Chapter Twenty-Nine

THE EXONERATION OF PROFESSOR JOHN WALKER-SMITH
A Great Wrong Partly Righted

David L. Lewis, PhD

My responsibilities at the National Whistleblowers Center (NWC) in Washington, DC, include serving on its board of directors and managing the Research Misconduct Project (www.researchmisconduct.org). On a voluntary basis, I investigate cases of “institutional research misconduct” in which government, industry, and academic institutions use false allegations of research misconduct against scientists whose research threatens government policies and industry practices. In 2011, philanthropist Claire Dwoskin, who helped organize a vaccine safety conference in Jamaica, West Indies,¹ invited me to attend as an outside observer and comment on my experiences involving the suppression of scientific research (see appendix to this chapter). Dr. Andrew Wakefield was one of the speakers. He, with twelve colleagues, wrote the controversial 1998 *Lancet* article in which parents linked autism in eight of twelve children with MMR (measles, mumps, rubella) vaccination.²

During the conference, news coverage of Brian Deer’s articles in the *British Medical Journal (BMJ)* alleging research fraud against Dr. Wakefield broke in the international media.³ I gave Dr. Wakefield my contact information, and he sent me a copy of his book, *Callous Disregard*. Afterward, he granted me full access
to his personal files, which included many important documents that had never been made public. In November 2011, the BMJ published my “Rapid Response” about the documents and accompanied it with an editorial by its editor-in-chief, Dr. Fiona Godlee, a feature article by Deer, and two external commentaries. After reviewing the documents, the author of one of the commentaries, Ingvar Bjarnason at King’s College Hospital, told Nature that he did not believe Dr. Wakefield fabricated the diagnoses published in The Lancet. The documents “don’t clearly support charges that Wakefield deliberately misinterpreted the records,” he said. Later, I filed a complaint with the UK Research Integrity Office (UKRIO) over Deer’s and the BMJ’s handling of the evidence I uncovered. This article is based on those experiences and my investigation of Dr. Wakefield’s case.

BACKGROUND

Brian Deer’s Allegations:

The controversy over the Lancet study began in 2004 when Brian Deer, a reporter working for Rupert Murdoch’s The Sunday Times, alleged that the study lacked proper ethics approvals and imposed clinically unnecessary medical procedures on the Lancet children for research purposes. He claimed that solicitor Richard Barr funded the study with a grant from the Legal Aid Board (LAB) to provide a basis for suing manufacturers of the MMR vaccine on behalf of parents claiming that the vaccine caused their children’s autism. According to Deer, it was all part of a scheme in which the lead author, Dr. Andrew Wakefield, stood to profit from a patent on his own, safer measles vaccine.

Reluctant to publish the allegations, The Sunday Times required Deer to obtain on-the-record quotations supporting the allegations from The Lancet’s chief editor, Richard Horton. Deer met with Horton and other Lancet editors in February 2004. He was accompanied by Evan Harris, an outspoken supporter of the MMR vaccine in the British Parliament. Horton, not surprisingly, refused to supply any quotations without first looking into the matter himself. After meeting with authors of the Lancet article and administrators at University College London (UCL) and the Royal Free Hospital, Horton and other editors published Deer’s allegations with their response just three days after the meeting with Harris and Deer.
The editors disagreed with Deer that medical procedures used in the Lancet study lacked proper ethics approvals and that the patients were not consecutively referred. They did agree, however, that Wakefield failed to inform Lancet editors about the LAB grant and his work with Richard Barr. Wakefield maintained that the LAB grant was for a separate study and that he had complied with The Lancet’s disclosure rules operating at that time. The Lancet editors decided that the alleged nondisclosures did not warrant retracting the paper. In short, the Lancet editors fully cleared John Walker-Smith and only chastised Wakefield over his alleged conflicts of interest. Unfortunately, before Dr. Wakefield could fully respond because he had moved to the United States, The Lancet’s support for some of the allegations gave Deer instant credibility in the scientific community. This outcome created nearly insurmountable obstacles to Wakefield’s ability to defend himself later. UCL, the only academic institution to evaluate Deer’s allegations, disputed all of them. Normally, all it takes to clear a scientist of fraud allegations is an investigation by the institution where the alleged acts occurred. But, because of the government’s interest in the case, The Lancet’s findings triggered a debate in the House of Commons. Harris wanted the Crown Prosecution Service to hold Wakefield and his coauthors responsible for the deaths of unvaccinated children and consider charging them under criminal statutes. In the end, the matter was turned over to the U.K. General Medical Council (GMC).

**Deer’s Nondisclosures:**

Further crippling Wakefield’s chances of a fair hearing, Deer either failed to obtain key evidence or chose not to disclose it to the GMC and others. For example, letters exchanged between Barr and Horton nine months before the Lancet study was published show that Horton, in fact, had been informed about Wakefield’s expert witness work with Barr. Deer also quoted Barr saying (wrongly as it turned out) that he paid for the Lancet research. Documents gathered after The Lancet’s investigation, however, show that A.J. Zuckerman, dean of the Royal Free Hospital Medical School, had sequestered all of the LAB funds until well after the Lancet study was submitted for publication. In May 1997, when it became apparent that the funds were in limbo, Wakefield requested that they be returned to the LAB. Zuckerman later confirmed to the GMC that LAB funds were not used to support the Lancet study.

Most damning of all, documents show that Deer obtained copies of the ethics committee approvals covering the research component of the Lancet...
study but apparently never disclosed them to the GMC. According to a Freedom of Information Act (FOI Act, a.k.a. FOIA) response from the London Strategic Health Authority of the National Health Service (NHS), Deer, in 2004, obtained copies of correspondence exchanged between Professor Walker-Smith and the Royal Free Hospital’s Ethical Practices Committee. One memo from Walker-Smith to the committee on February 27, 1997, stated: “We currently have formal approval to take research biopsies during colonoscopy (Code 162-95) and I am writing to organize formal approval for research biopsies to be taken during upper biopsies.” (Approvals for upper biopsies were later designated as Code 70-97.) In another memo, a member of Walker-Smith’s group transmitted a report to the ethics committee, which was titled “1999 Annual Report on ethical submissions 162-95 and 70-97.” It states, “Samples, with fully informed parental consent (using the consent forms as detailed in the submissions), were obtained from upper and lower endoscopies. . . .” In all cases, colonoscopies were performed on the Lancet children only after parental consent was granted on or before August 24, 1995 (Table 1). (The signed consent forms and other key documents, including the ethics approvals for 162-95, are available online at www.VaccineEpidemic.com.)

