In Harm's Way

MMR10-THEIR STORY

Autism apart from the world - Autism a part of the world.

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Trust for Autism

http://www.horne-roberts.co.uk/ebook/mmr10.doc

Editor's Note:

As will be apparent the present piece is a collaboration between a great many people and I would like to take this opportunity to thank them all for their valuable contributions. First of all the 'MMR10', parents of the children whose story this is. In particular I would like to thank Harry's mother, referred to throughout the text for professional reasons, simply as 'J H R'. She is the barrister who has given unstintingly of her time and professional advice and who has been truly and literally the group's friend at court . The case is currently on its way to the European Court of Human Rights in Strasbourg. This story could not have been told without her skill and commitment.

Among many others have been Peter Fletcher MD., Andrew Wakefield MD., F. Edward Yazbak MD**,** without exception people who it has been a huge privilege to have known.

Amongst many others I must mention in particular Jackie Fletcher, the founder of JABS, whose services to all victims of vaccines merits a special mention apart from the excellent briefing notes which she and David Thrower have provided and which round off the present piece.

Harry has provided the pictures in this book.

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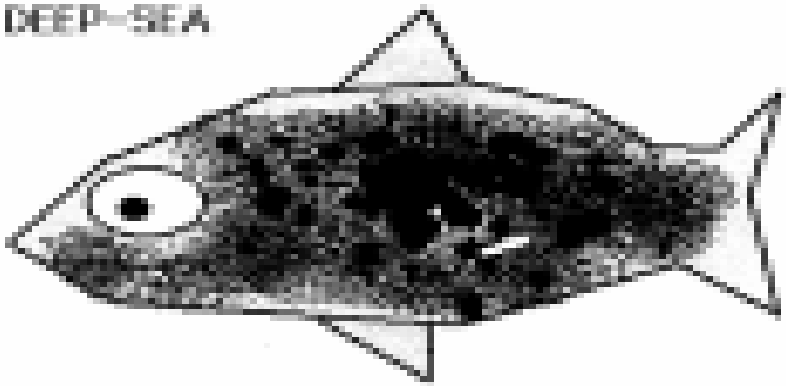
DEEP-SEA



Monster horse-fish; lantern fish
bioluminescence
blob, tassel,flap or fringe
big and large
deep sea-wildlife

1. Introduction

This is the story of 10 children who many, including their parents, believe have been damaged by MMR. Although born healthy they became, as the result of vaccination, autistic (ASD). Their ailments include also inflammatory bowel disease (IBD).

Dr Wakefield's research looks to the relationship (causal) between MMR and IBD/ASD, though a mechanism is still not clear. Research into this most distressing syndrome which, it is estimated, affects one in 160 or so children, almost all boys, is urgently needed. In the UK a conspiracy of silence and denial prevents such research from proceeding. Elsewhere in the world including in North America research is proceeding, though the funding is nothing like that accorded to Aids or diabetes research.

Yet a generation of children, and many millions worldwide, are victims, testimony to an epidemic of ASD/IBD which cannot simply be ignored or swept under the carpet.

The parents of the MMR 10 decided to do what they can to fight for legal redress for these children. They have challenged the decision to withdraw legal aid from most of the 1000 or so children whose case was proceeding to a trial in the UK until the summer of 2004; at a cost to date of some £15 million. All that sum was paid to the lawyers. None of the injured children received a penny.

Then when legal aid was withdrawn, so that the trial could not proceed, despite strong evidence of 28 expert witnesses for the claimant children, the carers of those children, led by the Barrister mother (JHR) of one of them, decided to fight on through the courts to challenge the decision.

By withdrawing Legal Aid, the Legal Services Commission, presumably acting at the behest of the government, prevented the 28 witnesses being called to give evidence publicly in London. That trial would have been held in public. It was a trial for which the world was waiting in order to hear that evidence and help to determine the truth of the alleged MMR: ASD/IBD link. Justice was denied to these children, and to the world's children vicariously.

The MMR 10 took their case to the High Court in London, by way of judicial review. They did all the legal work, including filing and serving all the documents and what should be done by solicitors, themselves. Despite a strong showing in the High Court in camera, a closed court, the case was rejected by Levison J, sitting in London on October 2005. In January 2006 our case went on appeal to the Court of Appeal, where Lord Justice May heard J H R the Barrister mother and Litigation Friend of all the parents and also had a full hearing with each parent giving a witness statement.

Both judgments found that the Legal Services Commission had the power and was entitled to make the decision it did, and were partially gagged, so publicity for the judgments was banned.

Now parents are fighting on, determined that their case shall be heard. They are taking their legal case to the European Court of Human Rights(ECHR) led by Keith Roberts, H's father, who prepares the case, and J H R the advocate who also drafts the papers. All the parents are totally involved and all contribute their utmost to the cause.

The case will be filed in the ECHR in the summer of 2006. The world should know the story, and see some of the evidence for themselves. So we have decided to publish this book, telling the story of the MMR 10 and also revealing some of the evidence which the UK tried to keep away from the public gaze, and out of the courts where a trial should have taken place.

2. Background to the MMR10 Story - what happened in the UK Courts.

All the MMR 10 applicants suffer from autistic spectrum disorders ("ASD") and inflammatory bowel disease ("IBD"). The children were among 1600 claimants in a group action against a number of drug companies. Each claimed that the conditions from which they suffer were caused by combined vaccines for measles, mumps and rubella ("MMR") sold by one or other of the companies. Leveson J's first main judgment in the UK High Court concentrated on the facts relating to H. His order dismissing the applicant gave the other 9 applicants a short time to make further written submissions specific to each of them. His supplemental decision of 13th February 2006 addresses this additional material and in the result dismisses each of the applications of the other 9 children.

Lord Justice May said the following in his judgment in the Court of Appeal of 28th February 2006, "It was agreed at the hearing before me that I would have to delay giving this judgment until Leveson J had given his supplemental decision. Leveson J's supplemental decision in effect is that none of the 9 children have a case which is materially different from that of H. I have, however, myself received and considered both written and oral statements from the parents of each of the applicants.

The LSC issued legal aid certificates covering generic work common to all claims in the group action. The LSC also issued individual legal aid certificates to 1364 of the 1600 claimants. These included certificates issued to lead claimants in the group action and also to the 10 applicants. As is usual in group actions such as this, work done under the generic certificates common to all or many of the claimants was essential to the progress of the individual claims.

The actions proceeded and expert evidence was exchanged. At this stage, three leading counsel for the claimants in the group action produced a lengthy advice. They advised that, as the evidence stood, there was no reasonable prospect of establishing that the MMR vaccine could cause ASD, but there was a reasonable prospect of establishing that it could cause a particular form

of IBD. They thought that the LSC might not consider that claims in respect of IBD alone would be cost effective. But they expressed optimism that, by the time of a trial, sufficient evidence would have emerged to establish a causative mechanism which would give ASD claims a reasonable prospect of success.

On 5th September 2003, the LSC discharged both the generic certificates and the individual certificates for the lead claimants. The practical effect of this was, of course, to bring the group action to a halt. There followed an appeal against these decisions to the FRC. The FRC upheld the decision to discharge the certificates. Just as the leading counsel who had advised the claimants were pre-eminent specialists in the field, so the FRC panel consisted of an independent specialist leading counsel and three very experienced solicitors. The panel conducted an appeal hearing. Leveson J said of this in paragraphs 10 and 11 of his judgment:

"That hearing was attended by all three leading counsel and three partners of the lead solicitors. The panel had seen and read the lengthy joint advice and material provided for them including experts' reports. There is no suggestion that this hearing did not give all counsel and, indeed, all concerned, full opportunity to advance arguments against the discharge of the certificates.

The upshot of the hearing was that the FRC dismissed the appeal on the basis that there were no longer reasonable grounds for continuing to take the proceedings in relation to ASD and so far as the IBD claims were concerned, it was unreasonable for legal aid to be continued on the basis of cost benefit: see section 15(2) of the 1988 Act and regulation 77(e) of the regulation 77(a) of the 1989 Regulations and section 15(3) and regulation 77(c) respectively. Written reasons were provided running into 10 pages: this included an analysis of the key expert evidence."

One lead claimant then challenged the FRC's decision by judicial review. Davis J dismissed the claim in the UK High Court and refused permission to appeal. The lead claimant did not seek permission to appeal to this court.

After the decision of Davis J, the LSC discharged the present applicants' individual certificates. All the present applicants appealed to the FRC. The FRC dismissed their appeals, upholding the discharge of the certificates on the grounds that the claims had no reasonable prospect of success or on cost benefit grounds. [I have considered the FRC's written decision].

The applicants then sought permission to apply for judicial review of the FRC's decisions. Permission was refused on the papers. Leveson J refused H's renewed application after a hearing and has now refused the applications of the other 9 children. The applicants applied for permission to appeal against his decisions.

Some of the applicants had discontinued their claims against the drug companies. They sought permission to bring judicial review proceedings of the refusal of legal aid, not to revive those proceedings, but to claim damages from the LSC for the loss of a chance of success in those proceedings. Leveson J foresaw great difficulty here, but did not dismiss the applications on those grounds.

The judge, in considering the effect and status of the decision of Davis J, correctly identified the issue before him in paragraph 25 of his judgment as follows:

"Whether on a super *Wednesbury* or a *Wednesbury* basis, and subject to however intensive a scrutiny, it has to be demonstrated that, in discharging an individual certificate, the FRC acted unfairly, applied an incorrect legal test, irrationally assessed the prospect of success (or based that assessment on irrational factual findings or assessments) or inadequately reasoned their decision. The FRC were undeniably entitled to take as their own starting point, the decision that they had reached in relation to the generic and lead certificates, with the added knowledge or comfort that their decision, vigorously challenged by judicial review, had been held by Davis J to be proportionate and rational, taking into account the relevant considerations, sufficiently reasoned and without procedural unfairness."

‘This correct formulation of the questions which the judge had to consider has an important bearing on what I consider to be the main proposed ground of appeal which Mrs H-R advances’. JHR who is the barrister mother of H, the first Applicant. She conducted the case throughout from the FRC to, now the ECHR on behalf of the MMR 10.

The generic certificates and those of the lead claimants had been discharged. This obviously put individual claimants who were not lead claimants into great difficulties, since there was no longer public funding for the mass of very expensive general work which would in practice be a precondition to success for any individual claimant. The whole point of group litigation of this kind is to pool for the benefit of the group expenditure which a single individual or a small number of such individuals could never contemplate alone. The discharge of generic funding would not perhaps make individual litigation literally impossible, but it would make it very much more difficult.

For H and the other applicants for whom Mrs H-R speaks, as the judge said, the FRC had to consider whether there was some new material relevant to this group of claimants which undermined the FRC’s earlier conclusion or made it inapplicable to them. He said, in paragraph 26, that Mrs H-R relied on Dr Fletcher, Dr Stott and the review which she herself, the claimants’ then solicitor, Dr Wakefield and Dr Fletcher had undertaken of the medical evidence which caused them to conclude that there was evidence sufficient on the balance of probabilities to prove the claimants’ case. The judge said that the FRC had dealt with each of these, and the judge did so also.

For Dr Fletcher and Dr Stott, the judge summarised the view which the FRC had taken, concluding that their view was unchallengeable in judicial review proceedings and that there was nothing to suggest the FRC had reached an inappropriate conclusion. The judge then turned to Mrs H-R’s own analysis of expert evidence, from which she argued that the case could be proved on the balance of probabilities. The FRC had said of this that, without detracting from its quality, it was insufficient in itself to establish the necessary prospect of success. H’s case was essentially a case that the MMR vaccine had

caused autism. But as to the possibility that his condition was, or was in part, a New Variant IBD, the FRC had emphasised their view that it would not be cost effective to investigate it further as a case capable of succeeding only as an IBD case.

The judicial review claim form has 27 numbered grounds for applying for judicial review. But the judge in the Court of Appeal, Lord Justice May (on appeal from Leverson J), said that there are essentially 7 reasons why it is said that the FRC's decision was unreasonable, irrational and wrong in law.

First, it is said that the FRC did not read the evidence of each of the claimants' 28 experts and so could not assess the strength of the case. The judge held that the FRC had in fact considered all this evidence when it reviewed the discharge of the lead and generic certificates, a decision which had withstood judicial review challenge before Davis J.

Second, it is said that the FRC relied on the joint opinion of leading counsel for the claimants in the group litigation which had been prepared without each counsel having read all the expert evidence. The judge held that this allegation was not supported by the evidence and that, although those who prepared the opinion had not each read all the evidence, they had read all of it between them. They were all specialists and could be relied on to pool the product of their individual reading.

Third, it is said that the FRC wrongly and irrationally rejected submissions made by Mrs H-R to the effect that H's case did have a reasonable prospect of success. The judge held that the FRC had considered these submissions and was entitled to take a different view. Of this, the judge said at paragraphs 32 and 33 of his judgment:

"As I have said, the FRC made it clear that in their view, these submissions were insufficient to establish prospects of success.

That conclusion is not entirely surprising because it is based on the premise that three specialist silks (writing the opinion), the panel, (including a further

silk and three experienced solicitors), and the silk advancing the judicial review proceedings before Davis J had all misunderstood the purport of the evidence and that all these specialist lawyers did not refer the court to the very best evidence that supported the case which they sought to make. It also assumes that Davis J similarly fell into error.

The issue is whether the FRC were entitled to reach the conclusion in these proceedings that they did about them: in my judgment, in the light of the history that I have recounted, it clearly was."

Fourth, it is said that the FRC failed to take into account evidence of the applicants' parents, and of two of the applicants' experts, in addition to that which was contained in their reports. The judge held that the FRC did, in fact, have regard to this evidence but that it did not cause them to reverse their previous adverse assessment of the prospects of success.

Fifth, it is said that the FRC was in error in that it referred to H as having received a vaccine known as MMR2, when he had in fact received Pluserix. The judge held that this did not advance his case.

Sixth, it is said that the FRC referred to a test result which post-dated the hearing. The judge held that this did not advance H's case.

Seventh, it is said that the FRC wrongly assumed that the applicants would have to prove their cases to a 100% scientific standard of proof, rather than on the balance of probabilities. The judge found that there was nothing to suggest that the FRC had applied the wrong standard Of this he said in paragraph 36 of his judgment:

"Finally, before turning to the Convention grounds, I make it clear that I agree with the LSC that, in the light of the joint FRC's professional experience, to say nothing of the professional abilities of all those who made submissions before them, it is inconceivable that a standard of proof of 100% was applied rather than the balance of probabilities; there is nothing in any of the

decisions (and in particular the decision in H's case) to support that allegation."

The proposed grounds for applying for judicial review were formulated as violations of Article 6, 8 and 14 of the European Convention on Human Rights. It was said that the discharge of the generic and lead certificates was a denial of access to justice and so a breach of Article 6. Mrs H-R referred to *Steel and Morris v United Kingdom* 68416/01 EHRR. The judge rejected this submission, holding that, as was expressly acknowledged in *Steel and Morris*, the right of access to a court is not absolute, and conditions can be imposed on the grant of legal aid based on the litigants' prospects of success in the proceedings. It was submitted that the fact that other claimants in the group action continued to have the benefit of legal aid made the decision to withdraw H's legal aid certificate a breach of Article 14. The judge found that those other claims were different from those of the applicants, and that the decision was not capable of being challenged under Article 14. It was submitted that the discharge of the certificate amounted to an interference with H's exercise of his Article 8 rights to respect for private and family life. The judge held that no such breach was arguable, as no public authority was interfering with such rights.

JHR explained to me, the Court of Appeal Judge, that the applicants are not now seeking to have legal aid restored to be able to proceed to a full trial. The teams of specialists and lawyers have long since disbanded. But they do seek damages for what they feel strongly a denial of access to justice.

The present structure of the claim is an application for judicial review. I shall suppose that it is structurally conceivable that on such a claim the court could make a declaration and direct an inquiry as to damages. I can see considerable difficulties with this, as did Leveson J, but I too shall suppose, without deciding, that it might be feasible. I do not decide this application on purely procedural grounds.

The formal written draft grounds of appeal to this court direct attention to Articles 6, 8 and 14 of the ECHR as scheduled to the Human Rights Act 1998.

To my mind, the heart of the matter has to address the claim under Article 6. There was, in my view, no viable claim based on a violation of Articles 8 or 14 for the reasons given by the judge.

As to a claim based on Article 6, it is obvious that H and the other applicants could not bring their claims to trial without very substantial funding. I will assume, again without deciding, that a refusal to grant legal aid or a withdrawal of a certificate could in some circumstances amount to a violation of Article 6. Such an assumption would, at the very least, need a whole string of heavy qualifications. It is not, I think, necessary to look into those qualifications for present purposes. The important point in the present case is that decisions about public funding for civil litigation can properly take account of a litigant's prospects of success and may take account of cost benefit considerations .

I will come to more detailed points which Mrs H-R makes in a moment. But the heart of the matter is that Mrs H-R says on behalf of H that he has a strongly arguable case that the MMR vaccine caused or triggered ASD/IBD in him and the other claimants. The LRC and the FRC decided otherwise. In judicial review terms, this was a decision for them to make, and the judge correctly articulated the limited grounds on which the court would interfere with that decision. I have referred to this articulation earlier in this judgment in paragraph 13. Those grounds did not require the judge to make a primary decision of his own as to the relative strength of the mass of expert material, except to the extent necessary to decide whether the FRC's decision in this respect was, or was not, untenable. As the judge himself said, that was an unlikely conclusion when the process of decision making had included specialist expert input from 3 leading counsel, and when the first decision had withstood a judicial review challenge before Davis J.

Mrs H-R submitted that there was some prospect of the applicants being awarded damages. The individual children's records were put before the FRC. Each of the parents have made statements, which were before the judge and which I have read. In addition, each of the parents bravely gave an

oral account to me of the causative effect, as they have seen it, of the MMR vaccine on their children. They were normal babies before having the vaccine. Immediately after having the vaccine, they changed and have suffered from varying degrees of autism and IBD ever since. These accounts were dreadful and heart-rending. The parents are angry that no one, as they see it, will take responsibility for the condition of their children; no one will enable their children to recover compensation from organisations that can afford to provide money which the children desperately need; and in some instances that no one will even provide proper treatment for the children's condition. The parents of the applicants are all convinced that the MMR vaccine caused their children autism and IBD. Set against this, however, is that the generic claims were judged not to be viable. It is difficult to see how an individual claim could succeed, even with the parents' evidence, unless the generic claim had first succeeded.

In the main litigation before it came to a halt, there were 28 experts' reports prepared on behalf of the claimants. Mrs H-R says that they take weeks, or even months, to read in full, and that she is one of the few people who has read all the evidence. She has made a digest of those parts of this evidence which best support the case that MMR vaccines do cause autism for a small proportion of mostly boys. She drew my attention to parts of her digest and to some relevant letters and reports. She said that it is one of the scandals of our time. Recognising, I think, that there was a mass of other evidence to contrary effect, she said that the tide of research was flowing in favour of the applicants' cases. It is said that the contrary evidence was epidemiological, and it was suggested dismissively that epidemiological evidence can prove or disprove anything.

Mrs H-R says that the FRC and the judge did not attach due weight to the evidence in the applicant's favour and her own analysis of it. She draws attention to the opinions of Dr Fletcher and Dr Wakefield. She argues that the judge's decision was against the weight of the evidence. This mischaracterises the judge's role in judicial review proceedings for the reasons which I have briefly given. Accepting this, Mrs H-R said that the

weight of the evidence that MMR vaccines can cause autism is so strong that the FRC's decision that the case was not strong enough to justify continuing the legal aid was irrational. She asked Leveson J to accept her digest – failing which he should have read the reports of the 28 claimants' experts in full. On the basis of the digest, any decision which did not adopt its conclusions as properly arguable for legal aid purposes was irrational.

The trouble with this submission is that the FRC had to make a decision about the applicants' prospect of success in the litigation in the light of *all* the evidence. They could not properly do this by looking at one side of the case only. Just as there were 28 claimants' experts, so there were, I am told, 32 defendants' experts. The claimants' three silks had concluded that the evidence as it stood gave no reasonable prospect of establishing that the MMR vaccine could cause ASD, although they added that they believed there was a reasonable prospect that the tide might flow in the claimants' favour by the time of a trial.

It cannot be said to have been irrational for the FRC to reach a conclusion equivalent to the first part of this conclusion. As to the second, it cannot, I think, be irrational for a funding body to decline to fund litigation whose success depended on speculative future research. In addition, that would not accord with Mrs H-R's third main ground of appeal, to the effect that funding was only sought for the relatively inexpensive process of bringing the action to trial on the then present state of the evidence.

In short, the FRC did not fail to take account of the evidence to which Mrs H-R refers. I have read their decision carefully. It is properly reasoned, and in my view, it was plainly open to them to take the view of the evidence which they did. The fact that some experts may take a view more favourable to the applicant's case does not detract from this.

Mrs H-R says that, if he were in doubt, the judge should have read the claimants' expert witnesses in full. That conflicts with what she appears to have told the judge, who said at paragraph 34 of his judgment:

"I ought to make it clear that the medical evidence has not been put before me. In the papers, the claimant notes the disks containing all the reports are available if requested. In argument, H's mother said that the material would take weeks of study to master and did not submit that I should read it. Given the background (including the way in which the matter is put), and the lengthy analyses to which I have referred, I have not done so."

It was, in my view, no part of the judge's required functions upon an application for permission to bring judicial review proceedings to read such a mass of evidence in full. He had to be persuaded on more structured grounds that the FRC's decision was untenable. If he had been so persuaded and had granted permission, and if the judicial review proceedings had eventually been successful, the only feasible order would have been to quash the FRC's decision and to direct the them to reconsider it themselves. It was no part of the judge's function to reach a primary decision as to the comparative strength of the expert evidence.

Mrs H-R says that the decision was disproportionate, because there would be comparatively little further expenditure if H's proceedings continued. That is plainly wrong. The actions could not proceed without large additional expenditure, even if there were no further research. The very bulk of the expert evidence to which Mrs H-R herself refers makes this obvious. The generic claimants' solicitor had apparently given an estimate of £10m. (in addition to the £15m. already spent) including further research, and the judgment was that the actions were not viable without further research. Further expenditure of this order might be justifiable for viable claims by a substantial number of claimants, but not for proceedings which are judged not to be viable.

Mrs H-R then says that there is clear evidence of a causal link between MMR and regressive autism, and that this should be taken with her and her husband's evidence about their own son and the evidence of the parents of the other applicants. She refers to Dr Wakefield's letter at page 49 of the bundle before me, which is dated 7th February 2002 and the evidence of

Unigenetics at page 63, which are reports of measles virus detection tests on samples received in 1999. There is no case for supposing that the LSC/FRC process did not take these and similar matters properly into account in reaching their decision. They are particular parts, of the greatest importance to the individual parents and children, of a much larger picture. The larger picture is that the individual cases were not going to succeed against the drug companies, if the generic case did not succeed. As I have said, the LSC/FRC made decisions on the generic and lead cases which withstood judicial review proceedings before Davis J. Leveson J was obviously correct to say that the FRC were entitled to refer back to and build on their earlier decisions.

In my view, the decisions of the FRC now under consideration are not amenable to judicial review for the reasons which the judge gave. The essential point is that there was no properly arguable violation of Article 6 of the ECHR because the FRC reached a proper, sustainable and properly reasoned conclusion about the applicants' prospects of success which in their view did not justify the continuation of public funding. The applicants had in fact had the direct or indirect benefit of substantial public funding during the time when certificates were in place. To that extent, they have all had publicly funded access to justice. The sad fact is that the product of the funding was a rational, properly informed and properly reasoned decision by the LSC/FRC that the litigation was not viable. That decision is not amenable to judicial review, as Leveson J correctly held.

For these reasons, I regret that I must dismiss these applications for permission to appeal."

Appeal to the European Court of Human Rights

The MMR10 , advised again by JHR of Counsel, are now preparing their appeal against the above judgment . The appeal will be lodged with the ECHR in the summer of 2006.

FOSSILS VERY OLD

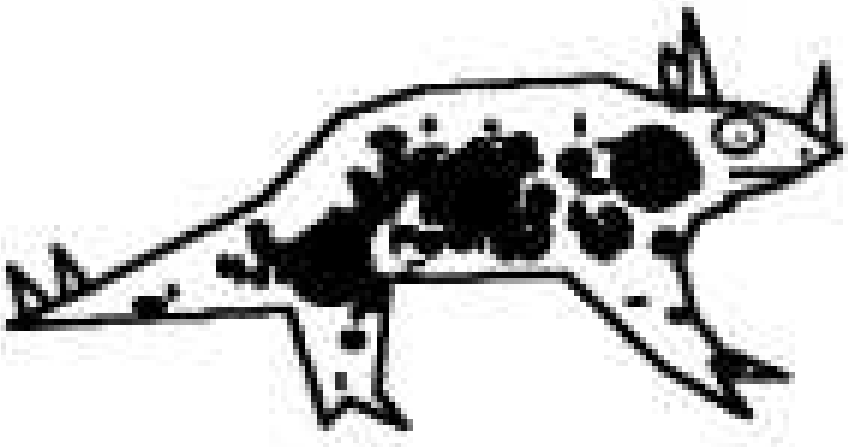
DRAGONS, WILD BEASTS

AND MERMAIDS

MAMMAL VARIETY

WINGED WONDERS

DINOSAURS DISCOVERED



3. Vaccine Information.

One-size-fits-all vaccination policies do not work. There is biodiversity among humans and to suggest that every human being will respond the same way to vaccination - or any medical intervention - is illogical given the different genetic factors inherent in biodiversity.

Until vaccine policies acknowledge the real risks and needs of the individual rather than dismissing individuals as expendable in service to the community, to many humans will become tragic casualties of the one-size-fits-all approach.

It appears that vets are more willing to consider the individual risks and needs of pets than pediatricians and public health officials are willing to consider the individual risks and needs of children when it comes to vaccination.

Most people are vaccinated for everything, even though the trend in medicine has been to tailor vaccine programs to lifestyle and risk.

The clarion call among doctors in recent years has been a movement away from reflexive annual "shots" and toward a more individualized approach: In its 2002 vaccine report, the American Medical Association rejected the idea of "one-size-fits-all" protocols, suggested that unnecessary over stimulation of the immune system might incur health risks, and divided vaccines into "core" and "non-core"categories.

A year later, the American Hospital Association went a step further: In its Vaccination Guidelines, it added a third category -not recommended at all - and gave suggested intervals of vaccination for each vaccine. Earlier this year, the association published an update of the guidelines, adding some new information about specific vaccines and the vaccination needs of very young children.

The original 2003 guidelines were "largely driven by the medical profession understanding that the way we have always done things may not be the way they will continue to be done," The fact that the 2003 protocols did not result in any obvious disease outbreaks reinforces the guidelines' message that "less is better".

Guidelines vs. habits.

While some doctors have kept up with changing times, old habits die hard. "We have a lot of work yet to change the attitudes of most doctors in practice. We are trying to get them away from the annual thing and get them to understand that immunity doesn't stop on the precise day" that the vaccine expires.

Some doctors resist this nuanced approach to vaccination because of habit and economics. Urging a client to come in for annual shots is more compelling than a postcard cheerily announcing that it's "wellness exam" time.

Labels aren't guidelines. Another problem is Byzantine labelling and clever marketing on the part of vaccine manufacturers. "The label means nothing". Vaccines licensed for one year and three years are often the same product. "The label has an arbitrary and capricious annual revaccination requirement, and it takes an act of Congress to take it off" - literally. The Department of Agriculture has applied to remove the language, a legislative process that is estimated will take seven years.

Too much, too soon.

Immunologist Jean Dodds of Santa Monica, Calif., a lecturer on vaccines, stresses that over vaccination can overwhelm the immune system. The new born child entering a new environment is at greater risk here, as its relatively immature immune system can be temporarily or more permanently harmed.

Consequences may be the increased susceptibility to chronic debilitating diseases and or brain damage.

Vaccine labels themselves state that vaccines should only be given to the healthy. Carers who worry about their children's' immunity are recommended titers, or blood tests that can measure antibody levels.

Titers: What do they tell us?

Many people who are trying to reduce vaccination are interested in using "titers" as a test to measure whether or not their child is still immune to a disease. They often speak of titers as showing "high" or "low" immunity, or of "having to" re-vaccinate when a titer is low. While there is not a tremendous amount of research on titers in children, I think it's fair to say there is quite a bit of misunderstanding on the part of carers, and even many doctors, as to what a titer test does or does not tell us.

A "titer" is a measurement of how much antibody to a certain virus (or other antigen) is circulating in the blood at that moment. Titers are usually expressed in a ratio, which is how many times they could dilute the blood until they couldn't find antibodies anymore. So let's say they could dilute it two times only and then they didn't find anymore, that would be a titer of 1:2. If they could dilute it a thousand times before they couldn't find any antibody, then that would be a titer of 1:1000.

A titer test does not and cannot measure immunity, because immunity to specific viruses is reliant not on antibodies, but on memory cells, which we have no way to measure. Memory cells are what prompt the immune system to create antibodies and dispatch them to an infection caused by the virus it "remembers." Memory cells don't need "reminders" in the form of re-vaccination to keep producing antibodies. (*Science*, 1999; "Immune system's memory does not need reminders.")

We should think about vaccines as a double-edged sword: necessary medical procedures that also have their risks and downsides. "Vaccination is an elective medical procedure that's going to be individual for each child instead of a knee-jerk sort of thing. Becoming informed yourself is very important. "

To that end, we encourage carers to discuss vaccination with their doctor - and if their doctor is unresponsive to their questions, to find someone who does respond. "The key is using the right vaccines absolutely only as often as the child needs." We conclude. "Most assuredly, less is more."

4. Why ? The Hear The Silence Rally – F.Edward Yazbak MD.

I am a grandfather, who happens to be a doctor.
The fact that as a grandfather my heart is broken, does not mean that as a doctor, my medical judgment is in any way compromised.

I trained as an infectious disease paediatrician.
I was taught to fight epidemics, but never did I dream that I would be fighting one of such magnitude.
For 40 years, I also practiced general paediatrician.
I was a clinician. I listened to moms and I loved kids.

The big shots - if you forgive the pun- sit in their ivory towers.
They look down on the rest of us humans.
They are convinced that only they know the truth, only they have seen the light.

A dangerous thing happens when people think they know everything.
They don't need to look anymore and they don't need to listen either.

