Before the General Medical Council
London, United Kingdom

In the Matter of:

Dr. Richard Charles Horton (#2927877)
Dr. David Maxwell Salisbury (#1413890)
Dr. Arie Jeremy Zuckerman (#0870254)
Dr. Michael Stuart Pegg (#1560424)
Dr. Michael Llewellyn Rutter (#0639943)

Docket No: _____

FIRST AMENDED COMPLAINT
(Breach of duty of honesty and candor; False Testimony; Misuse of Professional Position, Failure to Disclose Conflicting Interest, False Expert Testimony)

The autism and vaccine safety organizations (Organizations) in the United States and the United Kingdom listed below call upon the General Medical Council (GMC) to investigate the conduct of Drs. Richard Horton, Arie Zuckerman, Michael Pegg, and David Salisbury in the Fitness To Practice (FTP) hearing against Drs. Andrew Wakefield, Professor John Walker-Smith, and Professor Simon Murch. As set forth more fully below, Drs. Horton, Zuckerman, Pegg, and Salisbury breached their duty of candor to GMC and violated Good Medical Practice (GMP) guidelines by giving false and misleading testimony during the investigation and at the FTP hearing. Drs. Horton, Zuckerman, and Salisbury abused their professional positions of responsibility and trust by attempting to censor research critical of vaccine safety and interfere with relations between lawyers and scientists. Dr. Salisbury gave misleading testimony regarding the safety of the MMR vaccine and concealed information material to its safety from the public.

These actions have harmed, and will continue to harm, children by chilling and reducing funding for research into causes of and treatments for autism, and clinical care. The documentary evidence now reveals that there was no merit to the core allegations brought in 2004 by Brian Deer. Furthermore, the FTP proceeding has been irreparably tainted by false testimony. Accordingly, the Organizations

ask that the FTP hearing against Drs. Wakefield, Murch, and Walker-Smith be terminated immediately. Declaring this diversion at an end will facilitate a return to the urgent business at hand, finding the cause of and treatments for autism, and restoring public confidence in the vaccination program with an aggressive 'safety first" research agenda.

Drs. Horton, Zuckerman, Peg, and Salisbury gave false testimony as part of a wide-ranging campaign to discredit the work of Dr. Andrew Wakefield, Professor Simon Murch, and Professor John Walker-Smith and deter others with respect to an association between autism and inflammatory bowel disease and a potential association between autism and MMR, bowel disease, and regressive autism. The target of their false testimony was a paper published in The Lancet on February 28, 1998, "Ileal-lymphoid-nodular-hyperplasia, non-specific colitis, and pervasive development disorder in children" ("Lancet Case Series"), that reported a case series of 12 children who developed bowel disease and autism following MMR. Ex. 1. Their false testimony formed the core of allegations in the FTP hearing presently underway against Dr. Andrew Wakefield, Professor Simon Murch, and Professor John Walker-Smith. The GMC would likely not have convened this hearing were it not for the false testimony, and would have quickly dismissed the misguided and unfounded allegations of Complainant Brian Deer.

The false testimony and the ensuing GMC FTP hearing have had the effect of delaying necessary research into cause and treatment for autism, and dissuading scientists from pursuing research relating to vaccines as a cause of chronic disease. The ultimate victims of this false testimony are children whose autism could have been prevented or more effectively treated.

Horton's de facto "gag" rule censoring publication of science that calls vaccine safety into question obstructs justice by depriving the courts of the evidence they would need to find a vaccine-caused injury and is an unprofessional and misguided attack on the ethics of scientists and lawyers who would work together to seek justice for injured children.

Dr. Horton's claim six years after publication of the Lancet Case Series that it would never have been published had he known of Dr. Wakefield's participation in MMR litigation was false because he was twice informed of Dr. Wakefield's relationship with MMR litigation a year before and two days after publication. Horton, not Wakefield, decided that the disclosure of a "perceived" conflict (where no actual conflict existed) was simply not necessary as part of the published Case

Series. He concealed the Lancet's knowledge of Wakefield's participation in MMR litigation when the possibility of "litigation bias" was raised by a reader immediately after publication. By feigning ignorance of the Wakefield litigation relationship, and outrage at somehow being misled, six years later when the allegations were raised by Deer, Horton was able to shift "blame" for decisions he had made and information he had concealed to a scapegoat (i.e. Drs. Wakefield, .Murch, and Walker-Smith) once it had become evident that someone had to pay a price for the "unpleasantness" surrounding vaccine safety concerns. Moreover, Horton conspired with a "medical regulator" to motivate a GMC investigation while boasting that the GMC "had not a clue where to begin."

Dr. Zuckerman's claim that he was unaware that vaccines would be discussed at a press conference accompanying publication was false because he had specifically instructed Wakefield to urge continued use of the monovalent measles vaccine as a safer alternative to MMR.

Dr. Pegg's claim that the research aspects of Lancet Case Series were unethical was false because his own Ethics Committee had approved the collection of tissue samples well before the first child was ever examined.

Dr. Salisbury's claim that MMR has an "exemplary" record of safety is unfounded and misleading. He has misused his official position by attempting to discredit and silence Dr. Wakefield and others who have a moral and ethical duty, and a right of free speech, to criticize the safety of MMR. He has also concealed material information relating to the safety of MMR from the public.

Count VII (added to the First Amended Complaint) alleges that he failed to disclose in at least four papers published beetween 2005 and 2009 that he had a crucial conflicting financial interest as a highly paid expert witness for the vaccine industry (and for the U.S. Government that defends industry in Vaccine Court) in at least three major litigation projects, U.S. litigation concerning mercury (thimerosal) as a cause of autism, the U.K. MMR litigation, and the U.S. Omnibus Autism Proceeding (concerning both MMR and thimerosal as causes of autism).

Count VIII alleges that Dr. Rutter gave false expert testimony in this FTP hearing by stating his opinion that Dr. Wakefield had a duty to disclose his participation in MMR litigation in the Lancet Case Series. In the alternative, Dr. Rutter misled the Panel by hiding his own non-disclosure of the same type of conflicting interest for which he condemns Dr. Wakefield. If Dr. Rutter doesn't

honestly believe (although this would contravene the express language in the modern disclosure guidelines) that acting as a litigation expert on precisely the same subject discussed in his published papers (and on which he relies for his opinion in litigation) is a disclosable conflict, then he is falsely accusing Dr. Wakefield of breaching a non-existent duty. Or, if he honestly believes this is a disclosable interest, then his testimony is false and misleading because he has concealed the fact of his own pattern of non-disclosure.

Background.

Autism.

Autism is not a disease itself. It is a manifestation of a complex biological and neurobiological disorder that typically lasts throughout a person's lifetime. It manifests as a range of disorders known as autism spectrum disorders (ASD). Autism impairs a person's ability to communicate and relate to others. It is also associated with rigid routines and repetitive behaviors, such as obsessively arranging objects or following very specific and repetitive patterns of behavior. Symptoms can range from very mild to quite severe.

Autism was first described in the medical literature in 1943 by Dr. Leo Kanner of Johns Hopkins Hospital. At the same time, a German scientist, Dr. Hans Asperger, described a milder form of the disorder that is now known as Asperger Syndrome. These two disorders are listed in the DSM IV (Diagnostic and Statistical Manual of Mental Disorders) as two of the five developmental disorders that fall under the autism spectrum disorders. The others are Rett Syndrome, PDD NOS (Pervasive Developmental Disorder), and Childhood Disintegrative Disorder. All of these disorders are characterized by varying degrees of impairment in communication skills and social abilities, and also by repetitive behaviors. An autism diagnosis (usually at 1-3 years) can have very devastating consequences on families. Annual expenses for treatment can reach $100,000 and the total lifetime costs can exceed $5 million.

The exact cause of autism is unknown but a growing consensus in the scientific literature points to an environmental trigger in a genetically susceptible individual. A small number of cases have a true genetic origin. There is at present no "cure" for autism, yet recent evidence of recovery (and even loss of diagnosis) has given new hope to affected families.

The epidemic of autism is a national health crisis in both the UK (1:60) and US (1:150). Prevalence has increased rapidly over the past two decades. Some public health authorities deny the epidemic because the rapid rise in cases points to an environmental trigger

The US Government and Courts Have Concluded Vaccines Can Cause Autism.

Medicine has long-recognized that wild-type viruses, e.g. measles, can cause autism. For example:

> This study has examined the possible association between prenatal and early infancy viral exposure and the development of autism. The major viruses specified *a priori*—measles, rubella, mumps, and chickenpox—were selected because of their known encephalitic potential. The results of the current study suggest that for some, but not all, autistic children, viral experience in early infancy or during their mothers' gestation may have contributed to the etiology of their illness.

Deykin, E. and MacMahon, B., "Viral Exposure and Autism," Am J Epidemiol. 1979 Jun;109(6):628-38; Borchers, A. T., C. L. Keen, et al. (2002). "Vaccines, viruses, and voodoo." J Investig Allergol Clin Immunol 12(3): 155-68. See Libbey, Jane E., Sweeten, Thayne L., McMahon, William M. and Fujinami, Robert S. (2005) "Autistic disorder and viral infections" Journal of Neurovirology, 11:1, 1–10.

The Vaccine Court and the U.S. Government have concluded that vaccines can cause autism. Without baseline data for chronic conditions such as autism in unvaccinated children, it is virtually impossible to know how much autism (and other chronic diseases) is vaccine-caused. Although there has been an increasing awareness of this crucial gap, and the limitations of our knowledge regarding vaccine safety, the politicization of the vaccine-autism issue, exemplified most cogently by the present FTP hearing, stands in the way of this knowledge, changes in vaccines and vaccine policy, and threatens public confidence in vaccines. Following is a summary of events, primarily in the US, documenting the limitations in vaccine safety science and the urgent need to de-politicize the safety research agenda. With so much uncertainty in the basic science, and increasing numbers of people opting out of all or some vaccines, the vaccine safety debate

indeed in a state of crisis.

Vaccine-Caused Autism in the Scientific Literature

Vaccine-caused autism was first described in the medical literature by Sir Michael Rutter. In a lengthy review article on the biological basis of autism, Sir Michael described a genetic study of families affected by autism, from which some children were excluded on the basis that their autism could be explained by some known "medical condition of probable aetiological [causal] importance." Sir Michael explained one of the exclusions: "Only eight of the cases can be regarded as having a probably causal medical condition, a child with epilepsy and a temporal lobe focus on the EEG [Electroencephalogram] who had an onset following immunization." Rutter M et al., "Autism and known medical conditions: myth and substance," J Child Psychol and Psychiat. 1994;35:311-322.

The Institute of Medicine concluded in a 1994 report, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (1994). IOM explained:

> [I]t is biologically plausible that injection of an inactivated virus, bacterium, or live attenuated virus might induce in the susceptible host an autoimmune response by deregulation of the immune response, by nonspecific activation of the T cells directed against myelin proteins, or by autoimmunity triggered by sequence similarities of proteins in the vaccine to host proteins such as those of myelin.

IOM, 1994, at 48. Regarding measles vaccine and brain injury or inflammation, the expert panel concluded:

> The National Childhood Encephalopathy Study, a case-control study described in detail in Chapter 5, reported a significant association between measles vaccination and onset of either convulsions or encephalopathy within 7 to 14 days of receiving the vaccine (Alderslade et al., 1981). . . . There is demonstrated biologic plausibility that measles vaccine might cause encephalopathy. . . . There is demonstrated biologic plausibility that measles vaccine might cause encephalopathy. . . . Good case-control or controlled cohort studies of these conditions in similar unvaccinated populations, which

> are necessary for determining the causal relation between measles and mumps and encephalopathy and encephalitis, are lacking.

Id. at 129-30. Regarding SSPE, the expert panel concluded:

> SSPE is a recognized sequela of measles infection, and it is biologically plausible that it could occur after administration of the live attenuated viral vaccine. Identification of the cause of SSPE as wild-type or vaccine-strain measles virus has not been possible. The viruses isolated from patients with SSPE differ from the known measles viruses. The viruses may have become altered by the prolonged residence in the brains of the patients, or they may have been different at the time of the original infection.

Id. at 136. The panel also concluded, ominously: "The evidence establishes a causal relation between vaccine-strain measles virus infection and death." Id. at 178.

Liability for Vaccine-Caused Autism.

The rapid increase in diagnosed autism cases prompted an increasing number of parents and organized groups to call for research into the cause of what seemed an epidemic. This research has quickly moved toward a scientific consensus that autism can be caused by an environmental trigger in genetically susceptible individuals. There has been continued concern in the research community that vaccines are one of the environmental triggers in part because there have never been any animal or human studies to assess the extent of chronic adverse events (e.g. by comparing to unvaccinated individuals) and because ongoing research has pointed to immune, autoimmune, and inflammatory mechanisms in the development of autism. The epidemiology studies often relied upon by those claiming no evidence of an association between vaccines and autism are deeply flawed, and in some cases bordering on scientific fraud, in part because they do not include unvaccinated controls to measure a baseline of adverse events.

The "vaccine court" in the United States began compensating vaccine-autism claims in 1991. See Kleinert v. Dept. of Health and Human Services ("HHS"), 1991 WL 30664, (Cl.Ct., 1991 (No. 90-211V) (seizure disorder after DPT which is under control and a condition known as overfocussing, similar in

some respects to autism). Since then, the court has published at least nine more decisions awarding compensation for vaccine-caused autism. HHS has found the evidence so persuasive that it has conceded liability before trial in an unknown number of autism cases. In a 2001 concession, Hiatt v. HHS, a child with MMR-caused autism was awarded $5.1 million dollars. In a case conceded in 2007, Poling v. HHS, a child who received five vaccines (nine antigens) in one day, one of which was MMR, developed autism. See Kirby, "The Vaccine Court Document Every American Should Read," Huffington Post (Feb. 26, 2008) [http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-_b_88558.html]; CBS News [http://www.cbsnews.com/sections/primarysource/main501263.shtml?contributor=41919].

In a case handed down just one month after the trial in Cedillo, the court found liability for MMR-caused ASD. See Banks v. HHS, 2007 WL 2296047 (Ct. Cl. 2007) (No. 02-0738V). The Court found that Bailey would not have suffered this delay but for the administration of the MMR vaccine...a proximate sequence of cause and effect leading inexorably from vaccination to PDD (autism). The Court ruled in a subsequent MMR case, Zeller v. HHS, 2008 WL 3845155, that the vaccine caused brain injury and developmental delay.

The Vaccine Court launched an Omnibus Autism Proceeding in 2001 due to the large number of claims being filed, now over 5,000. Despite previous concessions and rulings, the Court recently ruled in three "test cases" (presently on appeal) that the scientific evidence was insufficient to support a finding of causation. Much of the Government's defense focused on Dr. Wakefield, the FTP proceeding, and the UK MMR litigation. Indeed, the Complainant in the FTP proceeding, Brian Deer, boasted that he played a crucial role in developing the U.S. Government's strategy. [http://www.ageofautism.com/2009/03/a-character-assassin-caught-in-the-act.html?cid=6a00d8357f3f2969e201156e333332970c; http://www.ageofautism.com/2009/02/did-the-department-of-justice-tip-off-brian-deer.html]. The US Vaccine Court (by decision) and the US Government (by concession) have concluded that vaccines, specifically MMR, can cause autism. The debate, and the need for reallocating research support, now shifts to how many children have been affected (for purposes of compensation) and how to prevent new cases and treat those already vaccine-damaged.

The Consumer Protection Act was passed in the UK in 1987. This amended the law on product liability and for the first time enabled individuals to bring

claims against the manufacturers of products which were alleged to be unsafe. It imposed a form of strict liability for unsafe products, thereby removing the requirement to prove negligence. The Legal Aid Board initially granted funding 1994 to claimants who alleged that brain injury had been caused by MMR vaccine, expanding to autism in 1996. Then it peremptorily withdrew legal aid necessitating the appeal (mentioned above). Despite the fact that a trial date had been fixed for April, 2004, legal aid funding was withdrawn in August, 2003. By that time, laboratory tests had found evidence of the vaccine strain of the measles virus in some of the claimants, 27 experts from many different disciplines had produced reports supporting the claimants' claim and the cases had the support of 3 QCs for the claimants. It came as a considerable surprise to many that legal aid was withdrawn at that late stage in the case. High Court Justice Keith eventually recommended terminating the class action status in June, 2007, explaining:

> "It is *not* because the court thinks that the claims have no merit. Although this litigation has been going on for very many years, the question whether the claims have merit has never been addressed by the court," Mr. Justice Keith said.
>
> The reason the claims had not been allowed to proceed, he said, was "because everyone has realistically recognized for some time that it is just not practicable for the claims to proceed without public funding."
>
> He went on: "With no realistic prospect of public funding being restored for any of the claims save for the two which are now to proceed as unitary actions, the dissolution of the litigation became inevitable."

Tait, N., "MMR Class Action on Verge of Collapse," Financial Times (June 9, 2007).

<u>FTP Hearing Involving Dr. Wakefield, Professor Walker-Smith, and Professor Murch.</u>.

Dr. Wakefield first became interested in autism and in a possible association between autism and measles containing vaccines in 1995. His interest in autism followed a long history of research and publications eventually postulating a possible link between Crohn's disease and measles vaccine Many of these papers were published in the Lancet, one of the UK's most prestigious medical journals.

See, e.g., Wakefield AJ, Pittilo RM, Sim SL et al. Evidence of persistent measles virus infection in Crohn's disease. J Med Virol 1993; 39: 345-353; Lewin J, Dhillon AP, Sim R, Mazure G, Pounder RE, Wakefield AJ. Persistent measles virus infection of the intestine: confirmation by immunogold electron microscopy. Gut 1995; 56: 564-69; Thompson NP, Montgomery SM, Pounder RE, Wakefield AJ. Is measles vaccination a risk factor for inflammatory bowel disease? Lancet 1995; 345: 1071-4; Ekbom A, Wakefield AJ, Zack M, Adami HO. Perinatal measles infection and subsequent Crohn's disease. Lancet 1994; 344: 508-10; Ekbom A, Daszak P, Kraaz W, Wakefield AJ. Crohn's disease after in-utero measles virus exposure. Lancet 1996; 348: 515-7. He also published "negative" findings, a somewhat rare occurrence in scientific publication. See, e.g. Thompson NP, Pounder RE, Wakefield AJ. "Perinatal and childhood risk factors for inflammatory bowel disease: a case-control study," Eur J Gastroenterol Hepatol 1995; 7: 385-90.

Dr. Wakefield was contacted by Richard Barr of Dawbarns Solicitors early in 1996. Dawbarns Solicitors (with the Nottingham law firm Freeth Cartwright Hunt Dickins) were appointed by the Legal Aid Board in 1995 (following a successful appeal against the refusal to grant legal aid mounted by both firms), to manage claims over serious neurological damage (including autism) arising from allegations that children had been damaged by MMR. Families started to contact solicitors in large numbers after two brands of MMR vaccine (Pluserix and Immravax) were withdrawn suddenly in September 1992 after it was found that these two brands were associated with considerably increased incidence of viral meningitis among children who had been vaccinated.

Richard Barr contacted Dr. Wakefield as he was aware of his work and the possible implication of measles vaccine in the cause of inflammatory bowel disease. Many of Richard Barr's clients sought his help because of their child's bowel problems which they considered to be related to their vaccination with measles-containing vaccines. Dawbarns Solicitors was appointed by the Legal Aid Board on 1995, to help manage claims over serious neurological damage (including autism) following MMR. Dr. Wakefield made no secret of his scientific curiosity and of his desire to help families to find answers to their urgent concerns. In the first instance his interest was, as had been previously the case, their bowel disease. It was only later that he became concerned that some children appeared to have their bowel disease concomitantly with developmental regression and autism.

The majority of the allegations against Dr. Wakefield, Professor Murch, and

Professor Walker-Smith by the GMC relate to clinical findings in the series of 12 children reported in the 1998 Lancet Case Series. The core allegations brought by the GMC against Dr. Wakefield, Professor Murch, and Professor Walker-Smith are: (1) that "research" was conducted on children reported in the Lancet Case Series without approval of the Research Ethics Committee; (2) that Wakefield's participation in potential MMR litigation was not disclosed to the Lancet prior to publication of the Lancet Case Series; and (3) that publication of the Lancet Case Series caused the media and public to have inappropriate concerns over the safety of the MMR vaccine. Dr. Wakefield made no secret of his scientific curiosity and of his desire to help families to find answers to their urgent concerns concerning the cause of and treatments for autism.

Drs. Horton, Zuckerman, Pegg, and Salisbury Violated Applicable GMP Standards.

The General Medical Council's publication "Duties of a Doctor" requires registered doctors to:

> Protect and promote the health of patients and the public.
>
> Be honest and open and act with integrity.
>
> Never discriminate unfairly against patients or colleagues.
>
> Never abuse your patients' trust in you or the public's trust in the profession.
>
> Be personally accountable for your professional practice and always be prepared to justify their decisions and actions

The Good Medical Practice guidelines (GMP) provide the standard of conduct against which the false and misleading testimony and misuse of professional position should be judged. Relevant GMP's are as follows:

> Being honest and trustworthy:
>
> 56 Probity means being honest and trustworthy, and acting with integrity: this is at the heart of medical professionalism.

57 You must make sure that your conduct at all times justifies your patients' trust in you and the public's trust in the profession.

Writing reports and CVs, giving evidence and signing documents:

65 You must do your best to make sure that any documents you write or sign are not false or misleading. This means that you must take reasonable steps to verify the information in the documents, and that you must not deliberately leave out relevant information.

67 If you are asked to give evidence or act as a witness in litigation or formal inquiries, you must be honest in all your spoken and written statements. You must make clear the limits of your knowledge or competence.

68 You must co-operate fully with any formal inquiry into the treatment of a patient and with any complaints procedure that applies to your work. You must disclose to anyone entitled to ask for it any information relevant to an investigation into your own or a colleague's conduct, performance or health. In doing so, you must follow the guidance in Confidentiality:

These rules put special emphasis on due diligence (e.g., reviewing files) prior to preparing documents or giving testimony.