To substantiate his allegations that the Lancet study lacked any ethics approval for research, Deer provided the GMC with an Ethical Practices Committee (EPC) approval from the Royal Free Hospital that was coded EPC 172-96. This approval was for a study of 25 children with autism spectrum disorder and intestinal symptoms. It described clinical investigations involving ileocolonoscopy and upper gastrointestinal endoscopy with biopsies, barium (enemas), lumbar punctures, and various blood tests as part of “normal patient care.” This proposed study included research investigations intended to examine the possible causes of the children’s disorders. It was approved on December 18, 1997, after seven of the Lancet children had already been investigated clinically for their intestinal and neurological symptoms. Absent the EPC 162-95 approvals, the appearance was created that Walker-Smith collected research biopsies from seven of the Lancet children without any ethics approvals. It also made it appear that the parental consent forms should have been included with EPC 172-96 (instead of EPC 162-95) and that none of the research in the Lancet study was covered under any ethics approvals. Finally, it made it appear that Wakefield and his coauthors were dishonest when they stated in the Lancet article, “Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent.”
The GMC Hearings:

The GMC, which regulates U.K. medical practice, held public hearings into allegations of ethical misconduct against the *Lancet* article’s three senior authors, Dr. Wakefield, Dr. Walker-Smith, and Dr. Simon Murch. The hearings, which were based on allegations Deer first published in *The Sunday Times* in February 2004, began in July 2007 and lasted until May 2010. Walker-Smith’s legal counsel, Stephen Miller, tried to correct Deer’s apparent omission of the ethics approvals for the research component of the *Lancet* study (EPC 162-95) by introducing Exhibits 86(a), (b), and (c).21 Dr. Wakefield and his coauthors described the research component as a “pilot study.”22 Miller quoted from Exhibit 86(a), a memo John Walker-Smith sent to the chairman of the Royal Free Hospital dated August 24, 1995:

> For some years. . . we have had ethical permission to take two extra mucosal biopsies for research purposes. During colonoscopy children routinely have multiple biopsies taken for diagnostic purpose (4-6). The parents have signed a [consent] form as attached granting permission. These biopsies are used for a variety of research investigations such as cytokine production where on occasion information of direct and immediate importance to the child’s illness has been obtained as well as of research importance. I would be very grateful if you would grant permission for this to continue after our move to the Royal Free.23

Opposing counsel responded that this was the first time that the GMC’s counsel had ever seen any of these documents concerning EPC 162-95. In a recent interview, Deer claimed that the correspondence he obtained under the U.K.’s FOIA concerning the research component of the *Lancet* study (EPC 162-95) was also entered into evidence by the GMC;24 however, it was not. Deer did produce these documents in the defamation lawsuit Wakefield filed after Deer’s *Sunday Times* articles of 2004,25 which Wakefield later voluntarily withdrew. Their significance to the GMC proceedings only recently came to light after a comparison of Deer’s disclosure to the GMC with a response from the NHS providing the documents Deer obtained under the FOIA in 2004.

Although the three documents introduced by Walker-Smith’s attorney clearly demonstrated that the research component to the *Lancet* study had been preapproved by the Ethics Committee, they were not nearly as comprehensive as the EPC 162-95 approvals Deer had obtained from NHS. In other words, while
Dr. Wakefield struggled to put all the facts together at the beginning of the hearings,26 Deer apparently sat on the evidence Dr. Wakefield needed. In fact, there is no evidence that Deer ever disclosed any of the EPC 162-95 research approvals to the GMC, which simply disregarded the few meager exhibits introduced by Walker-Smith’s attorney. In the end, the GMC sanctioned Dr. Wakefield and Professor Walker-Smith for not complying with the “conditions for approval and the inclusion criteria” for Project 172-96 (i.e., investigating children before the approval date and failing to keep copies of the signed parental consent forms with EPC approvals for Project 172-96).27 Dr. Wakefield and his senior coauthors, however, steadfastly maintained that EPC 172-96 had nothing to do with the Lancet study.28

Later on in the GMC hearings, Dr. Wakefield’s attorney submitted correspondence exchanged between Richard Horton, editor in chief of The Lancet, and Richard Barr. Deer had failed to produce this critically important evidence, which proved that Horton was made aware of Wakefield’s work with Barr nine months prior to publishing the Lancet article. But, instead of dropping the charge that Wakefield had not disclosed the work to Horton and apologizing for falsely accusing Dr. Wakefield, the GMC panel railed at Wakefield’s attorney for introducing the evidence. Wakefield’s attorney remarked to the panel, “Rather than [receiving] an apology, Dr. Wakefield has been the recipient of a vigorous attack by the Council for having had the temerity to bring these relevant documents to the Panel’s attention.”29

Ignoring key exculpatory evidence, the GMC found in 2010 that Professor Walker-Smith and Dr. Wakefield had falsely claimed that the Lancet children were consecutively referred. They also found it false that certain medical procedures, including lumbar punctures and endoscopic biopsies, and collection of blood samples were clinically necessary and that these procedures had been approved by the hospital’s ethics committee. But, the endoscopic biopsies were specifically approved (Table 1); and even British health authorities had employed lumbar punctures to collect spinal fluid in order to determine whether or not children were infected with the mumps virus from the MMR vaccine. They reported, “In Nottingham all children with febrile convulsions were lumbar punctured. . . .”30 Moreover, Evan Harris acknowledged that British medical guidelines in effect at the time permitted the collection of blood samples for research purposes without ethical approval.31 Separately, the GMC found that Wakefield failed to disclose the LAB grant and other purported conflicts of interest to the Lancet editors and that he had exhibited “callous disregard” toward
some of the *Lancet* children by collecting blood samples at a children’s birthday party. Based on its findings, the GMC revoked Wakefield’s and Walker-Smith’s licenses to practice medicine.\textsuperscript{32}