Besides, why would they listen to you anyway? You are just mothers.
What can you possibly know about autism?
How can you even talk about vaccines?
What big fancy university did you go to?
Did you publish anything in peer reviewed journals?
Where are your double blind crossover controlled studies?
You are obviously imagining things.
You are just grief stricken. It is all in your head.

Thank God my great teachers taught me differently.
They told me that the most accurate diagnosis starts with a good history.

They told me that I should listen to mothers.
They taught me that I had to go into a situation with an open mind.
That someone with a different point of view could be right.
That it was not a shame to change my mind.
That it did not make me smaller but smarter.

So I listened to mothers and I learned and I came to believe.
The mother who taught me the most is my own daughter Kathleen.
She is here today from London to be with you.
She too is fighting your same battle, and because of her, I devote the rest of my life to this cause.

Let me ask the lingering questions.

Why did this tragedy have to happen?

Why are 6 children per day, 7 days per week being diagnosed with autism in just one state?

Why will several children around the nation develop autism before this day ends?

Why, if this epidemic is so widespread, is no one looking at it seriously?

Why does Japan have so little autism now that Higashi schools are exported?

Why do we allow a federal agency to promote and at the same time regulate vaccines? Did we not learn enough from the FAA?

Why does it take less time to approve a vaccine than a shampoo for lice?

Why do 'epidemics' and "outbreaks" occur, and are heavily reported in the press, just before a new vaccine is marketed?

Why are vaccines mandated without proper safety studies?

Why are a few weeks of follow-up considered adequate?

Why do the vaccine manufacturers finance safety studies, when they are the very companies, which profit from sales?

Why do we have to prove a vaccine causes a problem when the manufacturer with all its might-- has no studies to prove that it does not?

Why do we have to give so many vaccines together when we know that they work better singly?

Why do we rush to give combined live virus vaccines to children in the absence of epidemics?

Why do we give them to such young and vulnerable children in such a short period of time?

Why are we obligated to repeat a triple vaccine at the age of five, when we know that 95% of the recipients are already immune?

Why do we have to invent a vaccine for every disease?

Why do we suddenly have so many new immune diseases?

Why are we seeing so many recurrent infections?

Why doesn't anybody listen to parents and just consider the possibility that vaccines may cause autism?

Why are thousands of children with autism less impressive than two hundred

with intussusceptions or 124 with vaccine induced paralytic polio?

Why do we think that Pokimon toys, infected ground beef, and rear gates of minivans deserve our immediate attention when we don't even look at the possibility that vaccines could induce autism? Aren't 54,000 cases of autism enough to merit a comprehensive and independent investigation?

Why don't doctors know more about autism: its diagnosis, and its treatment?

Why does my daughter-who is a headhunter and not even a medical professional-know more about the subject than most of the medical establishment?

Why do HMOs have to dictate multiple and combined vaccinations? They'll tell you it is because parents may not bring their children back. That is absurd and they know it. Parents are indeed more likely to return For a visit if a shot is needed. They'll tell you it is because they want to spare the children the pain of repeated injections. That is even more absurd. Show me any family of a child with vaccine-induced autism who wouldn't have gladly returned to get one vaccine at a time.

Why do policy groups which formulate vaccine schedules allow their members To sit on drug company boards? Such a conflict of interest would never be allowed in business.

Why do we allow anyone who owns drug company stocks to dictate vaccine policy?

Why do we repeatedly vaccinate women with live-virus vaccines when they fail to develop protective titers, or lose their immunity over and over again?

Why do we allow doctors to vaccinate women during pregnancy when it is totally contra-indicated?

Why haven't we followed up on the 10,000 people who were included in the original rubella vaccine studies?

Why are we giving a triple vaccine at 1 year of age, when just a few years ago the authorities insisted that it should not be given a day before the age of 15 months?

Why don't we tell mothers it is because the vaccine-induced immunity they Are now giving their children is not as lasting as that their own mothers gave them following natural infection?

Why aren't people convinced that vaccines are safe?

Why can't families who have doubts, have an option to request mono-valent vaccines ?

Why is the triple vaccine mentioned first to prevent the individual diseases of rubella, mumps and measles?

Why do the authorities continue to deny increases in autism, when every school department is going bankrupt trying to educate afflicted children?

Why is it that a lone, retired pediatrician can uncover more suspicious findings of a possible vaccine-autism connection than the vaccine proponents and manufacturers, with all their power and money?

Why did the Vaccine in Pregnancy Registry fail to find a single problem in 19 years? How did they manage to come up with a 0% complication result? Has there ever been any study anywhere with 0% results?

Why did they only look at the Congenital Rubella Syndromes?
Why didn't they even ask about developmental problems?

Why did eleven mothers, in just four months, report overt problems with Their children, some readily visible at birth?

Why did our vaccine officials endorse Dr. Brent Taylor's findings?
Why didn't they question his methodology and his results?
Why has he refused to show us his data?

Why, with all the fury about a possible vaccine link, was no blood drawn for Titers and Myelin Basic Protein Antibodies testing during the investigation of a NJ outbreak?

Why haven't the authorities been listening to our plea to look at autism as another disease to be stamped out?
Is it because they are afraid of what they may find?
Is it because vaccines represent a $2 billion industry annually?
Is it because vaccines are BIG BUSINESS?

Why are moneys from the vaccine compensation programs not being disbursed to the deserving children. What more do you need to prove?

Why are safer vaccination schedules not implemented now that there are no outbreaks?

Why take such risk when there is no real danger?

Why and why and why?

An entire generation of children is being needlessly damaged.

Their families will never be the same again.

America is staring down the barrel of a multi-billion dollar, decades-long program to help children with autism.

These are terrible and ugly truths.

These are unworthy and despicable truths in a country such as the United States of America.

Within walking distance from here are memorials that pay tribute to victims of horrible and unavoidable wars.

Our autism war is totally avoidable.

I came to this country in 1957, with the belief that America is the land of freedom and justice.

On the topic of autism, justice has not been served.

On the topic of vaccines, neither has freedom.

Let us resolve to continue on our course, and not give up until justice and

freedom are served.

F.Edward Yazbak MD, FAAP, TL Autism Research

F. Edward Yazbak, MD, FAAP, practiced pediatrics and was a school physician in northern Rhode Island for 34 years. Since 1998, when he founded TL Autism Research, in Falmouth, Massachusetts, he has devoted himself to researching the incidence and auto-immune causes of Regressive Autism.

Dr. Yazbak formulated the hypothesis that “Maternal Vaccination before, during and after Pregnancy Predisposes to Autism” and reported his findings at an American Academy of Pediatrics Conference *“New Challenges in Pediatric Immunization”* in June 2000. His research of nearly 400 mothers

revaccinated as adults is based on the postulate that “The failure of certain women to develop or maintain adequate titers after live virus vaccination denotes an immune problem and predisposes their children to autism”. He has been recognized as an expert witness in autism, vaccine injury and Shaken Baby Syndrome litigation.

He was formerly the Assistant Clinical Director of the Charles V. Chapin Hospital, the Pediatric Director of the Child Development Study at Brown University, Providence, RI, and the Chief, Department of Pediatrics, Woonsocket Hospital, Woonsocket, RI.

His professional affiliations include the American Academy of Pediatrics, New England Pediatric Society, Rhode Island Medical Society, Providence Medical Association,
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Dr. Yazbak has published extensively.

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April 2006


Harry the WhiteMonster
Dolly the Blue Monster

5. To conquer or control disease?

There is a heroic allure to ridding the planet of a horrible disease forever.
Louis Pasteur is famous as the inventor of the vaccine.
Jonas Salk is synonymous with the one he created to combat polio.
Donald Henderson and William Foege are honoured as the conquerors of smallpox.

Though the dream of eradication continues to animate scientists, doctors, and public health officials, the history is at best rocky. In the past century, eradication efforts failed against hookworm, yellow fever and malaria.

Today the struggling drive against polio has raised new questions about whether eradication of any disease is achievable, and, if so, whether the cost in terms of effort and dollars would be worth it, given all the other diseases that need attention.

The latest push began in 1993, when the International Task Force for Disease Eradication, a panel of experts, was convened in Atlanta by the Centers for Disease Control and Prevention, Emory University and the Carter Center. The experts reviewed 95 diseases and identified a handful they believed could be wiped out in a generation or less. Ancient scourges largely forgotten in rich countries, many of these diseases continue to cause misery and drain resources in the developing world, despite the existence of cures and vaccines.

Yet none have been driven into extinction, inflaming the debate over whether simple control was a more reasonable goal that would allow donors and health professionals to spread their resources to greater benefit for greater numbers.

Advocates of eradication say that it is a worthy goal to root out forever even one source of human misery, and that an unpredictable world offers brief

opportunities to do so. Dr. David L. Heymann, the World Health Organization director general's representative for polio eradication, noted that if smallpox had not been wiped out a year before the dawn of AIDS, it might well be impossible now, given that the smallpox vaccine was dangerous for people with compromised immune systems, like those with H.I.V. "Now we know that there are many people we can't vaccinate for smallpox," he said. "It's very possible we couldn't wipe out the disease. Think of what would have happened if we hadn't eliminated smallpox in that window of opportunity - a window we didn't even know about."

Others agree. "As soon as polio is done - and polio must succeed - I think measles will be taken up," said Dr. Donald R. Hopkins, of the Atlanta-based Carter Center, who heads the International Task Force for Disease Eradication.

But many, like Dr. Henderson, who helped vanquish smallpox, remain doubtful and believe the obstacles to eradication are far greater than advocates admit. The "siren song of eradication," he says, has led public health authorities to declare goals he considers more "evangelical" than attainable.

After the struggle with polio, "people will think very hard before taking on another disease," said Dr. Julian Lob-Levyt, executive secretary of the Global Alliance for Vaccines and Immunization, a group that includes countries, international organizations and the Bill and Melinda Gates Foundation. He says that, despite scientific advances, the increased mobility of people and chaos in places like Sudan and Somalia, where no one can be sure of the status of any disease, make eradication harder today.

"We're not talking about eradication the way we used to," he said. The following accounts were given in the UK Court of Appeal in the MMR case in January 2006.

6. Andrew's story

1. Andrew was born on the 12/ 8/96 following a normal pregnancy and birth

2. Andrew had to return to the hospital 2 days after being discharged from the hospital, as he was not feeding well, however when he returned home he was fine.

3. Andrew had no allergies and no unusual digestive problems prior to the MMR vaccination. He did not suffer from any of the natural diseases that he was vaccinated against, namely Measles, Mumps or Rubella prior to the MMR vaccination

4. Andrew was developing normally prior to receiving the vaccine; at 6 weeks he could kick his legs, make babbling noises and smile .

5. Andrew could walk well at 14 months, he was also able to use several words, he was able to transfer objects from one hand to the other and play with his hands and feet

6. Andrew was a very active child and he would climb on to furniture and walk down the stairs two steps at a time.

7. Andrew passed his 6 week and 6-9 month check. No concerns were noted during these assessments.

8. There were no signs that Andrew had any disabilities or had begun in any way to deteriorate before the vaccine was administered.

9. Andrew received the DTP, Polio and HIB vaccines on the 8/10/97, 19/11/97 and 14/1/97. He did not suffer from any adverse effects to any of these vaccinations.

10. On the 4/2/98 I took Andrew to Dr Jaiswal surgery, Hedgemans Road , Dagenham, Essex, to receive the MMR vaccination. The MMR vaccination, batch number HD46570 was administered by the nurse.

11. I was given a leaflet at the surgery entitled (A GUIDE TO CHILDHOOD IMMUNISATIONS)

12. 5days after receiving the vaccine (9/4/98), Andrew suffered from diarrhoea. 3 weeks after receiving the vaccine Andrew was unwell, 2 weeks after the vaccination he was vomiting and also had a viral rash.

13. Approximately 4 months after receiving the vaccine, there was a noticeable change in Andrew

a) He would sit in a corner at nursery school and cover himself with a toy or chair.
b) He had also begun to run up and down in straight lines. He would line shoes up in a half moon shape.
c) He became obsessed with watching videos, watching certain parts of the video over and over or watching the whole of the video in rewind.
d) I also began to notice that he was beginning to walk on his tiptoes; he was constantly on the move.

14. It was at this point that the nursery teacher mentioned that she did not feel that Andrew was responding to her any more.

15. Andrew will only interact with his immediate family. He does not interact with other children or adults. He is unable to speak but communicates by showing me what he wants. Typically he will give me his cup if he wants a drink, or take his nappy off when he is wet.

16. Andrew is very sensitive to noise and will often hold his hands over his ears. He also has a very disturbed sleep pattern and will often wake early in the night and not return to sleep.

17. Prior to the MMR vaccine Andrew's bowel habits were normal. 2 months after the vaccine Andrew began to suffer from diarrhoea. He has continued to have severe diarrhoea and constipation on a regular basis he also drinks copious amounts of liquid, prior to the vaccine, his drinking habits were normal.

18. In December 1999 Andrew was tested for Fragile x syndrome by Dr Vannisagarram, on the 15th march 2000 Dr Obeng confirmed that Andrew was suffering from an Autistic Spectrum Disorder.

19. Andrew also had a further Diphtheria and tetanus booster following the MMR vaccine on the 14/8/00 and 29/9/00, and a polio vaccination on the 22/1/00 but suffered no adverse reactions to these vaccinations.

20. On the 15/1/02 Andrew was seen at the Royal Free Hospital by Dr Hearshcal where a colonoscopy and endoscopy were carried out. Swabs were taken from his rectum and throat, Enterabacter was found in the throat swab and yeast in the rectal swab. On the 8/5/02 we were told that Andrew had bigger lymph nodes in his lower bowel than he should have.

21. I believe that the MMR vaccine caused Andrew's problems because he was interacting and talking prior to the vaccine: he also had normal bowel habits. Since the vaccine and the subsequent reaction he has regressed.

22. I wish to bring a claim against the manufacturers of the vaccine on the basis that the MMR is an unsafe product within the meaning of the consumer protection act 1987 and that Andrew has been damaged by it
Signed by A's mother


SMILODON
HYENA
ELKDEVIL
-TIGER

7. **Emily's story**,

Our daughter Emily was born on the 4th October 1993, a joy to behold, healthy happy and contented, she progressed over the following months full of life with a healthy appetite (would try anything), sleeping well only waking at night for feeds. She enjoyed all the pets we had at that time, two great Danes and two parrots who would mimic her voice, she would ride on the back of the dogs whilst we held her laughing and giggling without a care .

Emily was passing all her milestones, much to our joy, in time she knew her grandparents called them gamps and ganma and always loved a cuddle . Her early vocabulary was mama and dada and many other words like car, dog etc She interacted with all her peers and other children at toddler groups and loved going there . She was an absolute delight to my wife and I . Then came the dreadful day for her MMR vaccine (12 t' January 1995). The massive advertising campaign at the time costing some millions of pounds was a campaign using fear as its' bullet points .

Emily had a cold at the time and should not have had this vaccination however we were assured all was well and there was a million to one chance of encephalitis so sadly and now with much regret we agreed .

When we got home she was very unsettled, had a temperature and was distressed . She looked ill, we were advised to administer calpol . From that day on we began to witness-the unfolding nightmare that is to this day my wife and I still endure . I subsequently lost my company and property we then had to move to Swanage for 10 months, during this time Emily had regressed, she was babbling all the time, lying on the floor screaming, scratching, biting, pulling hair and twiddling bits of cloth near her face if we went anywhere (she did not recognise any of us any more grandparents etc). The doctors put it down to the terrible twos although she was not 2 . It was awful we could not take her anywhere except to the local park and swings and by the same route. She lost her appetite and would only eat tinned spaghetti, rusks and milk . She got worse and worse then we had to move again to Battle in Sussex . Emily had a febrile convulsion and stopped breathing, her lips turned blue, we rushed her to hospital after I managed to get her breathing again . Emily came out the next day, then followed dreadful screaming, rolling about on the floor

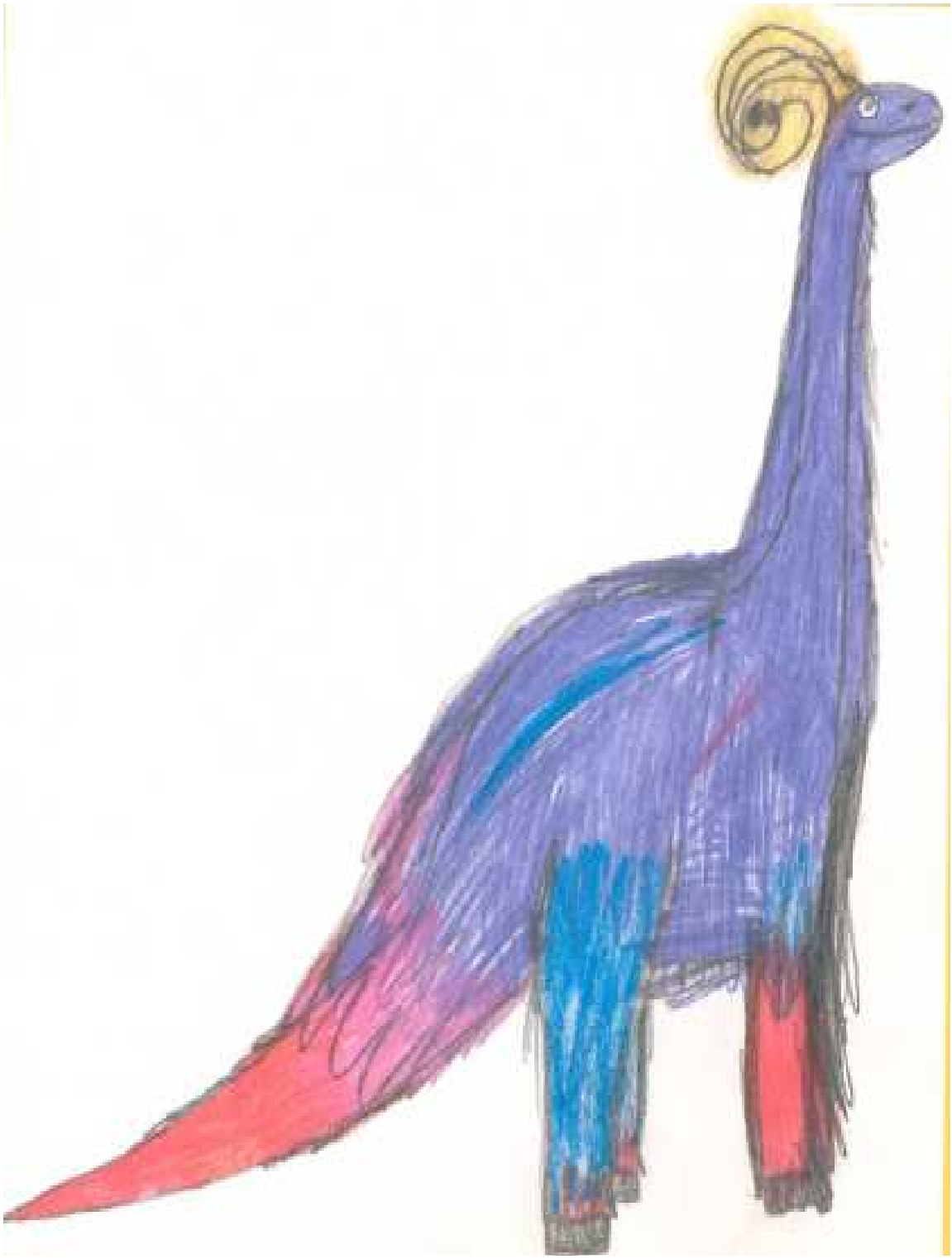
every night for nearly three weeks . It was -horrifying, the doctor was often reluctant to come out until I insisted, calpol was given . We now know she was in pain! Sometime after we found a local church who ran a playgroup which she walked in, to our amazement, some time later we met a health visitor from Sussex who first mentioned `autism' . Not one doctor had bothered since we left Ringwood to investigate her dreadful condition . After a few months of this scenario I manage to get a flat in Ringwood and moved back . Emily like the flat and could see the shops out of the window, she would still hide in corners, could not communicate at all would not have a bath and still ate very little . She would not acknowledge anyone except for my wife and only by pulling her by hand to show her what she wanted . Every day consisted of holding small bits of things near her eye and twiddling them round, watching Barney 10 hours a day and lining up her toys and books . If we went to friends she would scream, scratch and kick rather than go into their homes, the barney tape had to go everywhere .. The toll on my wife and I was catastrophic .

Over the coming months and years we would take Emily into the forest every day to show her all the animals, constantly repeating their names and words like tree, donkey, cow, horse and the sounds the animals made . She began to respond until one day, much again to our joy she took the barney video out

and never watched it again, after 2 years of watching it constantly . She had also started at a nursery in Ringwood, which she enjoyed . This was a huge milestone . She had been diagnosed formally with autism by this time at Salisbury hospital, we were broken hearted by this. However we persevered, Emily was still have screaming fits, pulling and scratching our face if we tried to calm her, anywhere we went . One day she lay on the floor in a supermarket doing the same thing, I sat down with her and she was puzzled by this and stopped screaming . I avoided being thrown after explaining to the supervisor when asked what was wrong . Some months passed and we were offered a house (which we still live in), Emily walked in and sat down and smiled! She saw a huge garden and smiled . We were happy for the first time in years . Emily progressed very well and went to school 12 miles away (in a special needs, classroom within a mainstream school with its own playground

. She seemed to enjoy herself and eventually would get on a bus outside the house and come home the same way (with her friend) . We were so proud of her knowing the effort that must have taken, however all this work, effort love and care we had provided was to be ruined by the school who had changed teachers, and an escort on the bus who started moving Emily away from her friend . I was furious, then to compound it all Emily came home one day with her knees covered in blood (she would not take her tights off for seven days!) she had been allowed into the mainstream playground where was bullied and pushed off the climbing frame . Needless to say we were very angry and complained bitterly to the `new headmistress' . Emily then started to scream and become very distressed each morning and did not want to go there anymore, we decided then to take her out of school . Emily was still using nappies but stopped in 2001 (aged 8). All our work was ruined, we started over again, teaching her ourselves and now have a tutor for her who is gentle and caring, Emily is very fond of her . Needless to say I found it impossible to start a new business over these years, having helped my wife and support Emily . Emily has regressive autism caused by vaccine damage . If it is genetic then how come Emily has come back to us? She is now 12 years old, likes rock and roll music and dancing . Uses computers, has excellent writing, is happy again in her way and is polite and loving, has lots of pets who she cares for, she is enjoying her life in her own way, although she is terrified of going to doctors or hospitals or crowded places . She would be even better if the school had not ruined everything, We require justice for out daughter and all the other children who without a shadow of a doubt were seriously damaged by the MMR vaccine, we demand justice and access to it, truth and compensation . Emily will now more than likely have no boyfriends, relationships, marriage, children and will need caring for the rest of her life. Especially after we're gone! God help her, all thanks to the MMR vaccine that was administered without proper testing for side effects, which damaged my child and all the other children!

The pharmaceutical companies know the truth but have engineered, with the help of political and financial institutions to cover up the truth and ignore the evidence, with no enquiry. We again demand justice.



8. Geoffrey's story

I write to represent our autistic son. My wife I, and our four children all live on the West Coast of the Scottish Highlands. Either my wife or I have journeyed to London a number of times now, an undertaking that has been extremely difficult both financially and logistically. I write once again on behalf of my son to challenge the decision of the LSC to withdraw Legal Aid Funding in the MMR Litigation, a decision that has denied him the access to justice that he deserves.

Our son was accepted as a claimant in the generic group action in the spring of 2003. Legal Aid funding was withdrawn from the same the following autumn. I have been advised that besides being fully familiar with the wider generic case you will have read all my son's individual papers and witness statement. If you have done so you are bound to have noted that my son was ill immediately following MMR vaccination and, as he recovered from this reaction we observed that certain aspects of his behaviour had changed; within a fortnight of receiving this vaccine our son had thrown off the physical symptoms of reaction (raised temperature, very worrying cough and flare up of very dry skin, but the initial behavioural/neurological symptoms had started to present and gradually increased in severity over the following months – self-imposed dietary restrictions, loss of eye-contact, failure to develop speech, loss of desire for social interaction, physical aloofness, repeated ear infections, alternating diarrhoea and constipation and the appearance of various bizarre, repetitive behaviour. I am frequently told that autism commonly presents in the second year of life but my child's initial symptoms had started to present within the 2 weeks immediately following vaccination. The timing is suggestive of something more than unfortunate coincidence and the possible link to vaccination is entirely credible.

The history and pattern of our son's regression into autism and his catalogue of symptoms, both physical and neurological, are remarkably similar to those of the other children represented in this group from all corners of the United Kingdom, some of whom have substantial medical evidence to support their case. The firm of solicitors, Alexander Harris, reviewed our son's history and

deemed that he had a case to be answered and, for that reason accepted our son as a claimant in the generic group action.

While I appreciate that it is not the purpose of Legal Aid and British Court Services to fund medical research for its own sake, in my son's case the evidence needed to bring an action to court would consist of medical tests and research. This evidence was being compiled on behalf of the lead cases and, at the time that the legal aid funding was withdrawn, individual test results and generic research were compelling. Research has moved on since then and further evidence of a causal link between MMR and autism has been published. Mrs H-R, who has been acting as our Mackenzie Friend in this appeal has referred to this evidence in her submission, as have some of the other claimants in this appeal. I cannot add to this evidence but endorse it and say that our son has a remarkably similar profile in terms of the presentation and timing of symptoms to the subset of children whose decline into autism is linked to the MMR vaccine. He has a case to be answered and we have simply sought, on his behalf, for the means to present his case. This has been denied with no good reason.

As full-time carers for our son my wife and I are both living on benefits. For the foreseeable future it is unlikely that either of us will be able to work again because of the implications of caring for our son. It is even more unlikely that our son currently aged 8 but with a developmental age averaging at 2, is ever going to be capable of receiving an education that will in any way equip him to work or otherwise contribute to society or state funds. It is equally unlikely that he will form a relationship with anyone other than us or paid carers given his devastating deficits of social development. The cost of this lifetime of dependency and non-contribution will be borne by the state. Given my child's young age this is likely to amount to considerably more that the costs of a fair trial to bring an action against the originators of his disability, namely the manufacturers of his MMR vaccine. We have been denied the right to have a fair trial so that the originators of my son's disability might be brought to account and so that British tax payers might be relieved of the financial burden of my son's care.

If we had the means my wife and I would gladly pay to bring this case to court ourselves but the fact is we can't. For many years, however, we worked, paid our taxes and National Insurance and contributed our share. It seems unjust in the extreme that immigrants to this country UK, who have contributed not one penny to its funds, can access the Legal Aid resources to justify grounds for residence in the UK, collectively costing the country millions, while our son is denied the means to seek justice and is hung out to dry.

No medical procedure is entirely without risk including vaccination; no drug is without side effects again including vaccination. At no time, however, during either of our two elder sons' vaccination schedules were we given any detailed information about possible side effects. Parents should be made aware of even the most remote possibility of any damage that might result from vaccination. Vaccine packages apparently contain inserts giving detailed information about the vaccine. We were not aware of this or aware that more detailed information was available. It seems that parents are deemed unfit to have this information and, indeed, some might not want it but it should at least be offered to us. After all, there are package inserts in over-the-counter and prescription medicines that we are warned to read before taking the medication. This is so that if we elect to take the medication we do so in an informed and responsible manner. Perhaps, based on this information we might decide against that medication and seek an alternative. Why are we not similarly informed when it comes to vaccination?

It is the case that not only has our son been hurt by the MMR vaccine but also that we, his parents, were not in possession of the facts; were not aware of the nature of possible side effects and had no opportunity to make an informed decision whether to proceed with vaccination or not.

I have many times come across the phrase "It is not in the public interest to know…..". It was apparently not in the public interest to know that some brands of MMR vaccine, including the brand administered to our son, contain

cells from aborted human foetuses. If my wife and I had known this we would have refused the vaccine on those grounds alone. Parents have a right to know what is being administered to their children. Quite apart from the possible side effects there are valid religious reasons for refusing such a vaccine. For example, gelatine is used in the vaccine but what is the source of the gelatine? I have not been able to discover the source but it could be pork. How would devout followers of Judaism feel if they found that they had unwittingly administered a pork derivative to their child? Interestingly, my son is intolerant to both pork and gelatin.

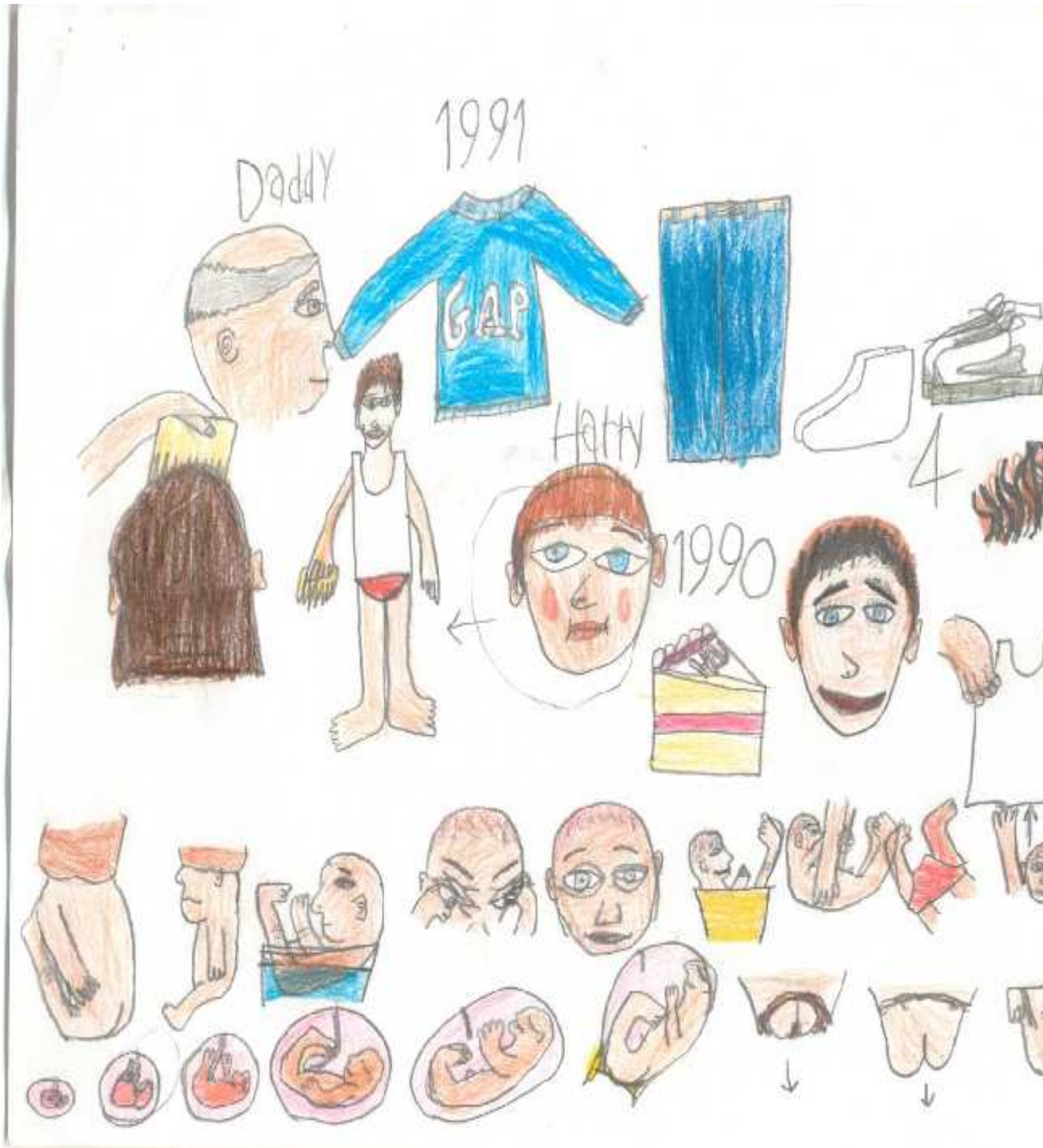
This issue of undisclosed vaccine components and side effects needs to come into the public domain. Why is this information being withheld and by whom? If vaccine manufacturers do not wish parents to have this information it begs the question “Are the vaccines are as safe as the medical establishment and pharmaceutical industry would have us believe?” If the MMR vaccine were as safe as its promoters would have us believe there should be no problem with disclosing its components together with an explanation of why each one is necessary. Indeed this information should be available with all vaccines. The big fear seems to be that if parents knew they wouldn’t vaccinate. This seems to be a tacit admission that there are significant risks and issues that parents would reject. That being the case shouldn’t the vaccines themselves change? This lack of disclosure had direct bearing on our decision to vaccinate our son, which resulted in the damage done to him in the form of autism.

