effect that I'm part of a conspiracy with government and industry to conceal possible evidence of horrific injuries purportedly caused to children by vaccines. They are so shocking that any right-minded person would be appalled.

Lewis pursues this campaign in collaboration with the charlatan Wakefield, and could have no honest reason for misleading Booth, or for failing to be straightforward about who Lewis is and the nature of his agenda, set out at your website. The degree of of guileful intent is extraordinary. I think that this whole shocking affair should now be placed before the board of the National Whistleblowers Center, as it goes to the question of whether you - in this instance now outside your previous attorney-client relationship with Lewis - or your organisation could have any honest belief in his integrity.

Yours sincerely,
Brian Deer
<http://briandeer.com>

[Attachment]

From: DavidL@uga.edu
To: i.w.booth@bham.ac.uk
Date: Wed Aug 10, 2011 5:24PM
Professor Ian Booth, Dean of Medicine
School of Clinical and Experimental Medicine

College of Medical and Dental Sciences
University of Birmingham

Dear Professor Booth:

Nature's reporter in Cambridge, Massachusetts is interviewing me pursuant to a presentation I recently gave at Harvard University concerning research misconduct.

I mentioned that someone had passed along to me an expert report that you submitted to the General Medical Council hearings in the matter of Andrew Wakefield and his coauthors. It appears that you were the first person to actually perform the analysis of documents that reporter Brian Deer later expanded upon and wrote about in the British Medical Journal and elsewhere.

This is an interesting bit of history, if the expert report (attached) is authentic. It would be most helpful if you could confirm that you did indeed submit this early analysis. If this is the case, the why didn't the GMC pay it more attention?

Yours sincerely,
David L. Lewis, Ph.D.
Director, Research Misconduct Project

Subject: RE: Brian Deer's Complaint
From: Reich, Eugenie Samuel <E.Reich@us.nature.com>
To: lewisdavel <lewisdavel@aol.com> fgodlee <fgodlee@bmj.com>
Cc: tdelamothe <tdelamothe@bmj.com> jsmith <jsmith@bmj.com> i.w.booth
<i.w.booth@bham.ac.uk>
Bcc:
Date: Mon, Oct 31, 2011 11:31 am

I am not working today so have only looked through this email that I was copied on briefly, but in case it's helpful, I did see David Lewis speak at a Harvard event and I did interview him. I also did ask questions about how the information he has come to him and suggested checking any leaked documents with original sources. This would be a pretty standard practice for a reporter thinking about relying on a leaked document so it was a natural idea from my perspective and I therefore wasn't surprised to see he did that.

A final word is that I haven't decided yet whether/what to write about this. If I did I'd obviously be contacting anyone who might be relevant both in regard to leaked documents and more generally, and I really hope for everyone's help doing a fair accurate story if that happens.

=====

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Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer

Attachment 5 - Revised Commentary

Brian Deer's Objections

David L. Lewis, Ph.D. Research Microbiologist
November 9, 2011

In June 2011, the National Whistleblowers Center (NWC) posted Professor Ian Booth's expert report submitted to the General Medical Council (GMC) and my preliminary conclusions. In my conclusions, I argued that the comparison of the Royal Free Hospital's routine pathology reports with Table 1 of the *Lancet* article that Deer published in the *BMJ* was, in fact, performed by one of the GMC's own experts four years earlier.¹ I pointed out that Table 1 was based on Amar Dhillon's and Andrew Anthony's grading sheets, and that the GMC stopped short of finding Wakefield or his coauthors guilty of falsifying the children's histopathologies, as Booth (and later Deer) had alleged.²

I also questioned how Deer came to repeat Booth's expert analysis, and why he - like Booth - didn't compare the GMC's copies of Dhillon's and Anthony's grading sheets with Table 1 of the *Lancet* article. Deer obtained copies of children's medical records and the Royal Free Hospital's pathology reports, which he used to accuse Wakefield of research fraud. It seemed odd, therefore, that he either never obtained or never disclosed Booth's report or any of the information in Dhillon's and Anthony's grading sheets.