**Targeting Wakefield in the U.S.**

In the wake of the GMC’s 2010 decisions, Deer and the *BMJ* began directing their attacks at Wakefield’s safe haven in the United States, where they characterized him as a criminal attempting to flee justice.\textsuperscript{33} In an interview with CNN, Deer called upon the U.S. Department of Homeland Security to “take a close look at Wakefield’s visa application and how he got into the United States.”\textsuperscript{34} Fiona Godlee and others at the *BMJ* complained that Wakefield was allowed to continue his work in the United States and called on the news media, government agencies, and others to respond. “[H]e continues to push his views. . . . Meanwhile, the damage to public health continues, fueled by unbalanced media reporting and an ineffective response from government, researchers, journals, and the medical profession.”\textsuperscript{35}

Taking up the gauntlet, CNN’s Anderson Cooper drew upon the *BMJ* articles to reject exculpatory evidence in Wakefield’s book *Callous Disregard* and denounce him as a liar: “But, sir, if you’re lying, then your book is also a lie. If your study is a lie, your book is a lie.”\textsuperscript{36} Cooper went on to say that a growing number of children have died from not being vaccinated, then asked, “Do you feel any sense of responsibility for that?”

Bill Gates spoke even more plainly with CNN’s Dr. Sanjay Gupta. Alluding to the *BMJ* series, he said:

Dr. Wakefield has been shown to have used absolutely fraudulent data. He had a financial interest in some lawsuits, he created a fake paper. . . .it’s an absolute lie that has killed thousands of kids. Because the mothers who heard that lie, many of them didn’t have their kids take either pertussis or measles vaccine, and their children are dead today. And so the people who go and engage in those anti-vaccine efforts—you know, they, they kill children.”\textsuperscript{37}
BRIAN DEER AND THE BMJ

In January 2011, the BMJ published a series of articles several months after the GMC’s decision to delicense Wakefield and Walker-Smith. It criticized Wakefield for his “involvement with a lawsuit against manufacturers of the MMR vaccine” and singled him out as a lone fraudster with a get-rich scheme. In the now-discredited trial carried out by the GMC, one of the government’s most damaging charges centered around Wakefield’s “failure to disclose [a] patent” on a transfer factor used to treat measles infections. These charges were based on Deer’s allegations that Wakefield was attempting to undermine the MMR vaccine in order to market his own measles vaccine. It is a common practice for universities to exploit the commercial potential for academic advances in science to allow the public to benefit. Researchers are required to assign all patent rights to their universities who, in turn, file patent applications and create commercial development projects. This arrangement, however, makes researchers vulnerable to being seen as profiteers, even unethical, despite the fact that advances in science and medicine cannot be commercialized absent patent protection.

The measles transfer factor was first described in a provisional patent application filed by the Royal Free Hospital in 1997. The application process was finally completed after the Lancet article was published. Wakefield risked having the U.K. Patent Office void the application if he publicly described the transfer factor in writing before the application process was completed. In the end, it didn’t matter anyway. The patent application was eventually abandoned, and it became increasingly difficult to proceed to clinical trials as Deer and the GMC pursued the fraud allegations.

The patent application referred to two possible applications of Wakefield’s work: a “measles transfer factor” and a “safer measles vaccine.” Transfer factors confer cell-mediated immunity in immune-compromised patients. They cannot be used to vaccinate the general population since they do not induce antibody immunity, which is considered a prerequisite for population-based vaccines. Hence, transfer factors cannot compete with the MMR vaccine manufactured by Merck and GlaxoSmithKline; and Wakefield, therefore, never stood to gain financially from the demise of the vaccine. Vaccines made from live viruses, such as the MMR vaccine, often cannot be safely administered to immune-compromised patients. In that sense, treatments derived from transfer factors for immune-compromised patients could be considered a “safer vaccine.”
But, for Deer and the *BMJ* to claim that Wakefield created an MMR scare to sell his own patented measles vaccine in its place is simply false.

**WAKEFIELD’S FILES**

In Deer’s 2010 *BMJ* article titled “Wakefield’s ‘Autistic Enterocolitis’ Under the Microscope,” he accused Wakefield of exaggerating the information in pathologists’ grading sheets in order to diagnose most of the *Lancet* children with colitis. The pathologists, Professor Amar Dhillon and Dr. Andrew Anthony, examined the biopsy samples as part of a blinded independent analysis that included healthy (control) biopsy samples from another hospital. But grading sheets, Deer argued, “don’t generate clinical diagnoses such as colitis.” The “ultimate proof” of Wakefield’s innocence or guilt, according to Deer, is the biopsy slides described in the grading sheets, which turned up missing by the time the GMC began its investigation.

Wakefield’s files contain the GMC’s copies of many of the grading sheets. They show that Dhillon included boxes to check for various diagnoses, such as Crohn’s disease and ulcerative colitis. Consistent with the *Lancet* article, both pathologists found that only one child showed no evidence of inflammation. Unfortunately, the only grading sheets belonging to Anthony were completed shortly after the *Lancet* study was published as he continued to examine the biopsy slides. Still, they showed that he indicated the diagnosis of colitis in marginal notes. Wakefield’s files also contained photomicrographs taken by Dhillon and Anthony for six of the children (Patients 2-6, and 9). The various cellular structures described in Table 1 of the *Lancet* article are clearly visible on the photomicrographs.

Other important documents in Wakefield’s files include Anthony’s PowerPoint presentation in which he meticulously illustrated the approach he and Dhillon used to grade inflammation levels in the biopsy slides. They also include copies of Dhillon’s and Anthony’s sworn statements to the GMC in which they described reviewing and approving Wakefield’s summary of their grading sheets published in Table 1. In my opinion, these and other documents in Wakefield’s files prove that he faithfully reproduced Dhillon’s and Anthony’s blinded analysis reported in Table 1 of the *Lancet* article.