Legal Aid was withdrawn some time ago and the Generic Certificate was subsequently discharged on the premise that, based on the evidence available at that time, the litigation did not have a reasonable prospect of success. Mrs H-R acting as our MacKenzie Friend in this matter, has made cogent, evidence-based representations against this decision arguing that, on the balance of probabilities, the litigation would have had a very good chance of success. My family and I cannot thank her enough for her hard work, professionalism, support, and commitment to this case.

I have only this blunt statement to make in summary. I believe, together with my wife, that MMR has hurt my child. If, as in any legal case, there is a belief that the injured party has a right to seek justice, then why are the means to do so being refused to my child? He is no longer part of a generic case, I ask you to look at him as an individual and assess his right to have access to justice on its own merits. He was not one of the lead cases. The process of compiling evidence supporting his case had scarcely begun before the funding was withdrawn

We are not just wretched parents railing at the injustices of life and seeking to find a scapegoat to blame. Something happened to our bright, bubbling baby. If translated into a graph you would see a visual representation of our son's normal development proceeding steadily to its apex then suddenly suffering a reversal that spiralled inexorably downwards into autism. The one event that coincides with that reversal is our son's vaccination with MMR. There is a correlation. His symptoms did not just appear during the second year of life; he started to change within 2 weeks of vaccination.

I am begging you to acknowledge the possibility that MMR has damaged my son and I am asking why our access to justice been denied which would have enabled us to compile evidence and bring an action to court on his behalf. Such an action is also in the UK and European public interest since there are issues arising that need to be investigated and resolved openly in the public domainWith autism growing at a rate of 10 to 17 percent per year, we recognize the need to address issues directly affecting these children. Although there is no known cure, early intervention and treatments hold promise and provide hope for families living with autism. This justice has been denied in the British Courts and what we have here is no more than a political decision where not one of these children have been looked at individually.
Without further ado.
Thank you.
Signed by G's father.


Daddy
1991
GAP
Harry
1990
4

9. Harry's story.

His Application for Review of discharge of Legal-Aid Certificate dated 21st June 2004

We submit that there is ample evidence and in this case to discharge the burden of proof and establish liability by the defendants at trial.
Prospects of winning before an impartial tribunal would be approximately 100 per cent.
Harry's mother is an experienced Counsel and has assessed the evidence..
There is plentiful evidence of witnesses including our selves as the parents of Harry.

We enclose 4 witness statements among others.
There is also ample medical evidence from the GPs' records and other records to prove that Harry was progressing very well as a baby up to the time of his MMR jab; and that afterwards he did not progress normally.
Copies of these records can be provided by on notice if the LSC have not already seen them.
Our son's former solicitors, Alexander Harris and Company have the full details.
There is also an increasing body of scientific evidence, since the published findings of Dr. Wakefield and O'Leary and a team of experts prepared for the trial has now been supplemented by findings in the USA.
The LSC will have seen the U.K. evidence in the Lancet and elsewhere. We can furnish copies if required.
We attach notice of further research findings in the USA, which lend support to our case.
There are also hospital records showing that Harry has vaccine strain measles in his gut (see letter from Dr. Wakefield of 7/2/2002).
There is further expert evidence from, Peter Fletcher M.D. and others.
Harry's mother is a barrister of 28 years in civil practice at the London Bar.

She was present at the Judicial Review hearing in London in the case of Nicholas Williams, one of the lead claimants.
In her view the case was not conducted properly in that it did not address extensive witness and medical evidence, and was not cognizant of emerging scientific evidence.
Harry's parents intend to take their son's case against withdrawal of legal aid as far as the European Court of Human Rights if necessary.
They have asked for a stay of the substantive trial pending Application to the ECHR (if necessary) if the FRC and UK Courts via Judicial Review turn down their application for renewal of legal aid.
In that event the case would be against public funds, and not the pharmaceutical companies.
Harry's mother would be prepared to represent their son at the substantive trial,
but without legal aid the family would not be protected against the defendants in costs. The defendants have made it clear that they will seek costs.
Therefore the family cannot take the risk, which would benefit Harry least of all, of facing bankruptcy if the tribunal, as a result for example of political pressure, do not find in their son's favour.
Accordingly we will seek delay of the substantive trial until following the hearing of the ECHR Application unless legal aid is restored meanwhile.
Counsel's reading of the ECHR law leads us to believe that we are likely to succeed before that Court.
Our son has a strong claim in the substantive action supported by plentiful evidence and his prospects of success before an impartial tribunal should be approximately 100 per cent.
We seek restoration of legal aid accordingly.
We ask for an F R C hearing in London as a matter of natural justice.
Documents enclosed;
J H R Witness statement
K R Witness statements + 2 further witness statements.
Dr. Wakefield letter of 7/2/2002
The Informed Parent News Letter. June 2004

Lancet article-Wakefield and O'Leary and their team. (copies available)
Harry's medical record (copies available if required)

Witness Statement of Keith Roberts

I, Keith Roberts make this Statement on behalf of my son Harry in connection with his claim for personal injuries and other losses after being vaccinated with the MMR vaccine on 20 June 1990.

Personal Details
I am married to JHR. We have two children. They are Harry and Francesca.

Family Medical History
I am and always have been very healthy. My father died at 51 following a heart condition. My mother died at age 90. I was previously married and have a son from that marriage who, is extremely healthy.

Apart from the usual childhood ailments my wife has always been very healthy. She has a sister who is six years older then her. She is very well and there is no history of illness in her family. Her mother is aged 86 and is still alive and well.

JHR's father had a serious allergy to wheat and tomatoes. JHR does not have any allergies
but she does have very mild asthma for which she takes medication. JHR's sister also suffered from mild childhood eczema which resolved with appropriate treatment.

There is no history of development delay or epilepsy in either of our families.

My daughter, Francesca, whose date of birth is 24 July 1990, is very bright, intelligent and is extremely healthy.

Francesca had the MMR vaccination, with no apparent ill effects.

Pregnancy with Harry

My wife's pregnancy with Harry was uneventful apart from a very slight bleed which occurred at approximately three months gestation. Otherwise JHR was extremely well throughout. The usual scans and blood tests were completely normal.

During JHR's labour with Harry, she had a trial of labour, and went on to have a caesarian section because she had a small pelvic cavity. When Harry was born his Apgar scores were 10:10. He was mildly jaundiced for a few days afterwards and had some phototherapy treatment but apart from that he was very well.- There were no problems or concerns about him.

The First Six Weeks of Harry's Life

Harry was a perfectly normal baby. JHR breast-fed for six weeks then he was bottle-fed on SMA. In fact, things were so unproblematic that JHR returned to work soon after he was born. We had a nanny to look after him. Our nanny never mentioned any problems with Harry's physical or mental development. Harry was reviewed by our Health Visitor when he was 5 weeks old. In the Health Visitor's notes she made a note that the examination was satisfactory. The GP from Kentish Town Health Centre also confirmed that there were no problems. There was no motor delay, his vision was satisfactory, and his hearing was fine in that he was responding to sound and his social behaviour was at the expected age level.
Early Health and Development

Harry slept well, fed well and was very advanced for his age. He was a lovely, bright and alert baby. He had very bright eyes and had extremely good eye contact.

There is a note in the Health Visitor records which specifically states that Harry's 6 month check was satisfactory.

Harry was a very hungry baby. I used to carry out the night feeds, which were sometimes up to four times a night. He would settle straight back to sleep without any problems.

During his first year, Harry developed baby babble and smiled a lot. He was an extremely social baby. Before he was one year old he was attending a playgroup with our nanny, he was very sociable and interacted well with the other children.

Harry was a relatively robust baby and when he was 6 months old, we went to Portugal. As far as I am aware, on holiday, in Portugal, he was not exposed to measles virus and has never been diagnosed with measles.

He walked at 11 months old.

Harry enjoyed his first Christmas party, he was very happy. Other mothers remarked on how lovely he was. He really enjoyed being with the other children. Some of our friends remarked on how he was advanced for his age. In fact, he was ahead, of their children of the same age.

Harry was healthy prior to the MMR. Apart from a bout of diarrhoea and vomiting, an upper respiratory infection and an episode of tonsillitis we did not have any problems with him.

Francesca was born on 24 July 1990 when Harry was 13 months old and I distinctly remember that he was saying words like "Apple", 'Watch" and "Ball".

The Pre-MMR Vaccinations

Harry was given the Diphtheria, Polio, Tetanus and Whooping Cough vaccinations on 1 October 1989, 1 December 1989 and 1 April 1990 without any ill effects. He was later given a single dose vaccine of Whooping Cough on 9 October 1992.

The MMR Vaccination

Before the MMR was given we were given a pamphlet at the Health Centre about the MMR vaccination. The information in the pamphlet suggested that there was only a million to one change of any side effects from the vaccine. In fact, it went on to say that the risks of not having the vaccination were so terrible that we felt there was no alternative but to have Harry vaccinated.

On 20 June 1990 our Health Visitor made a note in Harry's records that Harry was a healthy baby - for early MMR. She also noted that he had had no previous reaction or no contraindications to the vaccine.

On 20 June 1990, JHR took Harry to Kentish Town Health Centre for the MMR vaccination, which the GP, Dr. Dickinson, had approved first. It was given by the Practice Nurse. JHR noticed on entering the room, that the phial had been taken out of the fridge and placed on the work surface. JHR was concerned that this could have been a phial with a batch number that should have been withdrawn.

Immediate Reaction

Harry was grizzly that day and for a few days following the vaccination. He also developed a fever. JHR swabbed him with cool water, she spoke to our GP on the telephone who advised her to continue with the tepid sponging, and she gave him some Calpol. He also started screaming at night which he had never done before the MMR vaccine was given.

On 6 July 1990, Harry was seen by our Health Visitor. She made a note that he was slightly pale, that he had thrush on his bottom and in his mouth, and that he had been screaming at night. She said he might be teething.

On 18 September 1990, JHR took Harry to see our general practitioner because he had been unwell for at least a week. He had developed a fever and had had a cold for ten days. He had also developed diarrhoea. Our GP diagnosed that he had tonsillitis and prescribed a course of Penicillin for five days. JHR was advised to give him plenty of fluids and Calpol when necessary.

After the antibiotics had been prescribed, Harry developed a rash and it was decided that he was allergic to Penicillin. The rash that he suffered consisted of large purple spots.

When Harry was about 18 months JHR and I became concerned because Harry's words were not developing. He seemed to lose his eye contact. I would take him for walks in the park, and I noticed that Harry did not take an interest in his surroundings. If a football was kicked nearby Harry did not seem to respond whereas, before he had received the MMR he would have run after the ball.

We did not want to accept that there was anything wrong with Harry. We had a nanny who came to work for us shortly after Francesca was born and she recalls noticing that Harry had lost his eye contact very soon after receiving the MMR vaccine. At the time, we thought that Harry was just reacting to the birth of Francesca.

JHR's mother also suspected that there was something wrong soon after he had been given the MMR. Both JHR's mother and our nanny did not want to upset us so they did not say anything. They just hoped that they were wrong.

Also post-MMR, we noticed that Harry's diet changed. Whilst he did not have an extremely varied diet before he had the MMR he seemed to eat a very restricted diet after he had the vaccination. He would only eat things like tracker bars and he would only drink Ribena.

Referrals

On 5 June 1991, Dr. Dickinson, of Kentish Town Health Centre, saw that Harry had slow comprehension, did not understand simple commands and had few words.

On 29 August 1991, Harry was referred to the Child Development Team at the National Temperance Hospital because his comprehension was poor and his speech was practically non-existent.
36 At the Child Development Team Harry was seen by Dr. Martin H. Bellman, Consultant Paediatrician. He diagnosed that Harry had a deficit of language development. He also thought that Harry had social difficulties, lack of inhibition, lack of awareness of danger and needed constant supervision. He wrote this in a letter dated 13 February 1997 to our GP who was Dr. I. Robinson of St. John's Way Medical Centre.

37. At the age of 22 months, our nanny took Harry to the Health Visitor Clinic. She noticed that Harry's speech was poor in that he was only saying three to four words. She also recorded that our nanny felt that Harry did not understand tasks that were asked of him.

38. At Harry's three year check with the Highgate GP Practice things were not looking good.

39. Our GP referred Harry to Dr. Kenyon of Harley-Street. He was a doctor of complementary medicine. During the consultation Harry was very impatient and difficult to manage. The doctor could tell immediately that Harry was

autistic. He carried out some allergy testing and gave us some tips as to what Harry should eat and what he should not eat.

40. JHR and I were also referred, along with Harry, to the Tavistock Clinic where we met with Sue Reid, Consultant Child Psychotherapist. Initially, Harry attended three days per week. The Psychotherapist also saw JHR and me. Sue Reid's husband, an Educational Psychologist, gave us a report when Harry was 3' years old which helped to get him statemented and into a school for special needs.
Ms Reid diagnosed Harry with communication difficulties but did not feel at that time that he exhibited all the characteristics of what might be termed a "typically autistic" child.

Harry was subsequently referred again to St Ann's Child Development Centre for a developmental assessment by their team because he was still to have a confirmed diagnosis. He was seen by Dr Lingham, Consultant Paediatrician in Community Child Health who arranged for him to be referred to a child psychiatrist and also for specific blood and chromosome tests to be carried out. It was subsequently decided that the tests themselves were not necessary and unwise given that Harry was very reluctant to cooperate with such tests and this is still the case today.

Ultimately, the further assessments were not carried out and Harry continued to receive psychotherapy from Susan Reid at the Tavistock Centre. He made very good progress and was found to be advanced in a number of areas whilst still having a very clear and marked socialisation/communication disorder. He was assessed on 30.03.93 by Bernadette Gillespie, Speech and Language Therapists who confirmed that his level of impairment and social interaction and behaviour and symbolic development appeared to place him nearer to the autistic end of the continuum of communication disorder rather than the linguistic disorder end.

A report was subsequently prepared by Dr Lingham on 30.03.93 and he confirmed that Harry's overall diagnosis would, be in the autistic spectrum.

We commenced a number of therapies as a consequence of that diagnosis and have tried to stimulate Harry/s socialisation and interaction as much as possible. He was referred to Nordoff-Robbins Music Therapy Centre in September 1993 where he was seen regularly until January 1997.
Continuing Symptoms/Regression and Other Problems statement
As Harry got older we could not go out walking with him as he would try to escape. He had no sense of danger.

On one occasion when Harry was in the toddler's playground he went missing. He managed to get out of the gate and onto the road. This happened a number of times. He could manage to crawl through a hedge and go missing.

We used to regularly visit Hastings where JHR's mother lived for holidays which Harry enjoyed immensely. We would go to the country park near to JHR's mother's home. I would get up early with Harry and we normally go for a walk through a wooded area. Harry would like to take the same route, to climb the same trees and sit on the seats throughout the woods and we would have a regular routine.

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Bowel Problems/Diet

On 3 July 1997, it was noticed that Harry started having watery stools three or four times a day. Our GP referred him to the Royal Free Hospital where he was seen by Professor J.A. Walker-Smith.

Professor Walker-Smith referred Harry to see Dr. Andrew Wakefield also of the Royal Free Hospital. On 11 January 1998, Harry underwent a colonoscopy investigation and biopsy. We have not received the results as yet. We have been informed by Dr. Andrew Wakefield that Harry does have inflammatory bowel disease and an inoperative lymphatic system as at 11 January 1998. He is hoping to be able to make use of the biopsy material in his research.

Due to Harry's restricted diet, he was seen by a Dietician in February 1999. The Dietician advised that he should take a multivitamin and mineral supplement.

He was also seen in the Paediatric Autistic Clinic. The doctors are exploring exclusion of cows' milk and wheat. He is also seen in the Food Allergy Clinic and was commenced on Pentasa which is an anti-inflammatory drug. This was commenced in, March 1998, and there seems to have been good progress. Since October 1999 we have switched to homeopathic secretin. There has been further marked progress.

Whilst Harry developed loose stools after the age of 1 year old, it worsened when he was around 6 years old. He then developed some urgency which prompted the referral to the Royal Free Hospital in the first place.

He is seen every four months at the Royal Free Hospital for check-ups. He has commenced on Mazalazine (Pentasa), Senna liquid and Paraffin Oil.

Since March 1998, he has made some progress with his speech. Recently, since October 1999, we have given him homeopathic secretin which apparently is absorbed through the stomach and we have noticed that Harry's language is improving. Dr. Murch of The Royal Free Hospital approved the use of homeopathic secretin in October 1999.

Recent investigations carried out by the Royal Free have identified the existence of bacteria in Harry's bowel. They have recommended and implemented a 3 month course of triple antibiotics which is being co-ordinated by Dr Murch. This is an experimental course and it is hoped that if the antibiotics work to reduce the bacteria, they will then be able to concentrate upon managing the extent and nature of Harry's other problems. In addition, we have seen that Harry has stopped headbanging which he was doing a great deal before the treatment started and similarly, his language has improved and that he will now use a number of words to make a sentence. For example, he can use individual words and in some cases construct a full sentence such as "I want to go to Hastings".

We firmly believe that Harry is well aware of his problems and gets very frustrated by his inability to communicate what he wants and that this was the cause of his. head banging and to an extent any disruptive behaviour. We have had comments from the school that his behaviour is much improved with the treatment that he has received.

There has been some discussion in the past that it may be possible to remove measles virus from his system by boosting his immune system however, this has been proposed as something for the future and is not presently an option.

I understand that following Harry's assessments by the Royal Free Hospital, a sample of his bowel biopsy was tested for the presence of measles virus and this was confirmed to be positive. Harry has recently undergone blood tests to confirm the existence of measles virus in his

peripheral blood supply however due to Harry's aversion to any hospital procedures, has not been possible to take a blood sample.

We have found that in response to the Royal Free's involvement and in particular to the antibiotics, Harry has calmed down a great deal and we have seen an improvement in his level of concentration.

I have been shown a letter prepared by Dr Murch dated 19.09.2001 where he has suggested that Harry may have a primary genetic form of autism rather than an immune associated regressive form. This has subsequently been discounted hence the antibiotic treatment and probable future efforts to try to boost his immune system.

In terms of Harry's current diet, he has a relatively restricted appetite. He will eat a lot of grain based products such as toast, pizzas and poppadums. He is also very keen on cheese toasties, hotdogs and crisps. All the food he eats is cold and he can only eat it with his fingers.

Current condition

Harry is very aware of his own condition however he can cope with it to an extent. He throws himself into his routines and in particular, we have to follow a very specific and consistent routine at the weekend. Usually this will consist of going to the same museum or the zoo and if we do not then Harry gets very distressed. He loves to read books and can hold very articulate and informative conversations about science, history or the universe and space. This has to however be tempered with the fact that Harry still has very substantial difficulties in conducting his normal every day life. On occasions, Harry has gone missing and we have only been able to track him down by thinking about the routines that he will follow and invariably, we have found him either at a museum or on one occasion, the Police found him in a park but he had brought books from two different museums which he had clearly been to.

Whilst Harry has a number of very "intellectual" pursuits he is still very much an autistic child. He likes to play with soft toys and he has no friends to speak of. He is however well known at the zoos and museums that he goes to regularly and he likes to go to the book shops and is well known to the members of staff who always say hello to him. For example, we go to the zoo and museum once a week every week and on nearly every occasion, he buys either a book, CD rom or video.

The restrictions that Harry places on himself by his routines are also evident during the evenings during the week when he insists on going to the park. On a Sunday, we will always go to the Natural History Museum and then to the Science Museum. If we do not go to the museums then Harry will find a way of getting there himself, whether running off or making his own way there on another occasion

Education

Initially, Harry attended a Montessori nursery until he was aged 2'/2 years old. Following the MMR vaccination, Harry was always trying to escape and his safety has always been an issue for us to deal with.

Harry then started to attend St. Michael's Nursery School. There were two classes. He had one-to-one help there but towards the end of his time the teachers recognised that he would not go on to a mainstream primary school and the question of special needs education came up. JHR and I had a meeting with the Educational Psychologist and Harry's head teacher. They recommended that Harry should attend a special needs school. We subsequently went to see a NAS Special Needs School in Hertfordshire but we were not impressed by its suitability for Harry.

We then went to see Moselle school. There were two autistic unit classes with five or six children in each class. All of the children had mild or moderate

learning disabilities. Harry now attends Oak Lodge School which has a specialist autistic unit. There are 5 in his class and Harry has a one to one carer throughout the day. He is transported to the school which he stays at during the day and returns home every evening. He continues to do very well with his music and he enjoys singing although his language is poor and his social interaction at school is poor which is reflected in his lack of friends. A good example of Harry's poor interaction can be seen when he is in a crowd when he will quite often push to the front of the queue or a group so that he can see what is going on and will not say anything and people often take offence at this because they do not understand his difficulties.

Effect on our Family Life.

Since Harry had the MMR, there has been an enormous strain on our family. We have not had a holiday abroad since Harry was 6 months old. We used to go to Portugal because we had a property out there. Since then we have not been able to go at all.

JHR and I cannot go out at night as a couple. We cannot do trips together as a couple.

JHR frequently goes to bed very early at about 8.30 pm and she gets up very early in the morning. I go to bed later then her and get up later in the morning, about 6 to 7 am. We need to do this so there is an overlap and one of us will always be there to care for Harry. Sometimes Harry is up and about at 4 am in the morning.

We have not been able to make friendships, invite people round to our house and socialise as we used to.

The only friends we meet are our children's friends.

I started working from home shortly after Harry was diagnosed as autistic. Harry has always needed constant supervision. Getting good childcare has been a problem. JHR continued working for many years but she has practised part time in recent years. She has been concentrating mainly on writing, paperwork and the family house.

JHR had to work part-time from when Harry was 5 years old. She had to spend time with him in order to teach him to speak again. It was during the recession in the 90s, and my work had taken a slump. It had a major financial effect on us. JHR would have worked full-time, but Harry was becoming very anxious at the time, withdrawn and always running away. The Tavistock Centre said that if JHR personally did not spend much time teaching him to speak “he would withdraw from planet earth". He had to be watched every second for safety reasons. No nanny could do this.

JHR and I have sustained a huge loss of earnings over the years since Harry was affected by the MMR vaccination. We had a beautiful house in Highgate which was repossessed because we could not afford to maintain it, on account of our need to be with Harry constantly, so that our earnings were drastically reduced.

We currently live in a four bedroom house in North London which is a terraced house. Harry has a separate room to his sister and he is happy to play in the garden or climb trees. He has a very poor sense of danger and we therefore have locks on all the doors and windows. Whilst Harry
would not necessarily jump out of a window,-he would quite happily sit on a windowsill several stories up and not fully appreciate the risk that he was placing himself in.
These windows therefore only partially open. Similarly, Harry can be quite destructive. If I leave any of my own tools around, Harry does have a tendency to pick them up and start hitting the walls with them and we have a number of places where he has broken plaster off after hitting the wall with a hammer. I myself am still working in a family run business developing leisure

facilities. At present, JHR is also assisting me with this dealing with the contract aspects. She no longer practices as a barrister however may return to Chambers at a later date.
Harry's security has always been a problem for us. One of our nannies was not so vigilant, and Harry ran off from the 1 O'Clock Club at Parliament Hill NW5. Another time he ran across a field, and on another occasion he went missing in the woods when he was out with me, and he was rescued by a police helicopter.

JHR and I have to sleep in separate rooms. Harry often wants to be with one of us or gets up very early in the morning.

We have to go out alone if at all. We never get to go out to the opera anymore for example.

We always seem to take turns in looking after Harry.

84.1 used to like to play golf, but I only manage to do that about four times a year, if that. I used to like to play every week.
Francesca is a responsible little girl. Her friends like to stay over but unfortunately this can be embarrassing for her because Harry likes to take his clothes off.

Harry is very enthusiastic about swimming. Sometimes when we get to the baths he takes his coat off and he has nothing on underneath. This can be a problem if we go shopping and Harry decides to take his coat off in a shop. He has been known to be naked under his coat.

Harry's Prognosis

Harry's future is uncertain. He will hopefully attend a local day school where we hope he will learn a certain amount of independence. We intend to obtain help at home after school.

JHR and I constantly worry about his future.

We worry about his safety. He has no sense of danger and needs constant supervision.

On a positive note, Harry loves CD-ROMs, at home he is very competent at using the computer, and we have seen some improvement since he has been taking the homeopathic treatment. The Tavistock Centre say Harry is very intelligent. He is artistically and musically gifted, with a lovely singing voice.

Vaccine Damage Compensation Unit

We did make a claim to the Vaccine Damage Payment Unit on behalf of Harry but our claim was turned down. We understand that this is not unusual.

Continuing Svmptoms/Regression and Other Problems

As Harry got older we could not go out walking with him as he would try to escape. He had no sense of danger.
On one occasion when Harry was in the toddler's playground he went missing. He managed to get out of the gate and onto the road. This happened a number of times. He could manage to crawl through a hedge and go missing.

We used to regularly visit Hastings where JHR's mother lived for holidays which Harry enjoyed immensely. We would go to the country park near to JHR's mother's home. I would get up early with Harry and we normally go for a walk through a wooded area. Harry would like to take the same route, to climb the same trees and sit on the seats throughout the woods and we would have a regular routine.

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Witness statement of JHR:

I, JHR Barrister of London , make the following statements the contents of which are true:

I am the mother of Harry.

My son was born in 1989. The pregnancy was uneventful save for a slight blood loss at three months. Harry was born at University College Hospital London, by a Caesarean section following trial by Labour. He weighed just under 7llb(3.18kg) and achieved a 10: 10 Apgar test score. He had slight benign jaundice, which resolved several days later.

He was a wonderful baby, though wakeful at night for the first year or so. I breast-fed him for six weeks at which point he was transferred successfully to powdered milk (S.M.A). He was weaned successfully. He passed all his milestones early and was beginning to talk aged 1, saying words ‘apple, watch, and ball! He walked at 11 months. At six months, a most beautiful child, a neighbour with a child of her own stated ‘I would be so proud if Harry were my son’ for what he was not only normal but doing outstandingly well.

Our second child, Francesca, was due to be born by elective Caesarean the following July and as there was then a measles scare I was anxious to have Harry immunised before going into hospital for her delivery. The G.P. Dr. Dickinson at Kentish Town Health Centre nearby where we then lived, in Camden Square London NW1, approved early inoculation. Harry therefore received his MMR jab on 20th June 1990. I was concerned that the nurse who administered the jab had a single phial, out of the fridge, despite presumably inoculating other babies on the same day.

Shortly after the jab, I do not exactly remember how long but I think a day or several days Harry developed an extremely high temperature (104F) and was screaming. Having cooled him down we called the doctor who gave him a penicillin antidote. Subsequently he developed a large purple spots all over his body and my husband again cooled him down in the bath. The GPs thought that he must be allergic penicillin. However this is not the case, as he has not subsequently proved to be allergic to penicillin.

We could not believe the medical profession and the Government could get things so disastrously wrong, so it took time for the penny to drop for us to realise that the MRR jab was responsible for the devastating injuries which our son began to manifest.

He lost his speech and was no longer developing social skills. We thought at first he might be emotionally affected by the birth of Francesca on the 24th of July 1990.

We had a nanny as I was practising at the Bar part time and she noticed the failure to develop social skills before I did- this was my first child. My mother and husband were also getting alarmed though they did not tell me. By the age of 2 Harry was still not speaking. In August 1991 when the Health Visitor called he looked dreamily at the trees in the garden when we called his name, and did not respond. All alarm bells were now ringing and Harry was referred for specialist help to the UCH Consultant Dr. Bellman and to a Child

Development Team in Camden, and on one occasion a research student dropped on me the news that Harry was autistic ‘and what's more I think he has lots of other mental problems’. I remember it clearly as it was the day of the general election in June 1992. I was a parliamentary candidate and was so traumatised by this evil person that I was barely able to speak at the count that night. I never reported him for misconduct or cruelty-clearly we should have been spoken to by the Consultant not by a student sadist - although I wish that I had done so. I was too shocked, and preoccupied .

Then began the inestimably sad and painful process of Harry's referrals- to the Tavistock Center where assessment confirmed that he was on the Autistic spectrum and Albert Reid, educational psychologist whose examination found that he was ‘atypically autistic’ as he was highly intelligent (confirmed by his Tavistock Center therapist) with good cognitive skills although his speech and social skills were impaired. This was at age 3.