Count I
Richard Horton
False Testimony Before the GMC

Richard Horton has been Editor of the UK Lancet since 1995. As editor, he has overall responsibility for everything that is published in the Lancet. He was well aware of Wakefield's involvement in the MMR litigation a year before publication of the Lancet Case Series. Although Horton insisted that several measures be taken during editorial review to guard against misinterpretation of the findings reported in the limited case series, he found it unnecessary to require disclosure of Wakefield's participation in the MMR litigation, which was widely known by the public and to vaccine regulators, at the end of the Lancet Case Series

as a possible conflict of interest. He was reminded again of the Wakefield-MMR litigation connection in a letter titled "litigation bias" (Rouse letter) sent just two working days after publication of the Case Series. Ex. 15. Dr. Horton published the Rouse letter and Dr. Wakefield's reply but deleted Rouse's reference to "litigation bias" and Rouse's "black box" rendition of Wakefield's participation in the MMR litigation. The deletion of the critical details of Wakefield's involvement in the MMR litigation before publishing the Rouse letter in the Lancet enabled Horton to conceal his and the Lancet's prior knowledge of these facts. Ex. 16 (second page). When Brian Deer made his allegations against Dr. Wakefield in 2004, Horton feigned ignorance, claiming that he first learned of Wakefield's "prospective" involvement in the MMR litigation from Dr. Wakefield's response to the Rouse letter published in the Lancet on May 2, 1998 (Ex. 16). Added to this clear evidence of abuse of his position both as an editor and a registered medical practitioner, Dr. Horton has publicly taken credit for engineering the GMC proceedings against Dr. Wakefield, Professor Murch, and Professor Walker-Smith. He gave false testimony to GMC investigators and at the FTP hearing concerning his prior knowledge of Wakefield's participation in the MMR litigation.

Dr. Horton's Knowledge of Wakefield's Participation in the MMR Litigation Prior to Publication of the Lancet Case Series.

Dr. B. D. Edwards, an employee of the Medicines Control Agency (MCA)wrote to the Lancet in March, 1997, complaining that text and tables from various Lancet papers had been reproduced in a Dawbarns Fact Sheet of March, 1997. Dawbarns prepared the Fact Sheet for its clients and other interested parties. The Society for the Autistically Handicapped obtained a copy and posted it on the web. That Fact Sheet publicly disclosed Dawbarns' working relationship with Dr. Wakefield in the text accompanying the reference to Dr. Wakefield's paper in The Lancet:

> There is convincing evidence of a link between vaccination and inflammatory bowel disease including Crohn's Disease. It is a serious lifelong illness that has affected a large number of the children we are helping. We are working with Dr. Andrew Wakefield of the Royal Free Hospital London. He is investigating this condition.

Ex. 4 (emphasis added).

Ms. Sara Quick of the Lancet telephoned Ms. Kirsten Limb, a paralegal at

Dawbarns, on March 19, 1997. Ex. 2. Ms. Quick advised Dawbarns to apply for permission to reproduce material from The Lancet and indicated there should be no problem in granting the permission.

Richard Barr faxed a letter to Richard Horton at the Lancet on April 3, 1997. Ex. 3. Richard Barr's letter and enclosures to Horton explained that Dawbarns was involved in litigation relating to damage to children caused by the MMR and MR vaccines, that he was working with Wakefield, that Wakefield had given permission to quote his Lancet papers in the Fact Sheet, that MCA and the Department of Health were pressuring the Lancet to have the references removed from the Fact Sheet, and that the Fact Sheet and correspondence from Dr. Susan Wood of the MCA would be sent by mail. The enclosed Fact Sheet was quite explicit about Wakefield's involvement. He asked Richard Horton for retrospective permission to quote specific Lancet references "*contained in the fact sheet*" and he identified the four relevant references by providing their footnote numbers in his letter. Footnote No. 50 on page 21 of the Fact Sheet was a reference to a paper co-authored by Wakefield. The text associated with that footnote reads as follows:

> There is convincing evidence of a link between vaccination and inflammatory bowel disease (including Crohn's disease). It is a serious lifelong illness that has affected a large number of the children we are helping. <u>We are working with Dr Andrew Wakefield of the Royal Free Hospital London. He is investigating this condition.</u>

Exhibit 4 (emphasis added).

Horton responded to Richard Barr on April 8, 1997, denying permission to use the Lancet references in the Fact Sheet. Ex. 5. Richard Barr wrote again on April 16 seeking the intercession of the Lancet's Ombudsman. Ex. 6. Horton replied to Barr on April 23 saying that he would be happy to refer the matter to the Ombudsman. Ex. 7.

Richard Barr wrote to Horton on April 29, 1997 enclosing his correspondence with Dr Edwards of the MCA and asking to be put in touch with the Ombudsman. Ex. 8. Horton was apparently unable to deal with the matter since he was out of the country until June 9 on a business trip. Ex. 9. Horton finally responded to Richard Barr on June 12, giving him instructions on how to make contact with the Ombudsman. Ex. 10. Richard Barr acknowledged Horton's

letter on June 25 and subsequently corresponded with the Lancet's Ombudsman, Professor Thomas Sherwood on July 3, 1997, enclosing correspondence between Richard Barr and Edwards challenging Edwards' dual role as "private" citizen complaining to the Lancet about Dawbarns and as an MCA official. Ex. 11. Professor Sherwood subsequently ruled that permission should have been obtained by Dawbarns from The Lancet for use of the references and reproduction of tables but in the circumstances and given the not-for-profit nature of the Fact Sheets he agreed that the tables/references in them could remain. Ex. 12. Richard Barr thanked Sherwood for the permissions in a letter dated July 31, 1997. Ex. 13. This correspondence between Barr, Horton and Sherwood took place between March and July, 1997, just as the Case Series was submitted to the Lancet in draft for review.

Dr. Horton's Knowledge of Wakefield's Participation in the MMR Litigation Immediately After Publication of the Lancet Case Series.

A manuscript entitled "Ileal-lymphoid-nodular-hyperplasia, non-specific colitis, and pervasive development disorder in children" ("Lancet Case Series" Ex. 1) was submitted to the Lancet in the summer of 1997, in the midst of Horton's dealing with the copyright issues raised by publication of MMR-related material in the Dawbarns' Fact Sheet. Thus, as of the time when what was to become the Lancet Case Series was beginning the review process, Horton, as Editor of the journal with contemporaneous personal involvement in this copyright infringement matter, knew of Solicitor Richard Barr, the firm of Dawbarns, MMR-related litigation, Wakefield's relationship with Richard Barr, and the fact that Richard Barr was working with Wakefield on the investigation of possible vaccine damage. The references in the Fact Sheet that Edwards sought to remove and Richard Barr sought to retain were specifically related to the issue of MMR litigation.

The Lancet Case Series which is currently the subject of intense GMC scrutiny was published in the "Early Report" section of The Lancet on Friday, February 28, 1998. The Lancet, Vol. 351, No. 9103, pp. 637-41.

Horton explained in his statement to the GMC a crucial limitation contained in the paper:

> The paper itself made clear that there was no proof of an association between the MMR vaccine and the syndrome described. . . . It is my recollection that the section of the paper which states "We did not

> prove an association between measles, mumps, and rubella vaccine and the syndrome described. Virological studies are under way that may help to resolve this issue." Was contained in the original submission.

Horton Stmt. at ¶¶ 12-13 (Ex. 101).

As part of his commitment to "responsible" publication, Horton commissioned a commentary published in the same edition "which not only explained the limits of the findings contained in the paper, but also set out to describe the huge global benefits of measles vaccination. This commentary (Ex. 14) was entitled "Vaccine adverse events: causal or coincidental?" Horton Stmt. at ¶ 15 (Ex. 101).

Horton explained that publication of such case series containing perhaps controversial hypotheses was essential to the scientific process:

> [O]ur view at the time of publication of the 1998 paper, informed by the advice of our peer reviewers, was that the paper contained important new information that would be of interest to a general medical readership. It is unexceptional to publish a case series in this way and to include speculations on the cause of the syndrome or symptoms described. These kinds of responses may be used to construct hypotheses that require further study. Examples include the first reports of HIV and new variant CJD. This method is routine for developing hypotheses.

Horton Stmt. at ¶ 19 (Ex. 101). Regarding the temporal association between MMR and the onset of regressive autism reported by the parents, Horton explained:

> The testimony of parents about the potential events leading up to their child's illness is an important part of the process towards understanding a new syndrome or disease. I did not consider it wise for The Lancet to suppress or censor this information in this particular case. The issue was how to handle the information, i.e., by emphasizing that no causal link was established, by labeling the study as preliminary, and by commissioning a commentary to place the work in context.

Horton Stmt. at ¶ 21 (Ex. 101).

Dr. Horton received a letter headed "Vaccine adverse events: litigation bias might exist," from Dr. A. Rouse, Department of Public Health Medicine (Rouse letter), which was written on Tuesday, March 4, 1998, citing extracts from a Dawbarns Fact Sheet dated May 15, 1997, last updated July 16, 1997:

[in extra large type]
Vaccine adverse events: Litigation bias might exist

[return to normal type]
In their commentary on Wakefield's paper, Chen and DeSteffano ask: "Was there recall bias?" I suspect this might be. After reading Wakefield's article I performed a simple internet search and quickly discovered the existence of the society for The Austically Handicapped. Extracts from this fact sheet are produced below.

[following material contained in large box in center of page]

Extracts from a 48 page Vaccines FACT SHEET
prepared by Dawbarns for Society for
the Autistically Handicapped

* Inflammatory Bowel Disease. We are working with Dr Andrew Wakefield of the Royal Free Hospital London. He is investigating this condition. [Page 27]

* Inflammatory Bowel Disease and Autism. If your child has developed persistent stomach problems (including pains, constipation or diarrhea) following the vaccination, ask us for a factsheet from Dr. Wakefield. [Page 44]

* If you believe your child has been damaged: we propose to seek proper compensation in the courts, … we will also help with applications to the Vaccine Damage Tribunal. [Page 47 – 48]

Obtained from
http://www.mplc.co.uk/eduweb/sites/autism/index.html.

[end material contained in large box]

It would appear likely therefore, that some of the children investigated by Wakefield came to his attention because of the activities of the

> Society. Information gained from parents referred in this way would undoubtedly suffer from recall bias. It is a pity that Wakefield does not identify the manner in which the 12 children he investigated (e.g. Referral from local GP's, self, secondary, tertiary or international referral). Furthermore, if some of the children were referred (directly or indirectly) because of the Societies [sic] activities it is unfortunate that Wakefield did not declare his interest in the Society.

Ex. 15 (emphasis added). This letter was date-stamped at the Lancet March 9, 1998, yet it was not faxed to Dr. Wakefield until April 2, 1998.

Horton finally published Rouse's letter on May 2 but deliberately deleted the large-type reference in the title to "litigation bias" and all the material in the highlighted box in the middle of Rouse's letter that explicitly recounted Wakefield's participation with Dawbarns and his investigation of the condition for purposes of litigation. Ex. 16 (second page).

Horton's knowledge of the MMR litigation and Wakefield's involvement in it was concealed either to cover up Horton's foreknowledge of these facts prior to publication, from the complaints about Dawbarns' use of Lancet material in this Fact Sheet and Dawbarns' response and appeal to the Lancet Ombudsman seeking permission, or because participation in litigation was unremarkable, immaterial, and unimportant at the time.

An edited version of Dr. Rouse's March 4 letter was published in The Lancet on May 2, 1998, along with a response to the original unedited letter from Dr. Wakefield:

> A Rouse suggests that litigation bias might exist by virtue of information that he has downloaded from the internet from the Society for the Autistically Handicapped. Only one author (AJW) has agreed to help evaluate a small number of these children on behalf of the Legal Aid Board. These children have all been seen expressly on the basis that they were referred through the normal channels (e.g. from GP, child psychiatrist or community pediatrician) on the merits of their symptoms. AJW has never heard of the Society for the Autistically Handicapped and no fact sheet has been provided for them to distribute to interested parties. The only fact sheet that we have produced is for GPs which describes the background and

> protocol for investigation of children with autism and gastrointestinal symptoms. Finally, all those children referred to us (including the 53 who have been investigated already, and those on the waiting list that extended into 1999) have come through the formal channels described above. No conflict of interest exists.

Ex. 16 (second page).

The Royal Free's role in the MMR litigation was unremarkable as a disclosable interest. None of the LAB funding was used for the clinical observations reported in the Lancet Case Series; hence no disclosure was required under the then-applicable Lancet guidelines. The LAB funding was well known to senior officials at the Royal Free, Wakefield's colleagues, the Department of Health, the British Medical Association, and it had long since been publicly reported in the media. For example:

> William [a child pictured in the article] is one of 10 children taking part n a pilot study at the Royal Free Hospital in London, which is investigating possible links between the measles vaccine and the bowel disorder Crohn's Disease, and with autism. The study is being organized by Norfolk solicitors Dawbarns, one of two firms awarded a contract by the Legal Aid Board in 1994to coordinate claims resulting from the MMR vaccine.

"A Shot in the Dark: the complications from vaccine damage seem to multiply in the courtroom," The Independent (November 11, 1996) at p. 25. Ex. 17. Hence, revelation of participation in litigation would not have been viewed by the scientists and doctors at the Royal Free, including Wakefield, as in any way embarrassing (which was the then-applicable Lancet standard triggering a disclosure obligation).

Horton knew that Dr. Wakefield's reference to the MMR litigation referred to his involvement during the period before, not after, publication of the Lancet Case Series because he had been specifically advised (by references to and material quoted from the Fact Sheet) of Dr. Wakefield's participation in the March, 1997 letters from Dr. Edwards and Richard Barr, and in the March 3, 1998 letter from Dr. Rouse.

The extensive controversy surrounding publication of the Lancet Case Series

demanded the Lancet editor's closest attention to all matters arising out of publication including letters submitted in response for publication (such as the Rouse letter). For whatever reason, in 1998 Horton concealed his knowledge (from at least two different sources, the Rouse letter and the copyright correspondence) of Wakefield's participation in the MMR litigation prior to publication of the Lancet Case Series. He would make false statements and give false testimony categorically denying such knowledge in 2004, in his public statements, and again during his live testimony at the FTP hearing. Horton's denials had the effect of transferring his role and responsibility for publication of what he knew to be a potentially controversial Lancet Case Series to Wakefield's supposed concealment.

Dr. Horton's False Denials of His Knowledge of Wakefield's Participation in MMR Litigation.

Dr. Horton published an editorial on March 6, 2004, recognizing the scientific importance of a connection between autism and bowel disease:

> The reason that today's retraction [Ex. 23] is partial and not total is that the discovery of a possible link between bowel disease and autism is a serious scientific idea, as recognized by the MRC [Medical Research Council], and one that deserves further investigation. Although dismissing the entire 1998 Lancet paper as poor science gives a clear and correct message to the public about the status of any claim regarding the safety of MMR, in scientific and clinical terms it is both wrong and damaging. The autism-bowel disease link was considered part of a series of physiological observations judged by the MRC to be 'interesting and in principle worth investigating.' Subsequent research has yielded conflicting findings. This work should be supported. A forum to raise new and sometimes unpopular thinking, even on the basis of what at first might appear flimsy evidence, is important – and often vitally so for clinical, medicine and public health. How we discuss this new thinking then becomes a central question to answer, not whether we should publish it or not.

Horton Stmt. at ¶ 20 (Ex. 101).

Horton claimed he was unaware of Wakefield's participation in the MMR litigation prior to publication:

I understood this to mean, and particularly from the tense used ("has agreed"), that funding from the Legal Aid Board post-dated the publication of the paper. This was particularly the case because Dr. Wakefield was adamant that no conflict of interest existed.

Horton Stmt. at ¶ 18 (Ex. 101).

Horton amplified his false claim of ignorance at the FTP hearing:

Smith: [Beginning discussion of the Brian Deer meeting on 2/18/04] Was that the first you heard of there being an issue?

Horton: That is right. That was the first time that I was made aware of the connection, both with the Legal Aid Board and the specific funding of the work that was reported in The Lancet.

Horton Tr. 17-14D.

Smith: [After reading a portion of Wakefield's May 2 response to Rouse's March 2 letter] . . . When you read that letter, what did you understand Dr Wakefield to mean when he said one author has agreed to help evaluate a small number of these children on behalf of the Legal Aid Board?

Horton: When I read that letter two statements stood out: first, the assertion that you concluded that paragraph with, "no conflict of interest exists". At the time, in May 1998, I had no reason, no evidence before me, to suggest that that was an untrue statement so I took that statement on trust. With respect to the sentence that you ask about specifically, "has agreed to help evaluate", I must admit I read that as something that happened after publication. To my knowledge in February 1998 and during the peer review process going back into 1997, I was completely unaware of any potential litigation surrounding the MMR vaccine. I was not aware of the involvement of a firm of solicitors Dawbarns. I certainly was not aware of any activity going on with the Society for the Autistically Handicapped prior to the 1998 paper. I was not aware of any other (?does it say other?) relationship between Dr Wakefield and Dawbarns and Richard

Barr. When I read those statements I saw this as something that was triggered by the paper rather than the paper being in some senses a culmination of events up to February 1998.

Smith: Looking at the wording of the sentence you referred to "only one author that agreed to evaluate a small number of these children on behalf of the Legal Aid Board", you say you took that to mean since the publication of the paper and we are now some three or four months on from publication of the paper.

Horton: Yes.

Smith: Was there anything in particular about that wording which led you to think that?

Horton: It is the "has agreed." I know these are fine distinctions. If it had said "had agreed" then I would have thought that was more in the past tense. Reading "has agreed" in combination with the firm assertion that no conflict of interest exists, my suspicions were not raised at that time.

Smith: Did you accept that letter on its face value?

Horton: We certainly did, yes.

Horton Tr. 17-4B. Horton's testimony that he was unaware of Wakefield's participation in the MMR litigation prior to publication was false.

Horton's reliance on the tense in Wakefield's May 2 letter ("has agreed") is untenable in light of the sentence that follows ("These children have all been seen expressly on the basis that they were referred through the normal channels . . .."). "These children" clearly refers to the Lancet Case Series children some of whom form the "small number" that Wakefield has "agreed to help evaluate on behalf of the Legal Aid Board." By the date of the Lancet Case Series publication, February 28, they must by definition have been admitted and evaluated clinically. It is thus impossible that Wakefield's agreement to help evaluate them post-dated the publication of the Case Series. The correct English usage of "has agreed," not Horton's post hoc strained construction, was sufficient factually accurate information provided by Wakefield regarding the timing of his participation in

MMR litigation, i.e. prior to publication of the Case Series, to alert Horton had he, in fact, had the slightest concern or doubt over the timing issue.

Critically, Horton could not have reasonably believed that the working relationship between Wakefield and Dawbarns/Legal Aid Board developed after the publication in February of the Lancet Case Series because (1) he had known one year prior to publication and during the process of reviewing the manuscript from the March, 1997 letters from Dr. Edwards and Richard Barr of the Fact Sheet discussing the Dawbarns-Wakefield relationship; and (2) the March 4, 1998 Rouse letter to Horton highlighting the Wakefield-Dawbarns relationship (from the July, 1997 Fact Sheet) in a black box was written only two working days after publication of the Lancet Case Series. It is inconceivable that in this very short timeframe (i) Wakefield could have agreed to work with Richard Barr, (ii) Wakefield could have provided Richard Barr with the background discussed in the Fact Sheet, (iii) Richard Barr could have written and amended his own Fact Sheet (dated seven months prior to publication) explaining that "we are working with Dr Wakefield" (emphasis added), and (iv) the Society for the Autistically Handicapped obtained a copy of the Fact Sheet and uploaded it to their website. The contents and timing of the original letter from Rouse, and especially the careful deletion of the Wakefield-Dawbarns references from the published version of the rouse letter, that Horton's testimony regarding when he "first learned" of the of the Wakefield-Dawbarns relationship and the basis for his belief that the relationship post-dated publication of the Lancet Case Series is false and misleading.

Dr Wakefield's letter responded (among other issues) to allegations of "litigation bias," the legend on Dr. Rouse's letter. The legend "litigation bias" was deleted from the version of Dr. Rouse's letter published in The Lancet on May 2.

Pressure Mounts on Horton to Find a Scapegoat for His Publication of the Lancet Case Series.

Dr. Horton claimed that he was soundly criticized for publication of the Lancet Case Series, not because of the actual clinical findings reported, but more because it raised questions, appropriate or not, over the safety of MMR. Horton, Second Opinion: Doctors, Diseases, and Decisions in Modern Medicine (2003). For example, he says he was telephoned by the former president of the UK Academy of Medical Sciences "in a fury about the publication of a paper that raised questions about MMR." He describes how he was asked at a dinner party

whether he would ever be forgiven for this publication and its effects. He complains of "highly personal" attacks on him "unusual in scientific debate."

Horton falsely claimed that Wakefield's recommendation that single vaccines could be used as an alternative until the issue had been resolved scientifically was "for all practical purposes a recommendation to parents not to have their children vaccinated at all since the components were not available separately in the U.K.!" Horton, MMR: Science and Fiction , pp. 24 (2004). The individual monovalent vaccines were licensed and available at the time of the 1998 press conference and were only made unavailable, despite soaring public demand, by the intervening action of the government in September, 1998, to cancel the import license.

Horton falsely claimed that Wakefield has published extensively about the risks of MMR and measles infection since 1998 but that others have "convincingly refuted any association between the vaccine and autism in large studies across different populations. . . . Not one person or group has confirmed the original findings in the Lancet paper." In fact, the occurrence of bowel disease in children with regressive autism and an association with MMR has been confirmed.

The "retraction of an interpretation" published by some of the original Lancet Case Series authors specifically reaffirming their original findings of an "unexpected intestinal lesion" in autistic children, noted that "[f]urther evidence has been forthcoming from the Royal Free . . . and other groups to support and extend these findings." Ex. 23.

The U.S. Institute of Medicine concluded in its review of the literature that it could not reject a vaccine-autism link in a genetically susceptible sub-population: "Determining causality with population-based methods such as epidemiological analyses requires either a well-defined at-risk population or a large effect in the general population. Absent biomarkers, well-defined risk factors, or large effect sizes, the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or very unusual circumstances. However, there is currently no evidence to support this hypothesis either." Institute of Medicine, Vaccines and Autism at 11 (2004).