Although the *BMJ* and Deer took pains to portray Deer as the origin of the analytical underpinnings of his *BMJ* article, it never made sense that a freelance journalist with a lackluster career and no scientific or medical background would
fully comprehend the medical records and histological data upon which the *Lancet* article was based. Thus, it was both shocking and revelatory to discover a confidential report comparing routine pathology reports from the Royal Free Hospital with the *Lancet* article in Wakefield’s files. The report was prepared for the GMC in 2006 by one of its experts, Professor Ian Booth, who was a pediatric gastroenterologist. It was the perfect intellectual blueprint for Deer’s subsequent *BMJ* articles.

The discovery of Booth’s report raises serious questions about whether or not Deer obtained the information from the GMC, directly or indirectly, and whether or not he used it as a template for his own articles in the *BMJ*. Professor Booth confirmed the report’s authenticity to me in an email, stating:

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.

Shortly before the GMC sanctioned Wakefield and Walker-Smith in May 2010, the *BMJ* published Deer’s autistic enterocolitis article suggesting Wakefield fabricated the diagnosis of nonspecific colitis from Dhillon’s and Anthony’s grading sheets. Under the heading “MMR: Faking the Link,” Deer reported mismatches between routine (on-duty) pathology reports from the Royal Free Hospital and Wakefield’s summary of Dhillon’s and Anthony’s results in Table 1 of the *Lancet* article, just as Booth had done in his report four years earlier. Editors at the *BMJ* portrayed Deer as the original source of the analysis of medical records that purportedly unveiled Wakefield as a fraudster:

[I]t has taken the diligent skepticism of one man, standing outside medicine and science, to show that the paper was in fact an elaborate fraud. . . . the GMC launched its own proceedings that focused on whether the research was ethical. But while the disciplinary panel was examining the children’s medical records in public, Deer compared them with what was published in the *Lancet*. His focus was now on whether the research was true.
I posted Booth’s report on the NWC Research Misconduct Project’s website (www.researchmisconduct.org) and pointed out that it raised serious questions about how Deer came to publish, as his own work, the same analysis that the GMC solicitors asked Booth to perform. Outraged over my postings, Deer filed multiple allegations of ethical misconduct against me with the NWC executive director and demanded that my materials be removed from the NWC’s website. In an email to the NWC, Deer stated that he had never seen Booth’s report prior to its posting on the NWC website in June 2011, but whether or not someone with knowledge of it gave him the idea of comparing the on-duty pathology reports with Table 1 of the *Lancet* article is unknown.

**BMJ’s “RAPID RESPONSE”**

In September 2011, I submitted evidence from Wakefield’s files to the *BMJ*, along with a commentary outlining my conclusions. Editor in chief Godlee rejected my submission and invited me instead to revise the materials as a “Rapid Response” to Deer’s 2010 article on autistic enterocolitis. After I reformatted the information in accordance with the *BMJ*’s instructions to authors, the editors worked with me to make additional minor changes. As soon as these changes were made, the *BMJ* provided me a link to the prepublication version, complete with four attachments: Dhillon’s and Anthony’s grading sheets, photomicrographs of the children’s missing biopsy slides, and my revised commentary. In my commentary, I disputed the GMC’s findings over a wide range of issues and addressed the false allegations of ethical misconduct against me, which Deer had submitted to the NWC.

Godlee told me that she was having my Rapid Response, including attachments, externally peer-reviewed—an extraordinary measure for publishing online comments from readers. The *BMJ*’s editors and attorneys completely rewrote it as a brief description of the grading sheets with an explanation of how I obtained them. According to Godlee, the rewrite was based on the peer-reviews; however, in a radical departure from normal procedures for a peer-reviewed, scholarly journal, the editors did not forward the peer-reviews to me and ignored my request to provide me with copies. I also suggested adding a sentence expressing my overall views of the *Lancet* study. Although readers are normally allowed to comment on any part of an article, Godlee stated that I was only permitted to comment on the parts of Deer’s articles pertaining to grading sheets. Deputy Editor Tony Delamothe wrote, “We care about getting your opinion on the interpretation of the biopsies into the journal, but nothing more.”
On November 9, 2011, the *BMJ* published a Rapid Response, which the editors rewrote and misrepresented as my response to an article Deer published in 2011, titled “How the Case Against the MMR Vaccine was Fixed.” The reason that the editors and lawyers prohibited me from commenting on anything but the biopsy pathologies revealed itself when Godlee dismissed my Rapid Response in an interview with *Nature*. “Fiona Godlee, the editor of the *BMJ*, says that 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.”

Based on the documents I submitted *BMJ*’s editors and attorneys had only two choices: exonerate Wakefield and get to the bottom of what really went on between Deer, Evan Harris, and the GMC, or publish a new theory in which the *Lancet* authors and virtually everyone they worked with at UCL and Royal Free Hospital were involved in a very elaborate fraud. Unfortunately, they chose the latter and deleted almost all of the evidence in Wakefield’s files that exonerated him and his coauthors. To explain their new theory of research fraud, Godlee accompanied my Rapid Response with an editorial titled “Institutional Research Misconduct.” In it, she alleged that UCL administrators, the Royal Free Hospital, and all 13 authors of the *Lancet* study created an MMR scare so that UCL could sell its own safer measles vaccine, diagnostic kits, and “autism products.” She called on Parliament to hold an inquiry into the research fraud running rampant in Great Britain’s academic institutions. Andrew Miller, who chaired the Science and Technology Committee, responded that this was not the right forum and that he “must be careful not to appear to be vulnerable to public lobbying.”