Harry was also extremely anxious. He had lost eye contact. He was a very poor feeder. When he began to speak aged 5 he would perseverate and speak indistinctly. He would often cry. We were in a nightmare scenario. It is quite clear that Harry was born normal. It is also quite clear that some event had occurred which had caused him devastating injuries. Looking back on this-at the time we trusted the medical profession and what we were told by the Government pamphlets as to the need to protect our child - we believe the cause must have been the MMR jab. We are totally amazed by the hypocrisy and sheer cruelty of those in the Government and the medical profession dedicated to ensuring that the truth does not emerge.

Apart from the evidence of Dr Wakefield and his team, more evidence has been recently emerged from reputable research backed by the Journal of American Physicians and Surgeons posted on the internet, which we attach.

There is evidence from ourselves, from Harry's G.P. notes as to what happened to our son, how before the MMR jab he was progressing famously,

afterwards he was not. This is in addition to the growing body of scientific evidence in our favour, which Governments are apparently determined to conceal.
We shall take our fight as far as the European Court of Human Rights if necessary to seek to secure justice for our son, among a host of the world's children also injured by MMR. The ‘slaughter of the innocents’ comes to mind. Any compensation awarded by the European Court will be against the public funds, not the pharmaceutical companies.
We are under no illusions as to the difficulty of achieving justice for our own son in the U.K. We are deeply saddened at what has become of our country as well as of our son-that they can inflict such evil upon him and others.
We demand a hearing of the FRC in London. Our son needs a full-time care and neither of us can be spared to travel to the North East of England to pursue our son Harry’s claim.

Nicholas Williams and the lead cases Review and the Judicial Review dealt solely with the scientific evidence (I know because I was present throughout at the JR hearing in the High Court in London). There is substantial evidence as to what happened to our son from ourselves and other family witnesses. There is also substantial medical evidence from the GP records to the same effect. These records will be submitted to the FRC if the L S C has not already seen them. Please let us know. Harry's former solicitors have told us very little indeed about the way they conducted the case. At the JR hearing the conduct of the case was unsatisfactory. We demand proper and full assessment of our son’s case.

The case has to be proved in Court on the balance of probabilities i.e. 51% (not 100% as for scientific evidence). There is easily enough evidence to prove our son’s case on the balance of probabilities and indeed up to 100% proof is available. Legal aid should be granted for this case, which has worldwide importance, accordingly.

Statement of Carol and Martin Bailey

Harry always struck us as a very lively, bright and responsive baby. As our only nephew, and with two boys of our own, we were very interested to watch him as he met and clearly enjoyed the world around him. We have a clear recollection even at this distance of happy gigglings when we played a sort of peekaboo game with him for a few minutes while his Mother was holding him.

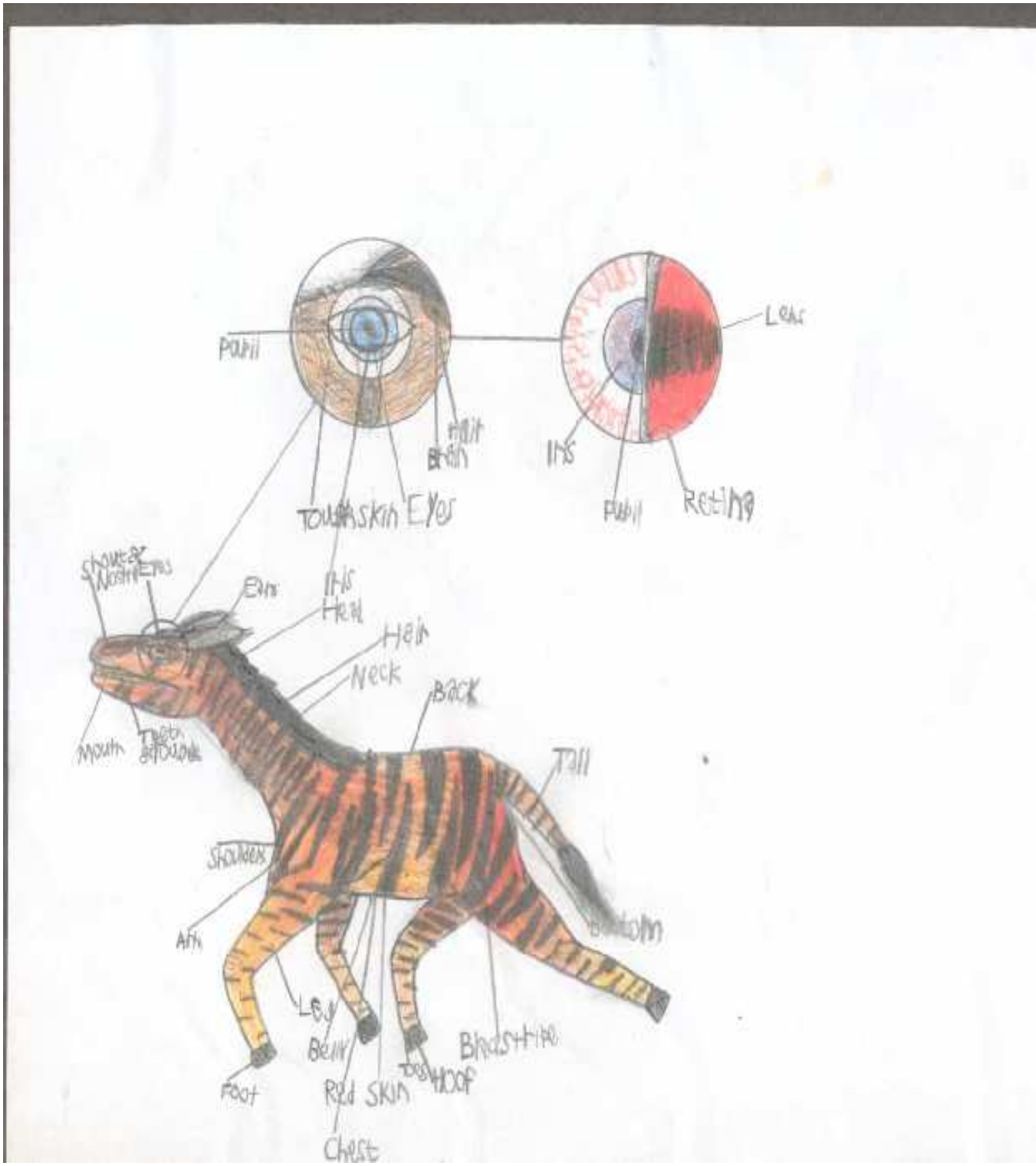
We certainly noticed nothing untoward about Harry's development during his early months; he was well advanced both physically and mentally.

We saw him pretty well weekly, and his progress seemed steady and sustained despite snuffles and minor bugs that afflict all babies. However, when he was about a year or so old, he developed what seemed a feverish cold which clearly made him feel wretched, made him very grizzly, and which followed an inoculation which we were told had been against a bundle of common illnesses including measles, mumps and German measles. Initially one assumed that the condition was attributable to a mild reaction against the injection; when his indisposition continued for several weeks, one forgot the injection and simply assumed that Harry was just suffering from prolonged sniffles.

It was after this that we first noticed that something about his manner had changed: he was not responding to people as he had done. After he had' finally shaken off his "cold", he seemed both oddly energetic and yet not interested in anything much. By now he was very mobile, rushing about the room, clambering up furniture and bookshelves. Over the next few months he noticeably failed to begin speech. He was also, now, quite clearly hypprdctive and uncontrolled. He would not look one in the face, seeming to ignore everyone else unless he needed something from his parents.

From then on, it became clear that there was a major problem and that Harry was not simply going through a difficult phase. He had been a normal, happy,

open, inquisitive baby, and had turned into a little boy who would not and could not engage with other people. His speech failed to develop; he could not dope with loud sounds, he seemed very rigid and unable to accept any compromise about what he wanted, and yet was wholly unable to explain what that might be. Inevitably, therefore, he appeared utterly frustrated and miserable, rather than happy and fulfilled.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10. Jack's Story

Jack was born in Glasgow in November 1992. Second son to parents John and Joan and younger brother to Jamie , four years his elder. Both boys happened to be breach deliveries at birth and as fate would have it the same breach specialist doctor was present at both deliveries both in London and in Glasgow much to Joan's relief.

Jack had no significant health problems as a baby. He did suffer from colic and had the usual colds and snuffles of childhood, but he was no sicklier than any other child was. Jack progressed as expected, developed normally making all the usual gurgling and babbling sounds, responses, attention, eye contact, vitality, crawling and playing (by himself and with his brother). His weight was satisfactory for his age and he had no problems feeding. Jack met all the usual milestones.

He was smiling at three months, looking at his hands at four months as well as laughing by then. He was sitting alone at seven months and he enjoyed his walker and would throw toys onto the ground to get people's attention. By the time Jack was ten months he was copying simple words such as 'ba' and 'da'. Walking by thirteen months and his hearing was normal. He would come when we called his name. Jack attended three different toddler groups and enjoyed going to all of them and playing with the other children.

It was when Jack was aged fourteen months he received his MMR jab. We like all parents had been given the advice and assurance that this was the right move at the right time to ensure Jack's and others health for the future. On the day of the vaccine Jack was in good health, but Joan recalls that in the three months prior to receiving the MMR vaccination, Jack had been suffering from a cough and high temperature. The doctor advised us that Jack could develop a high temperature, may be a bit under the weather and may need nursing after the MMR vaccine. We were not told about any of the serious side effects of the vaccine.

After Jack had the MMR vaccination, Joan recalls holding him for most of the day. The doctor did say that if Jack had a really high temperature and

prolonged crying fits, she was to bring him back to surgery, but at this Joan felt that Jack was just a bit clingy and unwell.

We noticed a bad reaction to the vaccine around twelve hours later at about one in the morning when Jack seemed to be very distressed and cried for a period of time. A cry that was different from his normal cry and Joan rubbed Jack's back because she thought he may have wind, but he also felt floppy. Jack had a fever and wanted to be held, but because we were told what to expect in terms of a reaction to the vaccine we were not too alarmed especially when he calmed down and went off to sleep. What fools we were not to take him to hospital.

Two days later Joan was out with Jack and he had another prolonged crying fit as if he was in real pain, so she brought him home immediately gave him something to bring down the temperature he had developed and for the pain. Again Jack settled. Jack went to the doctor seven days after receiving the MMR and we explained that he was not his normal self, he was listless, crying, suffering from wind, diarrhoea and occasional fever. It was explained about how Jack was on the night of the MMR vaccination, his crying and high temperature etc. His doctor prescribed antibiotics and none of the adverse symptoms from the MMR vaccine Jack had been administered was put into his medical notes.

Within a month of receiving the MMR around early summer, we both realised that Jack beginning to deteriorate quite significantly. He stopped responding when we called his name, had a gaunt almost stunned look upon his face and he would stare at things. He became anxious and his behaviours started to change. He would sit and constantly flip the pages of a book over and over again and when we tried to intervene to slow down and look at pictures or read from the book he would get upset and seem to need to get back to what he was doing previously. His diet changed dramatically, he craved certain food in particular and literally would not eat anything else together with being constantly thirsty all the time. From having at least six to seven words all he would come out with was eeeeeeh all the time

Nothing substantial stood out at the time about his true condition as he took further colds shortly after the MMR and the appearance of being listless was

by and large attributed to his bouts of illness. His lack of speech, playfulness, attention, focuses and habitual activities became more worrying. Again this was pointed out to our GP, family and others whom we came in contact with. Before the jab Jack would say teddy, light, mum and mimicked his favourite programme 'go go power rangers'. But now Jack was virtually silent. We became very worried and confused at this change. He stopped responding to his name and began to withdraw completely. Family and friends tried to reassure Joan 'my wee one didn't speak till he was four years old', but something wasn't right. It was only when others spent some time in the company of Jack and observed his interactions (or lack of them) that they too began to say yes there is something but it was difficult to put a label on it. Maybe he'll come out of it, maybe its just a stage, but we his parents knew, ever since the jab he changed and it was apparent it was getting worse instead of improving. Again we were at a loss not knowing and all others around us were in the dark as well. This was the beginning of a search to obtain a proper diagnosis.

We knew the cause, we were there, we saw the changes, we saw the effects, we felt the pain and anguish, but most of all *how* was Jack feeling, he didn't know any different, was he in pain, was he worrying, how uncomfortable was/is he. Was he deaf or hard of hearing that would at least explain the limited responses? Deafness was ruled out after more than one attempt at giving Jack a hearing test, they eventually had to give him one under anaesthetic. It wasn't until he was three and a half that he was properly diagnosed. We didn't even want to hear the word 'autism'. You immediately think of a child totally locked in his or her own world with no way out.

But the real explanation hurt so much and Joan remembers it quite clearly when the health visitor who came to see us said straight away 'I'm afraid Jack has a problem, he's in a world of his own'. Joan was in quite a state; it's one thing having suspicions. It's another having them confirmed by the medical profession.

Following his first bout of listlessness, he then changed dramatically again to being hyperactive and took to running up and down the house and garden. Followed by climbing everything and any thing irrespective of the danger. His

exploits are too numerous to mention in this summary but needless to say our attention is always on Jack, attending to him, watching out for him and constantly fighting for him, for his health and for justice.
Equally distressing were the difficulties his brother has had to endure both through experiencing his brother's troubles and the limited attention paid towards him. Over the years we made the effort to get Jamie involved in all sorts of activities such as sports, groups and youth clubs. This was difficult at times with having no family support like grandparents and aunts and uncles to assist us through the years. Trips to the cinema, local restaurants and especially the supermarket were out of the question and holidays were virtually non existent. Everything had to be centred on Jack's needs. We are proud to say that Jamie has come through all of this with such resilience and started University at the age of sixteen. Jamie never had the MMR vaccine. Sadly to say it is a different story for Jack and this has been the most taxing on all of us.
Nurseries and schools became the next hurdle. It soon became noticeable that Jack did not join in and participate with the set activities and other children but preferred to play or wander off his own. It was such a case that his mother had to stay with him in general if he attended nursery. We had to give up nurseries, as Jack became more of a disruption than conforming or participating, we enjoyed bringing him to outdoor play areas as that suited Jack so much more. This activity later had to stop because of Jack's fear of dogs and cats.
A record of needs had to be established to ensure some form of schooling that could meet Jack's needs there seemed at the time to be a constant barrage of hurdles and barriers at every turn. Investigations led to many more lines of inquiry other than his condition such as available services, medication, compensation you name it we needed to know more about what could be done. We were soon to find out that information was very limited or vague at every turn. We pursued a record of needs and found a special needs school fortunately in a neighbouring village.
We turned to homeopathic minerals and vitamins in an effort to improve Jacks life with some success over the years. His attention span has improved, as

has his response to his name, reduced stimming, some increased attention to tasks and increased awareness to what is going on around him. We enrolled with the Options Institute in America. (An alternative therapy based on allowing the child to take the lead in finding its own desire to explore and develop) Jack's father attended the start up programme and we initialised a form of programme with voluntary student assistants over a few years.
We also started proceedings in Scotland in 1997 for medical negligence after we had done extensive research on the subject of the MMR Vaccine.
There was, and still is little in the way of services to handle the needs of both child and parents. Joan along with other mothers formed a charity called Stepping-Stones Group our aim was to give advice and support to families who have children with special needs. We contacted the local authority to assist in providing services for our children, and after two years of meetings and consultations with the various departments of Education, leisure, this resulted in playgroups, after school services, care services and in some cases respite. But these again were very limited, and they did not suit everyone but again there would have been nothing if steps hadn't been taken.
At the outset you feel alone with no help but, gradually we found others saying the same things, had the same feelings and frustrations over the neglected children. Other groups started to appear, more records reviewed, investigations initiated and through such, the enormity and widespread problem started to reveal itself. Many thousands of parents in the UK stood up to attain some form of justice and care for their children and other parents and children whom may find themselves in a similar situation. Many articles and publications started to appear revealing an epidemic not just in our own country or indeed the UK but across the whole globe. The old myths of autism were being questioned.
Jack's mother has now been very involved over many years in Scotland with Action Against Autism (now Autism Treatment Trust) has, appeared on BBC television, many newspaper articles and radio programmes.
A breakthrough came about when Jack was six years when Joan noticed Jack had spelt the word 'toy' with a scrabble set. He then progressed to spelling nine letter words. We even got him to use notepad on the computer at home

to spell words, which he could do, but this has never progressed to anything further than copying. Now he points at things (after prompting) and you can tell he wants to tell you what they are, but the words don't come out.
Improved eye contact emerged around the age of seven and still holds good today. Jack's habits old and new (licking, biting, flapping, sounding) tend to last approx. four months or so. Some of, which can be distressing while others, can be endearing. Jack's medical condition it is in fact getting worse. Information's we now have show the adverse reactions shown in Merck's own vaccine information sheets of which many apply to our son Jack the day and night of the vaccine. The symptoms our son suffered were that of encephalitis and we are convinced that the damage was done the day he was given the MMR vaccine. He suffered many other side effects from that day on including fever, headache, dizziness, irritability, diarrhoea, conjunctivitis, possible nerve deafness as he wouldn't respond to his name.
One year after receiving the MMR Jack developed chronic arthritis, which has been associated with natural rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms. Luckily the duration of this condition was short lived.
The next problems Jack developed were his painful and bloating bowel disorder. We managed to travel from Glasgow to London for Jack to be seen by Dr Andrew Wakefield a specialist in the Royal Free where a x-ray and blood tests displayed a marked faecal loading in his gut colon and intestines. Jack has been on medication ever since to control his bowel movements. He attended the Royal Free in London four times to be observed. He had tests done previously by Paul Shattock at Sunderland University and was said to be a child with gluten and casein intolerance and a classic case of a child damaged by the MMR vaccine,
We all had a trying period starting in 2000 (Jack now seven going on eight) Joan still found herself unable to commit to any full time employment so her career as an artisan was put on hold. John found himself having to give up self-employment through a back injury. Jamie was having a difficult beginning at secondary school. Joan broke her leg after slipping on the stairs carrying a

loaded laundry basket the night before Jack went into Hospital for an operation.

Jack started having seizures of the most worrying kind at the age of nine. Over a period of two years he has had five seizures which has resulted in him having to be rushed to hospital due to frequent breathing difficulties each time he had a seizure. Since these seizures he has become incontinent. We are/were extremely concerned and worried at how our son has deteriorated, as there is no history of epilepsy or seizures in our family let alone Autism. Jack regressed, showing memory loss and inactivity, he basically had to be told to do almost everything. ' Yes you can have a drink of your juice, yes you can start eating. It was so noticeable and for a period he was back in nappies again. After toilet training him and managing to do it at the age of eight we were delighted. You can imagine our disappointment when he started soiling himself again. After his last two seizures he had trouble swallowing and held saliva in his mouth which, resulted in him dribbling from the mouth constantly. Thankfully, this dribbling has stopped at present.

Merck's own vaccine sheet states the swallowing difficulty sometimes causes the child to choke on its own saliva, resulting in pneumonia. The person may become blind. In the final phases, the body temperature may rise, which it has in Jack's case and the blood pressure and pulse become abnormal.

Jack needs constant care you see. He has behavioural and learning difficulties, bouts of incontinence, severe dietary problems and he goes through periods of regression. To this date and Jack at the age of thirteen going on fourteen he still has no language and a limited number of signs, which tend mostly to come through echolalia. Over the last year Jack has developed OCD, become more anxious, at times strips off completely at home and school and has shown some aggressive tendencies.

Most recently we attended a conference in Edinburgh regarding biomedical intervention and we are now prescribing Jack on a casein and gluten free diet. He has been diagnosed by specialist consultants from France and America and several interventions have been suggested utilising detoxification treatments i.e. methyl B12 injections along with vitamin and mineral supplements. These are new intervention techniques that have determined

that many viruses from inoculations remain in an individuals system, more so in autistic children and need to be removed. In many cases such treatment has had tremendous results but there is always some improvement. Autism is treatable but we are not at all sure that the damage Jack incurred from the vaccine can ever be repaired.

Jack may have acquired autism along the route but as far as we are concerned he reacted badly to the vaccine, which resulted in him, been mentally handicapped with neurological problems due to the adverse effects of the MMR vaccine. We can only do our best, and pray to God to give us the strength and conviction to go on. Obviously we love him dearly and feel tormented and broken hearted by this whole affair, as we are sure many other families do so as well. We feel very proud to be a part of the MMR 10 and shall forever keep in touch. With the expert help from Keith and J H-R we would not have been able to carry on fighting for Jack's right to truth and justice.

We have had no-one to represent our son's case after the legal aid certificate was withdrawn and we have had to constantly appeal the cancellations of his legal aid certificate as well as take on the Legal Services Commission. It was an extremely worrying time and the steps that needed to be taken at each event were a cause for concern. When you get no real support from your ex solicitors because they can't advise you anymore, other than 'Discontinue if your child suffers from Autism' and getting letters from the defendant's solicitors Lovell's saying we will be done for costs if we carry on without legal aid. You find the strength within.

This is the second time Jack's funding has been stopped. The first time was with solicitors in Scotland. Three years later they cancelled so we had to apply again and Alexander Harris in England took on his case. We have been dealing with Jack's legal right for a fair and proper hearing since 1997 and honestly we are appalled at the way our son has been treated as if no child has ever suffered a bad and devastating reaction to a vaccine. Again we find ourselves with no legal aid following the latest refusal following our latest appeal 2005/2006

The evidence and proof we need to win in court is staring us in the face, it's the children. It's a lonely world for the children and an equally lonely world for the parents and siblings. With our child's legal aid having been cancelled we feel cheated yet again. It is diabolical that our son has not ever had the chance to be examined for brain damage and adverse effects from the MMR vaccine. The drug companies claim that the MMR vaccine is safe and does not cause autism, IBD, epilepsy, deafness, arthritis and worst of all death, yet Merck and Co.'s own material information sheets list most of these reactions. We feel that the original trials carried out on the vaccine were not adequate enough and many learned men have agreed that the time span of three weeks following the injection is just not long enough.

The consequences are already shocking and the longer any decisions or determination of the true cause will remain vague and more children will be at risk. There is an epidemic of children with this and other disorders. Our son Jack in particular is one of the unlucky ones who have suffered badly.

There are complex issues within our son's case and the LSC have had to get a solicitor to review all the show cause letters which concerned us as the time was running out and still no news. We received our son's legal aid certificate cancelled on the 21st June no decision was made independently on our son's case. The decision had been made in London by the LSC's multi-party action group committee on all the cases rather than a personal assessment and decision for the individual child.

Coincidentally we are not convinced that the submission we put forward to support Jack's case has been read thoroughly or given careful consideration. Given the number of parents who we believe have submitted extensive responses to the show cause letters and it was found that the LSC only started to review them a week before the case.

If the LSC's multi-party action group committee make a decision in advance of parents submitting responses this could hardly be classed as fair or objective. To allow parents to go through the motions without having reasonable prospect of changing the outcome is cruel, hypocritical and appears to be designed to wear parents down without a fair hearing. Considering that many of the documents and letters we sent to the Funding Review Committee were

never read, as we found out later and the Judge did not have all the relevant papers before him to make an informed decision. This was not through his fault but the incompetence of the Legal Services Commission

What has changed to date from all the parent's intervention is that many inoculations are being scrutinised and some harmful ingredients removed. Autism is now *not* seen as an irreversible condition it can be treated and in some cases a near full recovery. But it is still early days and a lot is yet to be done in terms of research, early screening and treatment programmes. Lets prevent it happening in the first place.

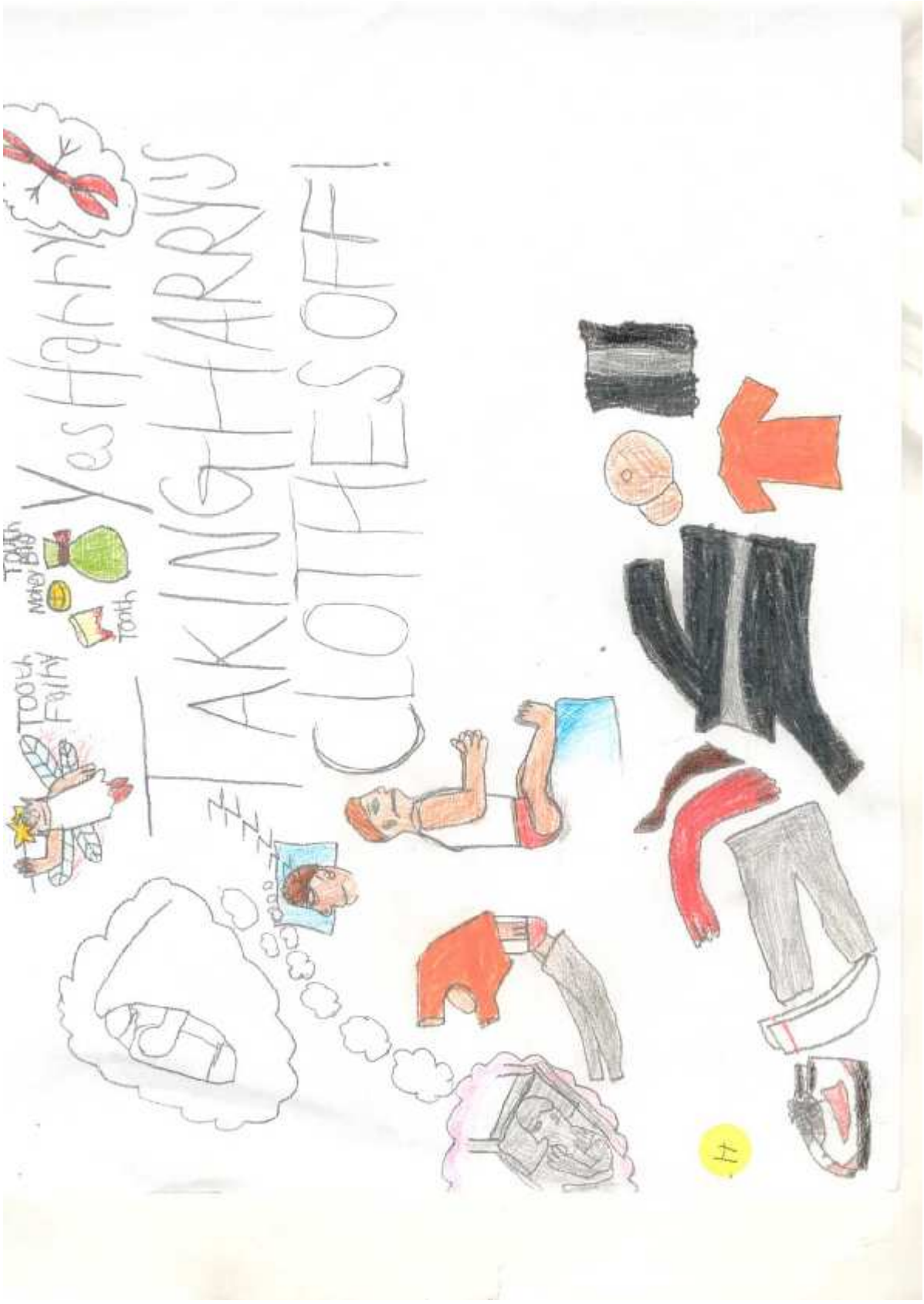
Jack will need care for the whole of his life and we are devastated that there may be no compensation for Jack so he can be looked after properly when we are gone and this prays on our minds daily. Every morning we wake up to the realisation that our child has and will be forgotten by the company who damaged him with their so-called safe vaccine. Our son has not been saved and dare we say cruelly treated by this whole affair. He can not talk for himself and he has extreme difficulty in letting us know what he needs

The pharmaceutical companies can well afford to compensate families who are telling the truth and by doing so the taxpayer will not have to fork out vast amounts of money to pay for services. It's pathetic that the multi-billion pound companies are in fact harming a larger percentage of our children and getting away with it. While the ordinary decent working person is paying for their mistakes.

The last eleven plus years have taught us a lot about compassion and searching for the truth. We are here to care, love and to teach the children, as they are the innocent ones. If it turns out that money is more important than life, then it will be a very sorry state of affairs. Fortunately most of the time, Jack is a loving, smiley, happy child but as we have seen that can always change as he gets older and more frustrated at not being able to get his needs across. Sometimes we wonder how our family has stayed together. We have had to at times work very hard.

We are reminded every day that our son is autistic, and every day we feel guilty. We allowed his system to be overloaded with an unsafe vaccine when he was just a small child. His little body was only just starting to develop. A

consent form was signed, believing and trusting in the system. Now we listen to him trying to participate when we are saying our prayers at night. We have taught him how to bless himself and our belief in god and the angels has helped us through this journey. There is no point in being bitter and the only way we have left is for us to have our say and to help Jack and others who are in a similar predicament. Without the support from the other parents we have met along the way it would have been a very lonely place.
Off to the European Court of Human Rights we go!


Yes Harry
TAKING HARRYS
CLOTHES OFF!
Tooth
Tooth Fairy
ZZZZ

11. Matthew's story

Until the MMR vaccination in January 1991, Matthew's development was entirely normal and his routine tests and checks confirm that. As a second child he was ahead of his milestones, thriving and developing physically, mentally, emotionally and socially. At an early age he was quite determinedly independent, very co-ordinated, affectionate, attentive and an inquisitive child with an extrovert personality. Matthew had excellent communications skills, he could easily string together a number of words, was able to understand and be understood.

Matthew had an extreme reaction to the MMR vaccination, he screamed continuously and was distressed for the rest of the day. By evening he had a fever and was delirious, the emergency services were involved and I spent the night comforting him. The next day Matthew continued to be very unwell, he was drowsy, pale, lifeless and could not hold his own weight. He constantly vomited, discharged green diarrhoea and could not keep either food or drink down. Matthew's system had been poisoned and as a direct result he became brain damaged. He remained very ill and one week after the vaccine he came out in a heavy cold and a rash, which developed into a very bad sore throat and swollen glands within two weeks of the vaccine.

Matthew was completely unrecognisable to the child he had been before the vaccination, he remained dazed, confused and in a lifeless state with no interest in his surroundings thereafter. He could not seem to co-ordinate his bodily functions, became frail, extremely head sensitive and resisted lights and noises. Matthew's did not seem to be able to focus, his pupils were permanently dilated, he had no eye contact, felt rigid and was clearly in his own world with no response to anything or anyone. He resisted being comforted, refused to be touched, could not sleep and was either carried or travelled in a buggy, as physical movement was too painful for him. Matthew had lost his earlier mobility skills.

