ON SECOND LOOKING INTO[1] THE CASE OF DR. ANDREW J. WAKEFIELD

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A Personal Introduction

My first introduction to the autism movement was through a memorable July 2006 meeting with Dr. Bernard Rimland, founder of the Autism Research Institute and the Autism Society of America. At that time, Dr. Rimland was in the last stages of his struggle against cancer, but he graciously agreed to meet me in the ARI office in San Diego. Instead of focusing on his accomplishments over nearly 50 years in autism research and advocacy, he wanted to talk about me and my interests. Disarmed by his candor and inquisitiveness, I found myself all the more eager to listen to him and his advice. At the close of our meeting he said one thing that has never left me, "Bill," he intoned, "never be afraid to search for the truth about autism and to tell it when you have found it."

I filed away that piece of advice, not knowing if and how it would ever come in handy. Then, in October 2008, at an autism conference in San Diego, I met a man, Dr. Andrew Wakefield, who has been both vilified and honored by people inside and outside the autism movement because of an article published 11 years ago that raised questions about possible links between the MMR vaccine, inflammatory bowel disease, and autism. But, even more to the point, in the 11 years since the publication of that article, he has faced a combination of personal and professional attacks that seem designed not simply to criticize his science but to destroy his reputation.

Over the last two years, I have read several of these critical accounts. Many of them raise issues of significant importance, but the one thing missing in all these accounts was evidence that anyone writing had actually talked to Dr. Wakefield to try to determine if the story told about him had any truth to it. Or, to put it in literary critical terms, I wondered if there was an alternative narrative of equally or even more compelling truth to it than was being told. So, when I met him in San Diego, I decided first of all to strike up a conversation with him. As with many encounters in life, conversations consist of some pleasantries and a lot of "taking the measure" of the other person. After a 30-minute conversation, I decided I would ask if I could come down to Austin, Texas, where he is Director of Thoughtful House, an autism treatment and research facility, to interview him on the non-scientific charges leveled against him (conflicts of interest, mistreating of research subjects, trying to leverage patents for personal gain, etc.). After considering the matter for a bit, he agreed. So, in a gambit as simple and as complex as that, I went down to Austin in mid-January 2009 and conducted more than 12 hours of interviews with him over three days.

In preparation for the interviews, I wrote a long memo, going through the chronology of events before the publication of the crucial 1998 article, listing dozens of questions that he needed to answer. In fact, as I was devising this rough draft memo for myself, I was thinking that he surely had a lot of questions to answer; indeed, I was a bit skeptical of his ability to pull it off well. Thus, when he and I greeted each other at 9:00 a.m. on January 15 at his office in Thoughtful House, I was genuinely open to him but felt, indeed, that the onus was on him to explain himself. This paper describes what I found upon seeking the truth about Dr. Wakefield, especially as it relates to the course of events preceding the publication of the 1998 paper. In doing this, I celebrate the memory of Dr. Bernard Rimland, who emphatically told me in July 2006 to seek and then tell the truth as I entered the autism arena. I have tried here to be faithful to that charge.

Introduction to the Paper

No name in contemporary English medicine is greeted with such polarized reactions as that of Dr. Andrew Wakefield, formerly of the Royal Free Hospital in London and now Director of Thoughtful House, an autism treatment and research facility in Austin. To many, he is a scientist who has abandoned the basic principles of his science by engaging in unacknowledged conflicts of interest, publishing shoddy research, inappropriately criticizing the MMR vaccine, and authorizing invasive procedures, not ethically legitimate or approved, on children. On the other hand, Dr. Wakefield is revered by a large number of people, including physicians and parents, for standing up for their interests and listening to their stories about the debilitating effect of the MMR vaccine on children.

Much of the reasoning of those who attack him is based on their understanding of the course of events leading to the publication of his now-famous, jointly-

written February 1998 article in *The Lancet* medical journal.[3] This critical or negative reading of Wakefield, most recently reinforced by Dr. Paul Offit in his book *Autism's False Prophets*,[4] consists of fleshing out five statements:

1 Dr. Wakefield's early work on Crohn's disease was flawed because he concluded that the measles vaccine might either exacerbate or precipitate symptoms of Crohn's;

2 His being paid 55,000 pounds by litigators suing makers of the MMR vaccine to help the litigators make their case—a case that Offit and others say was published in *The Lancet* in 1998—posed a fatal conflict of interest for him;

3 His selection of the children for the study published in *The Lancet* was done in awareness that these children were litigants in the aforementioned class action, and his procedures on the children were unnecessarily invasive;

4 His statements at the press conference announcing the publication of *The Lancet* article on February 28, 1998, where he recommended using monovalent (measles) rather than polyvalent (i.e., the MMR) vaccine, precipitated the immediate decline in use of the MMR in England, leading to virulent outbreaks of measles a few years after 1998 and even resulting in the death of one young person from measles a few years later; and

5 His motivation, all along, for denouncing the MMR was so that he could substitute his own vaccine, for which he was seeking a patent, perhaps leading to tremendous financial windfalls for himself.

Thus, this case against Dr. Wakefield is one that begins with his bargain with the devil (in the form of his being an expert witness in a class action lawsuit), continues with a flawed study, and ends with blood and money, figuratively, dripping from his hands.

This negative story concerning Dr. Wakefield forms the basis of charges pending against him before the General Medical Council (GMC) in the United Kingdom. That body has the power to strike him from the list of physicians authorized to practice medicine in the UK. Prosecutors made their case against him in 2007; he responded in 2008; and a decision is expected in 2009. It is not the purpose of this paper to re-tell or summarize the case before the GMC. Nor is it my purpose to analyze the scientific validity of any one of his theories. Rather, my purpose is to put a different interpretation on the events in the crucial two years between early 1996 (when he signed on as an expert witness) and February 1998 (when *The Lancet* article was published) than appears readily available elsewhere. I tell a different story because, as I delved into the case more and more, I began to see that the aforementioned five points are, in large measure, untrue, unproven or refutable by virtue of documents not available to those who made the case attacking him. I also tell a different story because of extensive interviews with Dr. Wakefield, interviews that not only revealed a consistently different but also a *much more convincing* story than his attackers' account.[5] The novel idea of actually talking to him seems not to have been successfully pulled off by most, if not all, of his critics. In the final analysis, I write this account in order not simply to "set the record straight," but to provide what anthropologist Clifford Geertz calls a "thick description" of important events in that crucial two-year window. As in many things in life, the most important point as this paper develops will be the demonstration of one simple fact—which I will enigmatically state here—that there were really *two* studies that the documents point to, and not just one. Well, this point, and its importance, will become crystalline, I trust, as the paper continues.

After the initial section **1**, this paper is organized into seven sections, not all of which correspond precisely with the five criticisms listed above, but which substantially get at all those issues. They are:

2 Dr. Wakefield's signing on with the class action lawsuit as expert and the First Study;

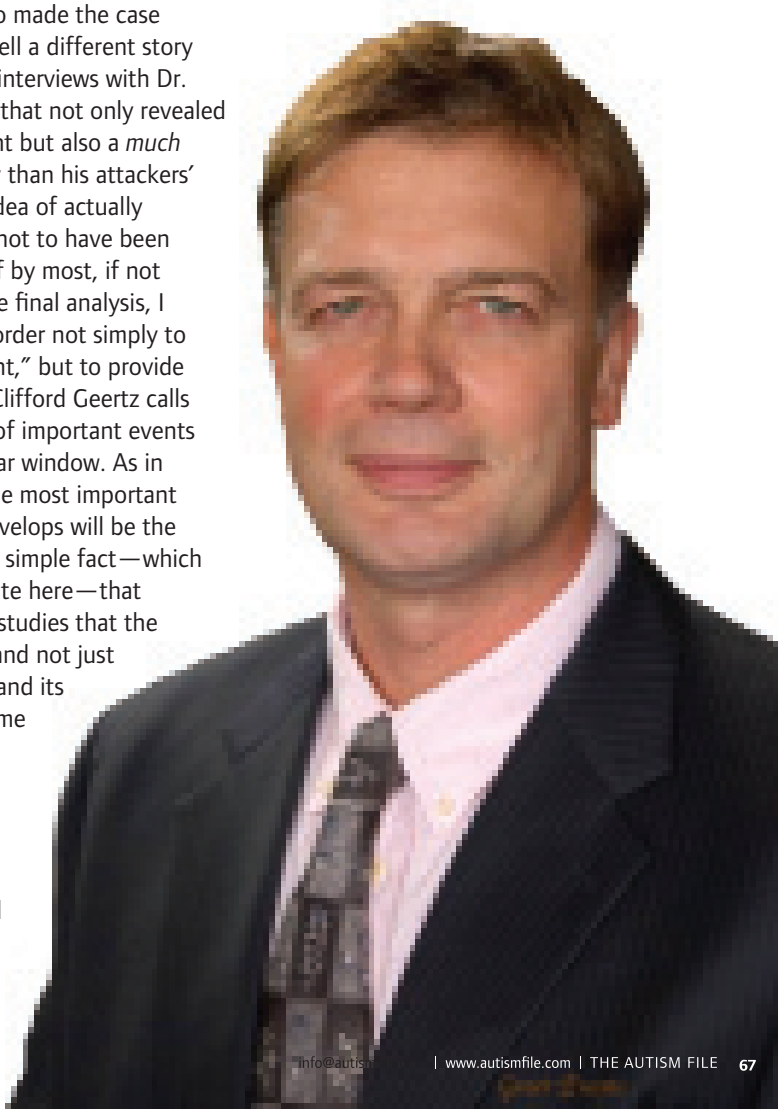
3 The emergence, and eventual dominance, of the Second Study (*The Lancet* study);

4-5 The confusion, and resolving the confusion, between the two studies;

6 A discussion of issues surrounding the publication of *The Lancet* article;

7 A description of issues surrounding Dr. Wakefield's June 1997 patent application; and

8 A description of the events relating to the release of first major journalistic story critical of Dr. Wakefield, which appeared in the London *Sunday Times* on February 22, 2004.