**THE UKRIO REPORT**

In January 2012, I filed a 167-page report with the UK Research Integrity Office (UKRIO) documenting how the *BMJ*’s editors and lawyers rewrote my Rapid Response to remove important evidence that undermined their allegations against Wakefield, and how Deer filed false allegations of ethical misconduct against me with the NWC to attempt to prevent me from posting the evidence on the NWC website. Evidence removed from my submission included photomicrographs Dhillon and Anthony took of the *Lancet* children’s missing biopsy slides, which Deer called the “ultimate proof” of Wakefield’s innocence or guilt; Anthony’s grading sheets where he wrote “colitis” in his marginal notes; and my commentary describing these and other important documents Deer appeared to have concealed from the *BMJ*. 
Without checking any of the facts, Deer informed NWC Executive Director Stephen Kohn that I was not qualified to comment on medical records involving colonic biopsies. He also called on the NWC’s board of directors to investigate me for ethical misconduct, claiming, for example, that I “improperly exploit[ed] a university email account” when I wrote to Professor Booth, and that I should have used email addresses published on the NWC website and elsewhere. He also claimed that I misled Booth by telling him that I “had been prompted to write to [him] by a question from a Nature reporter.” In response, I forwarded Deer’s emails to the BMJ editors with proof that I have been accepted by federal and state courts as an expert regarding the collection of colonic biopsies and that the University of Georgia had approved my use of its computers for my investigations into institutional research misconduct. I had, in fact, written to Professor Booth using my personal AOL email account and given the link to my Research Misconduct Project at the NWC. The Nature reporter who suggested I have Professor Booth verify his expert report also contacted the BMJ’s editors and disputed Deer’s allegations.

Apparently accepting Deer’s allegations, Fiona Godlee inserted the following statement in my Rapid Response: “I am not qualified in medicine or histopathology.” To counter these misrepresentations, I provided BMJ’s editors with an attachment to my Rapid Response that summarized my credentials as an expert in the collection of colonic biopsies. Godlee replaced the false statement, suggesting that I identify myself as “an expert in clinical studies involving the collection and examination of colonic biopsy samples.” Then, after deleting my attachment and editing down my Rapid Response, she described me in an editorial only as “a self-employed environmental microbiologist.” Likewise, in Deer’s feature article addressing my Rapid Response, he described me as a “self-employed American environmental microbiologist working with Wakefield.” I have not been employed as an environmental microbiologist, self or otherwise, since leaving the U.S. Environmental Protection Agency in 2003.

Research involving colonoscopy is one of my main areas of expertise and was my primary area of research at the University of Georgia from 1998–2008, as Deer and Godlee well knew. In 2003, the State of New York accepted me as an expert on colonic biopsy procedures at a hearing in which the State revoked a physician’s medical license. I have published research articles and commentaries in leading science and medical journals, including Nature, The Lancet, and Nature Medicine. In 2010, Annals of Internal Medicine rated me in the top 10 percent of its peer reviewers.
As is thoroughly documented in my report to the UKRIO, Godlee, Deer, and the *BMJ* removed key evidence exonerating Dr. Wakefield, misrepresented my qualifications, and in Deer’s case, created false allegations of scientific misconduct in an effort, I believe, to discredit me. How can anyone, therefore, argue that Godlee, Deer, and the *BMJ* did not do the same in Wakefield’s case?

**WAKEFIELD’S LAWSUITS**

Wakefield moved to the United States where, in early 2004, he and others founded the Thoughtful House Center for Children in Austin, Texas. Then, as Deer continued to vilify Wakefield, Wakefield filed a defamation lawsuit against Deer and a British television station in 2005. To continue evaluating the safety of pediatric vaccines, Wakefield collaborated with a primate research group at the University of Pittsburgh.

In 2005, the London court hearing Wakefield’s lawsuit against Deer denied a request from Wakefield’s lawyers to suspend its proceedings temporarily so that they could properly defend him in the GMC hearings. Given legal and financial constraints, Wakefield voluntarily withdrew his lawsuit against Deer in favor of pursuing the GMC proceedings and, eventually, his appeal against the GMC as well. In 2009, Wakefield and the primate group in Pittsburgh reported in the journal *Neurotoxicology* that they observed a significant delay in the acquisition of survival reflexes among newborn rhesus macaques vaccinated with thimerosal-containing Hepatitis B vaccine when compared with control animals receiving a saline placebo or no injection. But, when the GMC issued its findings in 2010, editors at *The Lancet* and *Neurotoxicology*, respectively, retracted both the 1998 study of autistic children by Wakefield et al., which raised concerns about the MMR vaccine, and the 2009 primate study implicating thimerosal. Finally, in 2012, Wakefield filed a defamation lawsuit against the *BMJ*, Deer, and Godlee over their allegations of research fraud published in January 2011 and thereafter.

**THE HIGH COURT’S RULING**

Professor John Walker-Smith contested each and every finding made by the GMC panel in its Fitness to Practice hearing. His lack of confidence in its findings was recently affirmed by the March 2012 High Court ruling of Justice John Mitting, which overturned all of the panel’s findings with respect to codefendant Walker-Smith. Justice Mitting criticized the GMC panel on many counts.
He concluded, for example, that the panel made “fundamental errors,” distorted evidence, and based its findings on an inadequate analysis of the facts. The panel, Justice Mitting ruled, provided inadequate and superficial reasoning and explanation for its conclusions, inappropriately rejected evidence, relied upon “flawed” and “wrong” reasoning, and “numerous and significant inadequacies” in its conclusions, particularly in its findings in the individual cases of the Lancet children. Overall, Justice Mitting described the panel’s findings as “not legitimate,” “perverse,” “odd” and “unsustainable,” “wrong,” and “untenable.” Justice Mitting went on to state that “Universal inadequacies and some errors on the panel’s determination accordingly go to the heart of the case. They are not curable.” At the hearing before Justice Mitting, the GMC counsel acknowledged “serious weakness in [the GMC panel’s] reasoning.”

Justice Mitting ruled that the Lancet children were, in fact, consecutively referred, and that medical procedures used in the study, including lumbar punctures and endoscopic biopsies, were clinically indicated and, therefore, did not require approval from an ethics committee. These aspects of the High Court’s ruling should apply equally to the GMC’s findings concerning Dr. Wakefield. Justice Mitting also concluded that the GMC panel failed to recognize that complex studies often contain elements of both medical practice and research, and that the GMC fell short of distinguishing the difference between the two. In the case of Walker-Smith, the High Court found ample evidence in the record that his primary goal was to diagnose and treat the Lancet patients and that some of the patients did, in fact, benefit from his treatment. On the other hand, he opined, “Dr. Wakefield’s purpose was undoubtedly research.”