Matthew continued to deteriorate further, his head swelled with distorted features and he was in constant pain with stomach cramps, permanently bloated and flatulent. Matthew did not have any bowel problems prior to the MMR vaccination, as a trained dietician I would have been particularly conscious of this, he had a sensible diet which was healthy and varied, even adventurous for his age. Matthew's eating habits changed considerably following the MMR vaccination. His taste and smell had become very distorted, he displayed serious aversions to strong smelling foods and different textures, he also developed peculiar cravings. Matthew rejected dairy products and his preference was for burnt toast, raw onions and salt, he no longer thrived and failed to put on weight, his skin became scaly and his hair would not grow. Matthew is currently on a Gluten/Casein and Salicylate restriction diet, free of Monosodium Glutamate, Aspartame, Tartrazine, Quinoline and 'E' Numbers and only has natural rock sea salt on his food. The unquenchable thirst has remained with him since and his body temperature has continued to be unpredictable and uncontrollable.

The emergency services attended to Matthew on numerous occasions and he went to see our GP on a regular basis. The symptoms were very similar to appendicitis and his distended stomach was examined each time, before painkillers were administered.

It was immediately obvious that this was a severe reaction to the MMR vaccination, I maintained that at the time and have done so ever since, it has been consistently recorded in Matthew's records and acknowledged as the cause at the time of his diagnosis in 1992. Matthew has a diagnosis of: a severe semantic and pragmatic language and communication disorder with associated learning difficulties and autistic tendencies. Subsequently this has been enhanced with Regressive Autism and an Inflammatory Bowel Disorder, regarded then as leaky gut syndrome and since as autistic entero-colitis.

As a family devastated by the damage this has caused, without resources, support or adequate healthcare we continue to do everything possible to

improve Matthew's quality of life, to enable him to live as comfortably as possible with his pain, difficulties and poor health. This has been and will continue to be a life-long struggle, which dominates our existence. Matthew is on a very restricted diet, has to drink filtered water, relies upon foods free of harmful ingredients and products of pure natural sources. He is also reliant upon a daily high concentration of fatty acid and multi-mineral/vitamin supplements, probiotics and nutritional dietary supplements, together with homeopathic remedies. Matthew is also dependent upon Cranial Osteopathy, Homeopathy, and Naturopathy to keep his suffering under control and bearable, all of which is privately funded.

Matthew is a day attender at a school for children with severe and complex learning difficulties, which indicates how torn we are between the extreme difficulties of living with Matthew and the impossibility of living without him. He is not able to voluntarily communicate, has no idea of danger and no concept of right/wrong or safe/unsafe. He does not respond to either reward or reprimand, requires constant supervision, stimulation and motivation to avoid remaining in his

own world of self-harm, rocking, flapping, monotonous babbling and delayed echolalia. This has become much more apparent and difficult to distract from or guard against, as he has become older and physically stronger. Matthew is unpredictable, he is not able to apply any form of self-help, continues to be susceptible to ill health due to his damaged immune system and is unable to indicate his suffering.

With our hopes and dreams for family life shattered by what has happened, we exist only on a day-to-day basis, with constant apprehension over what the future may hold for Matthew. Matthew is entirely dependent upon us as his parents, with no hope of an independent life of his own and we live with the daily fear of not being around for him. We are unable to do ordinary things

together as a family, but split ourselves between the needs of our daughter and coping with Matthew's difficulties. Our daughter has lived her life as an only child without those advantages, just the daily torment and anxiety of trying to exist, clutching at any glimpse of normality. This puts a tremendous strain on the three of us and is both psychologically and emotionally draining. Both my husband and I have spent our entire careers within public service, sharing the responsibility and care of our children between us, but because of what has happened to Matthew we have had to resist any opportunities for personal development or career advancement. Our lives could be better described as having been put on hold.

We lost our perfectly healthy and happy son at the time of the MMR, when he was eighteen months old and since then we have been tormented with the daily reminder. The enormous stress this has inflicted upon our lives is devastating and only compounded further by refusal of the medical profession to provide appropriate treatment. The Royal Free Hospital in London confirmed Matthew to have an ulcerated and inflamed intestinal tract, but following the departure of Dr A. Wakefield they removed him from the clinic list. This is a severe medical illness, yet despite the incredibly inhumane pain and suffering to Matthew, he is denied the most basis of life supporting exploratory tests or any hope of medical intervention.

It cannot be ignored that Matthew was knowingly put at risk by the authorities, when he was injected with a vaccine which had been proved to cause death and meningitis. A year earlier this same Urabe Strain vaccine was withdrawn in other countries, but continued in use here and is the direct cause of the damage to Matthew. Refusal to accept responsibility for the damage caused to Matthew also deliberately and intentionally ignores the fact that MMR vaccines used here were illegal, unlicensed or previously withdrawn from other countries.

Matthew is an innocent victim caught up in a conflict of colluding interests that dictates a refusal to acknowledge and a convenient dismissal of the life long

damage inflicted, which includes the removal of legal aid to enable us to challenge this on his behalf. We are left to live with the consequences, isolated and ridiculed for our conviction, with a very sick child who is disregarded and ignored as insignificant, because he had the serious misfortune to become a government and medical embarrassment.

We seek to prove that this particular vaccine was the cause of the damage Matthew suffered and this life sentence inflicted upon Matthew and ourselves as his loving family, but can only do so supported by legal aid. There cannot be a more worthy cause for legal assistance than for Matthew and children like him, who have suffered as victims of a vaccine programme, to have their right to access justice respected to ensure a future that is safe and secure. Whilst this will not give Matthew back the life he so deserved or the childhood our daughter so desperately longed for, it can go someway towards alleviating our fears and anxieties over what will become of Matthew, currently a considerable and ever increasing financial burden on public funding, more appropriately to be met by those responsible for the damage.


Cry
Angry
Pain
Tired
Crippled
Harry

12. Melissa's story

1. Melissa has one older sister, Samantha who is 17 years old. I am 40 years old. I am separated from Melissa's father. I am in good health apart from mild asthma. Melissa's father Keith is 42 years old. He is in good health with no history of chronic health conditions.

Present Condition

2. Melissa will never lead an independent life or have a job. She needs to be closely watched at all times to ensure her and others safety. She has severe learning difficulties with extremely challenging violent behaviour which is getting more frequent and severe. Melissa cannot write and can read only a few single words that interest her. She does not speak in whole sentences; she mainly uses single words or phrases that interest her. She needs to be kept constantly entertained. Melissa suffers from frequent painful spasms in her chest and stomach, which make her violent and aggressive. She self injures herself; she has thickened skin from years of biting herself. She requires 4 people to restrain her during her frequent violent outbursts. She will throw hard anything to hand no matter how large or heavy. She has extraordinary strength and she frequently breaks things, as I am unable to restrain her on my own. Melissa has frequently attacked me biting me up to 10 times in one attack before I am able to get her off me. She scratches, kicks, pulls my hair and head butts. I am in fear of my life around Melissa as she is highly unpredictable. She frequently exhibits inappropriate behaviour openly masturbating. Melissa remains extremely constipated. She has suffered from a non-bacterial stomach ulcer. She suffers from inflammation and reflux. Melissa suffers from extreme stomach and chest pain. She has been losing weight for over a year. Her stomach is often hugely swollen. It is hard to find clothing big enough to fit her stomach. Melissa has multiple food sensitivities or allergies. There is very little that she does not react aggressively to. She follows strict gluten, casein, no artificial colour, and flavour and preservative diet, with many other dietary exclusions. She

frequently has a strange rash on her face, hands bottom and feet. She has no sense of danger.

3. On a good day she can be a joy to be with. She can also be very loving and enjoys giving and receiving cuddles. She has good eye contact. She can be an adorable young lady.

4. Melissa was transverse in my womb; because of this Melissa's birth was induced when she was head down. I had a short labour, approximately 1 – 11/2 hours. Melissa was born by normal vaginal delivery. Her Apgar scores were 8 at 1 minute and 9 at 5 minutes.

5. The first weeks of Melissa's life were excellent. She was an alert child who gave very strong early eye contact.

6. In the first few months of life, Melissa had a couple of chest infections, but nothing serious. Melissa was breast fed until 10 months old when I weaned her onto formula milk. When I did this Melissa began to suffer from diarrhoea. She was diagnosed allergic to cow's milk.

7. On 21 January 1992, her GP records states:" German Measles". I think Melissa did indeed catch German Measles. She had a slight rash on her body and she was grizzly for a couple of days.

8. In February 1992, Melissa developed conjunctivitis and was prescribed eye drops by Dr. Fabre. (Melissa had conjunctivitis at the time of receiving the MMR, and for some weeks following.)

9. Prior to receiving the MMR, I had no concerns about Melissa's development. She attained her developmental milestones at the ages appropriate. She sat unaided and crawled between 6 and 7 months and walked at 14 months. Her first words were "milk – milk", Mummy and daddy". She had excellent eye contact and her understanding was very good. She

would cuddle her teddies and spend time playing on an activity mat. She would also hammer shapes into a box using a toy hammer.

10. I recall watching a TV programme on child development. I thought at the time that Melissa was doing everything she should. At the time she was laying on a rug in front of me and the tv presenter was talking about eye/hand co-ordination. Melissa was much too young to be able to take a rattle from me but I tried anyhow and was delighted when without hesitation she took the rattle from me and put it in her mouth.

11. Melissa was an adorable baby. She loved cuddles and gave excellent eye contact when feeding. She slept very well. I cannot remember any sleepless nights with her. I was a very relaxed mother with her. Melissa was able to point at objects she wanted and would understand questions such as "where's Mummy?" She was very cheeky, her eyes used to sparkle with mischief. She was great fun to be with. She used to crawl up to her wendy house and play peek aboo with the fabric door. (I have a photo of her doing this).

12. Melissa received her first, second and third DPT/Polio vaccinations on 28 February 1991, 20 April 1991 and 16 August 1991. She also received the HIB vaccination on 18 January 1993 and the MR vaccination on 7 November 1994. As far as I can recall I do not believe that Melissa had any reaction to the above vaccines, save that when she received the MR at school, her teacher reported she was unsettled for the following couple of days.

13. On March 1992, Melissa received the MMR vaccination at Dr. Fabre's surgery, April Cottage, High Street, Buxted, East Sussex TN22 4LA. The practice nurse administered the vaccine. I asked what side effects there were from the MMR vaccine and I was told that Melissa may get a temperature and be a little off colour. I was told it was very rare for anything else to happen. At the time Melissa was suffering from conjunctivitis and I queried whether

Melissa should have the MMR because of this. I was told it was not a problem.

14. Later that day, Melissa started screaming. It was not her usual scream; it was more high-pitched and very piercing. It seemed to go straight through me. Melissa seemed to scream for hours. I was obviously concerned and so I telephoned my mother. She advised me to call Dr. Fabere, which I did. When I related Melissa's symptoms to her she advised that I give Calpol. Melissa continued to scream despite being given Calpol, but eventually quietened. The following day, she was out of sorts and I recall she slept a lot.

15. Within approximately two weeks, I noticed Melissa was losing eye contact with me. It was not a total loss, but she was not giving strong eye contact as she had done prior to the MMR. She was also noticeably miserable, irritable and very easy to upset

16. Approximately over the next two weeks (well within two months of receiving the MMR) Melissa stopped saying the words she acquired pre-MMR and she developed obsessive behaviour. She insisted on watching videos all the time and would scream if I turned the videos off. Melissa became aggressive to everyone and to herself. She started to bite the back of her hands, bite Samantha and pull her own and Samantha's hair out. She would not just pull a single strand but complete handfuls. She also stopped pointing and her understanding seemed to go. She no longer seemed to understand when I said, "Where's Mummy", something she clearly understood prior to the MMR.

17. Her sleep pattern also changed. She was difficult to get into bed and woke up on numerous occasions screaming. She seemed to lose control of her temperature and would run around the house fully clothed, despite the heating being on. Also if it was cold outside she would often go out without wearing a coat and not seem to be bothered by the cold at all.

18. On reflection, Melissa's change was very sudden. She did not wake up the day after the MMR totally changed but she was certainly a changed little girl well within two months of the MMR. At the time I did not connect the change in Melissa to the vaccine. I thought her problem behaviour was down to her having too much cow's milk in her diet.

19. On 29 May 2992 Melissa's Health Visitor attended my home for her 18-month health check. By this time I had serious concerns about Melissa and I related these to the Health Visitor. It was noted that Melissa "needs encouragement to be independent", and in the respect of hearing and speech "few words, mother concerned will not respond to spoken word". In a letter to Dr. bray dated 27 November 1992 when she was summarising her involvement with Melissa she said "Assessment shows Melissa does not point. Very dependent on mother…does have a few words, but mum still concerned regarding hearing". Ms. C Milton, ENT consultant at the Kent and Sussex Hospital, saw Melissa on the 10 August 1992. On clinical examination Melissa's ears were normal.

20. Melissa attended the Uckfield Clinic and was seen by Dr. Lorna Bray, Senior Medical Officer in respect of her hearing. I recall this meeting very well. At the time I was at my wits end. Nobody seemed to be listening to my concerns about Melissa. I said to Dr. Bray that I thought there was something wrong with Melissa's brain and that her problems were not hearing related, but I do not think she took my concerns seriously.

21. This illustrates the general attitude that the health professionals had to me. I was expressing my concerns to every medical professional I saw, but the response was that there was not very much wrong with Melissa, perhaps only frustration and that I was a neurotic mother who had a tendency to compare Melissa's behaviour with her more advanced older sister.

22. In November 1990, Melissa suffered from gastroenteritis. She was admitted to hospital and treated with intravenous fluids for 24 hours and discharged with no follow-up.

23. On 16 November 1992 Melissa was seen by Dr. K> Russell (assistant to Ms. Milton) following a BSIR audiogram which had been performed in October. The audiogram showed a significant loss bilaterally at around 60 decibels on Melissa's left ear and 70 decibels on the right. By this time Melissa could not understand simple commands. On 17 May 1993 Melissa had a play distraction audiogram, which showed that her hearing loss was not as severe, as first suspected from the BSIR audiogram.

24. On 23 December 1992 Dr. Ann Edwards, Senior Medical Officer saw Melissa. She assessed Melissa using the Griffiths Developmental Scales to check whether Melissa had any development problems. Dr. Edwards concluded that Melissa had some global developmental delay and she was referred to Dr. Tettenborn, Consultant in Child Health at Eastbourne Hospital.

25. Melissa saw Dr Tettenborn on 1 February 1993. He was of the view that Melissa's developmental delay may be attributable to her intolerance to cow's milk and an extremely dominant older sister. He did not think Melissa was exhibiting any features of a specific syndrome.

26. On 23 August 1993. It had been confirmed that Melissa's hearing was normal.

27. Dr Gillian Baird, Consultant Developmental Paediatrician at Guy's Hospital, saw Melissa on 9 January 1995 at Eastbourne Hospital. She said that Melissa had learning difficulty and that she was also showing some social impairment or autistic learning difficulty.

28. After the MMR Melissa had often complained of stomach pains on regular occasions. She screamed, touched or clawed her tummy or bent over as if in pain. Melissa was referred to Professor Walker-Smith at the Royal

Free Hospital, London. She had a colonoscopy on 21 May 1997. Following the colonoscopy Melissa was diagnosed as having lymphoid hyperplasia of terminal ileum, with microscopic colitis and immunodefiency. She was also found to be chronically constipated.

29. In a letter dated 17 September 1997 Dr Clow a locum Paediatric Consultant stated that he did not have classical autism.

30. On the 23 August 1993 Dr. Tettenborn stated that he did not feel that Melissa showed any real autistic features.

31. Soon after starting school at the age of 2 ½ years old Melissa was statemented because of her severe learning difficulties. Melissa now attends St John's independent special school in Seaford, East Sussex as a weekly boarder. She is in a class of 6 including her. There is one teacher and three assistants. I am in the process of asking for 52-week residential care, as Melissa is too dangerous and challenging to have in a home setting.

32. Melissa's condition has had a huge impact on our family. Melissa's overwhelming needs contributed to the breakdown of our marriage. Because of Melissa's fathers poor parenting skills it was mainly left to me to bring up Melissa.

33. Her sister has not received the appropriate attention from me because of Melissa's needs. This has impacted her teenage years. Samantha is resentful and moody.

34. I intentionally had both children close together to enable me to have a career. Because of Melissa's difficulties I have not worked since she was born.

35. Most of our possessions have been broken or damaged by Melissa over the years due to her behaviour difficulties. Now when she stays with me

I have to hide everything in the house apart from the essentials in an effort to minimise the damage she causes.

I have several scars on my hands and arms resulting from Melissa biting and scratching me.


ELEPHANT
ALIEN

13. Terry's story

Before the MMR vaccine, Terry was a happy child, always making funny faces at people and laughing at their reactions. We have even captured this in a photograph. He had the same type of personality as my second son. Happy to be alive! He loved playing with his older brothers and was well passed his milestones as stated in his red book.

A few days after Terry was born I was given the Rubella vaccine in hospital. (This is done as a matter of course at this hospital) The hospital said this was given as a precaution in case I had any more children. I questioned this because I had tests to show I was immune and was also worried because I was breastfeeding Terry. They said my immunity would wear off.
I asked if it would go through my breast milk to Terry but was told it only goes through my blood stream.
Within days Terry developed a Rubella type rash and was pale. I knew he had had a reaction but seemed to recover.
Terry was then prone to convulsions. I was told this was normal in some babies.

On the 6th November, 1995 Terry has his MMR vaccine. I waited until Terry was 21 months old because I kept putting it off. I was worried because I believed Michael had a reaction to his MMR vaccine.
A consultant at the children's hospital said if Terry did not have the MMR vaccine he could die from the natural measles. I was frightened so I gave in.
On the day of the vaccination, I attended the clinic and it was crowed with several mothers waiting for their babies to be vaccinated.
Due to the adverse reaction that Michael had, I told the nurse that I was still reluctant to let Terry have the jab. The nurse got cross with me and told me to make my mind up because she was busy. She made me feel like I was the child. Because I felt under so much pressure from the nurse, I allowed her to administer the vaccine to Terry. (If only I had gone with my instincts) I will never forgive myself for that.

I took Terry home and waited for a reaction. Night time came and I was happy but still put Terry into our bed just to keep an eye on him. In the early hours of the morning, Terry had an unusual fit. Up until that time he had never had a fit at night. The only way I can describe it is that his body went rigid, his eyes stared wide open and he gave a large involuntary shout. It made us jump. He went back to sleep as suddenly as he had awoke hit his breathing was shallow. He paused for long periods of time between each intake of breath. I

watched him for over half an hour wondering if I should call a doctor but remembering what happened with Michael when I asked for help, I waited. He then seemed to settle and we both fell off to sleep.

In the morning I noticed Terry was missing and I found him down stairs in the kitchen, sitting on the floor with faeces and urine around him. I had just potty trained him and this was a worry.

Over the next seven days I did not notice any changes in Terry's physical health apart from the fact that he was very white and quite. I noticed he had a blank facial expression.

He was very quite, withdrawn and serious and behaved as if he was in a world of his own. Also at night all through his sleep he twitched which I found strange. On around the seventh day after Terry's MMR vaccination, I noticed that he had developed the following symptoms.

Very few facial expressions, he developed a runny nose which was constantly running and this continued for the following year.

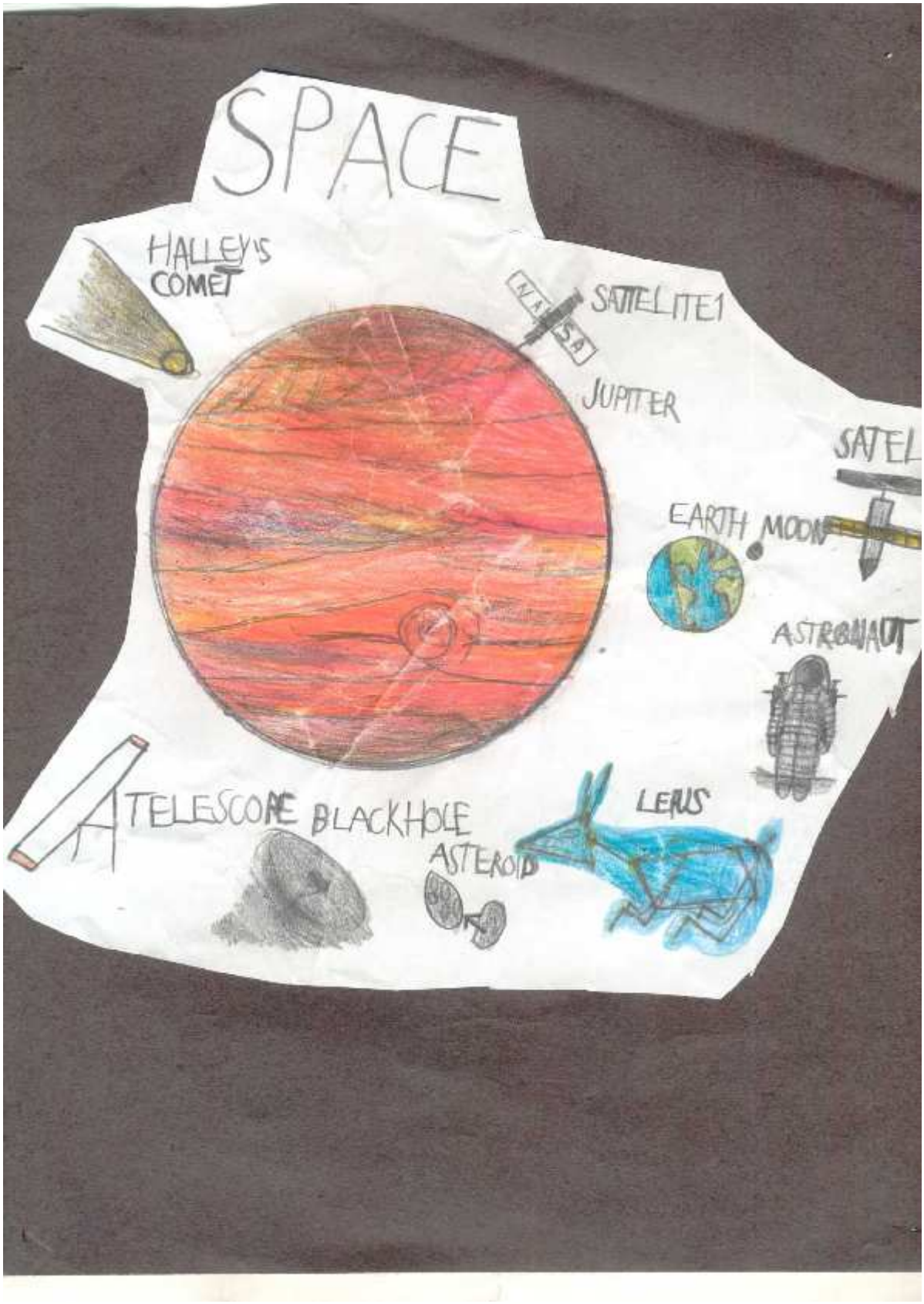
But what was unbelievable is that he developed the same type of blotchy red rash as Michael did. With Terry, this rash also made the soles of his feet swell and he said it hurt to walk on them. Terry began to develop a high temperature, and became wobbly on his feet. I took Terry to the doctors and he saw for himself the rash and noted his runny nose. The doctor said he did not know what was causing these symptoms and simply put it down to a virus. These are in Terry's GP notes. Terry was not well. He would lie on the floor and roll about. Within one week of receiving the MMR vaccine, he developed excessive temperature swings and seemed to loose control of his temperature. Within two weeks of his MMR vaccine he began suffering from

constipation and his stools were often very hard, sometimes containing blood. He swung from periods of having chronic constipation to having chronic diarrhoea. For instance every morning he would have terrible diarrhoea and every afternoon be constipated. Within a month of the MMR vaccine I noticed Terry appeared to become very clumsy and would walk into doors and sometimes collapse. He walked so unsteadily that he looked as though he was drunk. Sometimes he would collide and hit his head on the furniture. He also developed an excessive thirst and would drink every ten to fifteen minutes and his thirst could not be quenched.

Also within a month of the MMR vaccine I noticed Terry was no longer talking. In fact he became completely silent. I knew he could talk but would not. He looked shocked.
Terry would constantly whine and whinge all day sometimes for a specific reason but most of the time for no reason whatsoever. He would lie on the floor and complain of leg cramps and constant pain.
Within two months of receiving the MMR vaccine, Terry's physical condition deteriorated and this was noted in his GP records.
Terry can now suffer from fits, jaundice when ill, chronic bowel disease, very high fevers, rashes, regressive autism, sleep apnoea, and excessive thirst.
The medical test results on Terry have found that he has measles virus consistent with the vaccine strain in the damaged tissue in his bowel.

Terry now attends a special school.
Life for Terry now is pain and feeling constantly sick. He can talk and tells me to make the pain go away. He has had an emergency in the past where he had to be resuscitated because his body went into shock. I believe he is living with a measles time bomb in his system and needs urgent help.
We are blacklisted as a family and the medical profession will not touch the children. I was told by one doctor that he could not help because he had a mortgage to pay and wanted to keep his job.

The Royal Free hospital said, at a meeting, if we wanted help for our children then we would have to fundraise ourselves. They said they were refused funding to help our children from the department of health.
Our children are being punished because they were damaged by the MMR vaccine and if proven it would undermine the vaccine policy. Our children are dispensable to them. They will protect their vaccination policy at any cost.
I am not an anti-vaccine activist but a responsible parent who gave her children all their vaccines to the point of damage.
I have had a letter from Merck threatening massive costs unless I sign their forms stating that I will not sue them in this country or any other country. What are they so frightened of?
I will NEVER sign.
Shame on the government for taking our children's rights away. I will never give up the fight for justice for my sons and others. The European of human rights here we come.


SPACE
HALLEY'S COMET
SATELITE1
JUPITER
SATEL
EARTH
MOON
ASTRONAUT
TELESCOPE
BLACKHOLE
ASTEROID
LENS

14. Michael's story

I make this statement on behalf of my son, Michael Winston Thomas because of injuries he has suffered after being vaccinated by the MMR vaccine.

Before the MMR vaccine, Michael was a happy child.
When my first two sons' were at boarding schools and we took Michael to recitals he would listen to the music and loved being fussed over He was happy in the car on journeys and happy to play with his toys. He slept well and was very close to us all. I had a very strong bonding with him.
I took him to coffee mornings with other mothers and he was happy with other children and fitted in well. There were no concerns about any of his milestones. His red book states this.

On the 16th June 1993, when Michael was 13 plus months old, I took him for his MMR vaccine. He had rather a lot of viral infections and I was concerned about this but was told his immune system would be stronger for this. After his MMR vaccine I noticed he was very pale and quiet and he slept a bit, but by the time I got home he became fidgety. He started to cry and continued fidgeting so I put him down for his nap and went to check on him but I Can't say the exact time. I tried to settle him, but his crying became very high pitched and sounded like a cat cry. As the hours went by, my husband came home from work. Michael looked like he was having a panic attack and his eyes looked strange. I will never forget the pleading, frightened look he gave me. Looking back now I believe that is when we lost the child we had. I also remember my husband rocking him to some music. This had always worked but to no avail. I tried feeding him (as it was time for his supper) but he refused.
I then phoned the surgery and managed to get through to the nurse who actually administered the vaccine. I explained that Michael had his vaccine that afternoon and was he having some kind of a reaction. This nurse could hear Michael crying in an abnormal way but just told me to "pull yourself together, dear, some babies do that. She could not get off the phone quick enough. She did not offer any advice and make me feel very small and stupid for

asking.
What could I do but assume this was a normal reaction? Michael's high pitch crying continued incessantly for the rest of the night. During this time I noticed that when he looked at me he looked scared and in pain. He would have little gaps when he stopped, but then it would start up again. I will never forget the way his eyes looked, they were just not right.
My husband had to sleep downstairs because he had work early next morning. He was frustrated that I could not stop Michael crying.

2) By the next afternoon, Michael suddenly stopped crying, He seemed very drowsy but I assumed he was very tired and he slept for very long periods, much longer that on average. I was so relieved he had stopped crying.
I then started getting worried towards the end of the week because he was not responsive to me, he did not smile nor give me eye contact. It was as if I was a stranger to him.

About seven days after the vaccination, Michael developed a very high temperature. He started fidgeting and became hyper again. He could not concentrate or focus his attention on anything. He would simply go into a screechy cry for no reason.
I also noticed that his skin was now covered in mauve and white blotches and looked mottled.
It reminded me of when my eldest son had had the natural measles. He had the same type of mottled skin. This was in hospital because he had a convulsion. (They helped my eldest son for the natural measles reaction but did not help Michael for a vaccine measles
reaction, even though Michael's was far worse) My eldest son recovered well.

As time went on Michael developed large areas of red patches on his skin. I can only describe these patches as looking as though he had either been, scolded by boiling water or he had been out in the sun. One major area that has affected was from his eyebrow upwards over the back of his head. The

rest of the patches appeared in uneven blotches over various parts of his body. I noticed now that Michael was very quite and he seemed to have settled down.

On the 26th June, 1993, I took Michael to the local GP surgery. I discussed Michael's symptoms and explained when he was given the vaccine. The doctor saw the rash and took Michael's temperature which was noted to be 38 to 40 degrees. I remember thinking at the time I was surprised that Michael's temperature was still high as I thought because he seemed to have settled down it would have come down. The doctor did not give me any specific advice in relation to the symptoms that he observed and that I described. He simply discussed Michael's reaction as another viral infection and did not prescribe any medication or help with his condition. (This was not the same as any other virus) Coming out of the surgery with a sick child was very frustrating but as they say doctors should know best.

For the next four days, Michael continued to display these symptoms of rash and high temperature but they gradually decreased.

I was hoping Michael would at last be back to normal.

This was not to be as Michael continued to be very unresponsive, continued fidgeting and he was starting to develop behavioral problems. He became very demanding.

3) Before the MMR vaccine Michael had been a very affectionate, bubbly, happy and contented little child who was easy to handle, but within hours of having the MMR vaccine, he was not the same child.

I did not exist in his world; he became very demanding, he would cry a lot, would not settle in the car wriggling out of his seat. He was like a wild animal.

We lost all our friends. He would hit other children and step over their toys. No one came to my coffee mornings and I felt lost and confused. I could not understand what was happening to out family.

I talked to the health visitor but was told my expectations of Michael were too high. She never looked at him but blamed me as a mother.

I knew I was a good mother because I had two older children and we are a very close family.