First, however, a story.

1. A Story About Personal Identity

February 1996 was a portentous month for Andrew Wakefield. The previous month he had been approached by Solicitor Richard Barr, an attorney in the small Dawbarns firm in Norfolk, England, who asked him to be an expert for Barr in a planned class action lawsuit against vaccine makers. The proposed suit, at this early stage, was concerned with the safety of certain vaccines (the MR and then the MMR) and would be brought by parents who claimed that their children experienced a variety of disabilities as a result of adverse reactions to vaccines. Wakefield was only vaguely aware of the possible implications for his career and life if he accepted Barr's offer. He knew that there were powerful medical, pharmaceutical, and political forces "out there" that had huge domains to protect, and he suspected that if he waded into the issue of vaccine safety he might get caught in some of the riptides of reaction that would almost certainly ensue. On the other hand, he also knew from his medical training and sense of identity as a doctor that concerns of parents about vaccine safety, which had increasingly been his interest in the previous few years, ought not to be ignored. Or, to put it differently, parental concerns about vaccine safety needed to be honored. He talked with his wife and another member on the medical faculty of the Royal Free Hospital in London, where Wakefield was then a Senior Lecturer in Medicine and Histopathology, about becoming an expert witness. He was undecided.

Then, in February, came the decisive phone call. It wasn't from Solicitor Barr asking him to hurry up and make up his mind or from his medical colleague giving further advice. It was from a woman in the North of England whose child was severely autistic and who had, according to her, become so after the administration of a vaccine. Her husband was infirm. She was, literally, at her wits end and felt that there was no one in government or the medical community who was willing to provide either answers to her or help for her son. Her words over the phone were chilling: "When I go (and she was an older mother to begin with), I will be taking my son with me."

Upon hearing her words, Dr. Wakefield was gripped with a mingled sense of helplessness and responsibility. He *would* do whatever he could, even in a small way, to make sure not only that the woman's cries were heard, but also that she might have good information and, if possible, treatment for her son's condition. Yet he had, at that time, little knowledge of autism. In fact, he was first introduced to the possible connection of a vaccine and autism through a May 1995 phone call (see below). But his training was as a gastroenterologist, and the focus of his career, before getting into academic medicine in the late 1980s (he was born in 1956), was in surgery on the gastrointestinal tract, popularly known as the gut. However, he knew a lot about vaccines, for a reason I will state below and thought that there was a way that he could provide help, however little, in the woman's situation. He would, then, sign up to be an expert for Richard Barr. He called Barr soon thereafter and said that he was on board for the case. That decision, in all its simplicity, was the decision that has led ultimately to the countless articles written about him and, most recently, to the drama unfolding before the General Medical Council.

2. Understanding the Origin of the Lawsuit and Study One

An explanation needs to be provided regarding what Dr. Wakefield was signing onto in 1996 and why, indeed, it was a cause that arose in the mid-1990s. A confluence of three factors, from 1988 to1994, created the conditions that led to Barr's approaching him early in 1996. They were:

- **a** the passage of a 1987 law that enabled class action suits like this one to go forward;
- **b** the consolidation of what we might call "legal aid" into one national board with lots of money to support class action suits; and
- **c** the patchy vaccine record in the UK following the introduction of the MMR vaccine in 1988 as well as the controversy over a MR (measles-rubella) re-vaccination campaign promoted by the government in November and December 1994.

In other words, the lawsuit that he was invited to join was something that probably would not have arisen had the legal, financial, and vaccinological ground not been plowed in the previous several years. A word about each of these is appropriate.

The possibility of litigation against vaccine makers in England had effectively stalled by 1988 due to some adverse court decisions against plaintiffs.[6] The reason it was so difficult to prove vaccine maker liability for vaccine injury in the 1980s was that a central principle of tort law, the concept of vaccine maker negligence, had to be demonstrated by a preponderance of the evidence. This meant that in order for a plaintiff to make a case successfully, s/he had to show that the vaccine makers were aware of the risks facing the vaccine, that they chose to ignore these risks, and that the damage resulting from ignoring these risks resulted in injury to the child. Proving vaccine maker liability was a rather steep hill to climb, and one that plaintiffs ultimately were unable to climb until the passage of the Consumer Protection Act (CPA) in 1987. This act allowed for suits against producers of products (vaccines, of course, would be included here) but, significantly, the act lowered the quantum of evidence needed to establish liability. Instead of the traditional concept of showing negligence, the statute envisioned a regime of what is known as "strict liability."[7] Here a plaintiff only needed to show two things: that an injury had been caused by the vaccine, and that the vaccine was unsafe. One didn't have to try to get into the corporate decision making process or mind-set of the vaccine makers, even though evidence regarding their culpability would be helpful in making the case. Thus, new life was breathed into the concept of class actions regarding potentially dangerous products that consumers might use.

Second, legal aid services in the UK, which had been in existence for 40 years prior to the late 1980s, were now consolidated under one Legal Aid Board (renamed the Legal Services Commission in 2000), which would be the funding mechanism for those interested in pursuing class action suits, such as suits that could be brought under the CPA of 1987. As this site[8], titled "Legal Aid: History," says:

In 1988 the system was formalised and was brought under the control of central government who established the Legal Aid Board. With some exceptions the Legal Aid Board was given responsibility for the funding of all work paid for by the state.

Contrary to the reality in most class action suits in the United States, where plaintiffs' attorneys work on a contingency-fee arrangement and don't usually see any money until the case is resolved in favor of their clients, the concept behind the Legal Aid Board in the United Kingdom was different. The Board administered a fund that could be tapped into through an application process by attorneys who sought to bring class action suits. Thus, the attorneys would be paid as they went along rather than paid only if the action was successful in the end. There are virtues and drawbacks, of course, to both systems, but the pay-as-you-go system had just been implemented through the Legal Aid Board in the UK. In fact, the suit pursued by Barr against the vaccine makers was the first big class action lawsuit funded by the Legal Aid Board after its formation in 1988. Inexperience by the Board or, more charitably expressed, initial growing pains in understanding its role, led to expenditures in the case brought by Solicitor Barr that topped 14,000,000 pounds (about $25,000,000) by the time the case was actually dropped late in 2003. It truly is an astounding amount when you consider that no one allegedly injured by a vaccine ever received a penny for bringing the case. Most of the money was spent on legal counsel, expert witnesses, and laboratory expenses.

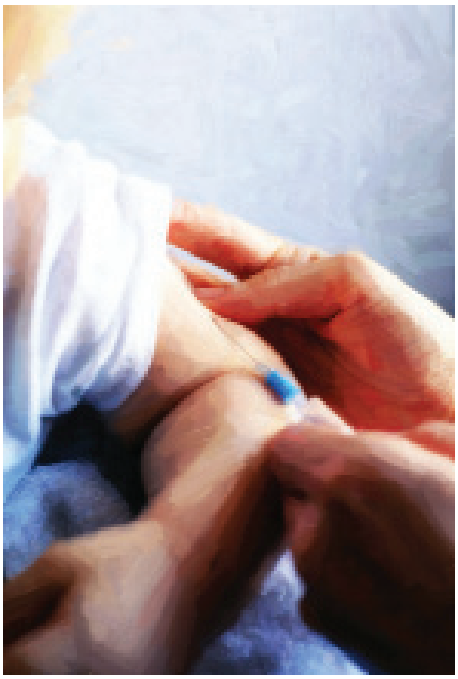
Third, the UK had a rocky recent history in the administration of the vaccines that are crucial to our story. The measles vaccine by itself (the monovalent) had been introduced in 1968, with a rubella vaccine following it a few years later and administered especially to girls or women in childbearing years.[9] The super-duper MMR (measles-mumps-rubella vaccine, the so-called polyvalent) was brought online in the UK in 1988. It had originally been licensed in the USA in 1971, introduced

in the USA in the early 1970s and in some other countries in the early 1980s.[10] But the introduction of the MMR in Britain was attended by some difficulties. In 1992, after only four years of administration, two of the three MMR vaccines (Immravax, made by Merieux UK, and Pluserix, made by SmithKline Beecham), both of which contained the Urabe strain of the mumps vaccine, were withdrawn from the market because authorities concluded that children faced an increased risk of contracting meningitis through these vaccines. Only the brand made by Merck & Co. (MMR II) was unaffected. MMR administration continued, of course, with assurances from public health officials that the remaining brand of vaccine was perfectly safe, but it certainly was not lost on the nation that there might be a problem with the MMR. The MMR vaccination rate in England began to fall in 1995, and continued falling for nearly a decade. Then, in Fall 1994, an urgent health warning was given that would require the re-vaccination of seven million English children, aged 5-16, using the MR vaccine. Why? Mathematical modeling convinced the Department of Health that without such a dramatic national campaign there might be a severe outbreak of measles in 1995. It was called a re-vaccination campaign because the children had previously been vaccinated, depending on their age, with the measles vaccine or with the MMR. This massive re-vaccination took place in November and December 1994.

Now, as we fast forward to January 6, 1996, when Dr. Wakefield first met Solicitor Barr and his assistant Kirsten Limb, we know that the meeting took place under the shadow of all of these events. Re-vaccination had just taken place. A new and more powerful law was set to help plaintiffs' attorneys and class action litigants. Money was available. Uncertainty regarding the safety of the vaccines was in the air. And, finally, parents had begun to call Solicitor Barr in great number when they heard that he was the one who was taking up the cause of those potentially injured from the administration of the measles or the MR vaccine (the MMR followed later, as the legal case evolved).