The High Court approach was to assess, individually, whether each scientist’s primary goal was to benefit the patients in the study versus patients in general. If the scientist’s primary aim was to benefit the patients in the Lancet study, he did not need an ethics approval for his work on the project. Ethical approvals, however, are granted to projects, not individuals. Thus, the High Court’s assessment yielded no direct insights into whether the primary goal of the Lancet study was medical practice or research.

Case studies, such as the Lancet study, are by nature “clinical research.” They usually come about when one or more physicians recognize that it would be useful to describe the circumstances, treatments, and outcomes of one or more patients under their care in the medical literature. Physicians often have their own ideas as to what may be causing their patients’ unusual disorders or diseases, and they experiment with various treatments accordingly. Usually, their primary
goal is to diagnose and treat the patients in the study. Publishing a paper in which they describe their patients’ circumstances, symptoms, the results of clinical tests, their own hypotheses about underlying causes, and the patients’ outcomes is an important, albeit secondary, goal. Another distinguishing characteristic is that case studies, which are typically clinically oriented, usually involve only a few patients. They serve as a starting point for research projects that require large numbers of patients comprising control and experimental groups, or for dose-response analyses. The *Lancet* study clearly fits in this category. It was primarily oriented toward diagnosing and treating the twelve children in the study.

Fortunately, even though the High Court focused on the primary goals of individual scientists rather than the project as a whole, it found that Walker-Smith’s main goal was diagnosing and treating the *Lancet* children. Thus, in the Court’s opinion, he did not need ethical approval because his research was clinical in nature; i.e., primarily aimed at diagnosing and treating the *Lancet* patients. But the High Court erred when it concluded that the ethics statement in the *Lancet* paper—“Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent” —was untrue. It was mistaken because the GMC should have acknowledged that the Ethical Practices Committee approved the research component of the *Lancet* study under Code 162-95, as the evidence showed, and signed consent forms specific for 162-95 were, in fact, included in the children’s medical records (Table 1).

Contrary to picturing Dr. Wakefield as a fraudster and child killer, which many in the news media and scientific literature have painted him based on the false allegations published by Deer and Godlee, the High Court’s 2012 ruling exonerating Dr. Walker-Smith projects a different image. It points to the transfer factor developed by Wakefield and others, which John Walker-Smith used in the *Lancet* study and noted that it improved the health of at least one of the immune-compromised *Lancet* children who had evidence of chronic measles infection. Unfortunately, the fraud allegations Harris and Deer launched against Wakefield and his coauthors in 2004 made it impossible for UCL to further develop this new therapeutic approach after the *Lancet* study was attacked. Such an approach could save countless lives and may be essential to eradicating the measles virus, especially in underdeveloped areas where malnutrition and other factors render patients susceptible to chronic measles infections.93

In conclusion, the majority of the GMC panel’s findings against Walker-Smith were based on identical charges leveled against Dr. Wakefield, and upon which the panel found Dr. Wakefield guilty. Therefore, the panel’s findings con-
cerning Dr. Wakefield were also “flawed,” “wrong,” “perverse,” “inadequate,” “unsustainable,” and “superficial.” In light of the High Court’s ruling, editors at The Lancet are now considering whether the retraction of the 1998 Lancet article by Wakefield et al. should be reversed.84

“NO RESPECTABLE BODY”

In my experience, the BMJ’s and Deer’s assaults on Dr. Wakefield lie completely outside the normal realm of reporting and editorial comment for scientific journals. Even Anderson Cooper began CNN’s coverage by announcing: “[The BMJ] did something extremely rare for a scientific journal. It accused a researcher, Andrew Wakefield, of outright fraud.”85 The explanation may lie in Godlee’s editorial responding to my Rapid Response. There, for the first time, she acknowledged that the BMJ receives funding from MMR vaccine manufacturers Merck and GSK.86 Shortly afterward, she corrected one editorial and two related Editor’s Choice articles and elaborated on the journal’s conflicts of interest: “The BMJ Group receives advertising and sponsorship revenue from vaccine manufacturers, and specifically from Merck and GSK, which both manufacture MMR vaccines.”87

Although it appears that the BMJ is simply using Deer to protect consumer confidence in its sponsors’ products, it has no plans to acknowledge the BMJ’s conflicts of interests in any of his articles.88 Still, the BMJ’s admissions seriously undermine Brian Deer’s credibility. For one thing, they call into question Deer’s contract with CNN, which Anderson Cooper used to vouch for Deer’s credibility, saying, “He’s actually signed a document guaranteeing that he has no financial interest in any of this, or no financial connections to anyone who has an interest in this.”89

Justice Mitting concluded, “There is now no respectable body of opinion which supports [Wakefield’s] hypothesis, that MMR vaccine and autism/enterocolitis are causally linked.”90 Aside from the fact that the rubella virus, from which the MMR vaccine is manufactured, is indeed causally linked to autism,91 it seems ironic that the High Court failed to understand that the absence of such a body of science may well be a direct, and intended, result of the GMC’s actions against Wakefield and Walker-Smith. As mice vacate a field at the sight of an owl devouring even a single mouse, so it is with scientists. It’s called the “ecology of fear.”92 If it were not for what was done to Wakefield and Walker-Smith, many outstanding scientists would likely be willing to conduct objective research on
vaccine safety and publish their results regardless of whether or not they may threaten government policies and industry practices.

Over time, science has evolved into a sophisticated marketing tool for supporting government policies and industry practices. As Godlee 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.” Marketing has a lot more to do with hiding the truth than publishing it, as Godlee’s convoluted statement makes clear. Virtually everything published in the peer-reviewed scientific literature is funded or carried out by government agencies, corporations, or universities. Governments hire scientists to support their policies. We know this because government agencies fire scientists who don’t support their policies. Corporations hire scientists to develop and defend their products and services. Universities hire scientists to bring in grants from government and industry; faculty members who fail at this don’t earn tenure. That’s not to say that all, or even most, science is untruthful. But what’s published is, for the most part, that portion of the truth of which government and industry have little at stake in the outcome. What is quashed is the portion that would pressure government agencies and large corporations to change policies and practices.