Deer responded by sending an email to Mr. Kohn, stating: "Indeed, a Professor Booth, who Dr Lewis mentions, raised the question of 'fraud' in his expert report, which, as a matter of fact, I had not read before a portion was posted at your website."³ In the email, Deer reiterated his position that the GMC "did not seek to rule on the issue of research fraud, much less reject it." "It is my understanding", he wrote, "that, since there were already a range of dishonesty charges laid over the research, the prosecuting lawyers advised that it would be impossible to add yet more and still finish the case in the three years it ultimately took."

At the GMC's hearings, which lasted from 16 July 2007 thru 21 May 2010, witnesses testified that the histopathologies published in Table 1 of the *Lancet* article were based on grading sheets used in an independent blinded analysis performed by Dhillon and Anthony. Booth submitted his expert report on 8 November 2006, approximately eight months before the hearings began. Therefore, I initially thought that Booth might not have known about the grading sheets when he submitted his report, and that this may explain why he used the Royal Free Hospital's routine pathology reports, instead of the grading sheets, to evaluate Table 1.

But then - in Wakefield's files - I discovered affidavits, which Dhillon and Anthony submitted to the GMC on 26 July and 18 October, 2006, respectively.^{4,5} In them, the two pathologists explained the basis of Table 1 of the *Lancet* article in great detail. Assuming that Professor Booth read their testimony as any expert witness would normally do before submitting a report, he certainly understood that Table 1 was based on grading sheets that Dhillon and Anthony provided to Andrew Wakefield. So, when it came to determining whether Table 1 was accurate, why did Booth choose to use routine reports from on-duty

pathologists and not mention any of the exculpatory evidence in Dhillon's and Anthony's grading sheets?

Since posting my preliminary analysis of Booth's report, Professor Booth responded to an email in which I asked him why the GMC did not pay more attention to his analysis of the hospital's pathology records, given the fact that Deer's replication of that analysis received so much attention. Booth replied: "My analysis of the case records of the children presented in the *Lancet* publication was carried out specifically at the request of the GMC's solicitors and it formed part of the basis of the case brought against Wakefield *et al* by the legal team acting on behalf of the GMC."⁶

From a lawyer's standpoint, this makes perfect sense. Prosecutors argue whatever evidence they have in hand to get a conviction, while ignoring any evidence they may have that hurts their case. In science, it is considered egregious misconduct to selectively present only evidence that appears to support one's conclusions, while hiding other evidence that contradicts those conclusions. But the GMC's hearings were not a scientific conference. The job of the GMC's solicitors was simply to make the government's charges stick. To make them stick, they needed an expert report from someone like Booth pointing out that the hospital's pathology reports did not match the *Lancet* article.

Deer, on the other hand, is a journalist. At least in theory, journalists are not supposed to promote or suppress evidence because it favors one side or the other. To my knowledge, there is no evidence that Deer ever conspired with anyone to help with the job that the GMC's solicitors gave Booth. But transcripts of the GMC's hearings show that the Government never introduced Booth's analysis into evidence; then it showed up in the *BMJ* in the form of Deer's investigative news report just weeks before the GMC sanctioned Wakefield and one of his coauthors.^{2,7}

All of this suggests that a calculated decision may have been made not to chance Booth's analysis being shot down by defense attorneys and, instead, have it published as investigative news after the hearings ended. Whether by chance or by design, the job that Government solicitors gave Booth passed on to Deer. Then it blossomed in the court of public opinion beyond the walls of Regents Place where attorneys hired by Wakefield, Murch and Walker-Smith had gathered to defend their clients against the GMC.

In his email to Mr. Kohn, Deer questioned my objectivity and whether I am qualified to comment on these matters. He also indicated that, even if my arguments were true, his allegations of research fraud do not rise or fall based upon mismatches in the histopathology records. The purpose of this document is to address these three issues.

Relevant qualifications

Brian Deer commented to Mr. Kohn that I appear to have "no relevant professional qualifications on these matters."⁶ By contrast, he noted that his investigations in medicine "have twice won the UK's leading journalism prize," and that his writings have been inspected by "*BMJ* staff and lawyers." Deer also noted that he has had the "benefit of

advice from leading figures in relevant medical and scientific fields," has "devoted many months to professional study," and that his findings have been "publicly presented to experts of the highest standing."