Why, you may be asking, had Solicitor Barr contacted Dr. Wakefield about this in the first instance? Dr. Wakefield was, at this time, a 39-year-old medical academic, who had already distinguished himself in gut surgery but who only had a relatively short tenure (seven years) by that time as a researcher and writer. His position, Senior Lecturer, is equivalent to the early stages of associate professor in an American university. Two studies, a 1993 paper titled "Evidence of Persistent Measles Virus in Crohn's Disease,"[11] and a 1995 paper titled "Is Measles Vaccine a Risk for Inflammatory Bowel Disease?" [12] launched his public visibility. The latter did so especially because it was published in *The Lancet*. America has no medical journal precisely equivalent to *The Lancet*, which is a medical magazine both for the medical researcher and generalist physician but which also, at the same time, reports on groundbreaking discoveries or hypotheses that challenge the accepted consensus of the medical community. Like the medical instrument to which it points, *The Lancet* sought to lance some of the boils of medical knowledge and practice that needed urgent attention.

In the 1995 article, Dr. Wakefield, along with his co-authors, explored the enigma of Crohn's disease, which had fascinated him since his undergraduate days at St. Mary's Hospital (University of London) in the late 1970s and early 1980s. Crohn's is a disease of the gastrointestinal tract that shows up with clustered cells, called granulomas, anywhere in the GI tract and, as later discovered, elsewhere in the body.[13] The mystery of the origin and growth of



these granulomas had occupied his mind for quite some time. In this 1995 article in *The Lancet*, he advanced a hypothesis that the persistence of the measles virus in a person, either through introduction of that virus through the vaccine or through its naturally-occurring presence, might be a causal factor in the emergence of these granulomas and of Crohn's disease. This persistent virus might be stimulated by an unidentified factor or trigger that could develop into the full-blown and devastating Crohn's disease.

One source of measles virus in a person was the administration of a measles vaccine. Hence, if Barr was going to sue vaccine makers on the safety of vaccines, he needed to find an expert who had spent most of his time, both in surgery and in academic medicine, thinking about the possibility of how the persistence of a virus in a person might precipitate developmental problems in children. While Crohn's disease was the focus of their first conversation, Barr became convinced that Dr. Wakefield possessed the requisite knowledge of vaccines and was already sympathetic to the role that vaccines might play in leading to debilitating problems, especially GI and developmental problems, in children. In fact, in the years immediately preceding this January 1996 meeting, Dr. Wakefield had written a nearly 250-page unpublished review of everything he could find on the safety of the measles vaccine.[14]

So, armed with this insight, and with Wakefield's assent to work with him, Barr then asked him two further questions. Would Wakefield be willing to do the same kind of vaccine safety study for the MMR that he had done for the measles vaccine? And, would he be willing to draft a proposed study protocol that would determine, first of all, if measles persisted after administration of these vaccines and, second, if the persistence of this virus could lead to GI problems and perhaps even to Crohn's or autism? In other words, Barr's interests were in trying to build what in law is called the causal bridge between one thing and another. In the first instance, he was interested in building that bridge between vaccine administration and GI problems, but, with Wakefield's work on Crohn's disease, he was further interested in the possible causal bridge between the GI problems and autism and/or Crohn's disease. And, again, you should know one more thing about the tactics of the plaintiffs' lawyers. The purpose of encouraging this kind of thinking was to help in building a theory of the case—a way of approaching the data that eventually might result in a financial recovery for clients.

Dr. Wakefield said that he could develop a protocol for such a trial/study and that he would be interested in updating or expanding his vaccine safety report. I will refer to this trial/study as Study One (or First Study), and it would lead to an application to the Legal Aid Board for funding in June 1996. I will turn to a more detailed explanation of Study One below. But, we must raise a different question at this point. Is there anything wrong with what Dr. Wakefield has done so far? Or, to be even more precise, has he compromised his integrity as a scientist or his ethics as a medical professional by agreeing to meet with Barr, by agreeing to work with him, or by agreeing to design the aforementioned study? The answer is a clear and unequivocal "no." Not only is there nothing wrong with this picture so far, but this is precisely the way that experts are recruited by plaintiffs' lawyers all the time. The lawyer needs expertise. S/he needs the expert to conduct a study that arises out of the expert's field of study, and that study must be able to show, or at least elucidate, the problem that the lawyer wants to address. Is there anything degrading, unethical, or improper in being such an expert? Only if you think that the legal system is so corrupt that any participation in it taints you. But very few people take that position.

Thus, by Spring 1996, Dr. Andrew Wakefield was an expert in a case that was still in its infancy. The full contours of his involvement were not clear at this time, but he now had two clearly identifiable tasks (drafting the protocol; studying MMR safety). Even before he agreed to help Barr on the case, he began receiving phone calls from parents and others who had read his 1995 article in *The Lancet*. The evolution of those calls and how that affected Dr. Wakefield back at the Royal Free Hospital is where we now turn.

3. The Phone Calls and the Genesis of Study Two

Seven months before Dr. Wakefield had met Solicitor Barr, he received a phone call from a distraught mother, Rosemary Kessick. This May 19, 1995 call led to a second set of circumstances and what I will call the Second Study or Study Two. I emphasize this point now because every online and book treatment of Dr. Wakefield I have read has conflated the two studies, thus leading to an improbable series of events that led to the hostile or critical narrative related at the beginning of this paper.

In any case, Mrs. Kessick, who had seen Dr. Wakefield's recently-released article in *The Lancet*, told him the wrenching story of her son's descent into autism after having received the MMR vaccine a few years previously. She said that her son, formerly an active and bright toddler, experienced a perceptible arresting of his development within weeks of administration of the MMR. He retreated, as it were, into a dark and strange world where he could not talk, play, or feed himself.[15] What, she wanted to know, could she do? Dr. Wakefield, a research scientist, urged her to seek a referral to the trusted clinician, Professor John Walker-Smith, a noted pediatric gastroenterologist connected with the historic St. Bartholomew's Hospital in

London, and then get back to him. She did so. Professor Walker-Smith took a blood test for evidence of inflammation and celiac disease and then reported to her that the boy's GI distress was not related either to celiac or Crohn's disease. He urged her to get back in touch with him if the boy's condition worsened.

Over the next several months, Dr. Wakefield was besieged by calls from other distressed parents. All of them had their own stories, but the common thread was that which Mrs. Kessick had related—their children had all either gradually or rather suddenly "disappeared" from them or become autistic after the administration of the MMR vaccine. Dr. Wakefield had never seen or heard of anything like this. I asked him if he was bothered not only by the stories but by the possibility that he was being set up in a way—i.e., that parents might have coordinated their stories in order to get his attention. The idea, he said, had never entered his mind. Even had the parents done so, however, the children's conditions still merited medical attention not only because the children and parents faced this devastating condition but also because the issue of vaccines and autism had not really been examined closely.

In each case, Dr. Wakefield told the caller that Professor Walker-Smith was the right person to examine their child, but they had to go through their own pediatrician or GP in to make this referral happen. Thus, in the months from Fall 1995 to Spring 1996, several parents who called Dr. Wakefield returned to their doctors to be referred to Professor Walker-Smith. He didn't examine them immediately because he was in the process of moving his practice to the Royal Free Hospital.

A slight digression is helpful at this point. Walker-Smith's move from St. Bart's to Royal Free was motivated by a number of reasons, not least of which was the goal of the new Dean of the Royal Free School of Medicine, the distinguished medical microbiologist Professor Arie Zuckerman, to raise the profile of the medical school at the Royal Free Hospital. At one time, from the 1950s to1970s, the Royal Free School of Medicine was without peer in the land. Anchored by the first female medical professor in England, the energetic dynamo Dame Sheila Sherlock (1918-2001), who substantially developed the modern field of hepatology, the medical school flourished. But its reputation had suffered after her retirement, and Zuckerman was committed to raising its profile.

When Professor Walker-Smith came over to the Royal Free, he brought not only his credentials with him but also his "blanket ethical clearance." More precisely, when he moved to Royal Free, he requested a transfer of his ethical clearance so that he would have the same status that he had at St. Bart's. This request was made of the Ethical Practices Committee at Royal Free, and it was granted. What this means is that as a condition of his being hired, he required that the Royal Free School of Medicine recognize his ability to work broadly in conducting examinations of children and in directing the research into the tissues that might have to be biopsied. Thus, he was granted the same status at Royal Free.[16] If, however, certain tissue examinations went beyond the scope of his blanket ethical clearance, he would need to submit requests to do those procedures to the Ethical Practices Committee of the medical school. This point provides important context to understand a submission to the Ethics Committee from September 1996, described below.

To return to our narrative, Professor Walker-Smith's move to the Royal Free actually delayed any kind of examination of a growing list of children with common symptoms of GI problems and autism spectrum disorders that were now being referred to him. But what significantly delayed the start of the project was the preparation of the clinical protocol. The complexity and number of disorders presented by the children meant not only that several other professionals had to be engaged in the examinations but also that all of this had to be organized and coordinated. It wasn't until July 1996, then, that the first of a number of children was seen by Professor Walker-Smith and his assisting pediatric gastroenterologist, Dr. Simon Murch. From July 1996 until January 1997, the two physicians investigated the cases of 12 children; Dr. Wakefield was involved in coordinating the results of their investigations, which included the pathology changes on the children's biopsies. These children then became the 12 children reported on in *The Lancet* study, published in February 1998. But the number of 12 children was rather an arbitrary cutoff because Walker-Smith and Murch, along with Wakefield and others, continued to examine many more children referred to them with similar constellations of symptoms for the next few years. An indication of this is a line at the end of the 1998 article in *The Lancet* that says that, at the time of publication, an additional 28 children had been fully examined. Thus, *The Lancet* study, which grew out of the first 12 referrals from the doctors throughout the country to Professor Walker-Smith, was really nothing more than what researchers call a case study—a sort of work in progress on interesting issues that colleagues and other interested people might want to learn about. It had no marks of the more sophisticated controlled clinical trials, the gold-standard of medical scientific research.

As mentioned, in order properly to examine the children with unusual combinations of bowel symptoms and developmental regression in his care, Professor Walker-Smith had to draw up a clinical protocol for their examination. Because of the complexity of the cases, the original team of three (Walker-Smith and Murch as clinical gastroenterologists, Wakefield as scientific researcher on the biopsies) was complemented by other professionals, including a neurologist, a child psychiatrist, and various neuro-imaging specialists. This group was the genesis of the 13 names on the title page to *The Lancet* article. Scholars in other disciplines, such as history or literature, when seeing 13 names as co-authors for a five-page paper, might tend to chuckle and calculate that this means that each person authored his three or four sentences and then bowed out. In fact, however, this is testimony to the work of a team of people, ultimately under the clinical direction of Professor Walker-Smith and the research direction of Dr. Wakefield.