The scientific literature contains some 300 studies that address various aspects of an association between autism and vaccines, but only five address the three major aspects of the Wakefield hypothesis: MMR exposure, regressive

autism, and GI symptoms. Although all five studies have methodological flaws, four present data which confirm elements of the original Wakefield hypothesis. Kawashima, et al found vaccine-strain measles in peripheral blood cells of some autistics with chronic intestinal inflammation but not in healthy controls. "Detection and sequencing of measles virus from peripheral mononuclear cells from patients with inflammatory bowel disease and autism," Dig. Dis. Sci., 2000 Apr;45(4):723-9. Uhlmann, et al. found persistent vaccine-strain measles in the intestines of 82% of autistic children with gut pathology vs. 7% of controls using PCR technology. "Potential viral pathogenic mechanism for new variant inflammatory bowel disease,." Mol. Pathol. 2002. 55:(2): 84-90. Richler, et al. found a clear association between regressive autistics and GI symptoms and an association between age of MMR vaccination and autism risk. "Is there a 'regressive phenotype' of Autism Spectrum Disorder associated with the measles-mumps-rubella vaccine? A CPEA Study." J Autism. Dev. Disord. (2006) **36**(3): 299-316. The latter finding was also made by members of the CDC researchers in their own study. DeStefano F, Bhasin TK, et al., "Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta" Pediatrics 2004, 113:259-266. The remaining two arguably relevant studies had such serious design and methodological flaws that their results are inconclusive. Further support for an MMR-autism association can be found in the work of Drs. Singh, et al. ("Elevated levels of measles antibodies in children with autism," *Pediatric Neurology*, 2003;28:292-294) and Bradsteeet, et al. ("Detection of Measles Virus Genomic RNA in Cerebrospinal Fluid of Children with Regressive Autism: a Report of Three Cases,"J. Am. Phys. and Surgs., 2004: 9(2): 38-45.).

The most recent arguably relevant study (Hornig M, Briese T et al. "Lack of an association between measles virus vaccine and autism with enteropathy: a case control study." *PLOS-1*. 2008; 3: e3140) only examined five autistics who regressed and developed GI pathology following MMR, finding vaccine-strain measles in one case and one control, but the biopsies were taken long after the last exposure to vaccine measles. That study nevertheless did confirm the ability of PCR technology to accurately detect vaccine-strain measles and the ability of multiple labs (including the Unigenetics lab that originally tested the samples reported in 2002) to accurately and consistently detect vaccine measles in biopsies and in positive and negative controls. The data do not support CDC's claim that the study proves no association between MMR and autism. Only 5 cases developed autism and GI pathology after MMR and the lack of vaccine viral persistence long after MMR is not a necessary part of any hypothesis linking

vaccines to autism. By comparison, it would obviously ridiculous to claim that smoking does not cause lung cancer based on cases of lung cancer in non-smokers and/or cases where asbestos is the known carcinogen. Moreover, the study confirms the appropriateness of the kind of investigation for which Drs. Wakefield, Walker-Smith and Murch are presently on trial at FTP hearing. Not only is this hearing a terrible injustice to the doctors - irrespective of whether the hypothesis is correct or not - but it has effectively infringed the rights of autistic children in the US and UK who are now widely being denied appropriate medical care and the benefits of research that would find the cause (leading to prevention) and treatments for their autism.

Numerous independent researchers have also confirmed the behavioral-bowel disease association, autistic enterocolitis. Gonzalez, L. et al., "Endoscopic and Histological Characteristics of the Digestive Mucosa in Autistic Children with Gastro-Intestinal Symptoms," Arch Venez Pueric Pediatr, 2005;69:19-25; Balzola, F., et al., "Panenteric IBD-like disease in a patient with regressive autism shown for the first time by wireless capsule enteroscopy: Another piece in the jig-saw of the gut-brain syndrome?" American Journal of Gastroenterology, 2005. 100(4): p. 979- 981; Balzola F et al., "Autistic enterocolitis: confirmation of a new inflammatory bowel disease in an Italian cohort of patients," Gastroenterology 2005;128(Suppl. 2);A-303; Galiatsatos P et al., "Autistic enterocolitis : fact or fiction?" Canadian Journal of Gastroenterology. 2009;23:95-98.

The most recent relevant study reported an increased prevalence for bowel disease in children with ASD and that "genetic vulnerability and gene-environment interactions contribute to ASD risk." Campbell, D., et al., "Distinct Genetic Risk Based on Association of *MET* in Families With Co-occurring Autism and Gastrointestinal Conditions," Pediatrics, 2009 Mar;123(3):1018-24.

Horton thus cannot reasonably claim that nobody has confirmed the "findings" in the Lancet Case Series.

At least as of 2003, Horton stood by his decision to publish the Lancet Case Series since progress in medicine depends on the "free expression of new ideas," and in science it was only this commitment to free expression which "shook free the tight grip of religion on the way humans understood their world." Wakefield's work, Horton says, has opened up an important new field of science--the relationship between the brain and the intestine in the aetiology of autism.

A meeting was held on February 18, 2004 at The Lancet offices in which Sunday Times journalist, Brian Deer, accompanied by Liberal-Democrat MP Dr Evan Harris, made accusations against Dr Wakefield and colleagues. Horton met with Drs. Wakefield, Professor Simon Murch, and Professor John Walker-Smith later that day to discuss Deer's allegations. Dr. Wakefield explained that the funding from the Legal Aid Board was for a separate study relating to potential MMR litigation, that the funding was not even available at the time the children reported in the paper were seen and evaluated, and that no funding from the Legal Aid Board or from lawyers was used for the case series reported in the Lancet Case Series. The Lancet issued a press release on February 20 "which concluded that the majority of Mr. Deer's allegations were not borne out by the facts as far as we could judge them." Horton Stmt. at ¶ 29.

Horton made the following statement in a press release:

> Such a disclosure would have provided important information to editors and peer reviewers about the context in which this work was taking place – a context that would have been vital in making a final decision about publication. . . . Finally, although the Legal Aid Board funding referred to a different aspect of Dr. Wakefield's work from that reported in The Lancet, the perception of a conflict interest nonetheless remains. This funding source should, we judge, have been disclosed to the editors of the journal.

Horton Stmt. at ¶ 30 (Ex. 101). "In my view, the mere fact that Dr. Wakefield had a dual commitment – namely, as an independent investigator on the 1998 paper and as a consultant to a Legal Aid Board review of the evidence supposedly linking the MMR vaccine to autism – should have been enough to trigger his disclosure to us. . . . It was the existence of this association that, in my view, constituted his dual commitment and his conflict of interest." Id. Horton continued: "We went on to say that we thought that the information would have been material to our decision making about the paper's suitability, credibility, and validity for publication." Id. at ¶ 31. In his March 6, 2004 editorial, Horton again referenced the supposed materiality of the MMR litigation: "It seems obvious now that had we appreciated the full context in which the work reported in the 1998 Lancet paper by Wakefield and colleagues was done, publication would not have taken place in the way that it did." Id. at ¶ 33. In a BBC interview broadcast February 20, Horton said: "In my view, if we had known the conflict of interest Dr Wakefield had in this work I think that would have strongly affected the peer

reviewers about the credibility of this work and in my judgment it would have been rejected."

The press release and Horton's BBC statement and testimony were false because he failed to disclose his own prior knowledge, on two separate occasions (February-July, 1997 and March, 1998), of Dr. Wakefield's specific participation in the MMR litigation. If it had been material to the review of the Lancet Case Series, Horton had every opportunity to advise the editors and peer reviewers, to discuss the matter contemporaneously with Dr. Wakefield, or to address the matter publicly in the pages of the Lancet in connection with Dr. Rouse's allegation in March, 1998 and Dr. Wakefield's response in May.

Dr. Horton reiterated in another press interview: "If we knew then what we know now we certainly would not have published that part of the paper related to MMR, although I do believe there was and remains validity in the connection between bowel disease and autism."

On February 22, 2004, the Sunday Times suddenly, after six years, published Brian Deer's allegation that Dr Wakefield's supposedly "hidden" conflicts of interest resulted in the Lancet Case Series being compromised.

The Lancet published statements online on February 20, and then in print on March 6, 2004, from Dr. Andrew Wakefield (Ex. 18), the Royal Free (Ex. 18, second page), Professor Simon Murch (Ex. 19), and Professor John Walker-Smith (Ex. 20) giving their detailed explanations of events that surrounded publication of the Lancet Case Series in 1998. That issue also contained a personal editorial from Horton on "The Lessons of MMR" (Ex. 21) and the Lancet's Statement evaluating (Ex. 22) the allegations:

> We regret that aspects of funding for parallel and related work and the existence of ongoing litigation that had been known during clinical evaluation of the children reported in the 1998 Lancet paper were not disclosed to editors.
>
> We also regret that the overlap between children in The Lancet paper and in the Legal Aid Board funded pilot project was not revealed to us. We judge that all this information would have been material to our decision making about the paper's suitability, credibility, and validity for publication.

Ex. 22. The Lancet statement went on to cite the Committee on Publication Ethics' guidelines for sanctions and concluded:

> Given the public health importance of MMR vaccination, together with the public interest in this issue, we have decided to pursue a course of full disclosure and transparency concerning these allegations, the authors' responses, the institution's judgment, and our evaluation.

Ex. 22.

Horton's personal statement in the Lancet (Ex. 23, emphasis added) claimed "Today's retraction [of an interpretation} comes after debate following the release of new information two weeks ago about the circumstances surrounding the publication of this work." The supposed "conflict of interest" issue was NOT "new information" to Horton. Horton concealed his own knowledge of Wakefield's involvement with MMR litigation six years earlier prior to publication of the Lancet Case Series to wrongly shift the blame for disclosure to Wakefield and to wrongly exonerate himself of responsibility for publication of the Paper. Horton has repeatedly claimed that he would not have published the paper had he known of Wakefield's involvement with Dawbarns and potential MMR litigation.

By his own account, Horton played a dual role as de facto Complainant and later witness in the GMC investigation. As he explained in his book MMR: Science and Fiction:

> The GMC seemed nonplussed by Reid's (the then Health Secretary) intervention urging the GMC to investigate Wakefield as a matter of urgency. In truth they had not a clue where to begin. At a dinner I attended on 23 February 2004, one medical regulator and I discussed the Wakefield case. He seemed unsure of how the Council could play a useful part in resolving any confusion. As we talked over coffee while the other dinner guests were departing, he scribbled down some possible lines of investigation and passed me his card, suggesting that I contact him directly if anything else came to mind. He seemed keen to pursue Wakefield, especially given ministerial interest. Here was professionally led regulation of doctors in action - notes exchanged over liqueurs in a beautifully wood-paneled room of one of medicine's

most venerable institutions.

Horton, MMR: Science and Fiction , pp. 7-8 (2004).

Dr. Horton has given conflicting accounts about the purpose of the Legal Aid Board research grant awarded to Dr. Wakefield. Brian Deer alleged during the meeting at the Lancet on the morning of February `18, 2004, that the Lancet Case Series was funded by the Legal Board and therefore that Dr. Wakefield had failed to disclose this funding source, which, if true, would have been an actual conflict of interest under the then-applicable disclosure rules at the Lancet. Dr. Wakefield was easily able to refute that allegation during his (and colleagues) meeting with Dr. Horton later that same day by explaining that the Legal Aid Board funding related to an as yet unpublished virology study while the Lancet Case Series was funded from the Royal Free and NHS.

Based upon this explanation, Dr. Horton immediately retreated from any of an actual conflict to a claim of a possible perceived conflict of interest. This led in turn to a heated debate because the then-applicable Lancet disclosure guidelines only applied to actual sources of funding, not perceived conflicts.

Dr. Horton would later write in his book that he was aware at the outset from Brian Deer of "two quite separate studies," and that his objection based upon a perceived conflict was consistent and unchanged:

> Deer also provided us with evidence suggesting that Wakefield was conducting <u>two quite separate studies [emphasis added]</u> at the time of publication of his 1998 article. One study included the work that we published in the Lancet. The other investigation was a Legal Aid Board funded pilot project, agreed between the Board and Wakefield in 1996.

MMR: Science and Fiction, p. 4 (2004). He concealed the truth that it was Dr. Wakefield, not Brian Deer, who had informed him on February 18, 2004, of the work, separate from the Lancet Case Series, funded in part by the LAB. By blurring the crucial distinction between actual and perceived conflicts, Horton was thus able to make it appear to his readers that he had a reasonable basis for believing that Dr. Wakefield had failed to make a required disclosure.

Dr. Horton changed his account of this issue in his GMC testimony,

admitting that Deer's allegation was that the Lancet Case Series was funded by the LAB:

> Smith: Were allegations – I will deal with them all because you set them out very clearly in *The Lancet* – did they include allegations in relation to funding issues?
>
> Horton: Yes, they did.
>
> Smith: Was that the first you heard of there being an issue?
>
> Horton: That is right. That was the first time that I was made aware of the connection, both with the Legal Aid Board and the specific funding of the **work** that was reported in *The Lancet*.
>
> Smith: How did you handle it, Dr Horton, obviously you listened to what they had to say. What did you do thereafter?
>
> Horton: Well the presentation by Brian Deer took the form of him standing up before a group of editors and laying out a series of allegations, not just relating to the Legal Aid Board funding of the work but also including the way the **work** had been handled by the ethics committee at the Royal Free Hospital – two specific allegations, one, that the work had not actually received ethics committee approval and, second, the approval that was given for a piece of work was in some sense a fabrication that the work that took place and was reported in *The Lancet* was done under cover of another ethics committee approval process for an entirely different piece of work which was an extra ordinary serious allegation.

Horton Tr. 17-14D. The "work" to which Horton refers is the Lancet Case Series and not the LAB-funded virology study disclosed by Wakefield to Horton (and not by Deer). Had Horton been truthful about this "conflicts" issue during the GMC investigation, i.e. that Wakefield had, at most, a "perceived" conflict (not a violation of the applicable Lancet guidelines), GMC would not have been able to charge Wakefield with an undisclosed "actual" conflict with respect to the LAB funding.

Dr. Horton provided a supplemental statement (Ex. 102) that addresses some

of the above allegations. Horton indicates that he personally handled in 1997 the claim that Dawbarns infringed the Lancet's copyright: "I reiterated the refusal [Dawbarns] had already received from those responsible for granting permissions at The Lancet." Horton Supl. Stmt. ¶ 4. It is difficult therefore to accept his denial that he did not read the Dawbarns Fact Sheet (which discussed Dr. Wakefield's involvement in the litigation) since he personally would have had to examine the alleged infringing document before deciding whether to grant or deny the requested permission. His denial is limited "to the best of my recollection." Id. ¶ 5. His denial of Dr. Wakefield's involvement in litigation is limited to the Legal Aid Board as the specific source of funds and to the exchange with Dawbarns regarding the copyright issue, and is not a general denial. Dr. Wakefield's participation was reported in the press and was well known to Dr. Zuckerman and others at the Royal Free, Dr. Armstrong at the BMA, and various officials at the Department of Health well before 1997. Dr. Wakefield was well-known to Dr. Horton, having published several of his articles in The Lancet and the MMR litigation was a matter of great public interest. It strains credulity to imagine that these matters escaped Dr. Horton's attention in 1997. His Supplemental Statement does not obviate the need for a thorough investigation.

Regarding knowledge of the MMR litigation from the Fact Sheet excerpts provided by Dr. Rouse in his March 3, 1998 letter, Horton claims that Dr. Rouse's and Dr. Wakefield's letters, published May 2, "were reviewed and edited for publication by the letters editor" and that "I would have seen both letters as edited proofs prior to publication." Id. ¶ 6. Horton does not deny in this carefully worded "explanation" that he had seen the original unedited Rouse letter or any involvement he may have had in the key deletions. As above, the many unanswered questions require further investigation.

Count II
Richard Horton
Censorship of Material Critical of Vaccine Safety

Horton published the Lancet Case Series knowing that an association between the new syndrome and MMR was a controversial topic. To avoid any risk of misinterpretation, Horton implemented a number of safeguards, including a companion commentary by Drs. Chen and DeSteffano explaining the difference between coincidence and causation. He explained that publication of potentially controversial material was one of the most valued missions at the Lancet. He was

especially sensitive to the risk of inappropriate censorship because of recent events in the UK:

> Horton: It would, with hindsight, have been easy to have taken that aspect of the paper out and just simply reported the syndrome with no parental testimony added, and we discussed this actually in our manuscript meetings: should we ask the authors to remove this part of the paper because it could be misinterpreted. We felt at the time that we had two views about this. The first view was, in the wake of the debate about BSE and Variant CJD, the Chief Medical Officer, Donald Acheson, had been criticized for not disclosing information that he had privately to the public. We thought, here we are in a situation where we have given information, it is admittedly weak from a causal point of view but, nevertheless, it is information that pointed to some possible clue that might require further investigation. Should we censor that or allow it to be published with appropriate caveats and caution? Our view was that it should be published.
>
> Coonan: I am grateful for that. All that comes down to is that, after proper and mature assessment, the decision by The Lancet to publish the paper in the form in which we see it, was a responsible and, as you thought it, informed basis for publication?
>
> Horton: That was my feeling at the time, yes.

Horton Tr. 17-41B.

> On February 20, 2004, Horton stated to the BBC:
>
> In my view, if we had known the conflict of interest Dr Wakefield had in this work I think that would have strongly affected the peer reviewers about the credibility of this work and in my judgment it would have been rejected.

In his March 6, 2004 editorial "The lessons of MMR" (Ex. 21), Horton restated his claim that the Lancet Case Series would not have been published had he known of Wakefield's participation in the MMR litigation:

> It seems obvious now that had we appreciated the full context in which the

work reported in the 1998 Lancet paper by Wakefield and colleagues was done, publication would not have taken place in the way that it did.

Horton Stmt. at ¶ 33 (Ex. 101).

Horton continued his hostility to publishing anything that might question vaccine safety in an interview he gave to the Guardian in April, 2006:

> It's hard to imagine that anything useful could still be written about the MMR vaccine. Too much has probably been said already, most of it either willful nonsense or wild speculation. So I hesitate. And especially because it was I who was responsible for publishing -- to the eternal damnation of many of my medical and public-health colleagues -- Andrew Wakefield's 1998 paper that fuelled a smoldering underground movement against the vaccine. A campaign that we now know was partly linked to efforts to win a legal claim against vaccine manufacturers.

Horton reiterated his censorship policy at the FTP hearing:

> Smith: Had [Wakefield's involvement with Dawbarns] been disclosed to you, had you known, how would you have handled it? Would it simply have been a matter of discussion or might it have affected your view of the paper generally? How would you have handled it?
>
> Horton: It is very difficult going back to 1997/1998 to try and guess how one would have handled it. I have thought about this long and hard. The first answer would be to say it would have been a material piece of information to influence our decision about whether to publish the work or not. That is not quite enough. When I think back to other papers that we considered, and either pursued or rejected on the basis of conflict of interest disclosures, I am sure that in a discussion with my colleagues as editors that information would have led to rejection of the paper.

Horton Tr. 17/17G.

Horton's policy of censoring material critical of vaccine safety has

compromised the integrity and independence of his position as Editor. He controls one of the most important forums for biomedical publishing in the UK. His public statements that the Paper should not have been published, even with additional disclosures, sends a powerful and chilling message directed squarely at research raising concerns about vaccine safety. Since research doesn't "count" in policy and professional circles until it is published, this policy of censorship has the effect of stifling the conduct of research itself.

Furthermore, Horton has improperly demeaned the reputation of both scientists (who would choose to work on vaccine safety) and lawyers (who would choose to represent sick children in service of their fundamental right to have their day in court).

Horton's stated policy of not publishing science critical of vaccine safety, i.e. that might support a litigation remedy for vaccine-injured children, is especially troubling in light of conflict of interest undisclosed in The Lancet. Horton's boss, Sir Crispin Davis, CEO since 1999 of Reed Elsevier, the publishing company that owns The Lancet, was appointed to the Board of MMR defendant Glaxo SmithKline in July, 2003, shortly before he denounced Wakefield for supposedly misleading him into publication of the Lancet Case Series. Sir Nigel Davis, the High Court judge who rejected an appeal by families with injured children for continued litigation funding on February 27, 2004, just seven days after the Horton allegations against Wakefield, was the younger brother of Horton's boss, Sir Crispen Davis.

Horton's policy that research relating to potential claims in litigation would not be published in the Lancet is not required by science publication industry ethical standards. Indeed, other studies funded by the Legal Aid Board have gained access to journals. See Altman, P., et al, "Camelford water incident aluminium sulphate: retrospective study of the exposed to drinking water contaminated with Disturbance of cerebral function in people," BMJ, 1999;319;807-811. This paper contained the legend: "The studies were commissioned by lawyers acting on behalf of the plaintiffs and funded through Legal Aid. Competing interests: None declared."

The extremist nature of Horton's censorship is further illustrated by another witness presented by the Prosecution, Sir Michael Rutter. Rutter claimed that Wakefield's involvement in MMR litigation was a serious conflict of interest that undermined the scientific validity of the Lancet Case Series. Yet he co-authored a

paper supporting the safety of MMR without disclosing (despite his membership on the editorial board) his own involvement in MMR litigation as an industry expert. Honda, H., Shimizu, Y., Rutter, M., "No effect of MMR withdrawal on the incidence of autism: a total population study," J. Ch. Psycho. and Psych. 46:6 (2005), pp 572–579. Professor Rutter again failed to disclose his own "conflict of interest" in another article, while conceding a potential environmental trigger, claiming "there is no convincing evidence in support of this [MMR-autism] hypothesis." Rutter, M., "Incidence of autism spectrum disorders: Changes over time and their meaning," Acta Pædiatrica, 2005; 94: 2–15.

Even the "Retraction of an Interpretation" published by Horton on March 6, 2004, was intended by Horton to block further MMR safety research. The editorial accompanying the "retraction" explained:

> The original report made clear that the authors did not prove an association between measles, mumps and rubella vaccine in a newly described syndrome but the authors did raise the possibility of a link on the basis of parental and medical histories and they suggested that further investigations are needed to examine this syndrome and its possible relation to the vaccine. This interpretation of their data, together with a suggestion made by Wakefield during a separate press conference held at the Royal Free that there was a case for splitting the MMR into its component parts, triggered a collapse in confidence in the UK's MMR vaccination programme. It is the interpretation expressed about a connection between the vaccine and the new syndrome that is now being retracted. Today's retraction comes after debate following the release of new information two weeks ago about the circumstances surrounding the publication of this work. An enormous amount of effort has gone into reviewing and analyzing the events before and after publication in the 1998 article. It is now time to look forward.

Ex. 23. The editorial thus made clear that the "retraction" was not in any way of the clinical findings, but was motivated solely by Wakefield's participation in litigation. Horton said at the FTP hearing:

> In this particular case it was a little more complex because nobody was saying that these children did not exist, nobody was saying that they did not have the findings that were reported in the paper or that

> the parents' testimony was not indeed genuine. The specific concern was that the basis of the interpretation, that is to say that there was a potential environmental trigger, MMR vaccination, which should be taken seriously and which should be the basis for further investigation. It was that which, in our judgment, and the judgment of this group of authors, was invalidated by the disclosure of a conflict of interest.