CONCLUSIONS

For his investigations uncovering Wakefield’s alleged research fraud, Deer was twice awarded the British Press Award, once in 1999 for articles in *The Sunday Times* “that ranged from vaccine-damaged children to the hidden side-effects of Viagra,” and then again in 2011 after the GMC removed Wakefield and Walker-Smith from the medical registry. According to Deer’s website, the British Press Awards are “the most coveted honors in UK news media—often described as the ‘Oscars of British journalism’ and compared with US Pulitzer Prizes.” When a panel of journalists presented Deer with his second British Press Award, it referred to his accomplishments as a “tremendous righting of a wrong.” But it was Andrew Wakefield and John Walker-Smith, not Brian Deer, who had it right. By clearing Professor John Walker-Smith, England’s High Court of Justice has righted a great wrong, but only partly. A full measure of justice requires that Dr. Andrew Wakefield also be exonerated.

The *Lancet* study, and other papers by Wakefield and his coauthors, documented a relationship between gastrointestinal disease and sudden developmen-
tal regression, which is now widely accepted. Researchers at Columbia University and Harvard Medical School, for example, recently cited papers by Wakefield and his coauthors and concluded that gastrointestinal disturbances are commonly reported in children with autism and may contribute to behavioral impairment. The only thing that was ever “wrong” with the *Lancet* article was that it documented the fact that some of the patients’ parents and doctors linked the onset of their gastrointestinal disease and sudden developmental regression to MMR vaccination. The truth is, large numbers of parents and physicians have linked the two, especially in cases where the children’s symptoms become markedly exacerbated as additional shots are administered.

Although Autism Spectrum Disorders (ASD) were exceedingly rare just over two decades ago, the CDC now estimates (based on the year 2000 birth cohort) that 1 in 88 children born in the United States have ASD (2012); and in South Korea, the estimate is 1 in 38 (2011). With numbers rising this fast and reaching these levels, it’s clear that environmental factors, not genetics, are mainly driving the epidemic. Scientists have implicated environmental pollutants and pediatric vaccines as possible causes. Unfortunately, government, industry, and the academic institutions they fund are highly motivated to predetermine the outcomes of research in these two areas. They do so by funding scientists who support government policies and industry practices and by targeting those who don’t, which is itself a form of institutional research misconduct.

In other words, autism is largely a man-made crisis created by government and industry. Institutional research misconduct is simply perpetuating the calamity. It appears that every nation has been set on a course to inject every human on the planet with increasingly complex mixtures of chemical and biological agents beginning at birth. The science supporting this bold experiment, however, is subject to government and industry manipulation on a scale that few other areas of science have ever experienced. This, combined with silencing reputable scientists who question vaccine safety, is a prescription for turning the hope science offers for future generations into a global disaster.

Disclaimer: The author’s views and opinions are his own and do not necessarily represent those of the National Whistleblowers Center.
APPENDIX TO CHAPTER TWENTY-SEVEN: THE “WAKEFIELD” TREATMENT

David L. Lewis, PhD

Below, I discuss two of my research projects, dental infection control and land application of biosolids, that changed government policies. In these and other projects that I carried out at the U.S. Environmental Protection Agency and University of Georgia, private corporations, industry-supported organizations, and government agencies used false allegations of ethical and research misconduct as part of an effort to discredit the researchers and stop the research.

I. DENTAL INFECTION CONTROL

Like the 1998 *Lancet* article by Wakefield et al, my research published in *The Lancet*¹ and *Nature Medicine*² linking HIV transmission to dental drills was highly controversial. When dental visits precipitously dropped, we were blamed for causing a dental scare worldwide and causing illnesses and deaths from a lack of proper dental care. One dentist who coauthored the research articles, who also took a controversial stand against mercury amalgams in fillings, lost his license to practice. Dentists balked at the solution we proposed, which was to heat-sterilize high-speed dental handpieces and other devices when the Centers for Disease Control and Prevention (CDC) considered high-level disinfection acceptable.

In an attempt to discredit the work, the American Dental Association (ADA) published an editorial claiming that I was a dentist with a patent in which I stood to profit if heat-sterilization became the standard of practice. I have never attended dental school, and the only patent I ever owned was for a home water filter that I never sold. Fortunately, the U.S. Departments of Navy and Air Force confirmed our results concerning the potential for certain common dental devices to transmit infections and recommended heat-sterilization.³ As a result of our research, the CDC, FDA, ADA, and other public health organizations
worldwide adopted the current heat-sterilization standard for all reused dental devices entering the oral cavity.

Every institution involved with dental health policies from the CDC to the ADA believed that all we would accomplish would be generating preventable illnesses and deaths by creating irrational public fears. Their approach took a different course in 1992, however, when ABC’s *Primetime Live* aired a segment called “Under the Gum.” It showed CDC Director Harold Jaffee watching a simple demonstration of our research for the first time. To illustrate how much blood and saliva were being retracted and ejected by the devices, I operated dental drills and prophy angles (used to polish teeth) in a laboratory model of the oral cavity that was contaminated with small amounts of blood. Then I handed them to a dentist to prepare for reuse following CDC guidelines.

Dr. Jaffee watched visible amounts of blood spit back out of the patient-ready devices when they were subsequently operated in a white porcelain container. ABC medical correspondent Sylvia Chase asked, “Is it not the same thing—this kind of blood transfer—as sharing a needle?” Jaffee opened his mouth to speak, but no words came out. After a long pause, he said: “Clearly, we don’t want one patient to be exposed to another’s blood.”