As they began the examination of these children, performing colonoscopies, lumbar punctures, MRI scans, and other invasive procedures (all of which were labeled as clinically indicated by Professor Walker-Smith), other issues arose. The principal one was whether additional research tests

needed to be performed on the blood, urine, and cerebral spinal fluid (CSF) being collected from the children (standard tests of urine for infection and diabetes, for example, had been done). In this regard, Dr. Wakefield wanted to learn from further investigations whether the children's urine, for example, contained evidence for an abnormal level of vitamin B-12 or the CSF gave evidence of inflammatory cytokines. Professor Walker-Smith felt that these additional research requests might be beyond the scope of his blanket ethical clearance that he brought from St. Bartholomew's to the Royal Free earlier in 1996. Thus, before these research tests could go forward, application had to be made and approval granted from the Ethical Practices Committee of the Royal Free School of Medicine. This ethical approval was sought in September 1996 and received, in its final form, in January 1997. An irony of all of this was that shortly after ethical approval was given for these tests, the clinicians and researchers decided that the tests didn't yield much helpful clinical information. Thus, in the later cases, beyond the original 12, examination of biopsied tissues alone would form the basis of the research.

It should be clear by now that there were two studies that Wakefield and others were pursuing. Right at this point a rather massive confusion arose. Or, more properly said, confusion can arise for those trying to reconstruct what happened in those days. The confusion, as I will now discuss, arose because a copy of the request for ethical approval for Study Two was mistakenly, even though for good reason, appended to an application for funding for Study One. I will need a few minutes to state the problem and then unravel the potential confusion.

4. Reconciling and Explaining the Two Studies

By mid-summer 1996, then, we have two efforts proceeding independently of each other. Study One was the protocol being drawn up by Dr. Wakefield at the urging of Solicitor Barr; Study Two was the clinical study, with research support from Dr. Wakefield, developed primarily by Professor Walker-Smith. Let's leave Study Two here now, with its method and ethical approval secured in January 1997 and return to the work that Dr. Wakefield was doing with and for Richard Barr in the class action lawsuit contemplated against the vaccine manufacturers.

You recall that Dr. Wakefield signed on to work as an expert for Solicitor Barr shortly after the February 1996 phone call. In the first instance, he needed to develop the protocol for a study designed to determine whether the measles virus was present in biopsied tissues. Subsequent studies would be necessary to determine if there might be a causal relationship between the administration of a vaccine and the development of severe GI symptoms and possibly autism or Crohn's disease in the children. Wakefield submitted a draft of this three-page document, written in lay language and entitled "Proposed Protocol and Costing Proposals for testing a selected number of MR and MMR vaccinated children," to Barr in June 1996. This "Proposed Protocol" called for an examination of 10 children, all of whom had GI problems. Five of the 10, in addition to having GI problems, also had developed autism; the remaining five had developed Crohn's disease. Specifically, Dr. Wakefield would analyze the biopsies already taken for clinical trials and, as ethical approval allowed, look for the presence of measles virus in the biopsies. If that virus was present, a case might begin to be made for the causal relationship between the virus and the GI and/or the autism/Crohn's conditions. With this proposal came a request for funding for the study—55,000 pounds, 25,000 of which would fund a technician's position and the rest would be used to defray the costs of clinical examination of the tissues.

So, in June 1996, this brief proposal was forwarded to the Legal Aid Board. But it was also thought important to give the Legal Aid Board a deeper scientific understanding of the process by which Wakefield would be looking for the measles virus, so that whichever science advisor the Legal Aid Board used in examining its applications would know of his method. The only easily accessible document describing where to look for the virus was in a rough draft of the ethics proposal that was eventually to be submitted to the Ethics Committee in September 1996 for Study Two. That is, in order to seek ethical approval for the three new procedures that Dr. Wakefield wanted to add to the clinical protocol for Study Two developed by Professor Walker-Smith, they decided they had to let the Ethics Committee know about the full scope of the study. Indeed, you can look at the final document actually submitted to the Ethics Committee for ethical approval of additional procedures for Study Two in the footnoted document.[17] You can easily tell that this is a Study Two document because it lists all the professionals needed to do the study, which precisely corresponds to the professionals who appear as contributors to *The Lancet* paper.

In June 1996 this "Clinical and scientific study" was in a rough-draft form, but it contained in an appendix a description of the methods to be used for determining the presence of measles virus in a biopsy. To fully inform the Legal Aid Board, Solicitor Barr submitted this appendix as a separate document along with the "Proposed Protocol and Costing Proposals." But mistake and confusion were introduced here because what actually was submitted to the Legal Aid Board was the *entire* rough draft of the "Clinical and scientific study." Thus, a confusion that ultimately must rest somewhere in Wakefield's camp was introduced. Instead of having the basic three-page protocol and costing proposal, with a five- or six-page description of how to look for the measles virus attached to it, two documents were submitted. Thus, you have *both* a Study One and a Study Two document submitted to the Legal Aid Board in seeking the 55,000 pounds.

This state of affairs obviously confused not only those who have reported on Wakefield's case but also the prosecutors in his case before the General Medical Council. For, if you check out the charges laid against Wakefield, you have as background the submission of two documents to the Legal Aid Board in June 1996, respectively entitled "Proposed Protocol and Costing Proposals" and "Proposed Clinical and Scientific Study."[18] When you look at the names of the two documents sitting side by side, your first reaction is, even if they were for the same study, "why is anyone submitting *both* of these documents for funding?" They

appear redundant in part, and the second appears to provide much more detail than the Legal Aid Board required. In addition, there is some confusion in numbers between the "Proposed Protocol" and the "Proposed Clinical and Scientific Study." The former called for 10 subjects and the latter for up to 25. No one would have thought that 10 turns into 25 in the same document. But an honest investigator of his case could be forgiven for concluding that these two documents, submitted together to the Legal Aid Board in June 1996 constituted just *one study*. In fact, they reflect two different studies; the second one was just improperly appended or, alternatively, was appended without a clarifying letter to the Legal Aid Board. There was no explanation given to the Legal Aid Board to ignore most of the "Proposed Clinical and Scientific Study." The only thing said at the beginning of the "Proposed Protocol" was "A protocol giving the detailed technical specification is attached."

From the perspective of hindsight, this is an error, a confusion unnecessarily brought into the process. But, when you consider life from the perspective of 1996 and the haste with which things needed to be done (and often are done by all of us in life), you can understand how documents from two separate studies would be placed together without precise delineation of why the material from the second study is included.

5. Legal Aid Approval and Study One Delay

The proposal submitted to the Legal Aid Board for the study of 10 children with GI problems and either autism or Crohn's disease was approved by that agency in August 1996. Enough money was authorized, 55,000 pounds, to pay for the technician for one year and the costs of clinical tests, if required. As it turned out, no money was needed for the latter and none of that money authorized was actually requested from the Legal Aid Board. Before the study could get underway and money could be released to Wakefield, however, the money for the technician had to be banked somewhere. This might sound easier said than done, but it was this problem—of the intermediary to hold onto and disburse the 25,000 pound technician salary—that caused more headaches than the actual project itself. The first thought was that the money would go directly from the Legal Aid Board to Richard Barr's law firm, then to the Medical School and then to paying the technician. But the Dean of the Medical School, Professor Arie Zuckerman, had other ideas. When he learned in Fall 1996 of the approval of the Legal Aid project and Wakefield's desire to set up a fund in the Medical School for its disbursement, he balked. He was afraid, he told Wakefield, that there might be a conflict of interest if the school received Legal Aid funds for a study.

Unknown to Wakefield, Zuckerman had been contacted in Fall 1996 by the Department of Health in an attempt to try to stop the project. Indeed, Wakefield was already on the Department's radar screen for his opposition to the re-vaccination campaign in 1994 and for occasional missives he sent to health officials on the safety of vaccines. From their perspective, Wakefield was up to no good. When explaining the Department's concern to Zuckerman, the point was made that Wakefield's effort with Barr might lead to a suit against the government, which funded the National Health Service. Thus, if Zuckerman were to bank the money at the Medical School, he might engage the school in a sort of conflict—both receiving money from the government and doing research that might lead to a suit against it. This fear, in fact, was groundless.[19] As a result of the call, Zuckerman contacted the Ethics Committee of the British Medical Association for a determination of whether this study would, indeed, involve a potential conflict of interest for the Medical School. The Ethics Committee eventually concluded that it would not, but, in the meantime, Zuckerman declared that the money wouldn't be housed at the Medical School.

Thus, Study One couldn't begin. Even as late as May 1997, Wakefield was still trying to find a place for the money. In a memo dated May 20, 1997, C. A. Tarhan, Deputy Secretary & Finance Officer at Royal Free sent a memo to Zuckerman saying that Wakefield was "unhappy with the fact that the School has not formally accepted the research funding." What did Wakefield propose to do? The memo continues: "[he] has asked that the funds be returned to the Solicitors."[20] Yet, as a last ditch effort, Wakefield sent a May 23, 1997, letter to the director of finance at the Royal Free Hampstead NHS (National Health Service) Trust, which eventually disbursed the money, indicating a desire that the amount up to the authorized amount would be placed in an already-existing account from which money was paid to fund a research assistant for what I am calling Study Two.[21] Finally, in early July 1997, the Chief Executive of the Trust wrote to Wakefield saying that he would establish a fund with the Special Trustees for the money, as long as Wakefield could assure him that there was no conflict of interest with the money.[22] Quickly then, on July 3, 1997, Wakefield wrote back to the Chief Executive saying that there would be no conflict of interest in the Legal Aid study.[23] What he meant by that is clearly stated in that letter.