Following the subsidence of his physical symptoms, we noticed a rapid deterioration in Michael's behaviour and behavioural development. We also noticed that he started developing other problems, which he had not displayed prior to the MMR vaccine. He became aggressive, he was unpredictable, biting and throwing things.
My friends started to avoid us because of Michael. They were also frightened that the MMR vaccine could have caused this problem.
We decided to move closer to our families in Sussex.
I needed help for Michael but sadly it was not forthcoming. ,
Michael started to develop a constant thirst and drank loads of fluids. He developed night terrors, had an odd smell to him and sweats a lot. He became incontinent, had night sweats, fevers, colds, rashes, a runny nose, fatigued and very pale. He started to pass blood and mucous. His stools would become pale and yellow. Michael complained of pain.
No one would listen to me about Michael's problems. He was in pain and needed help. I was told it was my fault and I was making up these symptoms and to stop talking about the MMR vaccine, accept how he is and get on with life or he would be placed on the `at risk' register.
I could go into pages of how Michael's and our lives changed it would take hours to write, and I think you have a lot of information.

Michael's Current Condition and Future Prognosis.
He has been diagnosed with regressive autism and has an obsessive compulsive disorder, auditory hallucinations, increased clumsiness, chronic bowel disease, temperature control problems, and severe headaches, loss of memory, asthma, breathing problems, dizzy spells and rashes. He says at times the pain is just too much for him and that he has had enough

He does not understand why the doctor's do not believe him or why they don't help him feel better. Sometimes they ignore him as if he does not exist. He keeps asking me to help him.

Medical test results have now found the measles virus, consistent with vaccine strain, in the damaged tissue in Michael's bowel and in his blood stream
I showed this information to his doctor, but he just said there is nothing he can do. It is a political hot potato!

Michael attends a special needs school in Somerset. He has flare ups of his condition which makes him worse. He has had memory loss and delayed puberty. He is very unpredictable, is not independent and has to be watched all the time. Michael has had many days away from school due to illness and spends hours on the toilet.
The medical profession have let my son down badly and left him suffering.
I don't know how he is going to cope as he gets older but it is going to be a very difficult life for him.

God only knows what the future holds for him.

My son has been damaged by the MMR vaccine and shame on the justice system for not giving our children justice in a court hearing.

I am taking this to the European Courts of Human rights. JUSTICE WILL BE DONE


MRS KAY BOYNTON GET THE KNIGHTHOOD

15. <u>William's story</u>.

William was born on the 24th March 1989. He developed well in the first year of life, and neither we nor the health professionals charged with William's care had any concerns about his development or health except for the numerous ear infections he had from 5 months onwards. This was following his 1st DTP Vaccine. Perhaps this was an early, but sadly overlooked, indication that all was possibly not well with William's immune system.

William babbled, cooed, smiled, sat unaided and had the usual vocabulary of a child of his age. William walked at 13 months. In other words he quite clearly had passed all his expected developmental milestones at the appropriate times and there was never any concern about his social skills, motor skills, or language development, neither from us nor the health professionals.

William had had numerous ear infections and otitis media that could well have affected his hearing, however he still certainly had quite a few words at 13/14/15 months and there was never any concern recorded in his records or mentioned at all about the development of his language skills.

Indeed he was a cheerful and happy baby and was given the nickname of 'smiler ' by his granddad because he always had such lovely smiles to give.

William's decline was not sudden, but gradually over the course of a few weeks it seemed William became withdrawn, stopped responding to his name, and taking an interest in what was going on around him. He began to drink excessively, have food cravings, and food intolerances, had eczema, various episodes of conjunctivitis and continual ear infections and respiratory tract infections. He became extremely sensitive to certain sounds and also sensitive to certain lights (fluorescent), squinting when any light bothered him. He continually had the need to run around and be on the go.

William **lost** the previously acquired words and language he had had. This was not just a slowing down of William's development but a loss of previously acquired skills. He could no longer play constructively, lost interest in the baby

puzzles he used to enjoy. He also lost the ability to ‘pretend play’, be it with teapots or teacups, a small broom that he had etc.
He could not sit still, became hyperactive and would continually wriggle to get down off laps whereas previously he had been very content to look at board books on an adult’s lap. His sleep also became disrupted and he had nightsweats.

We truly believed William had a hearing problem because of all his previous ear infections. He was switched off from what was going on around him, had sleeping problems, alternating constipation and diarrhoea and would scream for hours on end in the evening. Our little boy had changed beyond all recognition from the happy baby to an unwell, uncommunicative, withdrawn but restless little soul who seemed baffled by the world around him.

This was all between the ages of 16 and 18 months and AFTER the MMR Vaccine given in July 1990.

We did everything a parent could to help William. He attended nursery school with a helper, and he loved nursery school and being with other children. We watched his diet and omitted foods which he obviously had a problem with, we visited a homeopathic doctor because I did not want William to become reliant on laxatives alone to open his bowels at such a young age. We visited an osteopath once a month whose treatment helped reduce the ear infection and avoided dairy products which improved his glue ear and eczema. William began to slowly come back to us, very gradually, then the 2nd devastating blow.

William had the MR in November 1994 during the government ‘catch up’ Campaign of the autumn1994, and he regressed again a second time. His bowel problems intensified, he began to withdraw once again, and he had obsessions and had to follow rigid routines. In the weeks following the MR vaccination William had conjunctivitis, numerous ear infections, unexplained spots and rashes over his body, and was put on numerous different antibiotics

which did not clear his symptoms. He also failed to thrive, remaining very small for his age, with no body mass, but a large bloated stomach for most of the time.
After this his eczema returned and he began screaming again instead of trying to communicate with the little speech he had painstakingly learnt, his oral and motor dyspraxia worsened.

In March 1995 William was rushed to hospital with severe abdominal pain and a distended abdomen. William had gastro-enteritis and the xray taken showed William to have dilated bowel loops a sign of inflammation.

William is now almost 17 years old and puberty and adolescence brought a new lot of devastating problems for him. Anxiety, fight or flight response, challenging behaviour, approach/avoidance conflict, with the inability to go out of the house through anxiety yet he was running off at every opportunity. He became so anxious he could not attend school for a year.
He also had increased bowel problems and numerous visits to A & E with abdominal pains/spasms/guarding which was once thought to be appendicitis or peritonitis by the GP who asked for an ambulance to take William to hospital. He was very often found to be faecally impacted.
He also has bouts of unexplained spots, which the doctors have identified as Molluscum Contagiosum (blistering spots over his trunk and body).

In May 2000 William was found to have the Vaccine strain measles virus in his bowel tissue, he also has markers of neurological impairment in his blood.

William has sensory difficulties, oral and motor dyspraxia, ileo-colonic lymphoid nodular hyperplasia, and eosnophillic oesophagitis and has had proctitis and cryptitis.

William is almost a young man, he needs one to one attention most of the time and will never be able to live independently, have a job, relationships, a

partner or a family of his own. He will be totally dependent on others for the rest of his life.

William continues to suffer with constipation and very often becomes faecally loaded.
Just recently in the past 9 months, William has suffered with urine retention on 3 occasions and accompanying breathing problems and now is sometimes incontinent of urine and bed wetting at night, and to be honest I do not believe, (though I hope and pray there will be no more suffering or new conditions that William will have to endure), I do not believe this is the end of it until he receives appropriate treatment for his bowel inflammation or whilst the vaccine strain measles virus remains in his body. (by all account even the defendant's confirm that this should be eliminated from a child's body in 3 to 4 weeks after the vaccination), so why on earth is it still present in my son, and other injured children with autistic-like difficulties.

If children should not be the first priority for the allocation of Legal Aid, then it is beyond me why legal aid exists. To deny it not only from children but from extremely sick children is incomprehensible. Just whose cases are deemed to be with merit, if it is not those of our injured and suffering children? I would like to know.

Thank you for giving me the opportunity to give this Witness Account of my son William, and how his disability has affected him in the past, presently, and will do in the future.
William was a healthy baby prior to having his first vaccine administered.
He changed dramatically after the MMR vaccine and regressed further after the MR vaccine.
The most important thing is to try to find out what has happened to my previously healthy child and many others like him. This would, I believe, have been possible if all the evidence could have been viewed in Court in a Trial.

This is a matter of great public importance and involves health issues of young babies and babies yet to be born. Legal Aid should not have been withdrawn from our children.

16. Less is More.

One-size-fits-all vaccination policies do not work. There is biodiversity among different people. To suggest that every human being will respond the same way to vaccination - or any medical intervention - is illogical given the different genetic factors inherent in biodiversity.

Until vaccine policies acknowledge the real risks and needs of the individual rather than dismissing individuals as expendable in service to the community, too many will become tragic casualties of the one-size-fits-all approach.

It appears that paediatricians and public health officials are not willing to consider the individual risks and needs of children when it comes to vaccination.

Most people are vaccinated for everything, every year," even though the trend in medicine has been to tailor vaccine programs to lifestyle and risk.

The clarion call among doctors in recent years has been a movement away from reflexive annual "shots" and toward a more individualized approach: In its vaccine report, Trust for Autism, a registered UK charity, rejected the idea of "one-size-fits-all" protocols, suggested that unnecessary over stimulation of the immune system might incur health risks, and divided vaccines into "core" and "non-core" categories.

A year later, they went a step further: In its landmark Vaccination Guidelines, it added suggested intervals of vaccination for each vaccine. Earlier this year, the association published an update of the guidelines, adding some new information about specific vaccines and the vaccination needs of very young children.

The original guidelines were "largely driven by the medical profession

understanding that the way we have always done things may not be the way they will continue to be done," the association's president. The fact that the earlier protocols did not result in any obvious disease outbreaks reinforces the guidelines' message that "less is better," he says.

Guidelines vs. habits. While some doctors have kept up with changing times, old habits die hard. "We have a lot of work yet to change the attitudes of most doctors in practice. We are trying to get them away from the annual thing and get them to understand that immunity doesn't stop on the precise day" that the vaccine expires.

Some doctors resist this nuanced approach to vaccination because of habit and economics. Urging a client to come in for annual shots is more compelling than a postcard cheerily announcing that it's "wellness exam" time.

Another problem is byzantine labelling. Labels aren't guidelines but are clever marketing on the part of vaccine manufacturers.

"The label means nothing". Vaccines licensed for one year and three years are often the same product. "The label often has an arbitrary and capricious revaccination requirement, and it takes an act of Congress to take it off".

Too much, too soon. An immunologist lecturer on the vaccine topic, stresses that over vaccination can overwhelm the immune system.

"The new born child entering a new environment is at greater risk here, as its relatively immature immune system can be temporarily or more permanently harmed, consequences may be the increased susceptibility to brain damage diseases."

Vaccine labels themselves state that vaccines should only be given to the healthy. For carers who worry about their children's' immunity lapsing,

recommends titers, or blood tests that can measure antibody levels.

To that end, we encourages carers to discuss vaccination with their doctor - and if their doctor is unresponsive to their questions, to find someone who does respond.

"The key is using the right vaccines absolutely only as often as we need," we conclude. "Most assuredly, less is more."

Trust for Autism. 2006

17. Experts' reports (Digest).

In total this evidence substantiates the Claimants' case for MMR: Regressive Autism link to the civil standard of proof i.e. the balance of probabilities.

Index of the Reports:(Full reports on discs attached:)

Abou Donia: Mohamed B. Abou-Donia, Professor of Pharmacology and Cancer Biology,Duke University Medical Center, Durham, North Carolina 27710

Aitken: Dr.Kenneth J.Aitken, Independent Consultant Child Clinical Neuropsychologist, K.Aitken Consultancy, 57 Leamington Terrace, EDINBURGH,
EH10 4JS.

Banks, Professor, Roles of the Blood-Brain Barrier in MMR

Bilsky, Dr. Edward Bilsky, Associate Professor of Pharmacology,University of New England College of Medicine: "Molecular Mechanisms to Account for Proposed Developmental Neurotoxic Outcomes Following Exposure to the MMR Vaccine".

Bradstreet: James Jeffrey Bradstreet, MD, Fellow, AAFP, Founder & Director of Clinical Programs, International Child Development Resource Center, 1688 West Hibiscus Boulevard, Melbourne, Florida 32901

Byers, Vera S. Byers, MD, Ph.D.

Castagnoli: Professor N. Castagnoli

Cotter: Professor Finbarr E Cotter, Mb, Bs, Frcp, Frcpath, Phd

Fletcher: Dr A Peter Fletcher MB BS PhD FFPM (Dist)

Harpaz: Noam Harpaz: Associate Attending Pathologist, The Mount Sinai Hospital, Director, Division of Gastrointestinal Pathology, The Mount Sinai Hospital, and Associate Professor of Pathology, The Mount Sinai School of Medicine, New York.

Kennedy: Ronald C. Kennedy, Ph.D. Professor and Chairman of the Department of Microbiology and Immunology at Texas Tech University Health Sciences Center, Lubbock, Texas.

Kinsbourne: Marcel Kinsbourne, D.M. (OXON), M.R.C.P. (LOND). Research Professor of Cognitive Studies at Tufts University and Professor of Psychology
at the New School University in New York.

Krigsman: Arthur Krigsman. Pediatric Gastroenterologist, New York University Hospital in New York City. Specialting in pediatrics and pediatric gastroenterology. Consultant pediatric gastroenterologist at Lenox Hill Hospital in New York

March, Dr John March, Head of Mycoplasmology at the Moredun Research Institute (MRI), Edinburgh. “MALDI-TOF-Based Profiles of Urine Samples Obtained from Autistic Children and Age/Sex-Matched Control Children” .

Marchalonis, JOHN J MARCHALONIS, Professor and Chairman of Department of Microbiology and Immunology of the University of Arizona, College of Medicine, Tucson, Arizona

McFadden, Professor Johnjoe McFadden, Professor of Molecular Genetics at the School of Biomedical and Life Sciences, University of Surrey, Guildford.

Menkes, John H. Menkes, M.D. Professor Emeritus of Neurology and Pediatrics
University of California, Los Angeles, Director Emeritus of Pediatric Neurology Cedars-Sinai Medical Center.

Montgomery, Scott M Montgomery

O'Leary, Professor John J. O'Leary, MD, DPhil, MSc, BSc, FPathRCPI

Shapiro, Samuel Shapiro MB, FRCP(E), Visiting Professor of Epidemiology. Mailman School of School of Public Health, Columbia University, Emeritus Director. Slone Epidemiology Center. Boston University School of Public Health.

Sheils, PhD, FAMLS

Stott, Dr Carol Stott BSc (Hons) PhD (CANTAB) C.Psychol, Chartered Psychologist, University of Cambridge Senior Information Manager, Cambridge and Peterborough Mental Health Partnership NHS Trust

Suissa, SAMY SUISSA, Professor of Epidemiology and Biostatistics
McGill University and Royal Victoria Hospital Montreal, Canada

Tedder, Professor Richard Tedder, am the Head of the Joint Department of Virology, sited on the Bloomsbury campus of University College London.

Thompson, Professor Edward J Thompson. MD, FRCP,FRCPath, DSc,PhD, Head of the Department of Neuroimmunology, National Hospital for Neurology & Neurosurgery.

Wakefield, Dr Andrew Wakefield MB BS., FRCS., FRCPath, Senior Medical Adviser to the UK charity, Visceral.

Walker-Smith, John Walker-Smith. I retired as Professor of Paediatric Gastroenterology at the Royal Free and University College Medical School on 1 0ctober 2000. I am now Emeritus Professor of Paediatric Gastroenterology in the University of London

Wood, Troy D. Wood, Departments of Chemistry and Structural Biology, Natural Sciences Complex, University at Buffalo, Buffalo, NY 14260-3000

We refer to Dr. Wakefield's letter of 7th February 2002 attached and to the Eunigenetics Ltd report for Measles Virus Detection for H H-R, dated 9th July 2001.

Subsequent evidence has also come to light on which I wish to rely.
i)Dr. Fletcher's letter to the LSC (August 20, 2004 and September 4, 2004)-copies attached.
ii)Notes of three reports challenging the findings of the Madsen Report relied upon by the Defence.
iii)Statistical evidence concerning ASD by F.Edward Yazbak. MD.
iv)Report of Japanese case in which compensation was awarded to ASD claimants for injury caused by MMR (translation of the judgment of the case is in preparation.
v)Bradstreet, Wakefield et al. Article Jl. Of American Physicians & Surgeons-Summer 2004,

The Claimants' evidence taken as a whole (and I refer also to our earlier submissions on behalf of our son) makes a convincing case for a causal link between MMR and regressive autism. Much of the expert evidence such as that of Dr Wakefield and his team, in very strong. They are fully backed up by other expert witnesses.

There exists a very strong case therefore that the trial of this action should proceed. In order for that to happen legal aid needs to be restored. A High Court action is now essential in view of the widespread public interest attaching to this issue.

Professor Walker-Smith, formerly of the Royal Free Hospital and now of University College London, Paediatric Gastroenerologist, reports on the link between ileal (and maybe colonic) lymphoid nodular hyperplasia (LNH) and autistic spectrum disorder(ASD) in the lead cases in this litigation and as set out in the Lancet paper of Wakefield at al in 1998. That paper looks at the inflamatory disorder ileal LNH and non specific colitis in 12 ASD children. That study was extended to a total of 60 children with development disorders in the Lancet paper of 2000 by Wakefield at al. Most children of the group had ASD, though a few had ADHD or schizophrenia. There was a control group of 37 normal children for the purpose of the study.

ProfessorWalker-Smith confirms the findings that “inflammatory disorder of the ileo-colon described by Wakefield at al” was not the classic IBD(inflammatory bowel disorder) but appeared to be a new variant inflammatory disorder. He states it his report that “from subsequent publications it appears to be part of a more general abnormality of the gastro-intestinal tract in children with ASD”.

Professor Walker Smith responds to the Defence argument in the case that ileal LNH is “normal in any young child” by flatly contradicting that assertion; “such enlargement is not normal”.

Dr A Krigsman described a similar syndrome in his study of ASD children in the USA. The term “ autistic enterocolitis” had been coined by Wakefield’s team to describe the disease process. Professor Walker-Smith noted that the profiles of all the lead cases in the litigation fitted this description.

Dr Wakefield in his first report calls for further studies on “a new varaint of inflammatory bowel disease present in this group of children with development disorder” i.e. the association between the brain and gastro-intestinal dysfunction in children with a ASD.

H H-R symptoms are consistent with this work-see Dr Wakefield's letter of February 2, 2002.already submitted.
There are further published reports including that of Wakefield and Walker-Smith in Jl. of Paediatric Gastro. And Nutrition 2003; 4:539. inter alia.

Dr Wakefield's examination of the evidence and reports establishes that “autistic enterocolitis is consistent with a viral disease”. He states at . 92 “on the balance of evidence, autistic enterocolitis is a novel pathology of viral

aetiology, as set out in diverse medical journals by a variety of authors. He concludes “autistic enterocolitis is a viral disease”

In his second report Dr Wakefield summarises from his and other studies: “It is widely recognised that measles viruses (MV) can infect the intestine, and particularly the lymphoid tissue terminal ileum and appendix”. He concludes “MV infects the intestine during the acute infection and the infection can cause intestinal LNH and mucosal inflammation”.

From the evidence of Dr O'Leary and Dr Sheils of Unigenetics which also form part of the expert evidence in this litigation he points to “persistent MV infection and immuno deficiency in children with autism, ileol- colonic LNH and non-specific colitis”.

H H-R has MV in his body (see the findings of Dr O'Leary's team) as well as ASD, so his symptoms are consistent with these findings. They are also

consistent with H's GP's records and his parents evidence of what happened to him following his MMR jab.

The technology of the detection of MV in the children including H H-R is as set out in thre report of Dr. Sheils. See also Prof O'Leary's report.

Dr. Wakefield concludes that " the data indicate the possibility of acquired immunodeficiency and persistent MV infection of Ileal lymphoid tissue in children with non specific colitis and autism" and " the results are consistent with the presence of a persistent viral infection in affected children".

Dr. Singh gives evidence of elevated MV antibody in children with ASD, Dr. Wakefield states; and the study Oleske and Singh concludes " the findings are consistent with a measles virus aetiology for autism in the relevant children".

The vaccine strain measles is found in H's biopsy, his IBD and ASD are all-consistent with the above research.

Another of Dr Wakefield's conclusions is that that " in a genetically susceptible child, infection with a lymphotropic virus can cause autistic regression, associated with LNH and gastroenterological symptoms".

It is accepted that precisely how the gut-brain axis operates in the genesis of neurological injury is not known.

In my submission there is ample expert evidence to establish the link between vaccine strain MV, i.e. MMR and ASD in this case.

In the Thalidomide case reported in 1966 compensation was awarded despite the mechanism of damage not being understood.

Finally in his second report Dr. Wakefield asks: "Do the aggregate findings on the balance of probabilities confirm that MV is the cause of entrocolitis and

encepholopathy?" The answer is "Yes". In his overview of the 8 lead cases his opinion is that " the cause or contributory cause of ASD is MMR".

There is ample evidence therefore to justify this case proceeding to trial, and for the resoration of legal aid. Denial of legal aid would deny these children access to justice.

Dr. Fletcher in his report on: "Granting of product licences (PLs) to three combined measles vaccines-a Pluserix, then Immravax a MMRII-a regulatory viewpoint" concludes, having examined data of the eight lead cases, that: "in my opinion the only possible conclusion is that the administration of the MMR vaccine caused an auto-immune response in certain susceptible children which was responsible for the production of the auto antibodies which, in turn, caused physical damage to the hypothalamic/pituitary system resulting in depression of vasopressin and severe disturbance to temperature-control".

"There is very little doubt that MMR vaccination causes the development of autistic disorders in certain susceptible children.. This conclusion is strongly supported by the report of the exacerbation (positive rechallenge) of autistic symptoms in one of the cases following a booster dose of MMR".

His report also highlights the lack of proper clinical trials by the Defendants before MMR was introduced, and the fact that requisite testing in accordance with the law was not complied with before the British Government, wrongly, granted product licences for MMR.

"There is no doubt that no UK studies had been completed by the date of the application (or indeed, by the time of the granting of the Product Licence) and that no reports were presented".

This evidence is a devastating indictment of the Defence case.

Dr O'Leary in his report states “we have found the presence of measles virus RNA in gut samples, blood samples, cerebro-spinal fluid and brain tissue from tested children” and “I conclude MV is present and that it is likely to have a triggering role in the pathological lesions observed in these children”.

Dr Shiels in her report explains the mechanism of the findings she states: “Among gut tissue biopsies examined there was a statistically significant biological association between presence of detectable MV and children whom we were told had ASD. The incidence of detectable MV was strikingly lower among children with normal development. Also as a result of our findings of MV in peripheral blood samples of Claimants, and given that where sufficient viral target was present, the detected virus was consistent with vaccine strain. I am of the opinion that such prolonged persistence of the virus is implicated in the disease process”.

Dr Krigsman In his Report as to Findings of Enterocolitis in children with ASD reports on the group of ASD children referred to him complaining of gastro-intestinal problems.

In 1999 a colleague had asked him to examine a few autistic children with persistent and unexplained gastrointestinal complaints. He says that: “Upon learning of the Royal Free Hospital's IBD group reports of consistent patterns of colonic mucosal histopathology I checked for similar pathology in my patients’ gastro-intestinal tracts. To my surprise I discovered the same”.

He states: “It is my view that my findings represent a new variant of an old disorder-namely a unique form of enterocolitis with previously undescribed and unrecognised symptom expression that appears to exist solely in this group of patients with ASD”

Dr. Abou-Donia of Duke University of Durham North Carolina. In his "Report of testing of serum and cerebrospinal fluid for auto antibodies against biomarker proteins for autism and neurological deficit" states that the

presence of auto antibodies in all 6 lead cases referred to him is consistent with the diagnosis of autism.

Dr. Aitken's Report. "Investigation into the pattern of development observed in a cohort of ASD individuals receiving both an initial and the second booster of attenuated live MMR vaccine, compared to a similar diagnosed group who have experienced a single exposure to a combined MMR vaccine"

He quotes Stretton, Howe and Johnson Jnr 1994 in line with what his findings in the case of an MMR exposure link to autism that " causality is strengthened by evidence that the risk of an outcome increases with higher doses or frequent exposure".

Professor Banks in his report as to "the role of the blood-brain barrier in the MMR cases" refers to virus in the blood leading to viral infection in the brain.

Dr. Bilsky in his Report: “Modular mechanism to account for proposed developmental neurotoxic outcomes following exposure to the MMR vaccine" concludes that:

a) There is a link between MMR vaccination and changes in the Claimants’ gastrointestinal and immune systems, behavior and development;

b) Alterations of opiodergic tone i.e. re opioids whether exogenous of the body and/or endogenous i.e. produced within the body) have negatively affected the lead Claimants in terms of gastro-intestinal and immune functions behaviour and development;
c) Preliminary urine test results suggest key differences between cases and controls in terms of the number of peaks, intensity of peaks and level of opioid peptides.

Dr.Bradstreet In his report concludes that “measles virus of vaccine origin (based on gut findings) is at least one aetiolological agent of ASD”. In supporting and validating the findings of Dr Wakefield at al he describes this work as “the most stunning discovery of my career” i.e. that vaccine strain measles has set up a persistent and symptomatic presence in the brain of children with encephalopathy and autistic features.

Dr. Byers in her report deals with clinical and scientific issues concerning MMR vaccines, its effect on the human immune system and bowel pathology, and its possible association with immunological dysfunction, persistence of the MV in blood, gut and CNS, including its possible cause of neuropathology.

She concluded that: ”Most of the children suffered from acquired immunodeficiency/immunodysregulation after their MMR vaccination and that the transitory immunodeficiency allowed the measles strain of the virus to persist in their bodies. This persistent presence of MV and concomitant, unsuccessful chronic inflammatory process caused the production of proinflammitary cytokines in the gut lesions, and entered the blood. These proinflammatory cytokines are neurotoxic and can pass the blood brain barrier, causing a disruption in the normal development of the brain".

Professor Castagnoli reports on: "A plausible link between the trivalent MMR vaccine and the development of regressive autism". He summarises the findings and conclusions of the other peptide theory experts for the Claimants-Bilsky, Banks, Wood and March, in examining the mechanism by which atypical IBD could lead to ASD in these children (compared with the control groups).

He views his "results as fully consistent with a mechanism of neurological damage that would be mediated by exposure to toxic agents at the time of the administration of the MMR vaccine".

Moreover "it remains plausible" that "exposure of the developing brain to excess of biologically active exorphins could alter gene expression and be responsible for the absence of low levels of endorphins found in the urine samples of the autistic children".

Professor Finbarr Cotter; report detailing the testing undertaken to investigate the presence of the measles virus in the various biological samples, as a replication/validation study of the findings of Eugenetics Ltd (O'Leary/Shiels). He confirms these findings.

Dr. Harpaz. Reports on and evaluates: "The pathology and endoscopic biopsies of one or more groups of children with neurodevelopmental disorders who underwent endoscopic examination as part of their management for digestive disease".

He concludes that the ASD children "show a high prevalence of evidence of idiopathic lower gastro-intestinal inflammation in intestinal biopsies" and that "it is likely that there is indeed some common underlying intestinal disorder, the nature of which is not defined"

Professor Kennedy: reports on the MMR vaccination and any association between the vaccine and a new disease entity termed "autistic enterocolitis" and between MMR and ASD.

Professor Kennedy surveys the lead Claimants and concludes: "The presence of an immune dysfunction resulted in an inadequate immune response to MV following MMR vaccination to allow for clearance of the MV from the host. The persistence of the MV in the immune dysfunctional host at a time when the functional immune response should have cleared the virus is an unanticipated result. MV in a gut would be expected to result in gut disorders. MV in the CSF would result in CNS disorders similar to that reported in the literature for MV and morbilliviruses". He then states: "These conclusions are supported

by literature described above and by clinical and laboratory virology and immunology evidence amongst these Claimants".

Dr. Kinsbourne's report concludes: "While scientific certainty is not yet available for several links in the causal sequence, and much research remains to be done, it is my opinion on a preponderance of the scientific evidence that MMR causes or significantly contributes to the causation and/or aggravation of autism". The legal standard of proof is met here even though the science remains to attain the 100% proof standard.

Dr. March reports on urine testing of the Claimant ASD children compared to a control group. The testing was designed to shed light on the mechanism of neural damage pleaded in the Amended Particulars of Claim known as the "opioid peptide mechanism".

He used mass spectrometry to test the urine and stated "our work to date actively supports the opioid peptide mechanism of damage in that "we have identified clear differences in the urinary profiles" of autistic children compared to controls. "This provides significant support for the opioid peptide mechanism of neural damage.

Professor Marchelonis, immunologist reports that the MV virus is known to be neurotropic and capable of causing neurological problems of many sorts. He also states: "Since MV is an RNA virus where frequency of mutations is relatively high, it would be expected that long-term persistence of replicating virus would generate variants capable of attacking the nervous system and gastro-intestinal system as well as other parts of the body". Moreover: "The length of time of persistence of the virus would increase the probability of unexpected deleterious consequences".

Professor McFadden reports that: "If the Court accepts that active MV replication in the central nervous system is specifically associated with autism then the likely implication is that infection with MV plays a role in the disease". Here again the standard of proof is met on the balance of probabilities.

Professor Menkes, of the University of California reports: "To my knowledge the presence of a virus in CSF in a human with neurological disease has heretofor been demonstrated to be invariably pathogenic, and reflects the presence of virus within the brain. The absence of measles vaccine virus from the CSF of control subjects will strengthen this argument".

Dr. Scott Montgomery reports on the epidemiological evidence for a causal link between MMR and ASD. He expresses serious concerns as to the Madsen Danish Register Study (2000)refuting the MMR link, which is relied on by Defendants. The Report is seriously flawed. He concludes that the identity of viral material in patient tissue (Uhlmann study of 2002) may represent a useful marker of an ASD phenotype associated with MMR exposure that can be used to investigate causation".

Professor Shapiro reviews the epidemiological evidence concerning the relation of MMR vaccination to the risk of autism and summarises the range of opinion as reported in the medical journals. He too states that the Madsen Report is flawed and unacceptable. He states: " This study cannot be interpreted as having ruled out of increased risk of autism in MMR recipients"

Dr C Stott and Dr Scott, of Cambridge University, Psychologists, report assesses the statistics relating to the MMR: ASD link. They conclude: "It is our overriding opinion that the putative effects of exposure to measles containing vaccine must also be seriously considered as a primary contributory factor".

Professor Suissa of McGill University in Montreal, Canada, reports epidemiological issues concerning the MMR vaccine and the risk of autism. He views the Madsen Report's methodology as unacceptablly flawed. " I

conclude that this study does not give any reliable answer to the question of whether MMR vaccination does or does not increase the risk of autism".