Horton Tr. 17-34A. While scientific merit was sufficient to support the "interpretation" when the Paper was published in 1998, after thorough review and prophylaxis because of the MMR issue, the political discomfort of potential litigation somehow became sufficient to trump scientific merit by 2004. The focus of Horton's censorship was thus aimed directly at a safety issue "which should be taken seriously and which should be the basis for further investigation."

Count III
Dr. Arie Zuckerman
False Testimony; Misuse of Professional Position to Block Vaccine Safety Research

Dr. Arie Zuckerman became Dean of the Royal Free Medical School in 1998. He launched an aggressive program to heighten the prestige of the school, including holding press briefings to announce important, often controversial, research. He attempted to stop the research funded by the Legal Aid Board by interposing a false conflict of interest. He chaired the press briefing on February 26, 1998 to announce publication of the Lancet Case Series. He gave false testimony denying that he was aware that Dr Wakefield would, if asked his opinion during the press conference convened by Professor Zuckerman to discuss the Lancet Case Series, recommend the single (monovalent) vaccines in place of the combined (multivalent) MMR, and that he, Professor Zuckerman, had instructed Wakefield to publicly support the use of the single monovalent MMR components.

<u>Zuckerman Efforts to Block Vaccine Safety Research.</u>

Dr. Zuckerman was Dean of the Medical School associated with the Royal Free Hospital. He was advised by the Department of Health and by Professor Sir David Hull on the fall of 1996 that the Legal Aid Board desired to fund research relating to claims of injury against MMR manufacturers. Zuckerman Tr. 15-4E.

"But I refused to accept it due to the clear conflict of interest which I perceived." Zuckerman Stmt. ¶ 11 (Ex. 103); Zuckerman Tr. 15-6A, D.

Zuckerman sought to block Wakefield's research by interposing a false conflict of interest, the allegation of which Zuckerman never disclosed to Wakefield. Zuckerman wrote to Dr. Armstrong, Chairman of the Ethics Committee, British Medical Association (the UK's professional association for doctors), on October 11, 1996 marked "Strictly Private and Confidential":

> I should be grateful for your advice on a potentially difficult situation in which the Royal Free finds itself and on which therefore I must take a decision on the position adopted by the Medical School. A senior member of the School's clinical academic staff is engaged in work that has become somewhat controversial in that he is suggesting a causal link between the measles virus and in particular vaccination against measles and the onset of Crohn's disease and inflammatory bowel disorders. Arising from recent widespread publicity given to this research, the Legal Aid Board has provided funding through a firm of solicitors representing Crohn's disease sufferers and we have been asked to make an appointment to the staff of the Medical School specifically to undertake a pilot study of selected patients. Clearly this could lead to a case against the Government for damages.
>
> My dilemma is that the Medical School might be seen to utilize its resources which are largely funded from the public purse to take sides in litigation before there has been a finding. It is quite common of course for clinical academic staff to be called as expert witnesses in cases criminal and civil where they act as individuals although their reputation is clearly based in large measure upon their academic and professional appointments. This is however somewhat different to situation and I would find it helpful if you could let me know whether you have come across parallels elsewhere that might provide a precedent and also advise me on the ethical and legal position of the Medical School.

Ex. 24 (emphasis added).

Zuckerman wrote a "Strictly Confidential" letter on January 22, 1997, to Sir Kenneth Calman, Chief Medical Officer, stating that he and his colleagues

remained "very concerned about the unwelcome controversy surrounding the work on Crohn's disease which is carried out at this School by Dr Andrew Wakefield and his group." Ex. 25.

Zuckerman continued to press his case to block Wakefield's research to Armstrong in a subsequent letter:

> I suspect that the legal claim will be on the basis that measles vaccine and the combined MMR may cause Crohn's disease and inflammatory bowel disease and the safety of these preparations has not been established. Expert opinion and the advice of WHO and JCVI is that there is no confirmed evidence of an association with immunisation against measles (and rubella and mumps) and inflammatory bowel disease and that the epidemiological data are flawed.
>
> While I would not wish to attempt to balance the arguments for academic freedom and the public interest with respect to the protection of children against infection, the position of the medical school is difficult. Further I am deeply concerned by the unconventional funding of research work by interested lawyers acting on behalf of children with inflammatory bowel disease.

Ex. 26.

Wakefield wrote to Zuckerman on March 10, 1997, setting forth the ethical basis for conducting research funded by the Legal Aid Board:

> You mentioned a conflict of interest when we spoke. This is something which has exercised my mind greatly in the interim. I feel I must go on record as stating that I do not see how any conflict of interest exists. It is, as I am sure you would agree, our joint and several responsibilities as members of the medical profession to use our training and expertise appropriately. In the context of the current measles vaccine safety/consequences debate, I am providing independent expert guidance based on facts available to me. I do this in common with colleagues worldwide. The fair legal assessment of potential claims relies on high-caliber expert advice. The GMC and the Royal Colleges have long accepted this premise.

> In the particular circumstances with which I am dealing, there is, I believe, an even higher moral obligation to act as an expert adviser. We are faced with a situation where the most vulnerable category of patients, i.e. children, may be put at risk. It is right and proper therefore to review the faces, assess them, and offer guidance.
>
> I hope these comments are helpful. Please do feel free to contact me if you wish to discuss my role further.

Ex. 27. Zuckerman responded on March 13, but concealed his correspondence with BMJ and others from Dr. Wakefield:

> I do not think that there is any conflict between duty of care to patients or the provision of independent expert advice to lawyers. However, it is a different matter when lawyers fund a particular piece of research where a specific action is contemplated. This surely suggests that some preliminary legal discussions have taken place and that a specific action is contemplated. If so, then the interpretation must surely be that a conflict of interest may well exist. The School must, therefore, seek expert advice, but in the meantime you should know of my concern.

Ex. 28. This tortuous, tautological and spurious line of reasoning (i.e. funding compromises scientific integrity and independence) was not Zuckerman's true concern he had expressed to Armstrong, i.e. the possibility that the research might lead to suits against the government over unsafe vaccines (a concern made known to Zuckerman from the Department of Health via Sir David Hull). Moreover, the alleged conflict described by Zuckerman (which would be present in research funded by industry as well as by lawyers) is easily dealt with by disclosure in the relevant publication. The existence of such a "conflict" is *not* a reason to censor the science in the first place.

Zuckerman's reliance on "ethics" to stop research that might reveal safety concerns or aid plaintiffs in seeking appropriate compensation was rather disingenuous in light of his own financial ties to vaccines. He had his own personal reasons to support vaccine safety without question. In fact, Zuckerman had personal conflicts that interfered with his position as Dean. He held vaccine patents, he had been involved closely in clinical trials funded by the vaccine manufacturers, and had many colleagues in the inner circles of UK vaccine

promotion.

Wakefield replied to Zuckerman on March 24, enclosing the documents relating to the Legal Aid Board grant (proposal, letter from LAB, and protocol):

> I got the impression from Roy [Professor Pounder] that you were concerned that we were being contracted to provide a specific answer- that is that measles vaccine of the MMR vaccine was the cause of this disease. That is absolutely not the case. We are being funded to conduct a piece of scientific research to establish or refute the link between MMR vaccine and the disease. There are absolutely no preconditions concerning the outcome. If this were the case, you may rest assured I would have never been involved in the first instance. The science must lead and everything else follows. As with the medical expert's opinion elsewhere, I am being asked to provide my opinion, whether that opinion is positive or negative. It is on this basis, and only on this basis, that I have agreed to assist in this matter. I hope that his issue can be resolved as quickly as possible and my group is working to achieve this end.

Ex. 29. Zuckerman scrawled a handwritten note on his copy: "this does confirm my worst fears." Zuckerman Stmt. ¶ 19 (Ex. 103). In the end, Zuckerman refused to administer the LAB grant through the medical school. but when Dr. Wakefield said that the funds should be returned to the solicitors, Zuckerman agreed that the funds could be transferred to the Special Trustees, a charity within the Royal Free Hospital ((who regularly received and administered money from non-NHS sources), and in fact, signed the check that enabled the transfer. See Zuckerman Tr. 16-5D.

Armstrong finally replied to Zuckerman's on March 26, 1997, concluding categorically that no conflict existed and that the research should go forward. Armstrong identified the central ethical question as:

> whether the research project was scientifically sound and has been approved by an ethics committee….The question of whether health professionals may be involved in litigation was a matter to be borne in mind with regard to publication or use of data but should not determine whether the research itself is in a valid project.

Ex. 30. He pointed out the obvious ethical requirements that "there should be full and informed consent from the parents of children", and that "their confidential information should be protected." On the matter of research funded by the LAB the letter went on to state, quite bluntly, that it was:

> quite logical for the Legal Aid Board as a publicly funded body to fund research on relevant issues in law, using government money essentially to sue other government departments. Independently conducted research may establish whether or not they have case in law and is no different from commissioning a medical expert to provide a view". One question that had taxed Zuckerman - the funding of research where there was a "clear financial interest in the outcome" - was dealt with succinctly: Armstrong wrote, "funding of research by special interest groups is commonplace and as long as the findings or uses to which the data is put are not influenced by the wishes of the funders, this should not be problematic.

Id. As a final rejection of Zuckerman's political maneuvering and in particular, his attempt to put the government's interests above those of the damaged children, Armstrong concluded that:

> to delay or decline to conduct research which appears to be in the public interest on the grounds that it may embarrass the government or a particular health facility does not appear to be a sound moral argument.

Id.

Fortunately, Armstrong's letter derailed Zuckerman's plans for putting an end to scientific scrutiny of MMR vaccine at the Royal Free. Zuckerman kept this letter secret because it could have been used by Wakefield and others to endorse the ethical importance of undertaking vaccine safety research in general and with respect to MMR in particular.

Having lost the external effort to ban Wakefield's research on ethical grounds, Zuckerman reiterated on April 2, 1997, the same concerns to Professor Michael Pegg, Chairman of the Royal Free Ethics Committee, despite the fact that the BMA (the UK body advising the profession on medical ethics) had already comprehensively dealt with: "[t]he dilemma which the School faces is whether it is

ethical for lawyers to fund a particular piece of research where a specific action in law is contemplated rather than a scientifically-based research project". "Was it", Professor Zuckerman asked Dr Pegg "ethical for lawyers to fund research where a specific action in law was contemplated?" Zuckerman's creativity in re-representing the BMA's advice to suit his own purpose was evident as he continued: "It has been suggested that I explore with you whether the committee considered these issues." His letter ended reassuringly: "the Medical School does not question the scientific validity of the project, the independence of the research, the academic freedom of the staff and publication in learned scientific journals." Ex. 31. Zuckerman, a virologist and head of the Medical School had not questioned the scientific validity of the research project.

Zuckerman was proffering the ethical paradox of medical academia endorsing, indeed embracing, the conduct of clinical trails funded by the pharmaceutical industry with the vested priority of profit, but denouncing as something distasteful and prohibitively conflicted, the investigation of children who's lives may have been irreparably damaged by an inadequately tested vaccine, in pursuit of this profit. It is unethical for Zuckerman to permit virtually unrestricted access by industry to researchers and doctors in his dominion while at the same time trying to block access by lawyers.

Zuckerman misused his professional position in an attempt to block vaccine safety research that might, depending on the results, help vaccine-injured children win compensation by interposing a false and unjustified conflict of interest. He explained:

> . . . I considered very carefully that I have never come across a case where medical facts are actually going to be determined by lawyers, possibly in a court of law: that seemed to me extremely unusual and in fact unacceptable. I also felt that it seemed to me at the time most unusual that lawyers should even attempt to direct medical research. . . . It more or less appeared as if one was fishing for evidence. That is not the way one carries out clinical research, ...

Zuckerman Tr. 15-5G. He failed to recognize and respect the ethical obligation of medical researchers to honestly report results, including negative results, and the ethical obligation of lawyers to honestly present fact and opinion to any tribunal. He also failed to recognize or deliberately mischaracterized the fact that at no stage were lawyers going to direct medical research.

Zuckerman claimed that Wakefield should have disclosed the LAB funding in the Lancet Case Series, but that he "did not pick this up at the time." Zuckerman Stmt. 17 (Ex. 103). While couched in terms of opinion, Zuckerman's self-serving recollections stretch credulity beyond the point of candor. Zuckerman was fully aware at the time because of his control over the LAB funding that none of that money was used for the clinical findings reported in the Lancet Case Series. As a consequence of his actions, LAB funding was not even available until the fall of 1997, months after the manuscript had been submitted to the Lancet. Had the issue of an inadequate disclosure in the Lancet Case Series been true, important, or relevant at the time, there would have been no question that he would have raised an objection because of his ongoing personal involvement in trying to block the research, specifically on the so-called "conflict of interest" grounds.

Zuckerman supported the academic freedom of his staff in general, but not when research or media statements questioned vaccine safety. He personally authored a September 1, 1997 press release:

> As in all universities, academic staff at the Royal Free Hospital School of Medicine undertake lines of research in accordance with their interests and areas of expertise. The school encourages this. Work on vaccination and immunisation procedures is an area of inquiry in several departments.
>
> From time to time, staff may conduct research which has surprising or controversial findings. Staff are encouraged to submit the results of research for publication in the established medical journals, which subject them to a rigorous review by external experts.
>
> Until and unless the appropriate national and international authorities decide to review the policies relating to MMR immunisation, the Royal Free will continue to support the current programme. Immunisation has eradicated smallpox; it is likely to eradicate poliomyelitis in the near future; and it has prevented diphtheria, tetanus, peruses, measles, rubella, hepatitis A and B, rabies, some forms of meningitis and other infections.
>
> Vaccines meet the most rigorous national and international safety and efficacy requirements before being licensed and millions of doses of

MMR have been given in many different countries.

Ex. 32. Zuckerman explained that the purpose of this release was to rebut criticism of MMR safety:

> . . . The event that, if I recall correctly, led to this press release was the provision of information, two particular reporters, concerning the safety of MMR, the relationship with, the possible relationship, or the alleged relationship if you like, their alleged relationship with chronic bowel disease and autism, and in particular questioning the safety of vaccines. Now, that really puzzled me because vaccines are not issued just like that. They undergo a very rigorous testing, safety testing, evaluation, Phase 1, Phase 2, Phase 3 clinical trials and so on, and to suggest to the media, to the popular media that vaccines have not undergone safety testing was I suppose to my mind at the time absolutely bizarre, and I therefore decided, after discussing this issue with the media group which I chaired, that we must issue a statement to the press in order to stop the enormous amount of publicity and speculation which was taking place, which resulted in a significant fall in the number of children who had been immunised, which then became a public health issue, and I should add that nobody from the press took the slightest interest in that; not the slightest interest.

Zuckerman Tr. 15-24C.

<u>Zuckerman Knew Wakefield Would Recommend the Monovalent Alternative to MMR.</u>

Zuckerman chaired the press conference on February 26 and had previously reviewed the draft of the Lancet Case Series. Zuckerman Stmt. ¶¶ 26, 28, 37 (Ex. 103).

Wakefield wrote to professor Walker-Smith, with copies to Zuckerman and Pounder, on January 15, 1998 "Re: MMR and Autistic Enteropathy: forthcoming publicity:"

> I felt that in view of the imminent publicity regarding our work, it was important to write and clarify my own position. Clearly, pending a press briefing or other communications with the press, which now

seems inevitable, we need to have considered our points of view, well in advance of publication. . . . In addition to our own work and that of others, my opinion is also based upon a comprehensive review of all safety studies performed on measles, MR and MMR vaccines and re-vaccination policies. This now runs into a report compiled by me of some 240 pages, which I am happy to let you see. In summary, the safety studies are derisory, and appear to reflect sequential assumptions about measles vaccine safety, MMR safety and latterly, two dose vaccine safety, where each assumption has potentially compounded the dangers inherent in the first.

In view of this, if my opinion is sought, I cannot support the continued use of the polyvalent MMR vaccine. I have no doubt of the value of the continued use of the monovalent vaccines, and will continue to support their use until the case has been proven one way or another of the measles link to chronic inflammatory bowel disease. . . . I recommend that measles vaccination is deferred in children with a strong family history of IBD.

Paradoxically, attempts to sustain credence in MMR safety by quoting data from a surveillance scheme that is widely recognized to be inadequate, and to dismiss parent's claims of a link between their child's disorder and MMR without due investigation, in breach of the most fundamental rules of clinical medicine, is unacceptable. The failure of the regulatory authorities to honor their commitments to MMR vaccine safety has created a House-of-Cards that threatens all vaccine policies.

When parents have their claims dismissed, out of hand (as they have been by Salisbury and others) they create frustration, resentment and distrust; similarly dissatisfied parents form into self-help groups such as ATA and JABS, many of the members of which are articulate and well-read. Their anger is compounded as the case-numbers grow and their anxieties go unheard. Finally, Doctors such as us, perceive a pattern to the disease and its link with the MMR that becomes self-evident. When the data are presented, the anger of many parents boils over, the press have a field day, and the House of Cards crashes to the ground.

> Loss of trust in the regulatory authorities is inevitable and vaccine compliance, across the board, is affected – a difficult and dangerous situation. There is no doubt in my mind that the responsibility for the responsibility for this volatile state of affairs rests, not with us, but firmly upon the shoulders of the policy makers – that is, the JCVI and the Department of Health. They have started from the position that the MMR vaccine is safe, and that any change in policy following claims of adverse events, must be set against that position. Their starting point was, and remains, wrong. Any drug, and especially one that involves 3 live viruses, must be considered dangerous until proven otherwise: this has never been proven and, therefore, all claims of adverse events should have been thoroughly investigated. They have failed to honor this obligation.
>
> In an attempt to avert the House-of-Cards collapsing, I will strongly recommend the use of monovalent vaccines as opposed to the polyvalent vaccine. This will not compromise children by increasing their risk of wild infection, and may reduce the risk of an apparent synergy between the component viruses that has been identified by Dr. Scott Montgomery as a risk factor for inflammatory bowel disease, and may well be a risk for autism in our children, currently under investigation.

Ex. 33. This letter was copied to Zuckerman and Professor Roy Pounder, Head of Gastroenterology in the Department of Medicine.

Professor Pounder immediately wrote on January 16 to the Chief Medical Officer, Department of Health, warning DOH to stock adequate supplies of the single measles vaccine:

> It seems likely that at least some members of our team will recommend that there is a switch from MMR to monovalent vaccines, to ensure that the measles vaccination programme continues (excluding only those with a family history of inflammatory bowel disease or autism). We believe that there is only a limited amount of monovalent measles vaccine available at the present time, and your department may wish to investigate this potential problem.

Ex. 34.

Zuckerman wrote to Wakefield on January 22, 1998 endorsing Wakefield's support for the continued use of the monovalent vaccines:

> You kindly sent me a copy lf your letter of 15th January 1998 addressed to your senior colleagues stating your own position with regard to MMR and your various studies. . . . You support the continued use of the monovalent vaccines and you write that you have no doubt of their value. To my knowledge this has not been repeated by the media. Had this been made clear then I doubt whether immunisation rates would have fallen by some 20% and continue to fall at an alarming rate.

Ex. 35 (emphasis original). Later in the same letter, he reiterated his instruction that Wakefield announce his support for the monovalent vaccines:

> I am now alarmed by publicity in the popular media and the effect on immunisation programmes and the public health. It is vital, in your own interest and that of children, that you state clearly your support for monovalent vaccination.

Id (emphasis added).

The press conference took place as scheduled on February 26. A journalist asked what parents should do in relation to MMR. Zuckerman directed that question to Wakefield. Zuckerman Tr. ¶ 16-22A. In response to that question, referred to Wakefield by Zuckerman, Wakefield stated his concerns, supported continued vaccination, and recommended separating MMR into the three individual monovalent vaccines. Zuckerman Stmt. ¶ 37 (Ex. 103); Hutchinson Stmt. ¶ 24 (Ex. 106). Wakefield explained:

> The temporal association between MMR and autism was initially made in the United States and two eminent doctors have published upon this subject making the same temporal link. We have confirmed that temporal link in our small cohort. It is apparent when looking at the epidemiological data, although they are imperfect, it is apparent that this particular syndrome that we are describing is very new. If we look at isolated populations it may have come into being beyond 1988 when MMR was introduced. This is something that requires

> extensive investigation, but I think my concern is that one more case of this is too many and we put children at no greater risk if we disassociate those vaccines into three that we may avert the possibility of this problem. Vaccination policy in this country depends upon trust between the people and the regulatory authorities and I think that trust has to be maintained for protection of all vaccine strategies, and if we do not acknowledge this and investigate it to the best of our ability to establish or refute a link, then I fear that in the future there may the a breakdown of trust which adversely affects all vaccines policies, which would be a great shame.

Zuckerman immediately elaborated on the rationale for preferring the separate monovalent components of the MMR:

> Can I just try and try and actually answer that question more precisely? MMR consists of three live attenuated virus strains. In other words we are administering to the children in the MMR three attenuated vaccine strains against measles, against mumps, against rubella. A combination of three different viruses. It is theoretically possible that the immune system would be challenged by three separate viruses and that would be the rationale, I think, Andy, for giving these vaccines separately and of course before the MMR was introduced these preparations were available as monovalent vaccines.

Thus, Zuckerman was supportive of the Wakefield "monovalent" recommendation, which is exactly what he had urged Wakefield to "clearly" support in his January 22 letter (Ex. 35).

> Zuckerman issued a press release the next day:
>
> The Dean of the Royal Free Hospital School of Medicine, Professor Arie Zuckerman, said today the research team had discovered an important new syndrome which provided the opportunity to investigate inflammatory bowel disease and autism.
>
> Professor Zuckerman, who is also Director of the World Health Organisation Reference Centre on Viral Diseases, said the study did not provide a proven association with MMR vaccine. 'It is essential that the immunisation programme continues to protect children

> against these three serious infections. If immunisation rates fall, measles will return and children will die', he said.

Ex. 36.

Zuckerman falsely claimed that he was unaware of, and surprised by, Wakefield's statements:

> I did not know that Dr. Wakefield would suggest the use of monovalent vaccines in place of the MMR vaccine.
>
> Since Dr. Wakefield claimed that the measles vaccine was associated with Crohn's disease and then autism, I could not understand the logic behind recommending that the measles vaccine was to be given separately if this was the vaccine that he thought was causing the damage.
>
> I would not have agreed for the briefing to go ahead if I had known that Dr. Wakefield would recommend the use of monovalent vaccines. I was not aware that prior to the press briefing Professor Pounder had written to the Chief Medical Officer on 16 January 1998 warning the Department of Health to stock single vaccines.
>
> I was the chairman of the press briefing because I was the chairman of the Media Group. A question was asked of Dr. Wakefield whether he would give his children the MMR vaccine. I did not know that Dr. Wakefield would recommend the use of monovalent vaccines.