> **There are no preconditions to our grant. Furthermore, there is no intention whatsoever on behalf of the Legal Aid Board or its agent to take action against the National Health Service; it is against the manufacturers of vaccine that any future action will be taken if and when our studies indicate that is a valid strategy.**

Thus, when people were talking of a possible conflict of interest from late in 1996 to the middle of 1997, it was the possibility of a government-funded entity suing the government with government money. Wakefield here assures that the Legal Aid Board-funded study was only to develop a potential case against the vaccine makers. Indeed, had he known the specifics of the Consumer Protection Act 1987, under which Barr would bring the case, he would have known that the Act is specifically directed in Sec. 2 against producers of dangerous materials—the vaccine makers.

With this conflict resolved and the money having a home, the Legal Aid study, Study One, could begin. It actually began in October 1997 and concluded in 1999. But what is more revealing for our purposes is that the July 3, 1997, letter from Wakefield

to the NHS Trust Chief Executive mentions in passing that the study that would appear in *The Lancet*, which I have called Study Two, was *already completed*. Note the following sentence:

> **Please find enclosed a copy of our first paper submitted to The Lancet concerning children under investigation. This has been an extremely successful study and has clearly demonstrated a new pathology in these children and put the Royal Free Hospital as the world leader in this field.**

Several points could be made from this statement, but the obvious one is that *The Lancet* study, which is the source of all the controversy in the Wakefield case, was finished and had already been submitted to that periodical by July 3, 1997, before Study One *had even begun*. Indeed, this makes complete sense according to the chronology discussed above. *The Lancet* study was cut off at 12 cases in January or February 1997 so that a first case report could be made. The results were written up in Spring 1997, with submission to *The Lancet* in early summer. By February 1998, a further 28 children had been seen. The July 3, 1997 letter talks about 300 children who merit investigation. In other words, Study Two, already submitted to *The Lancet*, was really the first of many investigations that Wakefield hoped would place the Royal Free at the center of autism research. Indeed, it was this strategy that might have helped propel the Royal Free to the kind of reputation it had enjoyed 30 years previously. He was wrong on that one, but that was the hope at the time. To repeat, *The Lancet* study was completed *before* the Legal Aid Study (Study One), funded by a 55,000 pound grant, had even gotten off the ground.

One final detail is worth noting. Wakefield signed these letters as "Reader in Histopathology & Medicine." Up until this time, I have referred to him as a Senior Lecturer in Histopathology & Medicine. A Reader in the English university system is about equivalent to a senior associate professor or even full professor in the American university system. In other words, Wakefield had gotten a promotion while all this was going on. Indeed, on May 1, 1997, he had become a reader. This is not an insignificant thing for a person on the way to academic stardom in England. Most people stop at senior lecturer status. Becoming a reader means that you may not be far away from the most coveted position—professor. Clearly the academic establishment at Royal Free believed that Wakefield was doing *something* right.

6. Issues Surrounding the Publication of *The Lancet* Study (Study Two)

Most critics of Dr. Andrew Wakefield know the contents of the five-page study in *The Lancet*, released late in February 1998, better than theologians know the Gospel of John. But just as no competent biblical scholar would try to read the text of the Gospel of John without reference to the philosophical and historical background at the time of its writing, so no real interpreter of that article in *The Lancet* should read it without knowing something of the "thick description" of its origin and production, which I have tried to provide here. Now we are almost ready, finally, to look at that document, to see what it claims and does not claim, and to understand how it became the source of immense controversy in the UK for several years after its publication. But a few more preliminary points beckon.

As mentioned above, the study that resulted in *The Lancet* article was derived from the first 12 cases of children with bowel symptoms and developmental regression referred to Professor John Walker-Smith from general practitioners or pediatricians. Most of the children (10) were from England, but one was from the Channel Islands and one from the USA. The researchers cut it off at 12 cases because that was a reasonable size for a case study, and preliminary results presented themselves. Indeed, Kanner's famous 1943 article on autism, which sparked the entire field of autism research, was based on observations of 11 children.[24] Several of these 12 children would eventually become litigants in the class action lawsuit being developed by Richard Barr, but their status with respect to the lawsuit during the time of referral during 1996, was not known to the researchers and clinicians. Just to be clear, when pressed on this point, Dr. Wakefield said that they may have known that one of the children held a Legal Aid certificate at the time of colonoscopy, but at the time that each of the children was referred, none was involved in the lawsuit. A February 20, 1997, memo from Professor Walker-Smith to Wakefield was seemingly the first sign that researchers and clinicians were aware that some of the children's families were involved in Barr's lawsuit.[25] This might affect the way that they would look at future cases, but the 12 individuals who became the subject for *The Lancet* piece had already been examined by that time.

In the run-up to the publication of *The Lancet* article late in February 1998, Wakefield not only circulated the article to his colleagues in the Medical School but also indicated, in a letter to them, that if called upon to give an opinion on the safety of the MMR vaccine, he would recommend, by virtue of lack of convincing safety studies, cessation of the MMR vaccine in favor of the monovalent (i.e., the measles vaccine). This recommendation was partly based on his conclusions from the aforementioned study he did for Solicitor Barr. He mentioned that he knew this position would be controversial and would not be shared by all, or even many, of his colleagues. Nevertheless, the Dean of the School of Medicine, Arie Zuckerman, decided that he would "pull

out all the stops" upon the release of *The Lancet* piece. After all, his mission as Dean was to elevate the school to its former prominence. Even though he may have disagreed with Wakefield's conclusions on the MMR (and he certainly did), he felt that the article to be published in *The Lancet* would be the perfect occasion for bringing the kind of recognition to the school that so many people wanted. Thus, in preparation for its release date, he authorized the following: a 20-minute video explanation of the article, where Wakefield was featured for about eight minutes, and a news briefing, at the time of *The Lancet*'s publication. Zuckerman would chair that briefing and bring four of the 13 authors of the study along with him. He would field questions from the journalists from the podium and assign them to one of the four researchers or clinicians sitting at the table on stage. All agree that all of these preparations constituted a highly unusual procedure in releasing a five-page article.

One point should be clarified here. Many of Wakefield's critics have rather thoughtlessly said that Wakefield not only was supportive of this arrangement but that somehow he called the press conference or made the video. For example, Dr. Paul Offit, in his highly critical assessment of Wakefield, begins his treatment of Dr. Wakefield with the following sentence:

> **On February 28, 1998, Andrew Wakefield, a gastroenterologist working at London's Royal Free Hospital, held a press conference.**[26]

A moment's reflection is all that is needed to see how unlikely that is, especially for those who are in academia. Individual professors have no public relations arm; the school does. Individual professors, especially those still on the rise, don't have authority to order people around to make videos and set up news conferences. Deans do. It is much more likely that the moving force behind all the publicity for *The Lancet* piece was the school, in the person of the Dean, than some secret power that Dr. Wakefield had to orchestrate all of this (including making the Dean play the role he did).

Well, February 1998 came. The paper was released. The first reaction you might have in reading *The Lancet* piece 11 years after its publication is one of underwhelmment, if you permit the word. It isn't the gold standard of investigations—a controlled clinical trial. It simply reports on "what we have seen." And, when you get right down to it, the report consisted of certain medical findings—of certain nodular formations in the terminal ileum (that section of the short intestine that connects to the large intestine or colon)—and of reports of parents regarding when their child was administered the MMR. The interpretation of the data was similarly muted:

> **We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.**[27]

That is, what the study in its essence was saying was that three things seemed to be associated in time with each other in the 12 children: gastrointestinal distress, developmental regression (autism spectrum disorders, particularly) and the MMR (the environmental trigger). Not only is language of causation absent, but language even of correlation isn't present. Because Walker-Smith and Wakefield were currently investigating up to 300 children with similar complaints, it was far too early even to advance a causal hypothesis, much less to make causal findings. In other words, this was a first look into a baffling problem, a sort of heads up as to something mysterious that certainly would require more detailed examination, hypothesis formation, hypothesis testing and, perhaps eventually, a thesis that could be defended. Another sentence from the paper is important in this connection:

> **We did not prove an association between measles, mumps and rubella vaccine and the syndrome described. Virological studies are underway that may help to resolve this issue.**

In fact, to be fair to the authors, they did make a claim in the piece that has become hotly debated in future research, and that is whether there is such a syndrome as autistic enterocolitis, which this paper claimed existed in the children. This syndrome, as described by Wakefield, consisted of two things: a large intestine (colon) inflammation and a swelling of the lymph glands predominantly in the terminal ileum of the small intestine. This syndrome, Dr. Wakefield argued, might be correlated with a child's autism. It isn't the purpose of this paper to assess the validity of that theory, though it remains the subject of robust debate.[28]

But why, if the article is underwhelming in its claims, did it become, figuratively speaking, the face that launched a thousand ships?[29] It became so because it was, from the beginning, encased in the interpretive framework of the press briefing and the video released to the media. And, when you get down to it, there was only one question at the news briefing that led to huge headlines in the British press. The question was raised whether this study implicated the safety of the MMR vaccine. As we know by now, that question was a potentially explosive one because of the UK's difficult history with the MMR in the first decade of its administration. The Dean turned to Wakefield for a response, fully knowing what he was going to say. And, Dr. Wakefield responded as we now should have expected—that he wouldn't recommend further use of the MMR until further studies were done on its safety, and that the monovalent vaccine (i.e., the measles vaccine) was a suitable alternative for the time being. The Dean then said that there certainly would be disagreement with that statement, but the moment was over…

Or so he thought. In the ensuing days the headlines screamed from some of the UK's most visible daily newspapers to the effect that a prominent doctor was rejecting the "triple jab." As those who have been at the center of a news tsunami often relate, once this kind of headline comes out, the issue is removed almost completely from the subject's hands. Over the next few years, the rate of administration of the MMR in England continued to decline, albeit at a more rapid pace, and as health officials scrambled to try to demonstrate the safety of the MMR, additional cases of measles

were reported. As recently as June 2008, measles once again was endemic in the UK, fourteen years after measles was supposed to be wiped out.[30] Those who have fought so hard to eliminate this potent virus are, no doubt, livid over the situation. The easiest thing to do is to lay the blame for all of this at the doorstep of an individual and to try to discredit him professionally and personally.