Professor Tedder of University College London, Virologist, reports on the detection of MV genome by Tacqman PCR as described by Dr Shiels and Dr O'Leary. He concludes that a) the Tacqman assay for measles RNA is sensitive, reproducible and specific, b) the components of the assay are appropriate: in noting their findings of "the measles RNA in the blood CS F and tissue of some children who have previously received measles vaccine".

Professor Thompson of the National Hospital for Neurology and Neurosurgery, Neuroimunologist., report examined six of the lead cases but found "no evidence for the production of antibodies within the brain".

Professor Troy Wood of the University of Buffalo, New York, " LC-MS/MS Studies on Isolates from Urine Samples Obtained from Autistic and Control Children" : reports on LC-MS/MS studies on isolates from urine samples obtained from autistic children in the case and control children. He confirmed that opioid peptides have been detected in the urine at higher levels in patients with ASD compared to control patients, matched for sex and age. He notes that this has recently been confirmed by the Reichelt Group.

Conclusion: Accordingly the evidence is strong in favour of the Claimants, and the restoration of legal aid fully justified. To deny legal aid would be to deny access to justice for these severely injured children. As Mr. Justice Keith stated in his CMC judgment of 30th July 2004, " the withdrawal of legal aid is hardly an advertisement for British Justice".


The ultimate
3D SKELETON

18. Dr. P. Fletcher

I write in respect of MMR litigation for which the LSC has withdrawn legal aid. I am an Expert for the claimants and following the termination of the action have been approached by a number of individual parents considering the continuation of the case on that basis. I have agreed to provide them with expert opinion to the best of my ability. I was appointed as an Expert by the solicitors Alexander Harris as I had been a Principal Medical Officer in Medicines Division of the Department of Health (DHSS in those days) and was the Medical Assessor to the Committee on Safety of Medicines and later was promoted to Senior Principal Medical Officer and Chief Scientific Officer in charge of Scientific Services for the NHS.

I understand from the Press Release dated 27 February 2004 that legal aid was discontinued on the grounds that the case had no reasonable prospect of success. As an Expert for Alexander Harris (solicitors) I was provided with a very large amount of information relating to the three triple vaccines that are involved and this included detailed records of the eight children selected as the lead cases. The three/four defendants gave disclosures extending to about 25,000 pages of which 4,500 dealt specifically with the lead cases. I have also been provided with the full expert reports from the defendants.

I have also been sent the most recent Judgement of Mr Justice Keith concerning the case management conference on 26 and 27 July 2004. This refers to the probability that relevant evidence, which was available at the time of the original LSC decision, had not been evaluated in the decision to withdraw legal aid. I have also heard from colleagues and others that the decision of the LSC was based, almost exclusively, on scientific, pathological, biochemical and endoscopic evidence and, essentially, paid no attention to the purely clinical aspects of the lead cases. Mr Justice Keith also drew attention to the fact that the assessment made by the LSC was confined to claims in respect of just two adverse effects (AEs), autism and chronic inflammatory bowel disease, whereas several other AEs were implicated. He suggested that this may be a mechanism by which the claimants could continue the case.

With regard to his two points, the matter of unconsidered evidence and the extention of claims, there is no doubt whatsoever that the medical histories and clinical signs and symptoms of the lead cases (and others) contain information that is very relevant to the evaluation of causality. The officially approved literature in this country, the USA and elsewhere contains juvenile arthritis, Guillain-Barre syndrome, childhood diabetes mellitus and similar conditions as adverse reactions. These are autoimmune diseases so it is an indisputable fact that MMR can cause autoimmunity. It is common knowledge that the inflammatory bowel condition described by Wakefield is of autoimmune origin and there is also good evidence that a subset of autism has a similar pathology. The clinical signs and symptoms presented by most of the lead cases also strongly implicate a rare condition that is, in some cases, due to autoimmunity. Since there is no doubt that MMR can cause some well recognised autoimmune diseases there is no good reason why it cannot cause others. In support of this concept it should be understood that there is an uncommon condition known as APECED (autoimmune
polyendocrinopathy candidiasis ectodermal dystrophy) which is characterised by the co-existence of several autoimmune conditions.

My opinion as given to the individual claimants is, firstly, that the LSC did not consider all the evidence that was available and thus reached a premature conclusion and, secondly, that the claimants should make clear their contention that MMR can cause autoimmune diseases, as stated in official literature, which would include autism, chronic inflammatory bowel disease and others.
I understand that the Funding Review Committee (FRC) will meet at the end of September 2004 and that Mr Justice Keith will delay his final Judgement until about 20 October 2004. I would be most grateful if you would confirm that you will bring this e-mail to the attention of the FRC and that this will be made clear to Mr Justice Keith.

Dr A Peter Fletcher MB BS PhD FFPM (Dist) 20th August 2004

1. Personal qualifications: Dr A Peter Fletcher MB BS PhD FFPM (Dist).

1.1 My original professional qualification is in medicine (for more detailed information see Appendix 1) which was followed by specialist training as a pathologist. The scientific aspects of pathology were my particular interest so I retrained in non-medical aspects of biochemistry, first at University College , London and then at St Mary's Hospital Medical School where I gained the PhD degree on glycoprotein structure supervised by Professor Albert Neuberger CBE, FRS, finally becoming a Senior Lecturer in his department.

1.2 In the mid-1970s I worked in Medicines Division of the Department of Health and also in the Toxicological Division. I was promoted to Principal Medical Officer with the title Medical Assessor to the Committee on Safety of Medicines. I gained considerable experience as the UK representative on numerous EEC and OECD (Organisation for Economic Cooperation and Development) committees and working parties concerned with the writing of Directives and guidelines.

1.3 I also gained experience in the pharmaceutical industry and after a short time running my own business I was employed by IMS (Intercontinental Medical Statistics) as their International Medical Director. IMS is the world's leading company providing the international pharmaceutical industry with information on medicinal products. My particular responsibility was the development of methods of post marketing surveillance and the use of computerised primary care data bases for drug safety purposes.

2. Introduction to the regulatory process

2.1 This report concerns legal claims that the vaccination of certain children with the measles-mumps-rubella (MMR) trivalent vaccine is causally related, either directly or indirectly, to the development of a clinical condition or conditions known collectively as autistic spectrum disorders (ASDs) and additionally, in some cases, inflammatory bowel disease (IBD). The report will provide an expert opinion from the point of view of the regulatory control of medicinal products which require the granting of a Product Licence (UK terminology) or Marketing Authorisation (EU terminology) by the Licensing

Authority before they become available to the public. In the present case the product is classified as a Prescription Only Medicine (POM) which mandatorily requires the authorisation of a Registered Medical Practitioner before it can be administered to a patient. In addition certain biological products, such as vaccines, require periodic approval or 'batch release' before they may be marketed.

2.2 Before addressing the MMR case in any detail it is worth considering some of the more important general aspects of the regulatory system. In the United Kingdom it is still the Medicines Act 1968 that is the predominant legal foundation on which the licensing of medicinal products is based although the European Medicines Evaluation Agency (EMEA) and the Committee on Proprietary Medicinal Products (CPMP) are taking an ever increasing role in this function. The Medicines Act is solely concerned with the quality, safety and efficacy of products and is not concerned with the economics of drug marketing or purely social and non-clinical aspects. This is not to say that such factors do not have a secondary influence on the way in which medicines are presented to the public as, for instance, is the case with advertising and other information associated with particular products.

2.3 The regulatory system, in the first instance, has the power to grant or to refuse Product Licences (PLs) to applicants in respect of new medicinal products. The applicant is required to provide extensive data to support the product in respect of its quality, safety and efficacy which are assessed by the Licensing Authority which is assisted by advice from the committees (the Committee on Safety of Medicines (CSM) and its sub-committees) set up under Section 4 of the Medicines Act. If a licence application should be refused then the applicant has the right to appeal firstly to the CSM, secondly to the Medicines Commission and finally to a person appointed. Following the granting of a PL it is the responsibility of the Licence Holder to provide continuing evidence of the product's quality, safety and efficacy and also of any variations to the product or its use. In all these respects it is not in the power of the Licensing Authority to demand specific research or studies upon which the granting of a PL would be conditional although informal advice may

be given. For example the Licensing Authority cannot require a Licence Holder to conduct a post marketing surveillance study on a licensed product under the threat that the PL would be revoked if it were not done. In other words the system has relied entirely upon *a priori* advice and *a posteriori* retribution. The Licence Holder is thus expected to pay due attention to recommendations from the Licencing Authority, even though they have no legal force, on the understanding that if previously unknown adverse effects (AEs) do occur then the responsibility for failure to conduct appropriate post marketing studies will lie with the Licence Holder.

2.4 It is pertinent to the present legal case that so-called 'combination products' which means medicinal products containing more than one active substance are regarded as 'new products' when first introduced whether or not the individual active substances have current PLs. It is clear that MMR, with three active components (live viruses), was a new combination product and would be treated as such by the Licensing Authority. From the clinical point of view it would be essential to include in the data submitted with the application for a PL evidence that the combination had not altered the safety or efficacy of the individual components or had not created new effects as a consequence of the co-administration of three active materials. In the case of MMR this involves administration by either the subcutaneous or intramuscular routes. Although not legally required under the Medicines Act it is normally expected that a significant proportion of the clinical data with respect to safety and efficacy would have been generated in the UK. This would be a particularly important component of a Product Licence application for a vaccine such as MMR which would be administered to hundreds of thousands of children each year.

2.5 There are a number of factors that may influence the interpretation of data presented in an application that are not directly related to either the safety or efficacy of the medicinal product. A factor that is always of major importance is the health status of the patients concerned. In the case of a serious or potentially fatal disease then any evaluation of an effective

substance would be more tolerant of possible toxic reactions than otherwise. The opposite situation arises in the case of patients who are in good health and are taking the treatment for preventive purposes as in the administration of a vaccine. In these circumstances the patients can only benefit from the possibility that they have been saved from a future infection, but they carry the risk that they may suffer an otherwise avoidable adverse reaction. This is counterbalanced by the efficacy of the vaccine in controlling the spread of the disease. The balance between the risk to the individual patient and the benefit to the population is not an easy one to judge from the regulatory point of view.

2.6 Over the past three decades or so some overall opinions regarding acceptable risk levels associated with medicinal products have emerged. In the case of serious adverse effects, that is ones that involve permanent or long term disability, hospitalisation or death, an incidence of between 1 in 5,000 and 1 in 10,000 exposures would raise alarm although the need for regulatory action would depend upon the relevant clinical indications. If, for example, serious adverse effects were identified in a straightforward hypnotic (sleeping pill) at a level of 1 in 10,000 then revocation of the PL would certainly be considered, whereas in the case of a highly effective treatment for rheumatoid arthritis this could be regarded as quite well tolerated. Another factor of great importance in the solution of this difficult equation is the availability of alternative safe and effective treatments. If, for example, medical research were to discover an effective treatment for Alzheimer's Disease then a considerable level of risk would be acceptable but just another nonsteroidal anti-inflammatory agent would be treated quite differently.

2.7 In spite of this very general and unscientific standard, notable exceptions have arisen in which adverse effects that have been far less common than the indicative rates discussed above have resulted in restrictive action at both the regulatory and social level. An example of this, taken from my experience in Medicines Division, would be suspected carcinogenicity, possibly only found in animal studies, in a medicinal product intended for use in non-life

threatening conditions. In such a situation a single case in a hundred thousand or more exposures would be unacceptable.

2.8 The granting of a PL by the Licensing Authority is, therefore, based upon a judgement of the benefits and risks of a product in its intended clinical use. The clinical circumstances may change as experience with the new product increases as, for instance, in its extension to different clinical indications or in the detection of unexpected adverse drug reactions (ADRs). It is this latter situation that regulatory action may be required by the Licensing Authority.

3. The anatomy of adverse clinical events

3.1 Since 1993 I have been the author of the chapter entitled "The Safety of Medicines" in The Textbook of Pharmaceutical Medicine. This book has now run to four editions, is curently published by the British Medical Association and is generally accepted as the recognised textbook for the Faculty of Pharmaceutical Medicine for their examinations. The chapter addresses the matter of the detection of such adverse events, their quantification and their causality. These three elements are the inseparable triad upon which adverse drug event reporting systems are based.

The Adverse Clinical Event Triad

1. Observation and reporting of adverse events

2. The magnitude of a potential problem

3. The elucidation of causal relationships

3.2 The interrelationships between the three elements and their essential importance for regulating the safety of medicines is probably fairly self-evident but may require some further explanation.

3.3 Most medicinal product related adverse clinical events originate as a series of observational reports from doctors or other health care professionals

in respect of their patients. In such situations an immediate concern is the possible size of the potential problem and some assessment has to be made as to whether or not the event should be classified as serious or trivial and whether it might affect large numbers of patients or be restricted to a few susceptible individuals.

3.4 Closely linked to the magnitude of the problem is the fact that in many cases the nature of the adverse event may suggest a possible cause which will be based upon existing medical knowledge and previous experience. In some cases, however, the cause may be far from obvious either because it has not been previously described or because some considerable time has elapsed between cause and effect or because the reporting professional may not be aware of a potential relationship.

3.5 Observation, an estimate of magnitude and the elucidation of causality are thus inseparable components in the matter of safety. If we are confident of the accuracy of our clinical observations, if we have assessed the size of the problem and we have determined its cause then we will be in a good position to ensure safety.

4. The detection and reporting of adverse clinical events

4.1 By far the most commonly used system of adverse event reporting ('pharmacovigilance' in EU terms) in virtually all developed countries is either the same as or is a minor variation of the so-called 'Yellow Card System' in the UK. This system was developed by Professor William Inman in Medicines Division of the Department of Health and Social Security in the years between 1970 and about 1975. The generic term for this method is 'spontaneous reporting' and relies upon the voluntary participation of certain health care professionals to report to the regulatory agency any observation of a potentially medicinal product related adverse clinical event. Although not explicitly required this system inevitably involves a certain level of judgement in respect of possible causation on the part of the reporting professional.

Professor Inman himself recognised the shortcomings of spontaneous reporting but promoted it as being the best that could be done in the circumstances.

4.2 In the chapter on the Safety of Medicines referred to above I opened the section on 'Spontaneous Reporting' as follows: "Spontaneous adverse event reporting may be defined as any system of safety data collection which relies upon physicians, other health care workers and sometimes patients to report adverse clinical events which, they suspect, may be causally related to the administration of a drug (*or other medicinal products*) or drugs." The italics are not part of the quotation.

4.3 In the next paragraph I state that, "It is one of those illogical quirks of new drug development that a method which is almost universally agreed to be seriously inadequate is, nevertheless, a major consideration in the organisation and running of the pharmaceutical company medical department. For this reason alone it is necessary to look into spontaneous reporting systems in some detail. Misunderstanding and confusion start at the very beginning. Is the clinical condition that is the subject of a report an event or a reaction? At the very least, in the eyes of the reporter, it is potentially an adverse reaction, as there was the suspicion of a causal relationship with a drug or drugs. For the personnel of a regulatory authority, who receive thousands of such reports every year, the perception may be totally different, knowing that the reporting doctor usually has little evidence to support an attribution of causality. This is no fault of the doctor, as the well known common ADRs are of little interest and the uncommon ones are so infrequent that any individual doctor may only observe a handfull in his/her entire career. The reporting doctor thus has no frame of reference by which to assess possible causality and has to fall back on clinical judgement, which is largely subjective."

4.4 I have included these quotations in full even though they were first written a decade ago since the situation remains unchanged and is pertinent to the present legal case. Virtually all the clinical safety studies on the various

formulations of MMR have relied upon spontaneous reporting and, therefore, suffer all the limitations imposed by that method. The essentially voluntary nature of the system results in a high level of underreporting which has always proved difficult to estimate with any confidence. In the late 1980s and early 1990s more active monitoring systems had been developed which created the possibility of making comparisons with spontaneous reporting.

4.5 In 1991 I published a paper in the Journal of the Royal Society of Medicine on a number of large scale, observational cohort studies which provided an opportunity for such a comparison to be made [Fletcher AP (1991) Spontaneous Adverse Drug Reaction Reporting vs Event Monitoring: A Comparison J. Roy. Soc. Med. 84 341-34].

4.6 The design of these observational cohort studies required the participating doctor to complete a form every three months for the 1 year duration of the study which recorded all clinical events and prescriptions whether or not they had any relationship to the medicinal product under investigation. In particular the doctor was not required to make any judgement of causality but merely to record the event. A quality assurance programme monitored the recording capability of the doctor and provided advice if this should be required. Recording was thus an active (as against a spontaneous) process and interpretation of the findings was reliant upon retrospective analysis by the study organisers. The participating doctor was also provided with a special form which he was encouraged to complete at any stage of the study if, in his opinion, an adverse event was causally related to the study drug. He was also asked if, in this situation, he had completed a Yellow Card and sent it to the MCA.

4.7 The paper reported on more than 40,000 patients and showed that ‘spontaneous reporting’ as quantified by the special form was below 10% of ‘event monitoring’ and that Yellow Card reporting amounted to only 50% of that. This would suggest that all safety studies using ‘passive’ or ‘spontaneous’ reporting involve a shortfall of at least 90% in the detection of adverse events and in situations in which a latent period of more than 28 days between the administration of the medicinal product and the event occurs then this shortfall could be as high as 99-100%.

4.8 The availability of such observational cohort studies was well known by 1987-8 and two of the defendant companies (SB and MSD) had shortly after that used the method on two of their new drugs (nabumetone and lisinopril). As the International Medical Director of IMS (Intercontinental Medical Statistics) and Director of their subsidiary company PMSI Ltd (Post Marketing Surveillance International Ltd) I was responsible for both of these studies.

4.9 It should also be pointed out that the MCA were fully familiar with the observational cohort method which was the motivation behind their writing the so-called SAMM Guidelines (Guidelines for company-sponsored Safety Assessment of Marketed Medicines) in collaboration with the ABPI, CSM, RCGP and BMA. See "Textbook of Pharmaceutical Medicine. 3rd Edition. 1998 Appendix III".

5. The problem of causality

5.1 The determination of causality is frequently a major problem and in many cases places great reliance upon a continuing accumulation of circumstantial evidence. This may be no more than such a number of ADR reports that they constitute convincing evidence in themselves. A dozen or so reports may be dismissed as due to chance whilst a hundred or more demand some regulatory response.

5.2 More convincing evidence may come from biological, pharmacological or physiological studies in animal models or human subjects.

5.3 Further evidence may require the conduct of epidemiological or other observational studies in appropriate patient populations.

19. Harry's Biopsy-Andrew Wakefield, MB, BS, FRCS, FRCPath.

I am writing to you to give you the results of detailed analysis of H's biopsy tissue taken at the Royal Free Hospital. An extra copy is enclosed for passing on to your (GP. This biopsy was done as part of an investigation into your child's symptoms, and the possibility that the measles virus may be playing a part in the inflammation that has produced these symptoms.

This testing was carried out at the Unigenetics Laboratory at the Coombe Women's Hospital, Dublin by Professor John O'Leary and his team. Professor O'Leary is a molecular pathologist (he specialises in identifying at a molecular level, organisms such as viruses, which are affecting the tissues around them and causing reactions such as inflammation). Professor O'Leary uses up-to-date technology, which allows the identification of viruses even when they are present in very small numbers, and allows the virus to be identified within the cells it is infecting in the small biopsy sample available.

Professor O'Leary's technique identifies the virus present by detecting part of the gene of that virus. Measles virus genes are responsible for making certain proteins and other substances that are required for the measles virus to be able to copy itself, or replicate, in the body. This is how the virus spreads through the body. The main genes that can be detected for the measles virus are called F, N, M and H. Professor O'1 vary and his team use two techniques to detect the F-and the N-gene respectively. These two techniques are called TagMan PCR and In-cell PCR. TagMan is used to detect the F-gene, and In-cell is used to detect the N-gene of the measles Virus.

The tests carried out on H's sample showed that there was evidence of measles virus in the biopsy tissue. A copy of the result from the Unigenetics Laboratory is enclosed with this letter. You will see that the results page has been signed by Professor O'Leary who has personally checked the contents of the results. He has also included the working notes made during the

analysis, and other technical information relating to the testing procedure. These techniques use state of the art technology and while there may be false negative results (the virus is present in the child but cannot be detected in this particular sample) it is extremely unlikely that this positive result is caused by anything other than the measles virus. In H's biopsy at least one of the tests was positive for the presence of measles virus. The implications for [larry's health are unclear. We are currently working hard to understand how measles virus may be causing tissue damage in your child with a view to developing possible treatments_ Persistent measles virus infection has been associated with inflammation and disorders of the immune system, mid it may be that these will resolve over time.

Unfortunately, this type of testing does take a long time to complete and I am sorry that you have had to wait for these results to be sent to you. Because very little research has been done on viral infections persisting in children with disorders such as autism or inflammatory bowel disease, the analysis of these cases had to be set against "control" cases (cases which had been admitted for colonoscopy for other reasons), and to ensure that these results are scientifically admissible, publication of the results (using anonmnised data) in a fully peer reviewed, scientific publication is essential. A copy of this study is enclosed.

As you may be aware I am no longer at the Royal Free Hospital, but I am still very much involved in investigating the cause of there problems, and acting on the children's behalf.
Thank you for your help and patience in this matter.
A Wakefield MB, BS, FRCS, FRCPath

Dr Andrew Wakefield, MB BS FRCS FRCPath, is an academic gastroenterologist. He graduated in Medicine from St. Mary's Hospital, part of the University of London, in 1981, and pursued a career in gastrointestinal surgery with a specific interest in inflammatory bowel

disease. He qualified as Fellow of the Royal College of Surgeons in 1985, and in 1996 he was awarded a Wellcome Trust Traveling Fellowship to study small intestinal transplantation in Toronto, Canada.

Discoveries made during his time in Canada led him to pursue the scientific investigation of inflammatory bowel diseases such as Crohn's disease and ulcerative colitis. In 1998, he and his colleagues at the Royal Free Hospital reported a novel inflammatory bowel disease in children with developmental disorders such as autism; the condition later became known as autistic enterocolitis. No stranger to controversy, Dr Wakefield resisted pressure to stop his research on the possible links between childhood immunisations, intestinal inflammation and autism, and left the Royal Free School of Medicine in 2001. He is involved in many scientific collaborations in the US and Europe. The main focus of Dr Wakefield's research is an investigation of the immunologic, metabolic, and pathologic changes occurring in inflammatory bowel diseases such as autistic enterocolitis, links between intestinal disease and neurologic injury in children, and the potential relationship of these conditions to environmental causes, such as childhood vaccines.

During the course of his work on childhood developmental disorders, Dr Wakefield became increasingly convinced of the need for a research-oriented, integrated bio-medical and educational approach to these disorders in order to translate clinical benefits for affected children into measurable developmental progress. Dr Wakefield has published 132 original scientific articles, book chapters and invited scientific commentaries and was awarded the Fellowship of the Royal College of Pathologists in 2001. He is medical advisor to the United Kingdom charity, Visceral, and is the Executive Director of the not-for-profit organisation Thoughtful House Center for Children in Austin, Texas.


RENEWABLE HOUSE
9. TROPICAL RAINFOREST
WATERSHIP
DOWN
INDIA

20. Studies that Count, Studies that Don't.

Parents in England have a big choice: They can believe Andrew Wakefield or they can believe Tony Blair, Liam Donaldson and Richard Horton. They can trust Andy or they can trust the experts from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunization, several of whom have ties with the drug company that distributes the MMR in England.

We in the United States also have a choice between on one side, clinical research, with real children and on the other, one more epidemiological study by the CDC. The following quotes from presentations on Feb 9, 2004 to the Vaccine Safety Committee of the Institute of Medicine deserve attention:

"In light of encephalopathy, presenting in children as autistic regression closely following MMR vaccination . The findings confirm a highly significant statistical association between the presence of MV RNA in CSF and autistic regression following MMR vaccination." Jeff Bradstreet MD, Director, International Child Development Resource Center, Melbourne, Florida.

"The current genetic research estimates that no more than 10% of all autistic cases are genetic in origin. Simply put, the remainder 90% of autistic cases is sporadic with a non-genetic etiology. I tend to think that the sporadic form is by and large an "acquired" subset involving autoimmunity. This subset is likely triggered by a virus, possibly measles virus or MMR vaccine... Based upon our experimental research, it is plausible to postulate that an atypical measles infection that does not produce a typical measles rash but manifests neurological symptoms might be etiologically linked to autoimmunity in autism.

The source of measles virus could potentially be MMR vaccine or a mutant measles strain, but more research is necessary to establish either of these two possibilities. Fundamentally, I tend to think that autistic children have a problem of their immune system, which is the "faulty immune regulation." Hence they have abnormal immune reactions to measles virus and/or MMR vaccine" Vijendra K. Singh, Ph.D., Research Associate Professor of Neuroimmunology, Utah State University, an international expert in the

autoimmune causes of autism: US Representative Dave Weldon, a physician, commenting on the on-going clinical research said: "Mind you, half of Dr. Wakefield's theory has been proven correct and accepted in the medical community. Hundreds of children with regressive autism and GI dysfunction have been scoped and clinicians are seeing the inflammatory bowel disease he first described. The NIH is finally funding an attempt to repeat Dr. O'Leary's findings of measles RNA in Wakefield's biopsy specimens, though I am disappointed it has taken this long. A clinician in New York was poised to repeat Wakefield's work two years ago, but he ultimately was refused by his IRB and then subsequently had his clinical privileges withdrawn."

Instead of telling parents why they are suddenly losing their children, the CDC just published another long, pedantic and rather useless MMR "damage-control" epidemiological study: Age at First Measles-Mumps-Rubella Vaccination in Children with Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta by Dr. Frank DeStefano and others [Pediatrics Vol. 113 No. 2 February 2004, 259-266]. The authors did not discuss the causes of the present epidemic now affecting the United States (1) and the world (2), but simply stated that the MMR was unlikely to be the cause of regressive autism because children diagnosed with autistic disorders in Atlanta, Georgia received their first MMR vaccine at about the same age as unaffected children.

The CDC had previously published two local epidemiological studies, in which serious increases in autism were documented (3, 4). It also funded a third study in Denmark (5) that, though much publicized, was flawed and irrelevant to the situation in the United States. That study also seemed to have been primarily intended to exonerate the MMR vaccine and it will be discussed in some detail later.

The CDC has never proposed, designed, funded or carried out a single clinical study on autism. The only credible way to prove that the MMR vaccination does or does not precipitate autistic symptoms in children, who are genetically predisposed and have been previously exposed to Thimerosal-containing vaccines, is to compare affected children who have received the

MMR vaccine with children who have not. This is obviously practically impossible because most children in Atlanta have received the MMR vaccine. The theoretical question is therefore: "How many children in Atlanta would have developed autism if they had not received the MMR vaccine?"

A relatively easy study would be to compare the age of onset of autistic symptoms in children vaccinated at 15 months and those vaccinated at 30 months in Atlanta. I believe, from my own research, that such a study will show that: Autistic behavior follows MMR vaccination and That fewer cases and less severe manifestations are noticed among the cohort vaccinated at 30 months, since vaccination at a younger age appears most damaging.

Another easy study would be to compare Measles, MMR and Myelin Basic Protein antibody titers of children who developed autism shortly after MMR vaccination in Atlanta to an equal sample of normal children similarly vaccinated.

Dr. DeStefano states [under conclusions, page 259] "Similar proportions of case and control children were vaccinated by the recommended age or shortly after (ie, before 18 months) and before the age by which atypical development is usually recognized in children with autism (i.e. 24 months)." The CDC, certain pediatricians and the MMR lobby have consistently argued that autism is not due to the triple vaccine because autistic symptoms are "usually first noted" around the time the MMR is administered and that therefore the relationship between the two events is casual and not causal; in other words just a coincidence. Historically, this is not so.

Kanner's autism was known as Infantile Autism because affected children exhibited symptoms in early infancy. The more recent form of the disease, Regressive Autism, occurs at a older age with symptoms usually starting at 18 to 24 months or later: A child, most often a boy who is developmentally, socially and verbally on par for his age, suddenly stops acquiring new words and skills in the second year of life and then actually regresses, losing speech, cognitive abilities and social dexterity. Many parents have reported and documented such regression in their children after MMR vaccination.

Bernard Rimland, Ph.D., Founder and President of the Autism Research

Institute (ARI), a full-time professional research scientist in the field of autism for 45 years, stated after a thorough analysis of the extensive ARI database: "Late onset autism, (starting in the 2nd year), was almost unheard of in the '50s, '60s, and '70s; today such cases outnumber early onset cases 5 to 1, the increase paralleling the increase in required vaccines." (6) The study by DeStefano, though dazzling with figures and tables proves little, just like the epidemiological studies by Taylor, Kaye and Dales that were supposed to have previously "convincingly proven that there is no relationship between MMR vaccination and autism". Interestingly, Kreesten Meldgaard Madsen, author of "A Population-Based Study of Measles, Mumps and Rubella vaccination and Autism", (5) the study funded by the CDC stated "Studies designed to evaluate the suggested link between MMR vaccination and autism do not support an association, but the evidence is weak and based on case-series, cross-sectional, and ecologic studies; No studies have had sufficient statistical power to detect an association, and none has a population-based cohort design" (References 10-16)." In the Madsen bibliography, reference 10 is the first Taylor study (The Lancet); reference 11 is the one by Kaye (BMJ) and reference 12 is the study by Dales (JAMA). For reasons known only to him, Dr. DeStefano still mentioned the Taylor, Kaye and Dales studies as reliable and listed them as references 23, 22 and 19 respectively. Dr. DeStefano and Associates describe the Madsen MMR study as "particularly persuasive". In fact, that study, because of an integral flaw in its design, could not have shown, that indeed there had been an increase in autism after routine MMR vaccination was initiated in Denmark. The following is part of the analysis by Dr. Gary Goldman and myself of data from the Danish Psychiatric Central Register, the same data that Madsen used. It clearly shows that there has been a serious increase in autism in children under 14 in Denmark in the last few years. (Graph I) [Not shown] Graph I Incidence of Autism in Denmark by Age Group Source: The Danish Psychiatric Central Register.

The MMR vaccine was introduced in Denmark in 1987. It has been estimated that only 70% of the 15-month old children received the triple vaccine in 1987-1988. The percentage of vaccinated toddlers then reached and

remained at 80 to 88% for several years. It is estimated that in the last three years about 95% of the 15-month old children in Denmark received the MMR vaccine.