Zuckerman Stmt. ¶¶ 30-32, 37 (Ex. 103). Zuckerman continued to assert his claimed unawareness during his testimony. Zuckerman Tr. 16-17C. Zuckerman claimed that the "press briefing was to be restricted to pathological changes in the gut and nothing else:"

> [Organizing the press briefing] was decided by the media group which I chaired and I approved the briefing as it was considered that there was an important finding in relation to changes in the bowel in children with autism. I should qualify this I think now, because it was absolutely vital at the time, by saying that that briefing was to be only on the intestinal changes in the bowel. It had nothing to do with

> MMR or MMR vaccination and that was confirmed by a letter from Professor Pounder to the Chief Medical Officer on 15 January. So, it was absolutely clear that that press briefing was to be restricted to pathological changes in the gut and nothing else.

Zuckerman Tr. 15-25D.

> I knew that the press briefing was to be restricted to the pathological changes in the gut. The issue of vaccines was not relevant. I was reassured on this by Professor Pounder, I was reassured on this by Dr Wakefield, I was reassured by the letter that Professor Pounder wrote to the Chief Medical Officer on 15 January, assuring him that the press briefing would be restricted to pathological changes and therefore the issue of monovalent, polyvalent or any other vaccines was not an issue to be discussed at the press briefing, merely the pathological changes.

Zuckerman Tr. 16-17D.

> All that that press briefing was meant to do was to describe the findings in The Lancet paper and nothing else. Vaccines did not come into it, virology did not come into it, the measles vaccine did not come into it, monovalent vaccines did not come into it, polyvalent vaccines did not come into it, public health issues did not come into it, immunisation programmes did not come into it. This was entirely unexpected and was very, very difficult to control at the time, I assure you.

Zuckerman Tr. 16-33D.

This testimony is false. The above-quoted exchange of letters demonstrates beyond any doubt that Zuckerman knew specifically that Dr. Wakefield would support the monovalent vaccines over the polyvalent MMR. Indeed, Zuckerman emphasized that it was "vital" that Wakefield "state clearly your support for monovalent vaccination." The "logic" for Wakefield's recommendation had been clearly stated in his January 15 letter, i.e. lack of proven safety for the polyvalent MMR and the work on viral interaction done by Dr. Scott Montgomery. Ex. 33.

Zuckerman's self-contradictory oral testimony is further evidence that his

claimed unawareness was a contrivance. When first asked whether he was aware that Wakefield would express a preference for the monovalent vaccines, he claimed he "knew" that was Wakefield's position but that the vaccine subject was banned from the press conference:

> Coonan: . . . [Y]ou told [investigators for the GMC] that you did not know that Dr Wakefield would suggest the use of monovalent vaccines in place of the MMR vaccine.
>
> Zuckerman: That is correct.
>
> Coonan: That is correct, is it? You did not know that?
>
> Zuckerman: I knew that he held that view. I knew that the press briefing was to be restricted to the pathological changes in the gut. The issue of vaccines was not relevant. I was reassured on this by Professor Pounder, I was reassured on this by Dr Wakefield, I was reassured by the letter that Professor Pounder wrote to the Chief Medical Officer on 15 January, assuring him that the press briefing would be restricted to pathological changes and therefore the issue of monovalent, polyvalent or any other vaccines was not an issue to be discussed at the press briefing, merely the pathological changes.

Zuckerman Tr. 16-17B (emphasis added). However, when confronted during further cross-examination with the exchange of letters discussed above (part of the "unused" material not directly provided by Zuckerman), he quickly changed his testimony, stating a belief that Wakefield would support the polyvalent MMR:

> Coonan: I just want to ask you this. Can you remember, before the press briefing, being aware of Dr Wakefield's position on the debate between poly and monovalent?
>
> Zuckerman: Yes, indeed, I was and I have already said so. Let me just qualify this. It was an exchange of correspondence between Dr Wakefield and I where he wrote to me, assuring me that he had confidence in polyvalent vaccines.

Zuckerman Tr. 16-18H (emphasis added).

Zuckerman also claimed he was unaware of the content of a video news release (VNR) prior to the press briefing, specifically a reference by Wakefield that the monovalent vaccines would be a safer alternative to MMR. Zuckerman Tr. 16-18C. He claimed to have only watched the VNR after the February 26 press briefing and "completely disapproved of its contents." Zuckerman Stmt. ¶ 25 (Ex. 103).

Zuckerman's false testimony was further exposed by Ms. Philippa Hutchinson, press officer for the Royal Free at the time of the 1998 press conference. She explained that the purpose of the press briefing was to expose the press to the differing views of the authors, especially on the MMR issue, Hutchinson Stmt. ¶¶ 10, 25 (Ex. 106), that the press and Zuckerman were well aware of Wakefield's preference for the monovalent vaccines prior to the briefing, Id. ¶¶ 17-18 (Ex. 106), and that Zuckerman would have been aware of the press packet which contained a fact sheet ("What has the Royal Free found") setting forth Wakefield's view (pp. 4-5) that there was a case for separating the trivalent MMR, Id. ¶ 38. Ms. Hutchinson also explained that she sent a copy of the script for the VNR to Zuckerman on January 28. Id. ¶ 42. (Ex. 106).

When confronted with the glaring contradiction between his testimony and the objective documentary evidence from his own hand, Zuckerman claimed:

> I have been asked to comment on a letter which I wrote to Dr. Wakefield dated 22 January 1998 in which I said that he should state clearly his 'support for monovalent vaccination.' (AZ1/p. 103). This letter contains a spelling mistake in the penultimate paragraph and should read 'support for polyvalent vaccination.' This is clear from the tone of the rest of the letter.

Zuckerman Stmt. ¶ 34 (Ex. 103). Zuckerman repeated this claim at the FTP hearing. Zuckerman Tr. 16-37H. This self-serving denial cannot be believed. First, Wakefield's letter (Ex. 33) stated categorically: "I will strongly recommend the use of monovalent vaccines as opposed to the polyvalent vaccine." Zuckerman's letter (Ex. 35) does not protest this approach but instead <u>twice</u> insists on Wakefield's support for monovalent vaccinations. The first reference follows "monovalent" with the plural form "vaccines" and continues with the plural pronoun reference to "their value." The "overall tone" of the letter was exclusively concerned with MMR safety and what Wakefield should say about it, thus making a "spelling mistake" between "monovalent" and "polyvalent" impossible.

Count IV
Michael Pegg
False Testimony Denying Ethical Approval for Children Reported in Lancet Case Series.

Michael Pegg was Chairman of the Ethics Committee at the Royal Free Hospital since January, 1996. He falsely claimed that the investigation of the 12 children reported in the Paper did not have the approval of the Ethics Committee. In fact, the children were investigated according to their clinical need and not as part of a follow-on program of scientific and clinical investigation approved by the Committee on December 18, 1996. The one "research" aspect relevant to these children (collection of additional biopsies during colonoscopy and biopsy analysis for research purposes) had, in fact, been granted routine generic approval by the Committee on September 5, 1995 (project 162-95).

Professor Walker-Smith sought and obtained routine LREC approval for the taking of additional biopsies from his patient population and for conducting investigations on biopsies for research purposes. He had this approval at his prior institution and this was a pre-condition to his transfer to the Royal Free. On August 24, 1995, he wrote to the Royal Free, explaining:

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

Pegg Tr. 8-54E; Ex. 37.

The Secretary of the LREC granted the ethics approval on September 5,

1995:

> Re The taking of two extra mucosal biopsies for research purposes during the course of colonoscopy in children
>
> I am pleased to be able to inform you that your recent submission to the Ethical Practices Sub-Committee has now received approval by Chairman's Action.
>
> This approval will be formally documented at the next meeting of the full committee and meanwhile you are free to carry out the above procedure at the Royal Free.
>
> Please note the code number 162-95 that the submission has been given and quote this in all correspondence.

Ex. 38.

This generic approval was assigned number 162-95. Pegg described this generic approval as follows:

> [Walker-Smith's July 15, 1996 letter to LREC requesting extension of 172-96] also mentioned that the team "already have research permission for taking extra biopsies in children that we colonoscope." The reference to "research permission" is when samples are taken from waste tissue in the course of normal surgery, and is necessary to obtain patient consent for the tissue to be retained and used for research purposes. The type of consent form is standard and is often produced to all patients as a matter of course. It is my understanding that Professor Walker-Smith wanted to retain tissue samples from all of his child patients at that time, and this is very common practice. This is so that samples can be retained for research purposes. This requires patient consent but not LREC approval. In fact, prior to 1999, the retention of tissue in this was often done without patient consent and many practitioners would consider this to be acceptable practice at that time.

Pegg Stmt. ¶ 55 (Ex. 104). Pegg acknowledged this general research approval, even noting that was not necessarily required:

Smith: Can you explain to us, remembering again we are all starting from scratch, so in simple terms, the reference to Professor Walker-Smith saying: "We already have research permission for taking extra biopsies in children who we colonoscope", is that ---?

Pegg: That is another study.

Smith: Can you just explain that? How does that come about? Was that a general research application?

Pegg: They had made a previous application to take extra biopsies for children who were colonoscoped, and there is an information sheet and everything for that.

Smith: Was that children who were being colonoscoped in the course of normal clinical practice?

Pegg: It was for every colonoscope they do they took an extra sample, I think, but they had a permission for it and an information sheet for it.

Smith: Was that normal practice within the hospital at that time for doctors to have a general research permission in respect of their patients?

Pegg: I think it is ahead of practice at that time. I think if you go into the College of Physicians' guidance there was a view at that time that it was not even necessary to get consent.

Smith: If you were just taking an extra sample?

Pegg: Taking extra. There was a body of opinion at that time who did not even think that approval was necessary to take extra … If you were actually doing the investigation, i.e. the patient was not having any more risk, then taking extra samples you do not even need permission for, so this was almost ahead of feelings at that time, and of course we know now things have changed.

Smith: Yes, and that is as a result of all the ---?

Pegg: Yes, but remember this is pre the new Tissue Acts and all that sort of thing where practices were very different.

Smith: When you say it involved no extra risk for the patient, do you mean they were going to undergo ---

Pegg: You are going to have a colonoscope anyway, we are going to take one, can we take another one?

Smith: So you were taking one for clinical diagnostic purposes?
Pegg: Yes,.

Smith: And in addition to that you take an extra one for research purposes?

Pegg: Yes, with the risk being putting the colonoscope in, which you are already doing.

Pegg. Tr. 8-45E.

On cross-examination, Pegg made it perfectly clear that no further Ethics Committee approval was required for any research use of biopsies collected under this previously-granted generic approval:

Coonan: . . . This grant of ethical committee approval, which is numbered 162-95, was an approval which was capable of running continuously throughout the period with which we are concerned, was it not?

Pegg: Yes.

Coonan: We see that it relates to the taking of two extra mucosal biopsies, and we see that in the main heading, two extra ones, during the course of colonoscopy in children, and the taking of those two extra for research would therefore permit histology to be taken, is that right?

Pegg: It did not state what they were going to be used for, so by inference they could be used for anything.

Coonan: Well, in the light of that answer it therefore follows logically, it is a matter of common sense, that it at least extended to histology, yes?

Pegg: Well, as I say, the ethics committee is concerned with the risk to the child, therefore it has approved the biopsies. Whatever you use them for is not going to increase the risk to the patient. You can list a hundred things they can do with those and I will answer "Yes" to every single one of your questions, so if you give the list I will answer "Yes" to your questions.

Coonan: I will give you enormous reassurance because there are only two particular matters on my list that I want to put in front of you. The first, as I said a minute ago, is histology.
Pegg: As I said, I would say yes to that.

Coonan: The second one is immunohistochemistry.
Pegg: I will say yes to that. It does not matter what you say.

Coonan: It is just that I am using your evidence to assist the Panel.

Pegg: There is no relevance to an ethics committee as to what you do with them, because except for genetic research which was not even here in that era, we are not worried, it is no risk to the child whatever you do with those things. So that is not really our concern. It is just the taking of them that we are concerned with, so you can do what you like with them.

Coonan: Just to complete the picture on the biopsy front – just go back to volume 1 in the pro forma application at page 209, right at the bottom of the page, Dr Pegg, if you have got it, in terms of biopsies the difference between 162/95 and 172/96 is the fact that the people concerned with this study wanted to take an additional biopsy. Do you see that at the bottom of the page 209?

Pegg: Yes.

Pegg Tr. 9-24G.

Pegg also conceded that no Ethics Committee approval was required to write up a retrospective case series for a journal. Pegg. Tr. 9-21E. This was precisely the type of case series reported in the Lancet Case Series. Pegg also admitted that what Wakefield described as a "pilot study" involving investigations according to clinical need and pursuant to a rigorous clinical protocol also did not require Ethics Committee approval. Pegg. Tr. 9-25F.

Professor Walker-Smith submitted a Pro-Forma application and research Protocol (Proposed Clinical and Scientific Study – A new syndrome: enteritis and disintegrative disorder following measles and measles/rubella vaccination?) to LREC for routine approval on August 6, 1996. It was assigned the number 172-96. LREC met on November 13, 1996 to discuss the application and made recommendations for changes in the patient consent form. LREC sent a letter to Wakefield on November 14 approving the application. The application was again discussed at LREC's December 18 meeting, and was again approved after deletion of the Schilling test and modification of the consent form. Pegg gave formal ethical approval of the research elements of this project to Walker-Smith in a January 7 letter. Pegg. Tr. 9-16B.

Pegg claimed that children were included in the Lancet Case Series that were seen as research subjects but without ethical approval:

> I now believe that Dr. Wakefield did include information in a study published in the Lancet in February 1998 which was obtained from clinically indicated tests undertaken on children before the 18 December 1996 [sic]. I would not consider that he had LREC approval to do so.

Pegg Stmt. ¶ 32 (Ex. 104).

However, during cross-examination, Pegg conceded that children investigated according to clinical need before the December 18, 1996 approval date for the trial did not need to be covered by an Ethics Committee approval. Several such children were described in the documents supporting the 172-96 application as a "pilot study" and formed part of the rationale for the formal trial. Children from this group were part of the case series reported in the Lancet Case

Series. Pegg said of this group:

> Miller: . . . [I]n many cases involving clinical investigation there may be preliminary studies in which a small number of patients are investigated before they decide to make it into a formal trial?
>
> Pegg: People still ask ethics permission for pilot studies. We get them every month.
>
> Miller: But they may not do so if they feel that they are clinically indicated examinations?
>
> Pegg: That is right.
>
> Miller: You would have experienced both, presumably; people who, on the one hand, say, 'Let's do a pilot study" and others who think, 'Let's just get the thing together and then do a proper trial'?
> Pegg: It depends what you are doing. If you are doing research in your pilot study, therefore you need permission for a pilot study. It is as simple as that. You cannot do any study without an ethics committee, be it pilot study nor definitive study. You cannot have a go at giving the drug to a few people and see if it works before it comes to the ethics committee.
>
> Miller: Of course. That is a different situation from what we have been considering here, where there is undoubtedly and I think you would accept this a hefty clinical investigation part of this trial.
>
> Pegg: The five were not a study. They were just five people being properly investigated for a disease that they presented at their doctor's. You get information all the time from normal patients which you can then create a study from, but these five were just normal patients having investigations.

Pegg Tr. 8-84E. Accordingly, the children reported as a case series in the Lancet because their investigations were clinically indicated and because the 'research" aspect of the case series, the taking of additional biopsies, was covered by previous generic Ethics Committee approval 162-95.

Referring to Legal Aid Board funding, Pegg claimed that ". . . A failure to disclose funding sources would be an issue of misconduct in my opinion." Pegg Stmt. ¶ 44 (Ex. 104). This statement was misleading. Pegg conceded on cross-examination that Legal Aid Board funding first deposited with the Special Trustees of the Royal Free, which he knew was the case here, need not be disclosed to the Ethics Committee:

> Coonan: If you are saying that there was a requirement to declare Legal Aid Board funding, the requirement to declare it would have to fit in as an answer to the question, question 10, would it not?
>
> Pegg: Yes, if Legal Aid funding was coming directly into this study, yes.
>
> Coonan: If it is coming directly into it.
>
> Pegg: If the hospital has a bucket of funds to which there might be Legal Aid funds, tin cans and the high street, no, I do not ask the hospital to tell me. I think there is a thing here, if Wakefield was getting money, cheques in his pocket, direct from Legal Aid fund to this study, that is directly in the study. If the cheques are coming in to the special trustees, no, I do not want to know where it comes from because somebody has verified the source of the funds, the special trustees or whoever. So maybe I can qualify my thing because – I am not going to qualify it, no. Direct funding to the study from the Legal Aid Board, yes, I would like to know that because I am the only person on the line who has seen that funding. If it is passed through the finance departments of the Royal Free Hospital, then somebody else has looked at the origin of the funds.
>
> Coonan: So if that is right, if that is the position, others have scrutinised it.
>
> Pegg: Others have scrutinised it and said it is a proper source of funds. I do not know where the special trustees get their funds from. I cannot verify that it has not been stolen, pinched or anything. They verify it themselves.
>
> . . .
>
> Coonan: . . . Do I understand you to be saying that, in so far as Legal

> Aid Board funding has been dealt with through the hospital and the medical school, one or the other, or through the finance department, if they are satisfied about that, first of all you would not expect him to put that down?
>
> Pegg: I cannot question… As I say, you have Legal Aid Board funding, you have all sorts of funding coming to the hospital. I think my safeguards are the hospital looks at where things come from. So I would say that I do not want to know if it has been through a third party before coming to me. That is the answer, yes.
>
> Coonan: So the answer is "Yes"?
>
> Pegg: Yes is the answer.

Pegg Tr. 9-33C, 9-34E.

Count V
David Salisbury
Misuse of Official Position to Censor Criticism; False and Misleading Testimony.

Regarding Wakefield's suggestion at the February 26, 1998 press conference that parents should consider the alternative of monovalent vaccines, Salisbury said:

> I consider that Dr. Wakefield's public pronouncements were irresponsible.

Salisbury Stmt. ¶ 105 (Ex. 105). He further blamed Wakefield for putting UK children at risk:

> Dr. Wakefield's statements over the years have put the control of measles in the UK in jeopardy and also put at risk the lives and wellbeing of children.

Id. ¶ 125. He explained this as follows:

> Even a drop in [MMR] coverage of 3% is extremely important, and a fall of 11% is potentially catastrophic. If some parents choose not to

> immunize their children with the MMR vaccine, then the pool of unprotected children grows ever larger as each year of low coverage passes. This fall in coverage results in an increase in the number of susceptible individuals and a reduction in the level of protection within the community. This leads to an increased risk of exposure to measles, mumps and rubella in individuals who are too young to be immunized or those children who cannot receive MMR. Each year that parents choose not to immunize their children, more lives are put at risk.
>
> For this reason, I consider that it was irresponsible for Dr. Wakefield to use his research and the press conference in 1998 to call for single vaccines to replace MMR vaccines.
>
> I consider that Dr. Wakefield misused his position by using the media to present his personal views. Dr. Wakefield caused huge and inappropriate anxiety in the minds of parents.

Id. ¶¶ 147-49.

> Regarding the safety of the MMR, Salisbury said:
>
> It is hard to quantify how much the [Department of Health] has expended financially to deal with this. Huge resources have been spent in communication initiatives entirely for the purpose of restoring public and professional confidence for a vaccine with an exemplary safety record. The additional burdens placed on already hard pressed health professionals cannot be quantified and the anxieties generated in the minds of parents cannot be justified. Even worse, would be the generation of guilt in the minds of parents with autistic children.

Id. ¶ 150. As another example, Salisbury told the BBC: "Single vaccine programmes do not work. Every single concern about the MMR vaccine has been looked at in great detail over and over again. All of the research says this is a safe vaccine." "Single Measles Jab Rejected," BBC (Jan. 12, 2001).

These statements are a misuse of Salisbury's official position. Wakefield had a moral and ethical duty to bring to the attention of the scientific/medical

community and the public, as well as a right to speak freely and without government retribution, his concerns over the safety of MMR.

Salisbury falsely seeks to shift blame to Wakefield for being "irresponsible" and raising supposedly unjustified anxiety and guilt about the safety of MMR. The proximate cause of concerns over MMR safety pre-dated Wakefield's involvement and was largely due to the refusal or inability of the Government to adequately demonstrate the initial safety of MMR and of the childhood vaccination schedule. Any public "anxiety," whether expressed as lawful choices made about vaccinations or calls for more research, is caused by Government failure, and NOT by scientists and doctors calling attention to such failure. Furthermore, any decline in vaccination is much more likely due to the cumulative doubts caused by issues surrounding DPT and encephalopathy in the 1980's, the MMR-caused meningitis debacle in the early 1990's, and the "scandal" surrounding the vaccination status of Leo Blair, than to an appropriately reported case series and an obscure press conference at the Royal Free:

> In 1998 Wakefield published his paper in the Lancet. It's surprising to see, if you go back to the original clippings, that the study and the press conference were actually covered in a fairly metered fashion, and also quite sparsely. The Guardian and the Independent reported the story on their front pages, but the Sun ignored it entirely, and the Daily Mail – home of the health scare, and now well known as vigorous campaigners against vaccination – buried their first MMR piece unobtrusively in the middle of the paper. There were only 122 articles mentioning the subject at all, in all publications, that whole year. This was not unreasonable. The study itself was fairly trivial, a "case series report" of 12 people – essentially a collection of 12 clinical anecdotes – and such a study would only really be interesting and informative if it described a rare possible cause of a rare outcome. . . . But the biggest public health disaster of all – which everyone misses – was a sweet little baby called Leo. In December 2001 the Blairs were asked if their infant son had been given the MMR vaccine, and refused to answer, on the grounds that this would invade their child's right to privacy. . . . And while most other politicians were happy to clarify whether their children had had the vaccine, you could see how people might believe the Blairs were the kind of family not to have their children immunised: essentially, they had surrounded themselves with health cranks. There was Cherie Blair's closest friend

> and aide, Carole Caplin, a new age guru and "life coach". Cherie was reported to visit Carole's mum, Sylvia Caplin, a spiritual guru who was viciously anti-MMR ("for a tiny child, the MMR is a ridiculous thing to do. It has definitely caused autism," she told the Mail). They were also prominently associated with a new age healer called Jack Temple, who offered crystal dowsing, homeopathy, neolithic-circle healing in his suburban back garden, and some special breastfeeding technique which he reckoned made vaccines unnecessary.. . . The MMR scare has created a small cottage industry of media analysis. In 2003 the Economic and Social Research Council published a paper on the media's role in the public understanding of science, which sampled all the major science media stories from January to September 2002, the peak of the scare. It found 32% of all the stories written in that period about MMR mentioned Leo Blair, and Wakefield was only mentioned in 25%: Leo Blair was a bigger figure in this story than Wakefield. . . . Through reporting as shamelessly biased as this, British journalists have done their job extremely well. People make health decisions based on what they read in the newspapers, and MMR uptake has plummeted from 92% to 73%: there can be no doubt that the appalling state of health reporting is now a serious public health issue. We have already seen a mumps epidemic in 2005, and measles cases are at their highest levels for a decade. But these are not the most chilling consequences of their hoax, because the media are now queueing up to blame one man, Wakefield, for their own crimes. It is madness to imagine that one single man can create a 10-year scare story. It is also dangerous to imply – even in passing – that academics should be policed not to speak their minds, no matter how poorly evidenced their claims. Individuals like Wakefield must be free to have bad ideas. The media created the MMR hoax, and they maintained it diligently for 10 years. Their failure to recognise that fact demonstrates that they have learned nothing, and until they do, journalists and editors will continue to perpetrate the very same crimes, repeatedly, with increasingly grave consequences.