But let's reflect on this issue for a moment before returning to a few more points about *The Lancet* article. I would like to use a comparative hypothetical here, a staple of legal education, to consider the issue more precisely. Let us suppose, for the sake of argument, that a prominent judge or law professor in the United States does a study and then concludes that the U.S. tax system is not only unfair but also is unconstitutional. Let's say s/he further argues that the income tax itself violates the U.S. Constitution. This would be the fiscal equivalent of what Wakefield was arguing. Or, perhaps even more than Wakefield was arguing. Wakefield wasn't saying that the MMR was dangerous or that vaccines were bad; he was just raising questions about MMR safety and recommending a return to the single jab, which had been used since 1968. But let us return to our judge or law professor. If s/he made such an argument, it would probably merit a mention tucked in page 12 of some newspapers. Someone of equally high stature would write an op-ed piece to the *New York Times* declaring that the good judge/professor was mistaken in reasoning for X or Y reasons. After a week, the issue would completely disappear, people would sort of shake their heads about the judge and go back to their lives, paying their taxes with reluctance but not really thinking that they should alter their lives. What was it, then, that enabled a person in early mid-career in the UK, who had just been promoted to Reader, who had no previous experience in autism research, who was one of 13 authors of a piece, to make one statement to journalists about preferring the monovalent to the polyvalent vaccine, and then causing the UK's vaccine house of cards to come tumbling down?

The answer lies in the fragility of the UK's public health system in the 1990s. As mentioned before, it didn't have the most convincing track record on vaccine safety in the 1990s. People were already a bit skeptical of the health authorities. What Dr. Wakefield did was to voice some of the skepticism, though from a position of higher visibility. Should he have kept his mouth shut because the health authorities hadn't established their own credibility with the population at large? That, in fact, is a very interesting ethical question—what you should say to which groups about which beliefs. An analogous situation might be whether a preacher should share his/her doubts about the validity or truth of faith with members of his/her congregation. For the sake of their spiritual health, should s/he keep thoughts to him/herself?

Well, while ethicists and all of us, really, could debate this question, another question, on whether he would recommend the continued use of the MMR, was on Dr. Wakefield's plate. The question was pointedly directed to him by the Dean of the Medical School. What would he recommend about the MMR's safety? He recommended the use of the monovalent. The monovalent was available in the UK at that time, contrary to what some of Wakefield's critics have said. It was withdrawn, however, with only the MMR available, later in that year—in August 1998.[31]

Should Wakefield have said what he said? Maybe so, maybe not. But certainly the Dean knew he was going to say it. And if people think that statement caused the measles crisis of the next decade in the UK, shouldn't the burden equally or more be placed on the public health authorities for not being able to make a convincing case for its safety? After all, there are hundreds of them and only one of him. Indeed, if he is to blame, what kind of society are we, really?

In fact, if anyone wants to parcel out blame for Dr. Wakefield's statement at the news briefing, some should fall on Professor Zuckerman for orchestrating the media circus relating to the publication of the article. Indeed, some blame might as well fall on *The Lancet* itself for publishing the article. After all, it was not as if *The Lancet* is a vanity-press publication. It has various levels of scrutiny and review, and only the articles that seem to suggest promising research directions are published. So clearly is *The Lancet* implicated in the scandal, if indeed that is the right word, that the editor, Richard Horton (who was, in fact, a former colleague of Wakefield at the Royal Free Hospital), had to manufacture unconvincing reasons for the article's publication when pressed on the subject six years later (see below).

Therefore, to look at the events surrounding the publication of *The Lancet* piece and the subsequent decline in MMR vaccination rate in England[32] as the fault or blame of one person is not only naively simplistic but also defies common sense. If we play the fault game, there is the vanity of Zuckerman for publicity, the eagerness of Horton for a medical controversy, the failure of British health authorities to convince an unconvinced public, and the insatiable appetite of the English press for sensationally blowing up stories. Then, there is the statement of Dr. Wakefield. Rather than playing the blame game, however, one might choose to see the controversy sparked by his statement as a something useful in answering the basic question of the safety of the MMR—which was a legitimate one in the minds of many people.

There were two things appearing in *The Lancet* article that, in my judgment, were infelicitously stated and that have taken critics down rabbit holes that ultimately were misleading. First, the paper states,

> **Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent.**

This statement gives the impression that the practices pursued in the study were expressly approved by the Ethical Practices Committee in a decision of that committee. The only decision so made was in December 1996. That decision was, as stated above, only for three additional items to be added to the clinical protocol for the successor study to Study Two (blood draws, urine tests, CSF tests). And this approval was only given prospectively—i.e., for subjects to be investigated after mid-December 1996. By this time, the first 10 or 11 of the 12 subjects for *The Lancet* study were already scoped, imaged, and punctured. How, then, could the study possibly be

ethically approved, if approval came only *after* almost all of the children had been investigated? It is here that most critics of Dr. Wakefield have cried "Foul!" and this is the basis of several of the General Medical Council charges.

The answer to the question actually lies in the fact of Professor John Walker-Smith's blanket ethical approval, described earlier. This ethical approval for research was granted him by the Royal Free School of Medicine before he began his work with them early in 1996. This approval covered the children in *The Lancet* study; it covered not simply the clinical work, which needed no approval at all as long as the tests were "clinically indicated," which Professor Walker-Smith said they were, but the biopsy work done by Dr. Wakefield.

But the two lines just quoted could be confusing to people, especially since the quotation above gives the impression of a specific decision of the Ethical Practices Committee to approve the investigations. Actually, the approval of the investigations rested on the blanket ethical approval possessed by Professor Walker-Smith. That approval was originally granted him by the Ethical Practices Committee earlier in 1996 when he transferred to the Royal Free Hospital from St. Bartholomew's. Problem solved, even if one would have wished for a clearer statement in *The Lancet* paper.

Second, critics have pounced on the statement regarding funding of the study. *The Lancet* article says:

> **This study was supported by the Special Trustees of the Royal Free Hampstead NHS Trust and the Children's Medical Charity.**

Ah, isn't this precisely the place where the 55,000 pounds was banked after the flurry of correspondences between May and July 1997? Doesn't this, then, suggest that Wakefield knew the money had come from Barr to the Royal Free NHS Trust and then to the study? Isn't there, then, a patent conflict of interest here?

The answer is a clear "no." On the one hand, as we have seen, the 55,000 pounds was for Study One, which didn't get underway until October 1997, well after Study Two (*The Lancet* study) was completed. But, even more to the point, the money provided for *The Lancet* study had previously been granted to the researchers by the variety of sources quoted in the 1998 article. In other words, the money for *The Lancet* study came through an independent grant of money from the Special Trustees themselves. Researchers are well aware of how various pots of money might come from the same source; in this case, it would have been helpful (in hindsight) had the article spelled out the distinction from Study One. Yet, from the perspective of 1997 and 1998, there was absolutely no reason to think that any conflict existed, and so an explanation distinguishing sources of money would have been odd, to say the least.

7. The Patent Application

One of the allegations made by critics of Dr. Wakefield is that his motivation for opposing the MMR in the news briefing in February 1998 and afterwards was that he had a financial stake in the patent he was seeking at that time for an alternative vaccine that would compete with the MMR. This allegation was first made by journalist Brian Deer in November 2004 and then picked up by Paul Offit in *Autism's False Prophets* in 2008.[33] Offit states that Wakefield had other financial interests in opposing the MMR and that he was a co-holder, with the Royal Free Hospital, of the patent.[34] In fact, Wakefield was *not* listed as one of the applicants in the June 6, 1997, application; almost all the royalties from whatever vaccine was to be developed would accrue to the benefit of the Royal Free School of Medicine. The first applicant named on the form, then, was the Royal Free School of Medicine.

It is necessary both to put this patent application in historical context and then describe what it actually was designed to do. What no critic points out is that this patent application is the outgrowth of a March 30, 1995, letter Wakefield sent to administrators at the Royal Free Hospital proposing not simply the building of a new GI center at the School but that he, Wakefield, planned to develop "biotechnology to generate capital" to help fund that effort.[35] In fact, there were several correspondences between Wakefield and the school administration at this point because the latter were upset regarding the magnitude of Wakefield's ambition for the center (its proposed cost was more than 23,000,000 pounds). But Dr. Wakefield would do his part—by trying to develop some biotechnology in the form of patents that might raise substantial sums of money. This ambition of Wakefield dovetailed nicely with that of the Dean, Professor Zuckerman. Indeed, after securing the services of Professor Walker-Smith in 1996, and with the hoped for visibility of the school in the wake of the 1998 paper in *The Lancet*, it seemed that everyone was on the same page in working for the enhancement of the Royal Free School of Medicine's reputation. Recall that Dr. Wakefield's promotion came exactly one month before the patent application.

The co-applicant on the June 6, 1997 patent was *not* Dr. Andrew Wakefield; it was Neuroimmune Therapeutics Research Foundation.[36] This imposing-sounding foundation was really the work of one man, the South Carolina immunologist Hugh Fudenberg. Wakefield wanted to include him on the application as a way of honoring his lifelong work on transfer factors, which lay at the heart of the proposed patent. The choice to include Fudenberg probably did more harm than good for Wakefield in the long run. Unbeknownst to him at the time, but rather easily discovered, was the fact that Fudenberg had been suspended from the practice of medicine in South Carolina in November 1995 for "engag[ing] in the personal use of controlled substances and other drugs outside of a bona fide physician-patient relationship."[37] Though his license had been restored by June 1997, he had significant limitations placed on his medical practice.

But some more words need to be said about money because of the allegations that Wakefield sought to and did actually profit handsomely from his patent application and expert work on the case initiated by Richard Barr. We know this isn't true with regard to the patent. It was never developed. A clinical trial was never held. With respect to his status as expert, however, things at first appear to look different. In documents released in December 2006, Wakefield is said to have received 435,000 pounds for his work on the lawsuit—making him the highest-paid expert in the entire case.