My environmental research at the U.S. Environmental Protection Agency's (EPA) Office of Research & Development, which was published in *Nature* and other leading science journals, received EPA's highest award for research science presented by Administrator Carol Browner in 2000.⁸ Although this particular research is not directly related to the *Lancet* study in question, I am equally experienced in medical and scientific fields relevant to the collection and examination of biopsies during colonoscopies such as those Wakefield and his coauthors published in *The Lancet*.

I began my research related to the collection and examination of colonic biopsies as a member of the Graduate Faculty at the University of Georgia (UGA) in the mid 1990s, and continued this work under various adjunct and visiting scientist positions at UGA during the rest of my tenure at EPA. In 1998, EPA made research on colonoscopy part of my official EPA duties under an agreement with UGA; and I served as Principal Investigator for a prospective epidemiological study of hepatitis C associated with colonoscopy from 1999-2007.⁹

My research on the survival of HIV and other viruses in blood and tissues associated with colonic biopsies and dental procedures published in *Lancet*, *Nature Medicine* and other medical journals changed government infection-control guidelines worldwide.^{10,11} *Hippocrates* magazine won a national award for its 1998 cover story on this research.¹² In 2008, *Nature* published a news article and editorial applauding my research in which a multi-university study in Ohio confirmed my findings linking gastrointestinal disorders to exposures to biosolids.^{13,14} I am frequently called upon to review medical research papers; editors at *Annals of Internal Medicine* rated me in the top 10% of its reviewers in 2010.¹⁵

Numerous federal and state courts have accepted me as an expert witness in medical malpractice cases in which I am required to interpret patients' medical records and laboratory results involving the collection of biopsies during colonoscopies. In 2003, for example, the State of New York accepted me an expert on colonic biopsy procedures at a hearing in which the State revoked a physician's medical license.¹⁶ Last month, the United States District Court for the Southern District of Georgia agreed that I am the only scientist who has ever researched HPV infections associated with colonic biopsy procedures.¹⁷

My accomplishments in medical research have been covered extensively in news articles, editorials and documentaries in a wide variety of professional, scientific and popular publications and broadcasts including *Science*, *Lancet*, *JAMA*, *National Geographic*, *Reader's Digest*, *Voice of America*, *Time*, *Newsweek*, *U.S. News & World Report*, *Forbes*, *NY Times*, *Washington Post*, *London Times*, NPR's *All Things Considered*, PBS *Healthweek*, CBS *Evening News*, ABC's *Primetime Live*, and BBC *Panorama*.

Objectivity

In his email to Mr. Kohn, Deer argued that I am biased and lack objectivity because I filed whistleblower complaints against the U.S. Environmental Protection Agency, which distributed false allegations of research misconduct against me and my primary coauthor at UGA in an effort to protect its policies on biosolids.^{18, 19} These allegations were provided to EPA by one of the companies that distributed the biosolids I linked to illnesses and deaths in my peer-reviewed scientific articles. Deer stated: "I'm not really surprised that Dr. Lewis has apparently been suckered ... particularly given the longstanding sense of personal grievance he harbours, and which, to his credit, he owns up to on his page."

I look at my experience in litigating whistleblower cases as an important part of my credentials for investigating cases such as Dr. Wakefield's. Through it, I have accumulated a wealth of knowledge concerning the suppression of scientific research by government, industry and academic institutions. My cases were highlighted in Boston University's *Journal of Law and Medicine* as an example of a growing problem in which government agencies and industry-funded universities are using false allegations of research misconduct to suppress scientific research that threatens certain government policies and industry practices.²⁰

The Science Committee in the U.S. House of Representatives held two hearings into EPA's attempts to shut down my research.^{21,22} To better protect federal scientists from this form of institutional research misconduct, Congress passed the "No Fear Act," which specifically cited to my cases and was signed into law by President George W. Bush in 2002.²³ In May of 2011, Harvard University's John F. Kennedy School of Government included me on a panel to discuss my experiences.²⁴ Last month, President Barack Obama directed all federal agencies to develop scientific integrity policies to separate politics from government research and prevent what was done in my case from being done to other scientists.²⁵ Blowing the whistle on institutional research misconduct is not something a scientist should be ashamed of, or have to "own up to."