Goldacre, B. "The Media's MMR Hoax," The Guardian (Aug. 30, 2008) (emphasis added).

In fact, it was Salisbury who stubbornly made the single MMR vaccine

option unavailable despite consumer demand for choice, and despite a lack of scientific evidence that the multivalent MMR was safer than the monovalent options:

> This migration of the MMR autism scare to the US has worrying characteristics, ones which will make it harder for doctors to unpick for concerned parents, says Professor Salisbury. "Here vaccine was an individual, narrow, problem; when the science unpicked it, and Andrew Wakefield was in turn unpicked by press, it became very difficult to advance the argument that MMR causes autism.
>
> "But it is more diffuse in the US. First there was the concern about the mercury preservative thiomersal in vaccines, then MMR and autism, and then about the dangers of multiple vaccines—it makes it much harder to pick off what parents' concerns are."
>
> Professor Salisbury says the Department of Health's fight back was in part helped by the uncompromising position it took on the combined MMR vaccination, refusing to fund single vaccines. "The government did not appease—we didn't change policies. We did not offer a choice, despite the existence of single vaccines. [With whooping cough, patients were offered vaccine without pertussis.] We had no close links with dissenters.

Coombes, R., "Vaccine Disputes," BMJ 2009;338:b2435

Salisbury's constant claims with respect to MMR "safety," for example his claim that MMR has an "exemplary safety record," are unfounded and misleading. There are no studies demonstrating the safety of MMR, or of the childhood schedule, by measuring both acute and chronic adverse reactions in vaccinated versus unvaccinated populations, animal or human. Salisbury thus cannot possibly know the extent of chronic vaccine- or MMR-caused disease and has no basis for a claim of an "exemplary" safety record.

The Institute of Medicine had the following to say about vaccine safety: "In the course of its review, the committee encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent

information from case reports and case series, inadequate size or length of follow-up of many population-based epidemiologic studies, and limited capacity of existing surveillance systems of vaccine injury to provide persuasive evidence of causation. The committee found few experimental studies published in relation to the number of epidemiological studies published. Clearly, if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped." Stratton KR, Howe CJ, Johnston RB. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (1994).

The deficiencies in vaccine safety studies were later reinforced by the systematic analysis of Dr. Thomas Jefferson and colleagues from the Cochrane Collaboration, an internationally respected body that provides independent scientific oversight. They wrote, "The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing is largely inadequate. The evidence of adverse events following immunisation with MMR cannot be separated from its role in preventing the target diseases." Demicheli V, Jefferson T, Rivetti A, *et al.* Vaccines for measles, mumps and rubella in children. Cochrane Database Syst Rev, 2005(4):CD004407.

Count VI
Dr. David Salisbury
Concealing Material Information Regarding the Safety of MMR.

The Joint Committee on Vaccination and Immunisation began the MMR campaign in 1988. Salisbury Stmt. ¶¶ 12, 14-15. Two of the three brands of MMR sold in the UK contained the Urabe strain of the mumps vaccine, which was found to cause meningitis. Urabe-containing MMR was halted in September, 1992, in favor of MMR containing the Jeryl-Lynn strain of the mumps vaccine. Salisbury Stmt. ¶¶ 21-22. Salisbury failed to disclose in his statement and in his testimony before the GMC that Urabe-containing MMR was quickly withdrawn in Canada before being introduced in the UK. He also failed to disclose indemnity given to MMR manufacturers and falsely denied that such immunity was given. Ex. 39 (JCVI 5/7/93 Minutes ("SKB continue to sell the Urabe MMR without liability.")); Ex. 40 (indemnity provision); Ex. 41 (9/3/06 E-Mail from David Salisbury to Clifford Miller ("As has been stated on innumerable occasions, there was no immunity/indemnity given to MMR manufacturers.").

Count VII
Dr. Michael Rutter
Failure to Disclose Conflicting Interest in Published Papers

Dr. Michael Rutter was an expert witness in several litigation projects paid for his opinion that vaccines, specifically mercury (thimerosal) and MMR, do not cause autism but failed to disclose this conflict in several papers presenting evidence and opinion that autism is not caused by vaccines. His status as an expert witness constituted a disclosable interest under post-2002 guidelines because it could legitimately give rise to a perception of a conflict of interest in relation to his role as an author of papers (on which he relied in the litigation) claiming that vaccines did not cause autism.

Ironically, Dr. Rutter was the first scientist to describe vaccine-caused autism in the medical literature. In a lengthy review article on the biological basis of autism, Dr. Rutter described a genetic study of families affected by autism, from which some children were excluded on the basis that their autism could be explained by some known "medical condition of probable aetiological [causal] importance." Dr. Rutter explained one of the exclusions: "Only eight of the cases can be regarded as having a probably causal medical condition, a child with epilepsy and a temporal lobe focus on the EEG [Electroencephalogram] who had an onset following immunization." Rutter M et al., "Autism and Known Medical Conditions: Myth and Substance," J Child Psychol and Psychiat. 1994;35:311322.

Dr. Rutter was paid in at least three separate litigation projects to offer an "expert" opinion that vaccines, both thimerosal-containing and MMR, do not cause autism, and that the dramatic increase in incidence is not real (which would be evidence of an environmental non-genetic trigger such as vaccines) but simply the result of better ascertainment and a broadening of the diagnostic criteria. Yet he uses his position of prominence in the scientific community (e.g. being a distinguished Professor, author of countless books and papers, drafter of ASD diagnostic criteria, Fellow of the Royal Society, an honorary member of the British Academy, and knighted in 1992), to publish articles denying any population-level vaccine-autism causality without disclosing his conflicting interest that he was paid by industry lawyers and by the U.S. Government (in a statutory program to defend industry in Vaccine Court) for these very same opinions. While Rutter may well believe his published opinions are "independent" and honest, the objective standards applicable since approximately 2002 to disclosable conflicts of interest imposed a duty to disclose in published papers that he was employed by industry to

support its position in litigation. The ICMJE "Conflicts of Interest" requirements specifically reject any belief by Dr. Rutter's that money and other litigation-related relationships cannot compromise his "independent" scientific judgment, explaining that "the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment." [http://www.icmje.org/ethical_4conflicts.html].

Dr. Rutter has served as an expert in U.S. litigation alleging that mercury (thimerosal) in vaccines caused autism. He also served as an expert in the UK MMR litigation funded by the Legal Aid Board, and examined two of the children coincidentally described in the Lancet Case Series. Finally, he was an expert for the U.S. Government (in a special Vaccine Court created by statute in 1986) in the Omnibus Autism Proceeding. He was paid in each of these litigations for an opinion that vaccines (MMR and/or mercury) do not cause autism. His expert reports have not been made public but he did testify in U.S. Vaccine Court on May 27, 2008, in the test cases (Mead and King) In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorders or a Similar Developmental Disorder.

In one expert report in the UK MMR litigation dated June 23, 2003 (Ex. 42, excerpts only), for example, Dr. Rutter offered an opinion exonerating vaccines:

> The epidemiological findings show no systematic connection between the timing of the introduction of MMR and the timing of the rise in the rate of autism and other pervasive developmental disorders. Accordingly, the epidemiological findings provide no grounds for concluding that [Child's] disorder is likely to have been associated with MMR.

Dr. Rutter offered a similar opinion in an expert report he filed on February 18, 2008 (Ex. 43, excerpts only) in the US Omnibus Autism Proceeding. His "expertise," for which he was being well paid, was based in part on his published research:

> With respect to the possibility that toxins may contribute to the causation of mental disorders, I have reviewed the evidence on the effects of environmental lead, and have done the same for the effects of the measles-mumps-rubella vaccine. I have published extensively on genetics of mental disorders (Rutter, 2006) and especially on the interplay between genetic and environmental factors (Rutter, 2007; Rutter, in press). . . . With respect to the Vaccine Court hearings, I have particular expertise in the steps needed to

> identify environmental causes of disease (Academy of Medical Sciences, Rutter, 2007). . . . . I base my opinions on the available scientific evidence and, in the body of the report, I note the scientific papers that are relevant in relation to individual points. In addition, I also make use of my extensive clinical experience over the last four decades in diagnosing autism spectrum disorders and treating children and adults with these disorders.

He went on to explain his past and present involvement in litigation:

> With respect to the issues being considered by the Vaccine Court, I wish to make explicit that some four years ago I agreed to serve as an expert witness with respect to Thimerosal vaccine litigation. In that connection, I partially drafted a report that, in the event, was never submitted because the litigation was put on hold. Similarly, about a year before that, the same situation arose with respect to litigation over MMR. Once more, the draft report was never finalized and was never submitted because the litigation was dropped. Finally, last year I served as an expert in relation to the British General Medical Council's case against 3 pediatricians involved in Andrew Wakefield's research into autism and MMR. The issues involved there did not concern the scientific case at all but, rather, were involved strictly with the ethical conduct of the research undertaken. . . . Regarding potential conflicts of interest, I declare that throughout the whole of my career I have never received any funding for my research from pharmaceutical companies or any other commercial organization. I agreed to serve as an expert witness in litigation in the UK regarding the mumps - measles - rubella vaccine and received standard fees for the time spent in preparing for this role, but the litigation never resulted in a court hearing. I am, or have been, a trustee of several charities originally established by founders associated with commerce (the Wellcome Trust, Novartis Foundation, Nuffield Foundation, and Jacobs Foundation) but in all instances, the charities are completely independent in their functioning, and my main role has been in the distribution of grants, rather than in their receipt.

On the merits of the allegation, perhaps not surprisingly, Rutter concluded that (relevant to this series of test cases in Vaccine Court) there was no evidence that mercury (thimerosal) caused autism:

> There is no doubt that mercury is neurotoxic and that mercury poisoning results in severe neuropsychiatric disorders. The claim that these mimic

> autism is not supported by the research evidence. Epidemiological studies provide tentative evidence that high levels of ingested mercury may possibly cause subtle neurocognitive impairments even when there is not any overt poisoning. However, these do not seem to include ASD. The epidemiological findings provide no support for the claim that the use of Thimerosal has led to an 'epidemic' of autism indicated by the marked rise over time in the rate of diagnosed ASD. It is biologically plausible that, despite a lack of any general effect of Thimerosal on the liability to autism, there might be an unusual idiosyncratic response in a small subgroup of individuals. Nevertheless, although biologically possible, there is no evidence that Thimerosal actually causes ASD in a subgroup of children. The claims that the unusual susceptibility may be indexed by the presence of regression are not supported by research findings. The same lack of evidence applies to parallel claims on possible indexing by either metabolic responses or particular genetic allelic variations. I conclude that I find no support for the claim that Thimerosal causes ASD. The available epidemiological evidence runs counter to the claimed causal effect.

Dr. Rutter was paid quite well to offer his interpretation of the epidemiological data relating to MMR exonerating it from any responsibility for causing autism, even though this is a matter of extensive controversy, debate, and numerous calls for further investigations. Thus, he has a financial interest in preserving the absence of evidence or arguments for a causal association in the published epidemiological literature, <u>including his own</u>, much of which he cites in references and footnotes in his expert reports. It is the <u>potential</u>, if not the <u>reality</u>, of his ability to profit substantially from an absence of evidence of causal association in the literature (over which he has a great deal of control) that obligates him to disclose his role as an industry "expert" in the papers he publishes.

Dr. Rutter had a duty to disclose his role as a paid expert witness for the vaccine industry in published articles relating to the subject of litigation because modern (post 2001) guidelines recognize that such relationships carry a great risk for inappropriate influence and bias. A commentary published by several editors, including Dr. Horton, explained:

> Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. . . .

> Disclosure of these relationships is particularly important in connection with editorials and review articles, because bias can be more difficult to detect in those publications than in reports of original research.

Davidoff, M., et al., "Sponsorship, Authorship, and Accountability," Lancet. 2001 Sep 15;358(9285):854-6. This standard was subsequently incorporated into the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest [http://www.icmje.org/ethical_4conflicts.html].

Dr. Rutter has repeatedly violated his disclosure obligations. He published an article specifically addressing the association between autism and MMR in 2005. Honda H, Shimizu Y, Rutter M., "No effect of MMR withdrawal on the incidence of autism: a total population study" J. Child Psychol Psychiatry, 2005 Jun;46(6):5729. (Ex. 44). The paper began by misstating the conclusions of the Lancet Case Series:

> Publication of a study claiming a causal relationship between the measles, mumps, and rubella (MMR) vaccine and autism spectrum disorders (ASD) (Wakefield, 1999; Wakefield et al., 1998) sparked a heated debate, primarily in the USA and UK, which relates not only to the etiology of ASD, but also impacts immunization policy.

This study examined cumulative incidence of ASD up to age seven for children born from 1988 to 1996 in Kohoku Ward (population approximately 300,000), Yokohama, Japan. ASD cases included all cases of pervasive developmental disorders according to ICD10 guidelines. The MMR vaccination rate in the city of Yokohama declined significantly in the birth cohorts of years 1988 through 1992, and not a single vaccination was administered in 1993 or thereafter. In contrast, cumulative incidence of ASD up to age seven increased significantly in the birth cohorts of years 1988 through 1996 and most notably rose dramatically beginning with the birth cohort of 1993. The study interpreted these data as disproving the MMR-autism hypothesis:

> [I]t is possible to conclude that it is extremely unlikely that MMR has been responsible for the rise over time in the incidence of diagnosed autism. It follows that it is similarly unlikely that it causes autism frequently or at all. It cannot have caused autism in the many children with ASD in Japan who

> were born and grew up in the era when MMR was not available. Because this frequency is at least as high as in populations in other countries in which most children were vaccinated, it implies that MMR could not cause a substantial proportion of cases of autism.

The interpretation of the impact of the temporary withdrawal of MMR is severely undermined by data revealed in two additional papers. See Terada, K., et al., "Alterations in Epidemics and Vaccination for Measles During a 20-year Period and a Strategy for Elimination in Kurashiki City, Japan," Kansenshogaku Zasshi [Journal of the Japanese Association for Infectious Diseases]. 2002 Mar;76(3):180-4; Nakatani, H., et al, "Development of Vaccination Policy in Japan: Current Issues and Policy Directions," Jpn J Infect Dis. 2002 Aug;55(4):101-11. In fact, the paper shows, when corrected with the missing data, ASD numbers increased and decreased in direct proportion to the total number of measles and MMR vaccines given to children. When correctly analyzed, the data show a challenge-rechallenge response at the population level. ASD rates, adjusted to birth cohort and year of vaccine administration, went down following decline and discontinuation of MMR and again began to climb dramatically when measles and rubella vaccines were given together, three doses of the JE vaccine (containing mercury) were added to the series, and MMR was reintroduced. While there is no proof that the deficient analysis was deliberate, disclosure in the paper that Dr. Rutter was a paid litigation expert for the vaccine industry, hired to specifically defend the safety of MMR, would alert the reader to be critical and skeptical of the "scientific quality" of the reported conclusions.

The Author Guidelines for the Journal of Child Psychology and Psychiatry has a "Conflict of Interest" section as follows:

> All submissions to JCPP require a declaration of interest. This should list fees and grants from, employment by, consultancy for, shared ownership in, or any close relationship with, an organization whose interests, financial or otherwise, may be affected by the publication of the paper. This pertains to all authors, and all conflict of interest should be noted on page 1 of the submitted manuscript. Where there is no conflict of interest, this should also be stated.

[http://www.wiley.com/bw/submit.asp?ref=0021-9630]; see http://www.icmje.org/ethical_4conflicts.html (ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the

Conduct and Reporting of Research: Conflicts of Interest). Dr. Rutter did not make the required disclosure of his status as an industry litigation expert in this paper. Dr. Rutter's failure to disclose conflicting interests in this paper is all the more egregious because he was and is a member of the Journal's Editorial Board. See http://www3.interscience.wiley.com/journal/117960395/home/EditorialBoard.html ; Dr. Rutter's CV (Ex. 45); Tr. 3246 [U.S. Vaccine Court, May 27, 2008] (Ex. 46).

Dr. Rutter published another paper in 2005 containing a lengthy discussion denying any causal association between vaccines and autism. "Incidence of Autism Spectrum Disorders: Changes Over Time and Their Meaning," Acta Paediatrica, 2005 Jan;94(1):215 (Ex. 47). This was a review of the literature to consider the evidence from all epidemiological studies with respect to the hypothesized causal effect of MMR and thimerosal on autism spectrum disorders. Dr. Rutter concluded that the increased incidence is largely a consequence of improved ascertainment and a considerable broadening of the diagnostic criteria. Regarding causation, he concluded:

> Despite strong claims made about the possible role of MMR in relation to the causation of autism, there is no convincing evidence in support of this hypothesis. In particular, the rate of ASD shows no particular association with either the stopping or starting of MMR and there has been no change over time in the pattern of association between ASD and either bowel disturbance or developmental regression. The evidence with respect to a possible association with thimerosal, a preservative in some vaccines, is much more limited but, again, there is no supporting epidemiological evidence of a causal association. It remains possible that there has been a true rise in incidence due to some environmental risk factor but, if so, it remains quite obscure as to what that factor might be.

The "For Authors" page of Acta Paediatrica contains a "Conflicts of interest and funding" section which states:

> Authors are responsible for recognizing and disclosing financial and other conflicts of interest that might bias their work.

[http://www3.interscience.wiley.com/journal/117988202/home/ForAuthors.html]. Dr. Rutter failed to make the mandatory disclosures in this paper.

Dr. Rutter published a third article in 2005, an "invited review," again denying any association between MMR and autism, and again not disclosing his participation as a paid expert witness in vaccine litigation. "Aetiology of Autism: Findings and Questions," J Intellect Disabil Res. 2005 Apr;49(Pt 4):2318 (Ex. 48). Dr. Rutter rejected MMR as a cause of autism:

> During the last decade, the main focus within the realm of possible postnatal risk factors for ASD has been on the possibility that immunization constitutes a contributory factor for ASD. First, there was the suggestion that the measles mumps rubella (MMR) vaccine was responsible for the huge recent rise in the rate of diagnosed ASD (Rutter 2004). It was argued that through the route of a vaccine caused gut disorder, there was leakage of protein products into the blood stream and that these then caused a special regressive form of autism (in which there was a loss of previously acquired social and communicative skills). A range of epidemiological studies was undertaken to determine whether the use of the MMR vaccine might be responsible for the worldwide rise in the rate of autism as diagnosed, and in particular whether it led to this postulated regressive form of autism. The evidence is consistently against the MMR hypothesis. . . . Despite strong claims made about the possible role of MMR in relation to the causation of autism, there is no convincing evidence in support of this hypothesis. In particular, the rate of ASD shows no particular association with either the stopping or starting of MMR and there has been no change over time in the pattern of association between ASD and either bowel disturbance or developmental regression.

Dr. Rutter similarly rejected mercury as a cause:

> The hypothesis regarding Thimerosal (a preservative that was, until recently, used in many vaccines) is somewhat different in detail, in that mercury is known to be a neurotoxin; accordingly, a direct adverse effect on the brain was expected. However, it remains uncertain whether a 'bolus' effect causes damage (i.e. the immediate, large, but very transient rise in mercury level following vaccination) or whether the damage derives from the cumulative mercury buildup resulting from multiple vaccinations. The epidemiological evidence on Thimerosal is much less than that on MMR but again the findings are negative. . . . The evidence with respect to a possible association with Thimerosal, a preservative in some vaccines, is much more limited but,

> again, there is no supporting epidemiological evidence of a causal association.

But Dr. Rutter was left with the problem of "explaining" away the epidemic rise in incidence:

> These negative conclusions give rise to two main queries. First, if neither MMR nor Thimerosal is responsible for the rise in autism, what has caused the increase? It is clear that the main explanation is that it derives from a combination of better ascertainment and a broadening of the diagnostic concept. However, the possibility that, in addition, there has been a true rise in incidence because of some, as yet unidentified, environmental risk factor cannot be ruled out (Rutter, 2004). . . . It remains possible that there has been a true rise in incidence because of some environmental risk factor but, if so, it remains quite obscure as to what that factor might be. . . . It remains possible that there has been a true rise in incidence because of some environmental risk factor but, if so, it remains quite obscure as to what that factor might be.

He was at least prudent enough to leave himself an "out" by conceding that an unknown number of cases could be caused by vaccination in susceptible children:

> Second, although it is no longer plausible that MMR or Thimerosal have led to an overall increase in ASD, the epidemiological data cannot exclude the possibility that either might have a risk effect in a small proportion of unusually susceptible children. There is no evidence supporting this suggestion but it cannot be firmly excluded.

The "Conflict of Interest" section on the Author Guidelines page, Journal of Intellectual Disability Research, defines a disclosable conflict:

> Authors are required to disclose any possible conflict of interest. These include financial (for example patent, ownership, stock ownership, consultancies, speaker's fee). Author's conflict of interest (or information specifying the absence of conflicts of interest) will be published under a separate heading entitled 'Conflict of Interests.'

http://www.wiley.com/bw/submit.asp?ref=0964-2633. Dr. Rutter failed to make the mandatory disclosures in this paper.