That night, common sense prevailed over peer-reviewed scientific articles published over the previous three decades supporting government infection-control guidelines. Virtually everyone in the dental and medical community thought that science had established beyond any doubt that dentistry’s high-level disinfection standard fully protected patients from infection. But now all could see with their own eyes how six patients in a Florida dental practice could have contracted HIV from their infected dentist by sharing reused prophy angles. We demonstrated that lubricants contaminated with blood from AIDS patients could efficiently infect human lymphocyte cultures even after disinfection with FDA-approved germicides.

With no system for tracking sporadic infections in dentistry and with leaky dental devices designed with no thought of infection control, dentistry had a big problem. Patients’ fears, in this case, turned out to be justified. Government agencies adopted a heat-sterilization standard, and patient visits to the dental office soon returned to normal.

II. LINKING ILLNESSES TO BIOSOLIDS

My duties as a research microbiologist in the EPA’s Office of Research and Development (ORD) included investigating illnesses and deaths linked to land
application of processed sewage sludge (biosolids). My team included a medical microbiologist, an environmental engineer, and a pediatrician treating children exposed to biosolids. Together, we published case studies linking biosolids to skin, gastrointestinal, and respiratory problems.  

To stop our research, employees in EPA's Office of Water, including the director of the Office of Wastewater Management, requested help from corporate executives in the biosolids business. Several weeks later, one of the executives sent the EPA officials an anonymous white paper falsely accusing me of research misconduct and criminal fraud. One of the EPA officials distributed the allegations at public meetings in Georgia while the corporate executives brought them to the attention of EPA Administrator Christie Whitman.  

EPA's efforts to silence me and other scientists documenting problems with biosolids prompted science committee hearings in the U.S. House of Representatives in 2000. The hearings focused on actions taken by former EPA Administrator Carol Browner and Robert Perciasepe, who was assistant administrator of EPA's Office of Water. Browner's assistant administrators cut off my research funding and distributed allegations that I had violated the Hatch Act and ethics rules by writing a commentary in Nature critical of EPA's science. My research included investigating a potential deep-sea oil spill in the Gulf of Mexico.  

Perciasepe, who currently serves as EPA Deputy Administrator under President Obama, authorized funding for a Biosolids Incident Response Team (BIRT) to investigate cattle deaths on two dairy farms in Georgia linked to biosolids produced by the city of Augusta. Robert Brobst, an EPA employee who headed BIRT, arranged for the EPA to fund the University of Georgia (UGA) to determine whether or not Augusta's biosolids posed a risk to cattle. On the dairy farms, the cattle developed AIDS-like symptoms after consuming forage grown on Augusta's biosolids and died of various infections. Local veterinarians and environmental experts hired by the dairy farmers discovered high levels of cadmium, molybdenum, and other heavy metals in soil and forage samples from areas treated with the biosolids. They also found potentially toxic levels of the heavy metals in the cattle's liver, kidney, and milk samples. Augusta's biosolids also contained potentially toxic levels of organic chemical wastes, including PCBs and chlordane, which were also detected in environmental samples collected from the dairy farms.  

UGA provided me an office in its Department of Marine Sciences and promised to pursue hiring me for a tenured faculty position. Corporate executives who provided EPA and the NRC with the anonymous white paper, however,
filed the allegations of research misconduct at UGA. Some of the allegations closely paralleled Wakefield’s case. The company alleged that my research done as an EPA employee had not been properly approved and that my private work as an expert witness on behalf of patients constituted a serious conflict of interest and ethics violation.

By this time, the EPA’s Office of General Counsel had determined that none of the allegations were based in any facts. Serving as an expert witness was the only way I could have access to patient records tied up in lawsuits involving illnesses and deaths linked to biosolids. EPA informed UGA that my research and private expert witness work had been approved by EPA ethics officials, and UGA informed the company that it did not intend to pursue its misconduct petition. To overcome this obstacle, the company hired Georgia Senator Kasim Reed, now mayor of Atlanta, to pressure UGA not to dismiss its petition. As a result, UGA left the allegations in a state of limbo and never ruled on them.

Additional allegations paralleling those against Wakefield were filed against me by a city being sued over biosolids. The city alleged that it was a conflict of interest for me to donate my expert witness fees to UGA to fund my research on biosolids. UGA cleared me of any wrongdoing. My department head later testified, however, that UGA administrators no longer supported hiring me because UGA depended on “money either from possible future EPA grants or connections there might be between the waste-disposal community [and] members of faculty.”

In a further attempt to discredit our research, the EPA funded UGA to publish data fabricated by the city of Augusta, Georgia, to cover up cattle deaths that I was investigating on two dairy farms treated with Augusta’s biosolids. Predictably, the study concluded that Augusta’s biosolids did not pose a risk to cattle. UGA issued a press release quoting lead author Julia Gaskin: “Some individuals have questioned whether the 503 regulations are protective of the public and the environment. This study puts some of those fears to rest.”

The McElmurray family, which owned one of the dairy farms, sued the U.S. Department of Agriculture to recover damages from crops they lost as a result of Augusta’s biosolids contaminating their land with heavy metals and other hazardous wastes. Robert Brobst, Gaskin’s EPA coauthor, used the UGA study to argue that the biosolids did not contaminate the land. Judge Anthony Alaimo in the U.S. District Court in the Southern District of Georgia, however, ruled in favor of plaintiffs: “Brobst opined in a letter that the McElmurrays’ land was not
contaminated. [But] Brobst concedes that his conclusion is based on Augusta’s unreliable, and to some extent invented, data.”

Alaimo’s ruling and a multiuniversity study in Ohio confirming our findings were covered in an editorial and news article published in Nature. Editors described the EPA’s biosolids program as “a failure of three presidential administrations.” The dairy farmers and I filed a separate lawsuit on behalf of the United States to compel UGA to return the misused EPA funds and withdraw the fabricated data. When deposed under oath, Gaskin admitted she knew there were problems with the data when she submitted the paper, and she believed that Augusta’s biosolids harmed the dairy farms. EPA and UGA, nevertheless, refused to withdraw the fabricated data. In 2012, Judge Clay Land of the Athens Division of the Middle District of Georgia ordered the dairy farmers and me to pay more than $61,000 in court costs, which the EPA and the University of Georgia had promised to cover if we would stop commenting on the case publicly.