Brian Deer's other allegations

In his email to Mr. Kohn, Deer argued that "the finding by the editors of the *BMJ* of research fraud against Wakefield [is not] critically dependent on mismatches in histopathology records." I respectfully disagree. Deer and *BMJ*'s editors indeed raised a number of important issues, which potentially involve scientific misconduct. For example, the GMC's solicitors argued that communications between Wakefield and some of the referring physicians disqualified the 12 *Lancet* children as being consecutively referred.

Twelve consecutively referred patients simply means picking the first 12 patients referred. I suspect that many, if not most, scientists would not consider the patients consecutively referred had Wakefield disqualified children whose parents and physicians contacted him in the manner described above. Prosecutors, however, argued: "[W]e say

that the use of the phrase 'consecutively refers' implies again to the reader, whether he be scientist, journalist, member of the public, a routine process of referral. That is, one in which another doctor asks for his patient to be seen, not one in which an active role is played by the research investigators ..." ²⁶

I agree that research plans should address what course should be taken, for example, when a child's mother contacts a scientist and asks that her child be included in the study. Perhaps ethicists would consider it wrong for Wakefield to tell parents who contacted him that only their children's physicians could refer their children, and that their physicians could contact him if they had any questions about the study. If so, the rule should be that patients must be both "consecutively" and "independently" referred. But, a referral process such as the one described above is not the same as a researcher first examining patients and then "cherry-picking" 12 that he wants to include in a study.

Similarly, it raises serious ethical issues when a researcher applies for a patent related to his research and fails to disclose it to the editors. But the issues in Wakefield's case, and in most cases, are not that simple. Scientists at research universities in the U.S. and most other countries, including the U.K., do not normally apply for patents that arise from their university research. Tech transfer units at universities assume that responsibility. These units oversee and control the entire patent application process, as well as everything else associated with developing and marketing the inventions.

In order to be hired, faculty members are required to sign over their rights to any future patents related to their academic research to the university. Should a tech transfer unit ever take an interest in marketing products associated with their research, the researchers, *a.k.a.* inventors, are required to sign non-disclosure agreements. Patent applications can become void if they are publicly disclosed in writing one year or longer prior to completing the application process. Universities, therefore, require non-disclosure agreements that prohibit researchers from disclosing the university's patent applications - even to editors of scientific journals - prior to the university being granted patent pending status. Once these agreements are signed, the university's lawyers proceed to describe the invention in a patent application and file it with the Patent Office.

Oftentimes, the language attorneys use when describing inventions is far from being scientifically correct. Such is the case with the patent application filed by the Royal Free School of Medicine to cover Wakefield's research on a transfer factor for treating measles infections in immunocompromised patients.^{27,28} The university's lawyers described it as a measles vaccine; however, transfer factors cannot be used to vaccinate healthy populations.²⁹ It was not possible for Wakefield's transfer factor to compete with any MMR or measles vaccines. Moreover, the Medical School did not complete the patent application process until after the *Lancet* article was published.²⁸ Even if Wakefield had thought that the university's patent application posed a conflict of interest, he would not have been permitted to disclose it to *Lancet's* editors. He had to wait until the transfer factor was granted patent pending status, which was after his paper was published. As an aside, the Royal Free School of Medicine abandoned its patent application in 2006.³⁰

By patenting and marketing academic research, universities enable the public to benefit from the research.³¹ However, the whole process makes faculty members named as inventors appear to be profit-motivated; and non-disclosure requirements raise ethics issues with scientific journals. This enigma is often discussed at conferences involving research ethics; but there is no ideal solution.