A final example of Dr. Rutter's publications in 2005 is "Autism Research: Lessons from the Past and Prospects for the Future," J Autism Dev Disord. 2005 Apr;35(2):24157. Ex. 49. In a lengthy discussion of future research strategies, he warned against researching vaccines as a cause without disclosing he was paid by industry as an "expert" to defend against allegations of vaccine-caused autism. Such a recommendation is particularly insidious and damaging given Rutter's role as the "dean" of UK autism researchers and his eminence in the field. Dr. Rutter pointed to the possibility of non-vaccine environmental triggers:

> [A]ll researchers need to decide when to divert resources and energies to test implausible claims. . . . I have not spent much time investigating urinary peptides or the claim that the measles-mumps-rubella vaccine caused autism because in each case the original evidence was so poor. . . . As noted above, it is evident that over the last 30 years or so there has been a major rise in the rate of autism spectrum disorders as diagnosed (Rutter, 2005). The evidence shows that most of the rise is attributable to the combination of better ascertainment and a broadening of the diagnostic concept. What remains uncertain is whether, in addition, there has been a true rise in incidence. The possibility cannot be ruled out and, if there has been a rise, it would point to the operation of some environmental risk factor. The multifactorial nature of autism (Rutter, in press) means that such risk factors are likely to exist, even if they have not been identified so far. <u>The measles mumps rubella vaccine was postulated as a risk factor but the epidemiological evidence has been consistently negative (Rutter, 2005). There is not much to be gained from seeking to answer the general question of whether there has been a true rise in incidence</u>.

Although the Journal of Autism and Developmental Disorders follows the strict conflict of interest requirements of the American Psychological Association, Dr. Rutter's paper failed to disclose his financial conflict in defending industry against allegations of vaccine damage.

Following his testimony as an "expert" for the prosecution in the FTP hearing, Dr. Rutter continued to publish against a real risk in incidence and against vaccines as a cause of autism, but still failed to make the required disclosures that he was a paid litigation expert for industry. For example, "Commentary: Fact and Artifact in the Secular Increase in the Rate of Autism," Int J Epidemiol. 2009

Oct;38(5):12389. Ex. 50. Dr. Rutter repeated his standard mantra:

> Almost all reviews have concluded that a substantial part of the rise in the rate of diagnosed autism has been due to a combination of better ascertainment and a broadening of the diagnostic concept, but has there been, in addition, a true rise in incidence? In my view, we simply do not know. The rise has been seen in Europe, the USA and Japan, but there is a geographic variability in whether the main rise began in the 1970s and 80s, or rather in the 1990s. The claims that the so-called 'epidemic' of autism was due to either the measles–mumps–rubella (MMR) vaccine or mercury-containing preservative thimerosal that used to be present in many vaccines are not supported by the evidence. Most crucially, in Japan, where MMR was discontinued at a time when it remained in wide use in other countries, the removal of MMR was not followed by any fall in the rate of autism, or even by a reduction in the rate of rise. Similarly, the discontinuation of use of thimerosal in Scandinavia was not followed by any change in the rising rate of autism.4 Nevertheless, these findings do not rule out a risk effect from other prenatal or postnatal toxins or other hazards.

The "Conflict of Interest" form of the International Journal of Epidemiology states its policy as follows:

> IJE policy requires that all authors of all manuscripts sign a statement revealing (1) any financial interest in or arrangement with a company whose product was used in a study or is referred to in a manuscript; (2) any financial interest in or arrangement with a competing company, (3) any direct payment to an author(s) from any source for the purpose of writing the manuscript, and (4) any other financial connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated—including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition.

The legend at the bottom of Rutter's article stated: "Conflict of Interest; None declared." Dr. Rutter failed to make the required disclosures.

Count VIII
Dr. Michael Rutter
False Testimony as Expert Witness Before the GMC

Dr. Rutter gave expert testimony before the GMC's FTP hearing on October 1, 2007, claiming that Dr. Wakefield should have disclosed his involvement in MMR litigation in the Lancet Case Series. This testimony was false because Dr. Rutter failed in at least four papers to make precisely the same disclosures for which he faults Dr. Wakefield– involvement in MMR litigation – even under the more stringent disclosure obligations implemented in the early 2000's. If Dr. Rutter doesn't honestly believe (although this would contravene the express language in the modern disclosure guidelines) that acting as a litigation expert on precisely the same subject discussed in his published papers (and on which he relies for his opinion in litigation) is a disclosable conflict, then he is falsely accusing Dr. Wakefield of breaching a non-existent duty. Or, if he honestly believes this is a disclosable interest, then his testimony is false and misleading because he has concealed the fact of his own pattern of non-disclosure.

The GMC's Ethical Guidance for Doctors, Acting As An Expert Witness - Guidance for Doctors, provides that "the principles set out in Good Medical Practice also apply to doctors working as expert witnesses," specifically referring to ¶¶ 63-67. See http://www.gmcuk.org/guidance/ethical_guidance/expert_witness_guidance.asp. GMP 67 requires that an expert witness give honest testimony:

> 67. If you are asked to give evidence or act as a witness in litigation or formal inquiries, you must be honest in all your spoken and written statements. You must make clear the limits of your knowledge or competence.

The Ethical Guidance amplifies on this requirement by requiring that the expert be "not misleading" and that he "not deliberately leave out relevant information."

> 10. You must make sure that any report that you write, or evidence that you give, is accurate and is not misleading. This means that you must take reasonable steps to verify any information you provide, and you must not deliberately leave out relevant information.

Finally, the Ethical Guidance (¶ 14) requires that an expert " must be honest, trustworthy, objective and impartial."

Dr. Rutter was an expert (as opposed to factual) witness against Dr. Wakefield in the ongoing FTP hearing. Tr. 35-2C. He explained that he had been a member of his hospital's ethics committee "for a long time," and therefore was an "expert" in conflicts disclosure. Tr. 35-5B. He explained that he was an expert witness on behalf of the vaccine industry in the UK MMR litigation, and examined two of the "Lancet 12" children:

> This [examination of the two children] is in relation to what was to be litigation in relation to MMR. In fact it never came to court. My role in that was as an expert witness to deal with both general issues on the science and the specific ones in relation to a group of children chosen by both sides as representative, so I wrote a draft report. As I say, that never came to anything. That was concerned with different issues in that it was concerned with the science rather than the ethics and it did not involve the ethics at all.

Tr. 35-5D. His CV indicates that he has published over 400 articles, and that he is a member of 20 editorial boards. He was thus intimately familiar with disclosure obligations relating to financial and other real and perceived conflicts, and how these have evolved during the past decade.

Dr. Rutter gave his opinion that, in 1996 and now, a researcher had an objective duty to disclose conflicting interests, although he misunderstands the then-applicable Lancet standard:

> Smith: . . . In 1996 if you were a research doctor formulating a research project and subsequently when you submit it for publication, would any possible conflict of interest and I underline we are in 1996 would it be a subject to which you would have given consideration?
>
> Rutter: Yes, it would be routine to have done so and it is in terms not of the individual investigators actual conflict of interest as they think but of perceptions. There are umpteen documents on ethical issues and they all make clear that it is perceived conflicts which are important, and that in 1996 as well as now that would have to be seen as potentially relevant in the

way that people would read and interpret the findings of a paper. So, yes, it would have to be made explicit.

Tr. 37-55D. He gave the reason for the disclosure obligation is so that the reader of the published research can judge for himself whether the quality of the reported science outweighs the potential for the conflict to bias the interpretation:

> Smith: I know this is a huge subject but you say it would be something in 1996 that should have been given consideration to. Just in broad terms first, what is its relevance to scientific research, why is it regarded as something that should be considered and declared if there is a possible perception?
>
> Rutter: Because there is actually a [vast] substantial research literature which shows that everybody, that is all of us as well as the rest of the world outside, whether we like it or not is influenced in our judgments by what we think might be the case, so if there is a reason for favouring one interpretation than another you have to assume that although you may not be conscious of it, it will do so. That is the reason why these things have to be made transparent, made overt, so that people can judge for themselves is the science of such high quality that really the perceived possible conflict of interest can be cast aside because the evidence is so strong or is this open to a variety of interpretations where the fact that one answer will lead to one sort of outcome and another to a different sort of outcome may influence judgment.

Tr. 37-55E. In subsequent testimony concerning Dr. Wakefield's patent for transfer factor as a potential treatment for MMR damage, Rutter reiterated his opinion that disclosure was required under an objective standard whether the conflict might be "perceived" as a conflict by others:

> Rutter: Yes, I am because I think it does raise a perceived conflict of interest, if you like, in exactly the same way as Dr Wakefield was worrying about in terms of government experts. They may or may not have influenced their views, and this may or may not have influenced his views, but the point is that unless one knows that you have to worry. The rule is that you declare whatever the relevant interest is. The problem is not on conflicts. All of us have conflicts of various kinds through our employment, through our funding and so on. The problem is not making those known to other people.

Tr. 37-62A.

Dr. Rutter stated that this standard was objective, not subjective, i.e. up to the judgment of the individual researcher:

> Smith: Is that in your view, in fact, however brilliant you may be as a scientist, a judgment that a researcher is necessarily able to make for himself?
>
> Rutter: No, in fact the rules are perfectly clearcut that they cannot . . ..

Tr. 37-55G.

An author's duty of disclosure in the Lancet in 1998 was described in "Conflict of interest and Funding:"

> The conflict of interest test is a simple one. Is there anything--e.g. a shareholding in or receipt of a grant or consultancy fees from a pharmaceutical company or a contract from a medical devices manufacturer--that would embarrass you if it were to emerge after publication and you had not declared it. The editor needs to be informed and will discuss with you whether or not disclosure in the journal is necessary. All sources of funding must be disclosed as an acknowledgement in the text.

Tr. 37-57C (Ex. 60) (emphasis added); see FTP2 at 616. The Lancet policy on disclosure in 1998 was very narrow and based entirely on the subjective state of mind of the author. The disclosure obligation was subsequently, and appropriately, made much broader and based on an objective third-party standard of what a reasonable person would perceive to be a conflicting interest at the Lancet and throughout scientific and medical publishing. However, Dr. Rutter faulted Dr. Wakefield for violating the stricter standard well before it was implemented at the Lancet.

Ms. Smith then asked Dr. Rutter whether he would have disclosed his involvement in the MMR litigation under the then-applicable standard:

> Smith: . . . I want to ask you this, putting yourself in the shoes of a reasonably responsible and experienced submitter to medical journals would

you regard that test as triggering disclosure in relation to Dr Wakefield's involvement in the litigation?

Rutter: Yes, I would, for the reasons I have already given.

Smith: Would you regard it as a matter about which a doctor should have any hesitation?

Rutter: No hesitation I would have thought.

. . .

Smith: If you had uncertainties in your own mind you say you would not in fact but if you did as to the novelty of the monies and whether that did constitute a conflict of interest, what should you have done about it?

Rutter: I suppose consult with colleagues if you like, but it seems to me that the rule throughout all of this is transparency is the aim. Whether there is an actual conflict, whether there is an actual bias is neither here nor there, and that was so in that era as well as today . . ..

Tr. 37-57D.

Dr. Rutter gave dishonest and misleading expert testimony in violation of the above-cited GMP's and Ethical Guidance. As noted above in Count VII, Dr. Rutter has been a paid expert for industry in at least three litigation projects in the UK and US, yet he routinely fails to disclose this conflicting interest in his published papers. Thus, putting himself "in the shoes of a reasonably responsible and experienced submitter to medical journal," as Ms. Smith instructed, Dr. Rutter cannot honestly and in good faith testify that Dr. Wakefield should have made disclosures – even under the current broader objective standard – because he <u>fails to make the very same disclosures in his own publishing activities</u>.

<u>Nature of the Harm Suffered by Autistic Children</u>

The false statements and testimony described above have harmed patients, children with autism. By discrediting the Lancet Case Series and holding its authors up to public ridicule, they discouraged scientists and doctors from investigating causes and treatments for autism. Brian Deer, the complainant in the GMC action, infected US Vaccine Court with these falsehoods, thereby delaying

justice for vaccine-injured children in the U.S. Numerous false reports have been propagated throughout the media, based on the false statements alleged herein, further delaying vital research. For example:

> In 2004, however, 10 of the 13 original authors on The **Lancet** paper asked that it be **withdrawn**, saying that "no causal link was established between MMR vaccine and autism because the data was insufficient," the Sunday Times of London said.

Health Day (Feb. 11, 2009). This fails to state the limitation of the 2004 "retraction," i.e. that it was to the "interpretation" placed on the Lancet Case Series by the media. Further, none of the authors has ever requested that the paper be "withdrawn," nor has it been. In another example:

> For some people, medical science is a sinister business. Take the measles, mumps and rubella (MMR) vaccine, the subject of a dodgy piece of research in 1998 linking it to autism. The paper, which appeared in The **Lancet** , was subsequently withdrawn . . .

Ahuja, A. "Time for the MMR Vaccine Voodoo to Rest," Times (UK) (Feb. 6, 2008).

Children injured by vaccines have the legal right to seek redress in the form of damages in both the UK and the United States. The Consumer Protection Act of 1988 facilitated class actions which could be funded by the Legal Aid Board (now the Legal Services Commission).

Sick children and their families who believe they may have been injured by vaccines must have access to science, medicine, and law. Scientists must be free to find the cause and treatments for autism. Doctors must deliver proper care both in diagnosis and treatment. Lawyers connect science and medicine to justice as part of the overall social fabric of a civilized society. Contrary to the attempt by Dr. Zuckerman to block Dr. Wakefield's research, and the claim by Dr. Horton that he would not have published the Lancet Case Series had he known of Wakefield's participation in the MMR litigation, there are adequate safeguards to ensure the adequacy, integrity, and independence when doctors provide their expertise and research to lawyers in pursuit of justice. For example, see GMC, "Acting as an Expert Witness" [http://www.gmc-uk.org/guidance/ethical_guidance/expert_witness_guidance.asp], "Personal Beliefs

and Medical Practice" [http://www.gmc-uk.org/guidance/ethical_guidance/personal_beliefs/personal_beliefs.asp]; "Research: The Role and Responsibilities of Doctors" [http://www.gmc-uk.org/guidance/current/library/research.asp]. Lawyers are similarly bound by an ethical code to be honest in dealing with adversaries and any tribunal. See ABA, "Model Code of Professional Responsibility" [http://www.abanet.org/cpr/mrpc/mrpc_toc.html].

The childhood vaccine schedule must be as safe as it can be in order to produce the benefits to society of herd immunity while at the same time protecting individual children from harm. Lawyers accomplish this goal first, by regulation, and second, through the tort system.

MMR is not unique as a target of suppression and censorship of research questioning safety. The British Medical Journal published a Cochrane Collaboration analysis revealing that influenza vaccine studies are more likely to be published in medical journals and rated highly if they are funded by pharmaceutical companies, even when the vaccine studies are of poor quality. "Relation of study quality, concordance, take home message funding, and impact in studies of influenza vaccines: systematic review," BMJ 2009;338:b354 doi:10.1136/bmj.b354. The Court relied heavily on epidemiological studies published in medical journals - the same medical journals which give preferential treatment to methodologically flawed studies funded by vaccine manufacturers.

<u>The Government Policy of "Deliberate Ignorance" Regarding Vaccine Safety</u>

By displacing scientific inquiry and appropriate medical care with an inappropriate "show trial," the false testimony and statements alleged herein have contributed to a climate of "deliberate ignorance" exposing all children to great risk: chronic vaccine-caused injuries that could have been prevented or properly treated; and preventable infectious diseases that will return without an aggressive "safety first" agenda. It is impossible to achieve the goal of safer vaccines, or even to assess progress, without having an accurate baseline benchmark for acute and chronic disease in unvaccinated children. Without these data, we simply cannot know how much acute and chronic disease (adverse reactions or AEFI's) is caused by vaccines. Ellenberg, et al., "The complicated task of monitoring vaccine safety," Public Health Rep: 1997 Jan-Feb;112(1):10-20; discussion 21.

Ignorance is no substitute for science. It is impossible and unethical to communicate accurate and complete information about the risks and benefits of vaccines without knowing the actual risks from vaccination. Mandating a childhood vaccine schedule that causes unknown chronic adverse reactions raises serious ethical concerns, in spite of the obvious benefits from reducing death and serious disease from preventable infections. These ethical issues are especially serious because measures can be undertaken to reduce or prevent chronic adverse events (pursuant to the Congressional mandate cited above) while still retaining the benefits of vaccines. These could include, e.g., vaccine redesign, eliminating toxic metals and other problematic additives, screening for genetic susceptibility, alternative schedules, and greater reliance on antivirals or other interventions. But without complete baseline data, it is not possible to know what measures must be taken and how far we must go to provide children the safest possible vaccine program.

Growing doubts over the extent of vaccine-caused disease are fueling a rise in exemptions. Calandrillo, "Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children," U. Mich. J. Law Ref. 2004:37:2:353; Smith, et al., "Children Who Have Received No Vaccines: Who Are They and Where Do They Live?" Pediatrics 2004:114;187. Responding to increased parental concerns over vaccine safety is consuming a growing amount of time on pediatricians and their staffs. A growing number of healthcare providers have doubts about the quality of CDC vaccine safety science and are concerned that CDC is underreporting serious AEFI's. Linkins, et al., "Support for immunization registries among parents of vaccinated and unvaccinated school-aged children: a case control study," BMC Public Health: 2006 Sep 22;6:236. Vaccine refusals and delays are rising among the more affluent, educated, and professional parents (many of whom are in my Manhattan district), often citing concerns over safety, efficacy, and lack of trust. See, e.g., Salmon, et al., "Factors Associated With Refusal of Childhood Vaccines Among Parents of School Aged Children," Arch Pediatr Adolesc Med. 2005 May;159(5):470-6; Salmon, et al., "Parental Vaccine Refusal in Wisconsin," Wisc. Med. J. 2009 Feb;108(1):17-23. In a recent study, 28% of parents felt doubtful about vaccines, with 20% delaying or refusing vaccines for their children; 59% of those fully vaccinated had concerns over vaccine safety and side effects, while these concerns rose to over 75% in the groups delaying and refusing vaccines. Gust, et al., "Parents with doubts about vaccines: which vaccines and reasons why" Pediatrics. 2008 Oct;122(4):718-25. Indeed, it is the recent rapid rise in such refusals (and pursuit of alternative schedules) that lends urgency to the need for sound science in support of a "safety

first" agenda. Lack of public confidence in vaccines poses a serious threat to pandemic and biodefense preparedness as illustrated by the current pandemic of media coverage of swine flu.

Public confidence essential to support high vaccine uptake must be supported by sound science, and this is the responsibility of Government. Placing blame on increasingly worried and skeptical parents, critics, advocacy groups, or celebrities, and spending money on more and "better" risk communication and awareness campaigns will not substitute for the necessary safety science.

Claims that vaccines save lives and that "Vaccines are held to the highest standard of safety. The United States continues to have the safest . . . vaccine supply in history" are insufficient reassurance without adequate scientific support. [http://www.cdc.gov/vaccinesafety/basic/parents.htm] A recent paper conceded: "No studies have compared the incidence of autism [or other chronic adverse events] in vaccinated, unvaccinated, or alternatively vaccinated children (i.e., schedules that spread out vaccines, avoid combination vaccines, or include only select vaccines)." Gerber, J., Offit, P., "Vaccines and Autism: A Tale of Shifting Hypothesis," Clin Infect Dis. 2009 Jan 7.

To protect public confidence in vaccines, it is imperative that retrospective studies be conducted immediately and on-going prospective studies be initiated since adequate baseline data were not gathered during the past 25 years, a period during which CDC increased the number of recommended vaccines for children under five from 10 (against seven diseases) to 36 (against an additional seven). This crucial gap in our vaccine safety science has been noted for some time, both inside and outside government, and increasingly by advocacy groups and the public at large.

The Institute of Medicine panel that conducted a limited review of immunization safety concluded after its review of the literature that it could not reject a vaccine-autism link in a genetically susceptible sub-population:

> Determining causality with population-based methods such as epidemiological analyses requires either a well-defined at-risk population or a large effect in the general population. Absent biomarkers, well-defined risk factors, or large effect sizes, the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or

> very unusual circumstances. However, there is currently no evidence to support this hypothesis either. . . . A genetically susceptible subset of children who develop autism following vaccinations is one theoretical explanation for the findings in epidemiological studies of no association between vaccination and autism. . . . If there is a subset of individuals with autism syndrome triggered by exposure to vaccines, our ability to find it is very limited in the absence of a biological marker.

Institute of Medicine, Vaccines and Autism at 11, 127 (2004). Far from ruling out vaccine-caused autism or other chronic diseases, these findings clearly call for further research.

Thomas Verstraeten, the lead co-author of the only American epidemiological study relied upon by IOM subsequently disavowed the IOM's negative causation interpretation, stating in a subsequent letter to Pediatrics [2004;113;932]: "The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come. . . . A neutral study carries a very distinct message: the investigators could neither confirm nor exclude an association, and therefore more study is required. . . . The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required." NIH subsequently issued a report highly critical of CDC's vaccine safety datalink (VSD) on which Dr. Verstraeten's study was based. "Thimerosal Exposure in Pediatric Vaccines" (October, 2006) [http://www.niehs.nih.gov/health/topics/conditions/autism/docs/thimerosalexposureinpediatricvaccines102606.pdf]. CDC subsequently delivered a report to the House Appropriations Committee conceding errors in the design and methods of the supposedly exculpatory 2003 Verstraeten study. CDC, "Report to Congress on Vaccine Safety Datalink" (June, 2008) [http://evidenceofharm.com/VaccineDataLinkReporttoCongressFinal.pdf].

Dr. Julie Gerberding, then head of CDC, answered a question ("Have you looked at autism in a never-vaccinated population in the U.S. and if not, why not?") at a July 17, 2005 press conference as follows:

> . . . I think those kinds of studies could be done and should be done. . . . I think with reference to the timing of all of this, good science does take time and it's part of one of the messages I feel like I've learned

> from the feedback we've gotten from parents groups this summer struggling with developing a more robust and a faster research agenda, is let's speed this up, and let's look for the early studies that could give us at least some hypotheses to test and evaluate and get information flowing through the research pipeline as quickly as we can. So we are committed to doing that, and as I mentioned, in terms of just measuring the frequency of autism in the population, some pretty big steps have been taken and we're careful not to jump ahead of our data but we think we will be able to provide more accurate information in the next year or so than we've been able to do up to this point.

[http://www.cdc.gov/od/oc/media/transcripts/t050719.htm].