This might be expected, since his work on Crohn's disease, the GI tract, and the potential connection of the measles virus to the development of Crohn's disease was foundational for Barr's case. But a closer look at that 435,000 pounds ($780,000) reveals less than meets the eye.[38] The court overseeing the litigation decided that it wouldn't award 100,000 of those 435,000 pounds. Then, Barr's law firm decided to withhold about 35,000 pounds after the highly critical February 2004 stories about Wakefield began to appear. With the British tax of 40%, this brings his earnings down to about 180,000 pounds for seven years of engagement in the litigation. From this he paid for a research assistant and then paid at least 100,000 pounds to file and update the patent application.[39] Decisions to file in jurisdictions as wide as America, Europe, England and Japan drained a good deal of the expert fee money he earned. Thus, at the end of it all, Wakefield didn't get rich on either the patent application or the expert fees he earned. Most of it was invested in ways that it was hoped would benefit the School of Medicine and patients with intestinal disease.

Though a complete review of the patent is beyond the scope of this paper, a word should be said about the nature of the patent application. Was it actually for a competing vaccine? The patent application is quite difficult for a layperson to read and make sense of since it seemingly has sentences suggesting the patent would be for a *replacement* vaccine, and it has other sentences emphasizing that it is a vaccine/therapeutic agent that would ameliorate the potentially negative effects of a measles or MMR vaccine *already administered*. The quotation given by Dr. Offit in his book, which uses "replacement-type" language, appears in the section of the application relating to Crohn's disease. Dr. Wakefield stressed in my interview with him, however, that a basic knowledge of the immune system clearly pointed to the application's reference to what is called the cellular immune response—i.e., a response once a virus has already taken root in a person. The traditional measles vaccine injects a small and attenuated sample of the virus in order to *prevent* the virus from taking root at all. The word "vaccine" is applicable to injections that prevent the virus from taking root as well as those that root it out once it is in the body. Thus, Dr. Wakefield argues that the patent was not, in fact, for a competing vaccine to the measles or MMR vaccine. In addition, a transfer factor, which is what this vaccine would be, cannot work as a population-based vaccine because it can't stimulate the productive of protective antibodies, the cornerstone of any live viral vaccine.

If the British authorities had taken years to develop a good monovalent vaccine and years to struggle with developing a decent polyvalent vaccine, how would one lonely researcher, basing his work on the concept of transfer factors [which allow the transfer of an immunity from one source to another], think that he had developed an *alternative* vaccine? Such a person would be rightly dismissed by any clear-thinking scientist.

8. Coda—The Events of February 2004

Our story is just about told. What we have learned is that the facts leading to the publication of the 1998 article in *The Lancet* as told here are not simply a plausible explanation for Dr. Wakefield's conduct but also a *more convincing* explanation at every point than the explanation of his detractors. Was there a conflict of interest [i.e., not reporting 55,000 pounds of funding for *The Lancet* study]? No, because there were *two* studies. Was there unnecessary invasion of vulnerable children without ethical permission? Again, no. As we know, a blanket ethical permission existed for the senior gastroenterologist, Professor Walker-Smith, and that permission extended to those who worked with the samples he gathered from the colonoscopies and other procedures. All the procedures were said to be "clinically indicated"—i.e., they would have been performed absent any interest in the subjects for a research study/case report. Clinically indicated studies need no special permission from the ethics committee. Finally, was Dr. Wakefield's work fatally flawed because he was engaged as an expert in a long lawsuit against the manufacturers of the MMR vaccine? Well, to answer this we just have to say that if having knowledge of an area, as well as a theory, makes one unable to work as an expert witness and retain one's job, then most expert witnesses from all trials would have to be eliminated.

Our story concludes with a brief synopsis of the cluster of fast-moving events from Sunday, February 15 to Sunday, February 22, 2004. On that latter date, the story about Dr. Wakefield's alleged conflicts of interest appeared for the first time in the English press. By this time the MMR class action lawsuit had been "defunded," in bureaucratic language. Credit should be given to reporter Brian Deer for publishing many original documents in the case beginning in 2004 on his website, even though his interpretations of many of these documents are often highly tendentious and sensational.[40] There is no one more impressed with his own intrepidity than Deer himself. If he had been sympathetic to the notion of two studies, which is the basis of this paper, most of his allegations would have quickly disappeared. Perhaps that is why he wasn't sympathetic to it.

It was his story in the London *Sunday Times* on February 22, 2004, followed by a detailed letter to the GMC the next day that led to the subsequent charges being filed against Dr. Wakefield as well as to the theory of the prosecution case before the GMC. Though a few of the events of the week preceding February 22 have been related by Dr. Richard Horton, editor of *The Lancet* periodical, justifying his breaking of the story on Friday, February 20, another version of the story is as follows.[41]

On or about February 15, 2004, Andrew Wakefield received a communication from reporter Brian Deer with a series of questions that Deer wanted him to answer in a short space of time.[42] The tone of the questions was harsh; it was as if Deer had already made up his mind about his theory of the case (Wakefield had a conflict of interest by not declaring his Legal Aid funding to *The Lancet*) and was simply giving Wakefield the "courtesy" of an opportunity to respond so that he could say that he had tried to consult him for the article. Wakefield, who was in Austin, Texas, at the time working on the details for the opening of Thoughtful House, where he now is Executive Director, knew immediately he had to drop everything and head back to England to get to the bottom of what was happening.

He arrived in London on Tuesday, February 17 without documents or help

of any kind and immediately set up an appointment with editors at the *Sunday Times* for Wednesday morning, February 18. Present at that meeting were three deputy editors as well as the editor of the special section in which the article eventually appeared. They told him that the major problems he needed to resolve were his apparent conflict of interest—receiving 55,000 pounds from the Legal Aid Board to do a study on children who were litigants in the class action lawsuit, not informing colleagues about the money, and then publishing the results in *The Lancet*. As you see, the questions resulted from a failure to separate Study One and Study Two. Wakefield answered the deputy editors and the special section editor, who had not only commissioned the article but was the son of a scientist who was on the committee that approved the Urabe strain of the MMR vaccine, which was recalled in 1992. One of the deputies had to leave the meeting, and, as the story got back to Wakefield after publication of the February 22 article, the deputy thought there was unanimity among the editors that the story wouldn't run. Yet Wakefield had no inkling of this when he met with them. He simply explained himself the best he could. He had no idea if his explanation had any effect on the editors.

Then, having tried to put out that fire, Wakefield hastened over to the offices of Dr. Richard Horton for an afternoon meeting at *The Lancet*. He was accompanied by colleagues Walker-Smith, Murch, and Harvey. Horton had had a meeting that morning with reporter Brian Deer, and Horton voiced Deer's thoughts from that morning's meeting to the assembled group. Wakefield again responded to Horton that there was nothing to the idea of a conflict of interest. Horton wasn't deterred. Well, he wanted to know, if there was no conflict of interest [*The Lancet*'s conflict of interest standard in those days was as follows: "The conflict of interest test is a simple one: is there anything that would embarrass you if it were to emerge after publication and you had not declared it?"], could someone believe that Wakefield *might* have a conflict of interest? Could it be *perceived* that there was a conflict of interest? Wakefield thought that such a retreat by Horton meant that he was subtly shifting his ground. Was the standard an *actual* or a *perceived* standard? Well, round and round they went, inconclusively. Wakefield would later say that his weariness at the time, combined with the raw power of the assault directed against him, made that Wednesday one of the worst days of his life.

At the end of the meeting, Horton assigned tasks relating to Deer's allegations to Wakefield, Murch and Walker-Smith. Wakefield needed to answer the Legal Aid Board allegations, Murch had to deal with the ethics committee approvals, and Walker-Smith was to handle allegations concerning the clinical indications for the investigations. They were to report back to Horton by first thing Friday morning, February 20.[43] The three complied with Horton's demand. These answers were then published—along with Deer's allegations and Horton's conclusion that there had been a conflict of interest—on *The Lancet*'s website before the London *Sunday Times* story appeared on February 22.

On Friday afternoon, before the publication of the Wakefield/Murch/Walker-Smith answers and Horton's statement, and thus before Wakefield really knew what was going to happen, he was pleased to receive a call from Horton, in which Horton said that he had the greatest respect for Wakefield and had no doubt about his integrity, and he admired the way that Wakefield had put up with a great deal in the previous few years.[44] Wakefield was a bit bemused by the call but chalked it up to Horton's desire to extend a peace offering to him. He called his wife Carmel and mentioned the curious call from Horton. Immediately she responded, "Oh my God. What is he up to?" Sometimes males don't have the best intuitive instincts in the world.

Well, of course her worst fears were confirmed. Horton then called a news conference and announced that the 1998 study in *The Lancet* was fatally flawed because of the undeclared conflict of interest (the 55,000 pounds from the Legal Aid Board) behind the article. Horton admitted that the connection between GI distress and autism was certainly a live issue, but the interpretation given to the first part of the study, of the connection of the MMR to all of this, was "fatally flawed." Combined with these words at the news conference, the online version of *The Lancet*, published before the February 22 *Sunday Times* story, as mentioned above, included the allegations made by Brian Deer along with the answers of the three doctors to these allegations and an overview of the issue by Horton, in which he also concluded that Wakefield had an undisclosed conflict of interest in writing the article.

Of course, once the cat was out of the bag, the London *Sunday Times* had to publish the story, which it did it its Sunday edition on February 22, 2004. Wakefield and his family were then besieged by reporters over the next several days.

During the week following the February 22 article, Horton came up with the idea of extending an olive branch to Wakefield and the co-authors. This peace sign took the form of a suggestion that they could issue a retraction, not of what they had written in 1998 but of the interpretation that had been placed on the article after the media frenzy of February and March 1998.