In Wakefield's case, the university's efforts to enable immunocompromised patients to benefit from Wakefield's discoveries only added to the perfect storm of ethics and scientific misconduct issues gathering around him in the wake of Brian Deer's highly publicized allegations. Normally, such allegations are generated within the scientific community, subjected to a formal academic process, investigated by an impartial body of scientists, and kept confidential at least until a verdict is reached. This process is designed to prevent just the sort of uncontrolled frenzy that has occurred in Wakefield's case. Formal academic proceedings are not always fair and impartial; but whenever allegations of research misconduct are openly tried in the court of public opinion the outcome is never fair or impartial.

The crux of the matter in Wakefield's case, so far as research fraud is concerned, is whether Wakefield fabricated the diagnosis of non-specific colitis for 11 of the 12 *Lancet* children as claimed in Table 1. Dhillon's and Anthony's grading sheets clearly show that Wakefield did not fabricate the diagnoses of non-specific colitis reported in the *Lancet* article.

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APPENDIX 1. HEFCE PUBLIC INTEREST DISCLOSURE FORM

SUBMITTED TO: Pippa Thompson, Head of Knowledge and Information Management, HEFCE,
Northavon House, Coldharbour Lane, Bristol BS16 1QD

January 2, 2011

1. Which higher education institution is your disclosure about?

University College London (UCL)

2. Have you completed the formal public interest disclosure / whistleblowing / complaints procedure at the institution and do you have evidence to show this? Please attach a copy of the final decision.

☒

No

Your disclosure should normally be made to the institution you are concerned about first to give them an opportunity to consider your concerns and, if appropriate, offer a remedy.

☐

Not sure

Please contact us on 0117 931 7438 to discuss your disclosure

☐

Yes

Copy of these materials were filed at UCL Office of Provost (Health)

3. If you have not completed the formal process within the institution, please explain why you are raising the issue with HEFCE.

Relates to a matter which Fiona Godlee, per advice from Andrew Miller MP, chair of the House of Commons Science and Technology Select Committee, has taken up with HEFCE.

4. Have you corresponded with the institution about your disclosure in the last 12 months?

Yes X No

If you have not corresponded in the last 12 months please explain why below:

5. Have you taken, or are you planning to take, legal action against the institution?

☒

No

☐

Not sure

This may affect our ability to consider your disclosure. Please call our helpline on 0117 931 7438

☐

Yes

This may affect our ability to consider your disclosure. Please call our helpline on 0117 931 7438

6. About you

Mr/Mrs/Miss/Ms: DAVID L. LEWIS
surname):

Name (please underline

Address and postcode:

1310 Saxon Road
Watkinsville, GA 30677
USA

www.researchmisconduct.org

Daytime telephone number:

E-mail: LewisDaveL@aol.com

Do you have any special requirements when we communicate with you? No

Please describe your current and/or former relationship with the institution:

UCL is investigating "institutional research misconduct" based, in part, on documents I provided to Fiona Godlee regarding the matter of Dr. Andrew Wakefield.

7. I am submitting a disclosure on behalf of someone else

I am making this disclosure on behalf of:

Mr/Mrs/Miss/Ms: Name:

Address and postcode:

Daytime telephone number:

E-mail:

What is your relationship to this person?

Please explain why this person cannot make the disclosure themselves:

*If you are representing someone else, they **must** sign the authorisation in section 14 if they are capable*

8. What was your original disclosure to the institution and why are you unhappy with their response to you? (Use an extra sheet, if necessary)

9. How have you, or the person you represent, been affected? (Use an extra sheet, if necessary).

The BMJ's and Brian Deer's mishandling of evidence provided to UCL in Wakefield's case, which is incriminating to the BMJ and Brian Deer, included misrepresenting my professional credentials and relationship with Dr. Wakefield, and filing false allegations of ethical misconduct against me at the National Whistleblowers Center in Washington, DC.

10. What would you like to happen? (Use an extra sheet, if necessary).

The attached PDF file fully discloses all of the evidence I uncovered in my investigation of Dr. Wakefield's case, and chronicles the manner in which it was mishandled by the BMJ and Brian Deer. I want this information to be officially acknowledged by UCL and HEFCE, and fully included in their investigations into the allegations of "institutional research misconduct", which the BMJ and Brian Deer have published.