Dr. Tom Insel, Director of the National Institute of Mental Health and Chairman of the Interagency Autism Coordinating Committee, also conceded a crucial lack of knowledge when pressed on the urgency of vaccine-autism research at a Congressional hearing:

> Gerberding: . . . [W]e also know that no vaccine is ever going to be 100 percent safe, and we have a responsibility to investigate safety, not just from this lane but from the whole spectrum.
>
> HARKIN: I don't want to continue on this. We can discuss this as at further hearings that we'll have, Dr. Gerberding. My point is not that those vaccines aren't' safe. That's not my point. My point is that you add them all up, and do we really know that 31 of those given in the first 18 months, within that short span of time -- each one of them may be individually fine, but do we know what the outcomes, what the impact is, say, on someone who may be genetically predisposed to have autism? In any event, [****] 31 of these vaccines all compacted in a short period of time, how could that perhaps trigger that genetic predisposition? I don't know that you can answer that question.
>
> GERBERDING: Well, I can tell you that it's not related to thimerosal because the childhood vaccines that your children are getting don't contain thimerosal as a preservative.
>
> HARKIN: Except that one, that...

GERBERDING: Some of the flu shot vaccines still contain thimerosal. They're trying to take it out, but it hasn't happened across the board yet. But it's very small amount of thimerosal. And you know, we've been talking about is the prevalence of autism increasing in our country? It's continuing to either stay the same or increase, even though we have removed the thimerosal as a preservative of vaccine for several years now.

HARKIN: I'm not talking about thimerosal. I'm just talking about the combined affects of all those vaccines on a small body that may be genetically predisposed anyway. That's what I'm talking about. I'm not talking about thimerosal.

GERBERDING: It's one of the hypothesis that I think needs to be evaluated in the studies that are going on. I don't think it's the most likely hypothesis, but it certainly should be included in the risk profile.

INSEL: I think the message that we'd like to convey is it's too early to reach premature closure on any of this. We simply don't know. I think all of us agree that there must be something beyond the genetics.

HARKIN: There's got to be because, Dr. Insel -- and that's why I asked that question at the beginning: Do we know what's happening in other countries?

Senate Appropriations Committee, Subcommittee on Labor, HHS, Education, and Related Agencies, "Autism Research at the National Institutes of Health" (April 17, 2007).

Despite the inadequacy of the science recognized by Dr. Gerberding and her commitment to timely studies of unvaccinated children, the draft scientific research agenda released April 11, 2008 specifically stated (p. 44) that "risk-benefit studies" and "general assessment of baseline rates of clinical outcomes" were outside the scope of the CDC's Immunization Safety Office scientific agenda. [http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf]. CDC conceded on page 33 that "[u]sually simultaneous vaccination is incompletely studied at time of licensure." The draft agenda also admitted on page

17: "Little is known about the immune gene expression changes that occur after vaccination; even less is known about immune genes expressed during an [adverse event following immunization]."

The Vaccine Safety Working Group (VSWG) of the National Vaccine Advisory Committee (NVAC) discussed the ability of the NCS to powerfully assess vaccine safety:

> Dr. Peter Scheidt said that the National Children's Study could address a number of the questions raised in that there would be enough children enrolled in the study who have not received particular vaccines that comparisons could be made between exposed and nonexposed groups. The hygiene hypothesis, he said, is one of the specific hypotheses of the National Children's Study. Although the study's other hypotheses do not specifically address vaccines, vaccination data (by maternal report) will be collected. While there is no current plan to collect some vaccine data, such as manufacturers or lot numbers, that could be done if there is interest and funding. The study will collect toxicological and environmental data, and there is potential for generational followup.

NVAC, VSWG Meeting Summary, April 11, 2008 [http://www.hhs.gov/nvpo/nvac/minutes20080411.html].

The VSWG issued its draft report and recommendations on April 14. In particular, VSWG found:

> Given that vaccines are given to healthy individuals, often children, to prevent disease, expectations for vaccine safety are very high. In recent years, there has been highly visible public concern about the safety of immunization and the adequacy of safety research. . . . The focus of the draft ISO Scientific Agenda is on post-adverse event studies; little attention is given to studies that would help predict the risk of adverse events before the exposure to the vaccine and to prevent the adverse event (primary prevention). A fundamental principle in vaccine safety research should be to prevent vaccine adverse reactions whenever possible, and if that is not possible, to ameliorate the effects of the adverse reaction (secondary prevention). . . . As part of determining the likelihood that an adverse event

> following immunization (AEFI) is caused by a vaccine, it is important to identify the biologic mechanism of the adverse event. An AEFI is an adverse event temporally associated with an immunization that may or may not be causally related to the immunization. A biologic mechanism is an important criterion for investment into vaccine safety research and evaluating causality, and may also lead to development of safer vaccines or vaccination practices. The Working Group has previously stated (page 28) that prevention and amelioration of vaccine adverse events is the priority, and understanding the biologic mechanism is a key strategy to achieving this objective. This topic was originally dismissed by ISO on the grounds that it was not adequately defined.

[http://www.hhs.gov/nvpo/nvac/documents/NVACVaccineSafetyWGReport041409.pdf, pp. 13, 27-28, 31]. The VSWG went on to recommend a research program focusing on comparing the overall health outcomes of vaccinated, unvaccinated, and alternately vaccinated children:

> The Working Group endorses the Writing Group's recommendation for an external expert committee, such as the Institute of Medicine, with broad methodological, design, and ethical expertise to consider "strengths and weaknesses, ethical issues and feasibility including timelines and cost of various study designs to examine outcomes in unvaccinated, vaccine delayed and vaccinated children and report back to the NVAC.

Id., p. 32.

The U.S. Combating Autism Act of 2006, P.L. 109-416, authorized $640 million over five years to expand and intensify autism basic and clinical research conducted by NIH to "investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder." 42 U.S.C. 284g(a)(1). Both House and Senate legislative history singled out a single research opportunity, vaccines, transcending many of scientific disciplines listed in the CAA. House Commerce Chairman Barton explained:

> With respect to possible environmental or external causes of autism, some have suggested a link exists between autism and childhood

> vaccines. . . . I recognize that there is much that we do not know about the biological pathways and origins of this disorder, and that further investigation into all possible causes of autism is needed. This legislation is not designed to predetermine the outcome of scientific research. Rather, the legislation rightfully calls for renewed efforts to study all possible causes of autism-including vaccines and other environmental causes. Simply put, we should leave no stone unturned in our efforts to find a cure, whether it means exploring possible environmental factors, paternal age, genetic factors, or any other factors that may hold answers.

152 Cong. Rec. H8787 (December 6, 2006). Autism Caucus Co-Chair Smith explained:

> Importantly, the bill directs that NIH-funded research include investigation of possible environmental causes of ASDs and that CDC-funded epidemiological centers develop expertise in specialty areas, including environmental exposures. I applaud this recognition of the need to pursue research into environmental factors and epigenetics to further advance and clarify the science. While not specifically addressed in this bill and although some are fearful to even mention the issue, I believe that we do not yet have the answers we need regarding the biological effects of thimerosal, and I am hopeful that research on environmental factors will include further study to find those important answers.

Id. Senate HELP Committee Chairman Enzi explained the CAA research mandate as follows:

> [T]he bill reported by the HELP Committee contemplates key research activities, including environmental research, that focus on a broad range of potential contributing factors, with meaningful public involvement and advice in setting the research agenda. However, I want to be clear that, for the purposes of biomedical research, no research avenue should be eliminated, including biomedical research examining potential links between vaccines, vaccine components, and autism spectrum disorder. . . . No stone should remain unturned in trying to learn more about this baffling disorder, especially given how little we know.

152 Cong. Rec. S8772 (Aug. 6, 2006). In their December 7, 2007 letter to HELP Chairman Kennedy requesting a hearing on CAA-funded research, Sens. McCain and Lieberman stressed: "We have heard the concerns of many Americans that a number of environmental exposures, such as thimerosal, pesticides, metals, organic pollutants and other ambient factors, may be linked to autism. Our research efforts should support broad approaches to understanding the wide range of etiologic factors in our environment that may be related to autism for both prevention and treatment purposes."

NIH announced two funding opportunities for R01 and R21 grants related to vaccine safety on August 28, 2008. [http://grants.nih.gov/grants/guide/pa-files/PA-08-256.html; http://grants.nih.gov/grants/guide/pa-files/PA-08-257.html]. However, no funding was set aside to fund such research.

US News quoted Dr. Anthony Fauci, Director of NIAID, on December 11 with respect to such studies: "If we can show that individuals of a certain genetic profile have a greater propensity for developing adverse events, we may want to screen everyone prior to vaccination (for) undetectable diseases like a subclinical mitochondrial disorder."

At its December 12, 2008 meeting, IACC voted to include two crucial vaccine-autism initiatives in the strategic plan for autism research mandated by the Combating Autism Act:

> 1) "Study the effect of vaccines, vaccine components, and multiple vaccine administration in autism causation and severity through a variety of approaches, including cell and animal studies, and understand whether and how certain subpopulations in humans may be more susceptible to adverse effects of vaccines by 2011. Proposed costs: $6,000,000
>
> 2) Determine the feasibility and design an epidemiological study to determine if the health outcomes, including ASD, among various populations with vaccinated, unvaccinated, and alternatively vaccinated groups by 2011. Proposed costs: $10,000,000.

12/12/08 Tr. 139-165.

Unfortunately, urged by CDC, both research initiatives were deleted from the strategic plan at the January 14 IACC meeting. Not only was there no notice on the agenda that the final decision on these proposals made in December would be revisited, IACC Chairman Insel made the stunning admission that HHS has a conflict of interest in funding research that might be critical of vaccine safety because of the 5,000 cases pending in Vaccine Court in the Omnibus Autism Proceeding.

IACC Chairman Insel wrote to NVAC seeking collaboration:

> Communication between the IACC and NVAC will permit each group to be informed by the expertise of the other, enhance coordination and foster more effective use of research resources on topics of mutual interest. Examples of such topics include: studies of the possible role of vaccines, vaccine components, and multiple vaccine administration in ASD causation and severity through a variety of approaches; assessing the feasibility and design of an epidemiological study to determine whether health outcomes, including ASD, differ among populations with vaccinated, unvaccinated, and alternatively vaccinated groups; and investigating the reasons as to why some sub-groups may be a higher risk for vaccine injury and how to identify such risk factors.

Dr. Insel invited Dr. Bruce Gellin, Director of NVPO, to make a presentation to the IACC meeting on February 4. Dr. Gellin explained that NVPO was happy to collaborate with IACC but that he had no funding and infrastructure for research projects.

Dr. Duane Alexander, Director of the National Institute of Child Health and Human Development, explained at the December 12 Interagency Autism Coordinating Committee (IACC) how the impending National Children's Study would gather the missing baseline data:

> The National Children's Study will have 100,000 kids to study, but we will only have for comparison unvaccinated 5,000 to 10,000. And that is barely enough, really not enough to give you a sample of sufficient size to make a determination of some of the issues.

Tr. 141:11-17. He later elaborated on the existing lack of adequate data:

MS. REDWOOD: So if you had 10,000 could you not look at total health outcomes in those 10,000 children compared to 10,000 age-matched controls that were completely vaccinated following the CDC schedule? I'm just curious. I'm just asking that question.
DR. ALEXANDER: You could do that. And in fact what we will have is essentially 90,000 age-matched controls. But the problem is for each one of those outcomes, the number gets small. And within the 10,000, the 5-10,000 cohort the numbers of any of those outcomes is going to be very small. And this is one of the things that has hampered vaccine studies all along is, the numbers of unvaccinated controls and the outcomes that are relatively rare demands a very large population. We really seriously need to try and develop better methodologies to get the populations that we need for these kinds of studies. Because the studies that have been done all have suffered from the same problems of lack of numbers and so forth. Right now we don't have a very good way to do this. Within the National Children's Study, we can and we will address these issues, but it probably will not yield definitive answers on this kind of issue because of the unvaccinated sample that maybe quite different in composition in general from the vaccinated sample of kids. . . ..

Tr. 142:21-144:8.

Dr. Alexander explained the need for autism-vaccine research in an interview with Dr. Geri Dawson, Chief Science Officer of Autism Speaks:

One question that still remains to be addressed in a study of adequate size and precision is the one described in the preceding response, which is whether there is a subgroup in the population that, on a genetic basis, is more susceptible to some vaccine characteristic or component than most of the population, and may develop an ASD in response to something about vaccination. We know that genetic variations exist that cause adverse reactions to specific foods, medications, or anesthetic agents. It is legitimate to ask whether a similar situation may exist for vaccines. No clear evidence yet exists to implicate a specific relationship, but questions persist about whether there may be subpopulations unable to remove mercury from the body as fast as others, some adverse or cross-reacting response to

> a vaccine component, a mitochondrial disorder increasing the adverse response to vaccine-associated fever, or other as-yet-unknown responses.

[http://www.autismspeaks.org/science/science_news/nichd_alexander_interview.php]

Numerous public figures have joined the call for vaccine safety research, noting that legitimate doubts threaten public confidence in vaccination. For example, Dr. Louis Cooper, former head of the American Academy of Pediatrics explained:

> It's hard for a single court decision to compete with ongoing allegations from grieving parents and celebrities that vaccines created an epidemic of autism. Those allegations have generated confusion and fear in the minds of many young parents, reduced public trust in the remarkable benefits and safety of U.S. immunization programs and put both vaccinated and unvaccinated children at increased risk from preventable diseases. Furthermore, significant unanswered questions about the safety of vaccines have been documented by the Institute of Medicine and the National Institutes of Health. For example, are some few individuals genetically more susceptible to adverse reactions from certain vaccines? A more common worry among parents is "Are too many vaccines given too soon?"
>
> . . . As a result, rates of vaccine refusal have climbed to levels allowing clustered outbreaks of vaccine-preventable diseases such as measles, pertussis and meningitis, posing a threat to those unvaccinated because of medical contraindications, age and parental choice. For example, in Washington, statewide refusal rates now exceed 5 percent, including rates exceeding 15 percent in some counties. Other states show doubling rates. Also worrisome is the disproportionate amount of time pediatricians must now spend to assure fearful parents that vaccination is the best choice for their child. At what level will the growing refusal rates put us at risk of major epidemics?
>
> What has been missing in order to give parents confidence that immunization is one of the best ways to protect the health of their

> children? Our national failure falls into two categories. First, we've had inadequate ongoing, credible education of the public and health professions from trusted public-health officials concerning the known and unknown benefits and risks of vaccines. Today's parents have little fear of diseases they mistakenly think have been eliminated by vaccines. Second, there's been grossly insufficient investment in research on the safety of immunization. Together, these failures contributed to undermining of public confidence.

"The Confidence Gap: Why the Obama Administration Needs to Restore Public Faith in the Safety of Childhood Vaccines," Newsweek (Feb. 23, 2009) (emphasis added) [http://www.newsweek.com/id/185986].

In a May 12, 2008 interview with CBS News producer Sheryl Atkisson, Dr. Bernadine Healy, former Director of the National Institutes of Health, explained:

> "I think that the public health officials have been too quick to dismiss the [autism-vaccine]hypothesis as irrational, Healy said. "But public health officials have been saying they know, they've been implying to the public there's enough evidence and they know it's not causal," **Attkisson** said. "I think you can't say that," Healy said. "You can't say that."
>
> Healy goes on to say public health officials have intentionally avoided researching whether subsets of children are "susceptible" to vaccine side effects - afraid the answer will scare the public. "You're saying that public health officials have turned their back on a viable area of research largely because they're afraid of what might be found?" **Attkisson** asked.
>
> Healy said: "There is a completely expressed concern that they don't want to pursue a hypothesis because that hypothesis could be damaging to the public health community at large by scaring people." "First of all," Healy said, "I think the public's smarter than that. The public values vaccines. But more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show." . . .

> "What we're seeing in the bulk of the population: vaccines are safe," said Healy. "But there may be this susceptible group. The fact that there is concern, that you don't want to know that susceptible group is a real disappointment to me. If you know that susceptible group, you can save those children. If you turn your back on the notion that there is a susceptible group… what can I say?" Government officials would not respond directly to Healy's views… but reiterated, vaccines are safe.

Atkisson, S., "Leading Doctor: Vaccine-Autism Worth Study," CBS News (May 12, 2008) [http://www.cbsnews.com/stories/2008/05/12/cbsnews_investigates/main4086809.shtml].

Dr. Peter Fletcher, former Chief Science Officer for the UK Department of Health, cited the urgent need for safety research in a March 22, 2006 interview:

> Dr Peter Fletcher, who was Chief Scientific Officer at the Department of Health, said if it is proven that the jab causes autism, "the refusal by governments to evaluate the risks properly will make this one of the greatest scandals in medical history." . . . He said he has seen a "steady accumulation of evidence" from scientists worldwide that the measles, mumps and rubella jab is causing brain damage in certain children. But he added: "There are very powerful people in positions of great authority in Britain and elsewhere who have staked their reputations and careers on the safety of MMR and they are willing to do almost anything to protect themselves." . . .
>
> He first expressed concerns about MMR in 2001, saying safety trials before the vaccine's introduction in Britain were inadequate.
>
> Now he says the theoretical fears he raised appear to be becoming reality.
>
> He said the rising tide of autism cases and growing scientific understanding of autism-related bowel disease have convinced him the MMR vaccine may be to blame.
>
> "Clinical and scientific data is steadily accumulating that the live measles virus in MMR can cause brain, gut and immune system

damage in a subset of vulnerable children," he said. "There's no one conclusive piece of scientific evidence, no 'smoking gun,' because there very rarely is when adverse drug reactions are first suspected. When vaccine damage in very young children is involved, it is harder to prove the links."

"But it is the steady accumulation of evidence, from a number of respected universities, teaching hospitals and laboratories around the world, that matters here. There's far too much to ignore. Yet government health authorities are, it seems, more than happy to do so."

"Why isn't the Government taking this massive public health problem more seriously?"

Dr Fletcher said he found "this official complacency utterly inexplicable" in the light of an explosive worldwide increase in regressive autism and inflammatory bowel disease in children, which was first linked to the live measles virus in the MMR jab by clinical researcher Dr Andrew Wakefield in 1998.

"When scientists first raised fears of a possible link between mad cow disease and an apparently new, variant form of CJD they had detected in just 20 or 30 patients, everybody panicked and millions of cows were slaughtered," said Dr Fletcher.

"Yet there has been a tenfold increase in autism and related forms of brain damage over the past 15 years, roughly coinciding with MMR's introduction, and an extremely worrying increase in childhood inflammatory bowel diseases and immune disorders such as diabetes, and no one in authority will even admit it's happening, let alone try to investigate the causes."

He said there was "no way" the tenfold leap in autistic children could be the result of better recognition and definitional changes, as claimed by health authorities.

“It is highly likely that at least part of this increase is a vaccine related problem.” he said. “But whatever it is, why isn't the Government taking this massive public health problem more seriously?”

His outspokenness will infuriate health authorities, who have spent millions of pounds shoring up confidence in MMR since Dr Wakefield’s 1998 statement.

But Dr Fletcher said the Government is undermining public confidence in vaccine safety by refusing to do in-depth clinical research to rule out fears of MMR damage to children.

He added that the risks of brain and gut damage from MMR injections seem to be much higher in children where a brother or sister has diabetes, an immune disorder.

“That is a very strong clinical signal that some children are immunologically at risk from MMR,” he said. “Why is the Government not investigating it further - diverting some of the millions of pounds spent on advertising and PR campaigns to promote MMR uptake into detailed clinical research instead?”

Now retired after a distinguished 40-year career in science and medicine in Britain, Europe and the US, Dr Fletcher said that without such research, health authorities could not possibly rule out fears about MMR.

He said: “It is entirely possible that the immune systems of a small minority simply cannot cope with the challenge of the three live viruses in the MMR jab, and the ever-increasing vaccine load in general.”

He said he had decided to speak out because of his deep concern at the lack of treatment for autistic children with bowel disease, as revealed in The Mail on Sunday two weeks ago.

He called the sudden termination of legal aid to parents of allegedly vaccine-damaged children in late 2003 “a monstrous injustice.” After

> agreeing to be a witness for the parents, he received thousands of documents relating to the case.
>
> "Now, it seems, unless the parents force the Government to restore legal aid, much of this revealing evidence may never come out," he said.

Corrigan, S., "Former Science Chief: 'MMR Fears Coming True,'" Mail on Sunday (March 22, 2006) [http://www.dailymail.co.uk/health/article-376203/Former-science-chief-MMR-fears-coming-true.html].

The present state of ignorance, whether deliberate or merely negligent, with respect to baseline health outcomes in unvaccinated (and alternatively vaccinated) children puts at risk confidence in vaccines and the Congressional mandate for safer vaccines. Accordingly, I want to explore what steps are being taken by DHHS immediately and in the near future to address this critical gaps in our knowledge.

Conclusion and Prayer for Relief.

The false testimony concerning publication in February, 1998, of the Lancet Case Series have leached their way into the American judicial system. They have prevented the orderly development of science, medicine, and justice. They have led to a protracted and expensive FTP hearing that has further diverted attention from the urgent need for more science and medicine in aid of autistic children. They have delayed the conduct of vaccine safety research, crucial to maintaining public confidence in mass immunization. The undersigned autism and vaccine safety Organizations call upon the GMC to immediately dismiss the Complaint brought against Dr. Wakefield, Professor Murch, and Professor Walker-Smith. Further, GMC should immediately initiate a full investigation of circumstances surrounding the investigation leading to the FTP Complaint that, had the truth been told, would have never been issued, and to the apparent false testimony of Drs. Richard Horton, Arie Zuckerman, Michael Pegg, and David Salisbury.

Respectfully submitted,

/s/ James A. Moody

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Supporting Autism Organizations in the United Kingdom:

Autism File [www.autismfile.com].
Autism Clinic [www.theautismclinic.com].
Autism Rights [www.autismrights.org.uk].
Autism Treatment Trust [www.autismtrust.org.uk].
Autism Trust [www.theautismtrust.org.uk].
CryShame [www.cryshame.co.uk].
Open Your Eyes to Autism [www.openyoureyestoautism.com].

Supporting Autism Organizations in the United States:

Age of Autism [www.ageofautism.com].
Autism File USA [www.autismfile.com].
Autism One [www.autismone.org].
Autism Research Institute [www.autismresearchinstitute.org].
Heal Autism Now Delaware (HAND Foundation) [www.handelaware.org].
Generation Rescue [www.generationrescue.org; putchildrenfirst.org].
Medical Veritas International [www.medicalveritas.com].
National Autism Association [www.nationalautismassociation.org].
National Vaccine Information Center [www.nvic.org].
NoMercury [www.nomercury.org].
Talk About Curing Autism [www.tacanow.org].
US Autism & Asperger Association [www.usautism.org].