In other words, he was giving them a chance to back off from the study. Wakefield, predictably, said there was nothing to retract. But 10 of the 13 contributors to *The Lancet* article (excepting Wakefield, Peter Harvey, and John Linnell) signed the following statement:

> **Interpretation. We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.**

The retraction stated[46]:

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

We should pause for a moment to consider what is happening here the week after the *Sunday Times* story appeared (by the way, this retraction wasn't published by *The Lancet* until March 6, 2004, which was 13 days after the February 22 story). Horton was clearly giving the authors of the article a chance to separate themselves from the article. But if you look at the words bolded immediately above, you realize how confused this whole process is/was. What Horton asked the authors to do was to retract *an interpretation* to the article. Interpretations come in two kinds: those of the data in the article itself and those extrinsic to the article. If the interpretation that there could be a causal link between the MMR and GI symptoms and autism was actually in the article, then it would have been possible for authors and co-authors to retract an interpretation. But what Horton was asking people to do was to retract an interpretation placed on the article by others—the news media, especially. How can they do that? How can they retract an interpretive statement that someone else made? Of course, they can't.

Some may have signed the retraction because of fear, others because they were angry at Wakefield for drawing them into this whole mess, and others because they were saddened or even chagrined that the MMR vaccination rate had fallen in response to the article. In any case, these 10 signed the retraction. While the retraction process was underway, Wakefield, Linnell, and Harvey wrote a detailed explanation of why they could not, in good conscience, put their names on the document. This letter was not published by *The Lancet* until April 17, 2004.[47] The controversy was kept alive by periodic articles published on the case by Brian Deer between 2004 and the convening of the GMC in 2007. A decision of that Council, as mentioned at the beginning of this article, is expected sometime this year, more than 11 years after the publication of *The Lancet* article.

Conclusion

The aims of this essay are, in fact, relatively limited. My principal focus has been to examine the charges against Dr. Wakefield of financial conflict of interest, of having performed invasive procedures on children that weren't ethically approved, and of questioning the safety of the MMR because he was secretly trying to devise an alternative vaccine that would make him rich.[48] In my judgment, none of the arguments made by critics stands up to close scrutiny. But in the final analysis, all I am trying to do here is to clear the decks so that his *scientific* work can be dispassionately considered. After all, you would think that this would be the interest of most scientists in the first place….

References

[1] A play on the title of John Keats' 1818 sonnet "On First Looking Into Chapman's Homer." In that poem Keats expressed his wonder at the clarity and potency of the *Iliad* upon reading George Chapman's new translation of it.

[2] Writer/consultant living in Oregon. Former law professor, litigation attorney, pastor, professor of history and government, editorial writer, professor of religion and humanities, author/editor of 10 books and the equivalent of 60 more 200-page books on web page: **www.drbillong.com**.

[3] Reprinted here: **http://briandeer.com/mmr/lancet-paper.htm**. The title is "Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children," *The Lancet* 351, (Feb. 28, 1998), 637-41.

[4] Columbia Univ. Press, 2008.

[5] I conducted approximately 12 hours of interviews over three days (Jan. 15-17, 2009) with Dr. Wakefield in Austin and Dallas TX.

[6] Helpful legal background to the case is provided in the May 1997 Dawbarns newsletter, available here: **http://briandeer.com/wakefield/dawbarns-news.htm**.

[7] I will say more about the range of possible defendants below, since it is an important point in understanding the Fall 1996 reaction of the Royal School of Medicine's Dean, Professor Arie Zuckerman, to Wakefield's securing 55,000 pounds from Legal Aid for a study.

[8] **http://209.85.173.132/search?q=cache:pZ0RWR5oFkQJ:www.lawcentres.org.uk/uploads/Legal_Aid.pdf+legal+aid+board+history&hl=en&ct=clnk&cd=3&gl=us&client=firefox-a**

[9] A helpful and easily accessible history of administration of vaccines in England is "Evolution of Surveillance of Measles, Mumps, and Rubella in England and Wales," *Epidemiologic Review* 24 (2002), 125-136, reprinted on the Internet at: **http://epirev.oxfordjournals.org/cgi/content/full/24/2/125**

[10] A few words on MMR history are here: **http://www.mmrthefacts.nhs.uk/library/whatinfo.php**

[11] *Journal of Medical Virology* 39 (1993), 345-53.

[12] *The Lancet* 345 (1995), 1071-74.

[13] A helpful primer on Crohn's is: **http://digestive.niddk.nih.gov/ddiseases/pubs/crohns/**

[14] Dr. Wakefield offered me a copy of this study on the safety of the measles vaccine when I interviewed him. I politely declined his offer.

[15] Here is the text of a Nov. 1996 article from the *Independent* about her situation. http://briandeer.com/wakefield/dawbarns-kessick.htm

[16] Dr. Wakefield made this point to me on several occasions in the interviews. I have not seen this point mentioned in any of the published literature on the case.

[17] http://briandeer.com/wakefield/protocol-1996.htm

[18] http://74.125.95.132/search?q=cache:LzYXsQO4YAoJ:www.circare.org/consents/wakefield_20070716.pdf+proposed+protocol+and+costing+proposal+and+proposed+clinical+and+scientific+study+wakefield+general+medical+council&hl=en&ct=clnk&cd=3&gl=us&client=firefox-a. In order to get directly to this information, do a search of the document based on one of the names of the studies.

[19] As just indicated, this was a specious concern. If you study the Consumer Protection Act 1987, the act under which suit was brought, you see that suit can be brought against "producers," "importers," and "own-branders." See a summary at this website: http://209.85.173.132/search?q=cache:peU7CgF18W8J:www.berr.gov.uk/files/file22866.pdf+consumer+protection+act+1987+text&hl=en&ct=clnk&cd=2&gl=us&client=firefox-a#6. For one thing, the British Government was not a producer. Then, even if such a suit were allowed to go forward, it would take decades to resolve. Finally, the English legal system has such a robust doctrine of sovereign immunity that any attempt to pierce this doctrine would take more than the resources of what critics of Barr denominate as a "small time" tort lawyer could provide.

[20] Text and description is here: http://www.vaccinationnews.com/.

[21] The letter is the first document of three on the following site. As you see, I interpret the data differently than did the reporter who placed this letter on his web site. http://briandeer.com/wakefield/wakefield-deal.htm

[22] The second document on the site in the previous footnote.

[23] The third document on the aforementioned site.

[24] See my summary of Kanner's work and its significance: http://www.drbilllong.com/Autism/Kanner.html

[25] See the following news article from later in 1997: http://briandeer.com/mmr/st-jaws-warning.htm

[26] *Autism's False Prophets,* 18.

[27] Text of the paper is here: http://briandeer.com/mmr/lancet-paper.htm.

[28] A recent article summarizing the state of the question by Dr. Wakefield is: "Autistic enterocolitis: Is it a histopathological entity?-reply," *Histopathology* 50 (2007), 380-84.

[29] The reference, for those unfamiliar with classical mythology, is to the beauty of Helen of Troy, which led to her abduction by Paris and the subsequent Trojan War, memorialized in Homer's *Iliad*. The phrase is actually derived from Christopher Marlowe, a contemporary of Shakespeare.

[30] http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/official-warning-measles-endemic-in-britain-851584.html

[31] Here is a discussion of the question: "The UK had a single dose measles vaccine program since 1967. The single rubella and mumps vaccines became available in the early seventies. The MMR vaccine was introduced in 1988. When parents started requesting the monovalent vaccines in increasing numbers, the DOH decided in August 1998 to withdraw their license. Those who could afford it crossed the Channel to get their children vaccinated or purchased the single vaccines at private clinics." http://www.whale.to/a/ya45.html.

[32] The following article gives some vaccination figures for England in the years before and then following the release of *The Lancet* article. http://www.guardian.co.uk/society/2007/jul/08/health.medicineandhealth1 According to the article, at the time of the press conference 91.5 percent of children in England had the MMR jab by the time they turned two. After the headlines of the next weekend, MMR immunization rates dropped to 87.4 percent. The lowest ebb was 79.9 percent nationally, with lower figures for some sections of London.

[33] Offit, p.47.

[34] *Ibid*.

[35] Letter of March 30, 1995, in Dr. Wakefield's possession, perused by author on January 15, 2009.

[36] A copy of the patent application is here. http://briandeer.com/wakefield/vaccine-patent.htm

[37] The Final Order suspending Fudenberg is here: http://www.casewatch.org/board/med/fudenberg/1995order.shtml. He was re-instated in 1996 but his authority to prescribe drugs was taken away from him.

[38] I derived the following points from my January 15, 2009, interview with Dr. Wakefield. I saw the law firm billings on two large pink sheets from 2000 and 2001. A quick addition of the figures yielded nearly 100,000 pounds expended in legal fees for furthering the patent application.

[39] The author studied some of the billing records from a prominent London patent law firm to Wakefield for their services in the late 1990s and 2000.

[40] http://briandeer.com/

[41] His book on the subject, *MMR Science and Fiction: Exploring the Vaccine Crisis* (2004), appeared seven months after Deer's first article.

[42] The series of events narrated here comes from Dr. Wakefield's memory and documents, and the story will be told in more detail in a book he is writing on his role in this controversy.

[43] For example, Dr. Murch's statement on the issue is on this website: http://briandeer.com/mmr/lancet-murch.htm.

[44] In the years between 1999 and 2003 many studies had been published which called into question any link between the MMR and gut disease or autism. As more and more studies came out to this effect, the crescendo against Dr. Wakefield began to build. Horton's words over the phone to Wakefield are to be understood in that context.

[46] This retraction of an interpretation was published in *The Lancet* 363 (March 6, 2004), 750.

[47] The text of this letter is here: http://briandeer.com/wakefield/retraction-reply.htm.

[48] Indeed, Dr. Paul Offit, one of Wakefield's bitterest critics, *did* make a lot of money, in the eight or even nine figures, for patenting the rotavirus vaccine. One might have thought that one who hit the jackpot on such a venture would understand another person submitting a patent for a vaccine, even if that other person might have had little personal financial stake in the outcome.