11. Which of HEFCE's functions and interest does this disclosure relate to? Please refer to the relevant paragraph of the Financial Memorandum (FM): HEFCE 2010/19 http://www.hefce.ac.uk/pubs/hefce/2010/10_19/ and explain how it is connected

FM paragraph	
	<p>Broadly, Andrew Miller MP, chair of the House of Commons Science and Technology Select Committee, stated that the issue raised by Fiona Godlee pertaining to the evidence in my possession should be handled by the Higher Education Funding Council for England, which deals with issues involving academic standards of publicly funded schools. [Godlee F. Institutional research misconduct. <i>BMJ</i>. 2011 Nov 9;343:d7284. http://www.bmj.com/content/343/bmj.d7284?tab=full (See also, Editor's <i>Rapid Response</i> update.)]</p> <p>In the Financial Memorandum, Paragraph 18 of the section on "Institutions' responsibilities to HEFCE Governing Bodies" states: "In accordance with the institution's own statutes and constitution, there should be effective arrangements for providing assurance to the governing body that the institution ... has an effective framework – overseen by its senate, academic board or equivalent – to manage the quality of learning and teaching and to maintain academic standards."</p>

The attached document is titled "Apparent Egregious Ethical Misconduct by *BMJ*, Brian Deer." It directly bears upon the issue of whether UCL lacks an effective framework for maintaining proper academic standards. Fiona Godlee and Brian Deer have alleged, based on evidence I provided to the *BMJ*, that UCL engages in institutional research misconduct, and that this misconduct "raises questions about the prevailing culture of Britain's academic institutions."

The attached document chronicles how Dr. Godlee and Mr. Deer apparently misrepresented the evidence I provided to the *BMJ*, and apparently engaged in the sort of misconduct of which they accuse UCL of engaging in. They allege that UCL created an "MMR scare" over the MMR vaccine manufactured by Merck and GSK so that it could market its own safer products. The *BMJ* is funded by Merck and GSK.

The PDF file I am submitting shows how the *BMJ* and Mr. Deer apparently cherry-picked and manipulated my documents to support its case against UCL. It includes important evidence favorable to UCL, which the *BMJ* apparently chose not to disclose when it published its allegations of institutional research misconduct.

12. Please list the documentary evidence you are supplying. This may be: copies of invoices, a print out from an institution's database, minutes of internal meetings etc. NB. We cannot approach an institution without evidence.

Type of evidence	How it supports your disclosure
72 emails between BMJ editors and me	<ul style="list-style-type: none"> Chronicle the apparent cherry-picking and manipulation of evidence by the <i>BMJ</i> and Brian Deer to support their allegations against UCL Contains evidence of apparent ethical misconduct related to the publication of patient medical records copyrighted by UCL
4 emails between Brian Deer and NWC	<ul style="list-style-type: none"> Contains Evidence of Deer's and the BMJ's apparent involvement in fabricating allegations of ethical misconduct against me to apparently prevent the National Whistleblower Center from publicly disclosing incriminating evidence, which the BMJ apparently removed from my Rapid Response to support its allegations against UCL
Photos and other documents from Wakefield's files	<ul style="list-style-type: none"> Critically important evidence favoring UCL, which the BMJ removed from my Rapid Response and failed to disclose when alleging institutional research misconduct at UCL

13. Would you be willing to meet the HEFCE Officer, if one is asked to take this case forward?

Yes X

No

☐

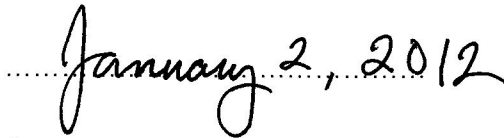
1. Authorisation

I wish HEFCE to consider my disclosure and understand that this information, including my name, will be shared with the organisation. I understand that HEFCE does not offer any guarantee of confidentiality. Where I have asked a representative to make this disclosure on my behalf I agree that all correspondence will be through them.

Signed



Date



Please remember to include all the evidence you have about your disclosure – in particular letters to and from the organisation you are concerned about.