The present rise in autism in Denmark has clearly started 4 to 5 years after the introduction of the MMR vaccine and it appears to correspond with the percentage of children who received the MMR. The mean age at the time of diagnosis in Denmark is probably around 4.7 years ("The mean age at diagnosis for autism was 4 years, 3 months,
and for autistic spectrum disorders 5 years, 3 months.") Approximately 25% of autism cases in Denmark are reported in children under the age of 5 with the remainder 75% of affected children being reported when they are 5 to 19 years old. Given these percentages, any inferences about disease in the under-5 group, in which the disease has not yet become manifest, are potentially flawed. The 2,129,864 person-years reported in the Madsen study divided by the number of children 537,303 indicates that the average age of the children in the study is less than 4 years (range 1 to 7 years). Those children would be 5 to 12 years old in 2003. Because the mean age at diagnosis is 4.7 years
in Denmark, the Madsen study could NOT have detected many of the cases of autism that were subsequently diagnosed when these children were older, thereby missing the temporal connection between MMR vaccination and autism.

The 0-4 year old group of children (Graph I, black) remains the lowest from 1980 to 1991, because autism was/is rarely diagnosed under the age of 4 in Denmark. The prevalence of autism in that age group starts climbing after 1991, 4 years after the introduction of the MMR vaccine, to become the second highest by 1993.

The 5 - 9 age group is the earliest cohort that received the MMR vaccine after coverage has improved and is also old enough to be diagnosed. There are consistently more and more affected children in this age grouping.

The 10 -14 age group (dark green) represents the earlier cohort that first received the MMR vaccine, but at lower coverage rates. Those affected children aged 10 to 14 in 2003 were aged 1 to 5 in 1994. They reflect the

startup of the autism increase associated with the startup and progression of the MMR vaccination program.

The 15 -19 age group (light green) were aged 1 to 5 in 1989; their number increases but at a much slower rate than in the younger age groups. Lastly, the 20 - 24 age group (brown) shows only a slight increase starting in 1994 possibly because few if any of this cohort, received the MMR vaccine at a vulnerable age.

Even when one takes into account the classification change that took place in 1993/1994 and the addition of outpatients to the database in 1995, it is evident, when five additional years are considered, that the conclusions of the Madsen group are invalidated and that the data appears to support the hypothesis that increases in autism in Denmark, may be correlated with increases in percentage coverage and number of children receiving MMR vaccination.

It is likely that in Graph I, the 0 - 4 year group of affected children represents those who were not generally diagnosed earlier, that the 5 - 9 age group represents the highest increase that occurred after wide-spread coverage of the MMR vaccine and that the 10 - 14 age group represents the earlier cohort that first received the MMR vaccine, but at a
low coverage rate.

It is possible that the rate of autism will now level off at the higher rate since children receiving MMR immunization have now saturated the age groups and replaced individuals in the age groups that were previously unvaccinated.

Approximately 65,000 babies are born every year in Denmark. Graph I shows the early slow ramp-up period due to low vaccination rates. When MMR vaccination coverage improved beyond a certain level, from 1993 to 2001, there was a steady and increasing trend in autism every year. That gradual rise leveled out after the entire cohort aged <10 was almost "completely" vaccinated (vaccine coverage at >95%). It is entirely possible that many of the children of the most affected 5 to 9 group, could have started with symptoms as early as the second year of life.

The prevalence rate of autism in Danish children under the age of 14 has

increased by 729% from 17.67 per 100,000 Population in 1980 to 146.42 in 2002. (Graph II)

Graph II [Not shown] Children with Autism under Age 14 In Denmark per 100,000 Population. Source: The Danish Psychiatric Central Register.

The prevalence of autism in children and teens under the age of 14 in Denmark, which was 131.42/100000 in the 7 years before the MMR vaccine, increased by 542% to 843.73/100000 in the last 7 years. Indeed, the prevalence of autism in that group was 11% higher (146.42/131.42) in 2002 alone than in the combined 7 years before the introduction of the MMR vaccine.

Two doses of MMR are administered in Denmark, one at age 15 months, and one at age 12 years. The data suggest that the main concern is the vaccination given at age 15 months.

The prevalence of autism in Denmark in the 0 to 14 year-olds leveled off in the last 3 years, when toddler MMR coverage reached the 95 - 98% level. The reason why this did not take place in the United States in the 90 's was probably because pediatric vaccines in the US contained Thimerosal, further supporting the argument that the study was flawed in principle because countries with strikingly different vaccination practices cannot and must not be compared.

Conclusions

Autism has increased in Denmark after the introduction of the MMR vaccine as evidenced by the fact that the rate ratio i.e. the incidence of autism after vs. before MMR vaccination is 8.8 (95% C.I., 6.3 to 12.1) among 5 to 9 year old Danish children. The Madsen study did not reveal this statistically significant increase.

Dr. DeStefano and his colleagues at the CDC should research the causes of Regressive Autism rather than defend a vaccine in trouble.

Parents are more likely to forgive errors than cover-ups.

F.Edward Yazbak MD.

21. Dr Peter Fletcher-from the Mail on Sunday 5th February 2005.

A former Government medical officer responsible for deciding whether medicines are safe has accused the Government of "utterly inexplicable complacency" over the MMR triple vaccine for children.

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 added that after agreeing to be an expert witness on drug-safety trials for parents' lawyers, he had received and studied thousands of documents relating to the case which he believed the public had a right to see.

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."

His warning follows reports that the Government is this week planning to announce the addition of a jab against pneumococcal meningitis for babies, probably from next April. It is also considering flu jabs for under-twos - not to protect the children, but adults they may infect.

In the late Seventies, Dr Fletcher served as Chief Scientific Officer at the DoH and Medical Assessor to the Committee on Safety of Medicines, meaning he was responsible for deciding if new vaccines were safe.

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 vaccinerelated 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 Sunday, 05 February 2006refusing 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.

February 2006

22. Dan Olmsted – Autism in Amish population where parents do not ordinarily vaccinate their children.

According to officials in the nation's regulatory agencies, the main obstacle to proving or disproving a link between the autism epidemic and the mercury-based preservative, thimerosal, that was contained in childhood vaccines until a few years ago, and is still in flu vaccines, has been the inability to find a large enough group of people who have never been vaccinated to compare with people who have.

In fact, a few months ago, CDC officials claimed that such a study would be nearly impossible. On July 19, 2005, the CDC held a Media Briefing on the topic of vaccines and child health. On the issue of government research on autism, a reporter asked CDC Director, Dr Julie Gerberding: "are you putting any money into clinical studies rather than epidemiological studies, to verify or disprove the parents' claim about a particular channel, a particular mechanism by which a minority of genetically suspectable kids are supposed damaged?"

Gerberding replied: To do the study that you're suggesting, looking for an association between thimerosal and autism in a prospective sense is just about impossible to do right now because we don't have those vaccines in use in this country so we're not in a position where we can compare the children who have received them directly to the children who don't.

Dr Duane Alexander, of the National Institute of Health, agreed and said: It's really not possible ... in this country to do a prospective study now of thimerosal and vaccines in relationship to autism. Only a retrospective study which would be very difficult to do under the circumstances could be mounted with regard to the thimerosal question.

However, Dan Olmsted, investigative reporter for United Press International, and author of the Age of Autism series of reports, appears to have solved this

problem when he came up with the idea of checking out the nation's Amish population where parents do not ordinarily vaccinate children.

First he looked to the Amish community in Pennsylvania and found a family doctor in Lancaster who had treated thousands of Amish patients over a quarter-century who said he has never seen an Amish person with autism, according to Age of Autism: A glimpse of the Amish on June 2, 2005.

Olmsted also interviewed Dick Warner, who has a water purification and natural health business and has been in Amish households all over the country. "I've been working with Amish people since 1980," Warner said.

"I have never seen an autistic Amish child -- not one," he told Olmsted. "I would know it. I have a strong medical background. I know what autistic people are like. I have friends who have autistic children," he added.

Olmsted did find one Amish woman in Lancaster County with an autistic child but as it turns out, the child was adopted from China and had been vaccinated. The woman knew of two other autistic children but here again, one of those had been vaccinated.

Next Olmsted visited a medical practice in Middleburg, Indiana, the heart of the Amish community, and asked whether the clinic treated Amish people with autism.

A staff member told Olmsted that she had never thought about it before, but in the five years that she had worked at the clinic she had never seen one autistic Amish.

On June 8, 2005, Olmsted reported on the autism rate in the Amish community around Middlefield, Ohio, which was 1 in 15,000, according to Dr Heng Wang, the medical director, at the DDC Clinic for Special Needs

Children.

"So far," according to Age of Autism, "there is evidence of fewer than 10 Amish with autism; there should be several hundred if the disorder occurs among them at the same 166-1 prevalence as children born in the rest of the population."

In addition to the Amish, Olmsted recently discovered another large unvaccinated group. On December 7, 2005, Age of Autism reported that thousands of children cared for by Homefirst Health Services in metropolitan Chicago have at least two things in common with Amish children, they have never been vaccinated and they don't have autism.

Homefirst has five offices in the Chicago area and a total of six doctors. "We have about 30,000 or 35,000 children that we've taken care of over the years, and I don't think we have a single case of autism in children delivered by us who never received vaccines," said Dr Mayer Eisenstein, Homefirst's medical director who founded the practice in 1973.

Olmsted reports that the autism rate in Illinois public schools is 38 per 10,000, according to state Education Department data. In treating a population of 30,000 to 35,000 children, this would logically mean that Homefirst should have seen at least 120 autistic children over the years but the clinic has seen none.

It looks like the problem is finally solved. Thanks to autism's Dick Tracy, the government now has thousands of unvaccinated people to compare to people who were vaccinated.

December 21, 2005

23. Virus Detected in children with Autism, but not in controls

These data published today in the most recent Journal of American Physicians and Surgeons, represent the second in a series of direct observations of Measles Virus (MV) persistence in children with Autistic Regression. All children had been vaccinated shortly prior to the development of autistic symptoms. While all of the controls had also been vaccinated - they were all negative for viral persistence. Taken together with the finding of MV in the intestinal tract of these and other children previously reported by Uhlmann, this represents evidence of active replication of virus and further indicates either failure of the vaccine to protect these children from natural infection or more likely, given the lack of any history of MV apart form the vaccine, this represent vaccine strain persistence.

Presently there is no proven intervention for viral persistence and it is the hope of the authors that these observations will stimulate additional reearch into the nature of the viral persistence and means of assisting the children in completely clearing the virus.

While MMR vaccine is generally considered safe, we propose a subset of genetically vulnerable children lack the ability to clear the vaccine strain of the virus and that this is - on the balance of the available biological data - a direct cause of their symptoms. We recognize the failure of epidemiology to validate these observations, and beleive this specific hypothesis has never been adequately tested with any previous epidemiological study.

Jeff Bradstreet MD FAAFP
Director ICDRC Professor of Child Development
Southwest College of Naturopathic Medicine and Adjunct
Professor Stetson University 321-953-0278

This study is the latest in a series that examines the relationship between persistent measles virus infection and regressive autism. While the Institute of Medicine were made aware of these findings, and indeed similar findings in a larger group of autistic children, they chose to ignore them in their latest report. This situation is quite unacceptable.

24. Forward to the European Court of Human Rights

As well as the evidence of the 28 expert witnesses showing a link between MMR and ASD/IBD that should have been heard at the trial in the courts in London, the MMR 10 presented further evidence to the UK courts in October 2005 and January 2006 at the judicial review hearings.

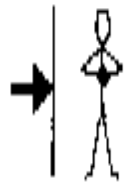
Evidence from John Hopkins and New Jersey universities in the USA was adduced in evidence before the Court of Appeal, prior to the judge's handing down of his decision on 28th February 2006. So was further evidence from Dr Peter Fletcher, as published in the Mail on Sunday in February 2006. As was also the Dan Olmsted evidence of the Amish and other exclusive communities in the USA which do not vaccinate their children. *In those communities autism is unknown*. This evidence and its overwhelming significance are part of the MMR 10 story.

The UK judges ignored that evidence and relied instead on the contention that the Legal Aid Funding Review Committee were entitled to take the decision they took not to renew legal aid to these 10 children. We put this evidence in this book for all to see.

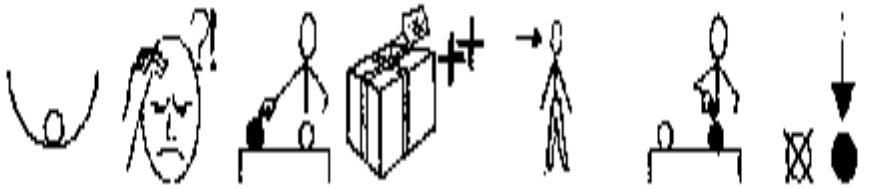
It will all go forward to the ECHR. As William's mother asked at the hearings, if legal aid is not for these injured and most vulnerable children what is it for ? A good question.

This story of the MMR 10 and the world's ASD/IBD children, is one of the greatest medical/legal scandals of our time. It will not go away. This book is to bring that story out of Courts, often meeting in closed session, to where it belongs. That is in the public domain.

Harry 6.11.03

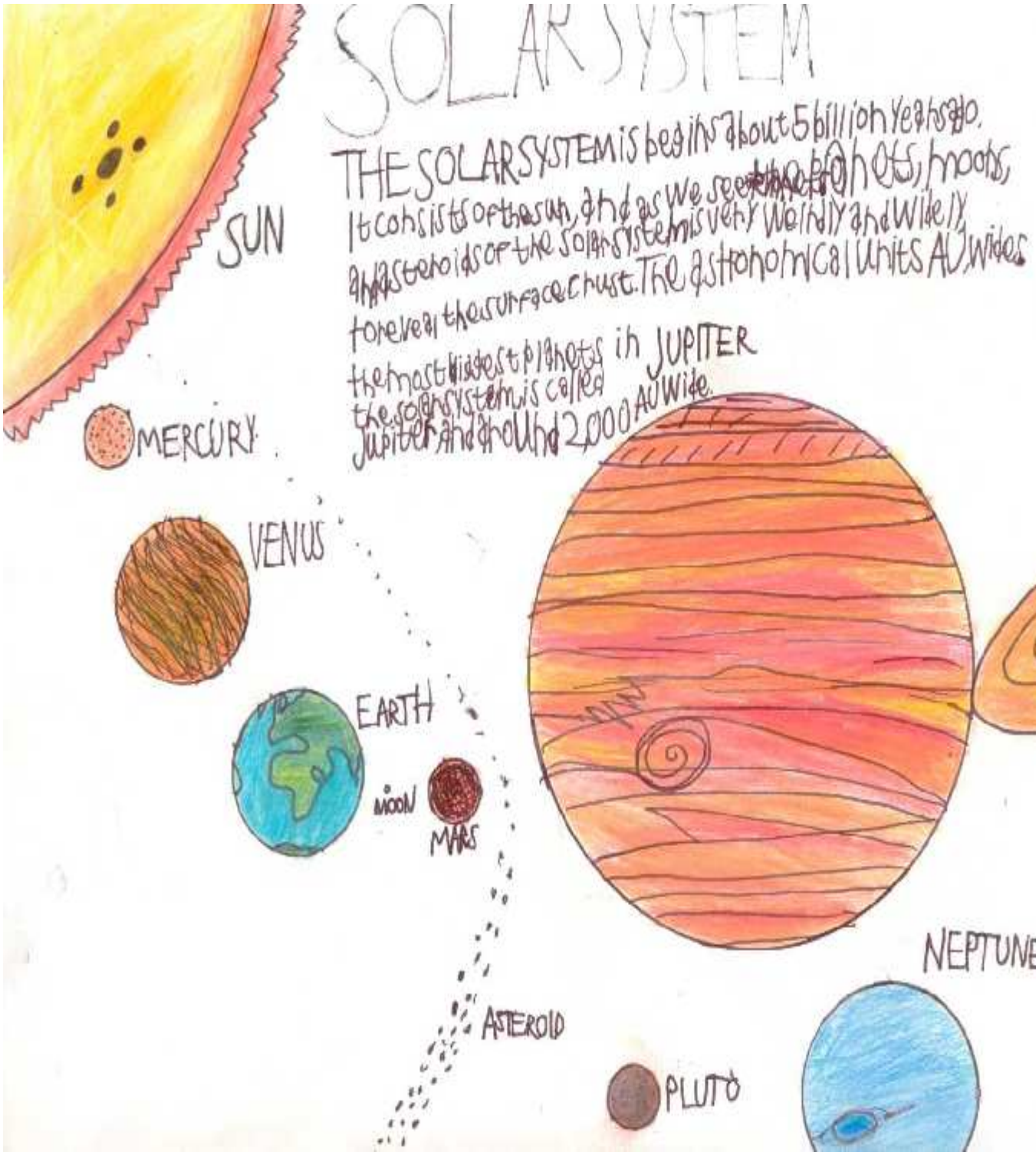


To mine mind.



The only difficulty, that presents himself in this otherwise,

very, clear, case. Is.


SOLAR SYSTEM
THE SOLAR SYSTEM is begins about 5 billion years ago.
It consists of the sun, and as we see the
and asteroids of the solar system is very weirdly and widely
forever at the surface crust. The astronomical units AU wides
the most biggest planets in JUPITER
the solar system is called
Jupiter and around 2,000 AU wide.
SUN
MERCURY
VENUS
EARTH
MOON
MARS
NEPTUNE
ASTEROID
PLUTO

MMR Vaccination Briefing Note - April 2006

MMR vaccine introduced into UK vaccination schedule 1988:

Three brands of MMR vaccination were introduced into the UK childhood vaccination programme in October 1988. The vaccines were heralded as a one-off, life-long immunisation against three serious diseases, measles, mumps and rubella. The manufacturers' were SmithKline Beecham, brand name Pluserix , Merieux, brand name Immravax and Merck Sharpe, Dohme, brand name MMRII.

SmithKline Beecham and Merieux used Schwartz strain measles, Wistar RA27/3 strain rubella and Urabe AM9 strain mumps. Merck Sharpe Dohme used Enders Edmonston strain measles, Wistar RA 27/3 strain rubella and Jeryl Lynn strain mumps.

JABS group founded in 1994 as serious vaccine problems were reported:

When the JABS group was founded in January 1994 parents contacted us with their concerns about their children's serious ill health following childhood vaccinations. We asked parents to complete questionnaires on the vaccines given and to describe in detail their children's experience.

We were astounded by the responses. Parents stated the number of days after MMR vaccination when their children had started to become ill and in many cases the number of days quoted were consistent with the incubation period of the vaccine viruses given. Many of the symptoms described were listed in the vaccine manufacturers' own product sheets.

The parents reported that their children had suffered serious consequences after the initial symptoms and had not recovered to the health point they had had before the vaccination was given. The most remarkable aspect of` this is that the long term serious health problems that the children now have were also, in the main, listed in the same drug product sheets as the 'rare' events known to be associated with the vaccine.

The UK adverse event surveillance system - 'yellow card': We asked each family if their child's doctor or consultant had reported the symptoms and

change in the child to the UK's Committee on Safety of Medicines, using the adverse events surveillance mechanism known as the 'yellow card' scheme. The vast majority responded that the health professional had declined to use the reporting system as he/she had dismissed the link with the vaccination as 'just a coincidence'. Therefore, the suspected reactions had not been put forward to the central body for detailed investigation.
In theory the system should work to flag up any serious problems with drug products - the guidelines note that all suspected reactions should be reported. In practice the system was largely ineffective because health professionals made their own arbitrary decisions on whether to report the problems.
The Health Protection Agency in its former role as Public Health Laboratory's Service is on record in the Lancet (Vol. 345. March 4, 1995) stating "..there is an urgent need to find more reliable methods of adverse event surveillance." The point being that unless all reactions are put forward to a central body instead of being dismissed as "unrelated" or "just a coincidence" the central database will never hold accurate information on adverse events. How many coincidences are needed before it becomes meaningful enough to warrant scientific, clinical investigation?

Investigations:

Families have urged their medical practitioners who are dealing with their children's problems to investigate the suspected connection with the vaccinations. Some parents have also reported that the doctor/consultant was not interested in finding the reasons for the child's ill health, stating that their role was to treat the problem and, therefore, they did not want to be involved in this aspect. During the course of the JABS group investigations we have discovered that the UK pre-introductory trials for MMR were inadequate in that they failed to follow up adverse reactions for more than just a few weeks. Serious degenerative conditions are known to take weeks and/or months to develop.

Withdrawn MMR brands:

Proof of inadequacy is in the knowledge that it took the Department of Health four years to identify problems and withdraw two of the three original MMR brands that had been introduced into the UK vaccination programme in 1988. These two brands, Pluserix and Immravax were withdrawn by September 1992 because they contained a mumps strain known as Urabe which had caused mumps meningitis in some children. Many of the badly affected children known to JABS have had these brands of MMR. It is also of concern that this problem must have been known by the UK's Department of Health Chief Medical Officer: The licence for the MMR vaccine containing the Urabe strain in Canada was revoked from May 1990. In Japan it was banned in 1993. A version of this vaccine made by Chiron was also withdrawn from use in Italy in March 2006.

Drug manufacturers' product sheets:

The drug manufacturers of MMR vaccines have provided the Government's vaccine policy makers with product sheets which list the adverse reactions known to be associated with their vaccines. These lists are virtually identical from each of the drug companies. They state the minor side effects which doctors are happy to describe to parents: namely - rashes, raised temperature etc. These same sheets also state reactions only recently acknowledged in public by the Health Protection Agency e.g. febrile convulsions, blood disorders (ITP). The information sheets also state the severe adverse events: to name but a few - diarrhoea, nerve deafness, arthritis, Guillain-Barre syndrome (a paralysis syndrome), severe vision problems, seizures and encephalitis. Encephalitis (inflammation of the brain) can lead to a range of disabilities such as epilepsy, loss of speech and communication and acquired autism.

Responsibility for vaccine damage:

Richard Ley, of the Association of British Pharmaceutical Industries said in the Daily Express (May 18 2000): 'The Government implemented the vaccination programme knowing in full detail what the possible

side-effects were. They knew what they were taking on, the damage is therefore their responsibility and they should compensate people accordingly.'
The MMR vaccine contains three live attenuated viruses; their major disadvantage is a danger of reversion of the virus strains to more reactive and virulent forms. In plain terms, if the wild virus can cause inflammation in the brain, joints, spine, eyes, ears and bowel then so can the vaccine-virus and to quote an extract from a letter published in the Times (February 9 2002) from Dr David Hall, President of Royal College of Paediatrics and Child Health : 'Some children develop encephalitis (brain swelling) when they catch measles, mumps or rubella viruses and may be left with a variety of handicaps, including physical and mental impairment, deafness, internal organ damage and autism.....'
Raising the issues with UK Government Minister and Health Chiefs:
In October 1997 Dr Andrew Wakefield and Professor Walker-Smith from the Royal Free Hospital, London, JABS and its legal representatives, took part in a meeting with the then Health Minister, Tessa Jowell, also the Chief Medical Officer, Principal Medical Officer and others. During the course of the one hour meeting a full list of children, then affected, was presented. We asked that the Government should instigate a scientific investigation of the children believed to have been damaged which could have been useful on at least two fronts:
i. To answer the question of MMR safety.
ii. If the vaccine was found to be causing harm it may have been possible to identify "at-risk" groups which may have led to a screening programme with the potential to have improved vaccine safety for all children
The Health Minister at the time stated she was willing to look at all scientific evidence but as parents it is very difficult for us to produce this. That is why we believe the current claims by the vaccine policy-makers that there is no scientific evidence to show the MMR vaccine is unsafe will continue to be made. Until the Government instigates a full investigation of the children believed to have been damaged, the "scientific evidence" required by the Department of Health is unlikely to emerge.

Vaccine Damage Payment Act 1979:
The Government is well aware that vaccines sometimes cause severe damage; there is a branch of the Department of Social Security known as the Vaccine Damage Payment Unit. It was set up in 1979 following the Vaccine Damage Payment Act 1979. MMR vaccine damage payments have been awarded for various adverse effects including: epilepsy, Guillain-Barre syndrome (a paralysis condition), SSPE (a brain-wasting condition), neurological problems,
profound deafness and death. Some of the children who received payments are detailed in the following article:

US experience:
Any debate on vaccine damage will have Department of Health officials quoting the massive number of doses given to children in the United States. What is never stated by UK officials is that in the US they have a National Vaccine Injury Compensation Programme. In the last 18 years this programme has paid out hundreds of millions of dollars in payments to vaccine damaged children of which a 14% share has been paid out for MMR or its components.
The drug companies have to contribute to the programme and up to August 1997 they had to pay an excise tax on each dose using a risk-based formula. The DTP and MMR were taxed at $4.56 and $4.44 respectively, polio vaccines at $0.29 and DT (diphtheria/tetanus) vaccines at $0.06. This must surely give an indication of which vaccines carry the highest risk of a serious adverse reaction. The problems associated with childhood vaccines are also being reflected in the United States as has been reported on the JABS web pages and on US sites:

Japanese experience and compensation:
The MMR vaccine was introduced into the Japanese health programme in April 1989. Shortly after its introduction Japanese parents started to complain to the authorities that their children were suffering severe neurological

damage. The Japanese Government failed to act. Many parents started to reject the MMR vaccination for their children and the Japanese Government continued to ignore public concern. Outbreaks of measles then occurred and, unfortunately, it was the most vulnerable group in society, babies under twelve months of age and too young to receive a measles vaccine, that were hit hardest and 69 deaths were recorded.

The Japanese Government banned the MMR vaccine in 1993 and introduced a policy of separate measles and rubella vaccines. (The single Urabe mumps vaccine would not have been accepted as it had been held responsible for the neurological damage when combined in the Japanese MMR vaccine.) The Japanese MMR court cases were heard in March 2003. Over 1,000 children were awarded MMR damages against the Japanese Government and the Research Foundation for Microbial Diseases at Osaka University in Suita, Osaka Prefecture.

MMR and Autism:

The statement that the health secretary, John Reid, made on GMTV in November 03: "It is unequivocal that there is no evidence at all that MMR is linked to autism." needs to be challenged. World experts in the field of virology and pathology have replicated results found by Dr Wakefield's team when he was at the Royal Free Hospital, London and other independent Japanese scientists have also duplicated the findings. (Ref. 1 below) Children who have developed autism, epilepsy and other neurological conditions were progressing normally before they were vaccinated, had passed all milestones and had acquired skills appropriate to their age.

* They did not simply fail to progress; they actually regressed, losing skills which they had already attained. In many instances this is borne out by videos taken of the children before and after they were vaccinated.

* They showed other physical changes at the time that they became autistic (such as sleep patterns, appetite changes, temperature control etc. in addition to many of them suffering bowel problems).

* The development of autism and other conditions are closely linked in time to

the administration of the vaccine. The onset of this condition generally started within about a month of vaccination whenever the vaccination took place. In other words, it would be later for children vaccinated at 18 months than those vaccinated at 12 months. On top of that, a substantial proportion of the children had an immediate reaction to the vaccination, and the change which came over them dates directly from that reaction.

For more information on MMR, Thiomersal, Autism connection please refer to the home page of JABS (www.jabs.org.uk <http://www.jabs.org.uk>) and http://www.putchildrenfirst.org/

MMR Legal Cases:

Unfortunately, the UK MMR victims had their legal aid stopped just six months before the cases were to be heard at the High Court in April 2004.
In some cases legal aid had been provided for nearly ten years to children with wide ranging health problems including autism, epilepsy, loss of speech and communication skills, chronic arthritis and deafness.
Each family had to personally apply to try and prevent their child's legal aid certificate from being discharged. In the interest of justice, these children deserve to have the issue of MMR safety resolved in court and for this reason families need the help of legal aid.

* Many parents believe that the withdrawal of legal aid prior to the court cases being heard was another way to delay or prevent access to justice for vaccine damaged children. The families' representatives were able to present to the legal aid appeal committee (the Funding Review Committee) evidence not only that measles virus had been found in cerebro spinal fluid (CSF) taken from three out of six of the test cases, but also that it had not been found in 19 out of 20 controls. If the measles virus is in the CSF then it must almost certainly be in the brain. Bearing in mind:

* that these children, like all autistic children, suffer from a form of brain damage,

* that measles is known to be able to cause brain damage and

* that no other cause of autism has been suggested for the overwhelming majority of the families involved. Adding to the stress of this situation, one of the MMR drug companies had sent some parents a letter offering not to seek costs against the child or them if they signed an undertaking "not to issue any further proceedings arising out of vaccination with MMR against them in this or any other jurisdiction".

The MMR court cases were and still are vital not only to the families involved in the pursuit of justice for their children, but for all parents who are concerned about whether the vaccines they are giving their healthy children are safe. JABS believes the Government can no longer claim that MMR is the "safest way to protect your child" as they have denied the parents an opportunity to have all the information out in the open and heard properly. Until the evidence is formally presented in court the question mark over the issue remains.

At the moment (April 2006) a small number of parents have had MMR legal aid certificates re-instated for their children. Also, ten families who lost their appeal plan to take their children's cases to the European Court of Human Rights.

Single vaccines:

The Government's Chief Medical Officer needs to reconsider the availability of single dose vaccines as a matter of choice. If there is a potential for measles epidemics they must provide a real choice for those parents who have lost confidence in the combined MMR but still want to vaccinate against the separate illnesses. It should not have to be MMR or nothing situation. It does not require new legislation it just needs the Department of Health to place orders with the drug companies currently supplying the UK market with the MMR vaccines.

When the MMR vaccine was introduced into the childhood vaccination schedule the doctors' Green Book, 'Immunisation against Infectious Disease'

clearly stated: 'MMR vaccine will replace measles vaccine in the second year of life, or after this age if appointments have been missed. For children whose parents refuse MMR vaccine, single antigen measles vaccine will be available.' (Page 60, 10.2 Recommendations) Reference to this choice appeared in the 1988, 1992 and 1996 editions of this book. Why has this option been quietly removed without explanation?

Cochrane Review:

A study by the respected Cochrane Library (October 2005) has said, on the basis of 31 pieces of research into the possible side effects of MMR, that it found no association between MMR, autism, Crohn's disease and long-term disability. The Department of Health is hailing it as another 'final nail' in the MMR controversy but there is another side to this that they have missed. Since the MMR vaccine was introduced in 1988 many parents have complained publicly that they believe their children have been seriously damaged by MMR vaccine. Each time the Department of Health have cited many reports as being conclusive proof that the vaccine is both safe and effective. It is important to note that the authors of the Cochrane Review have scrutinised 5,000 related studies and in this context found the majority lacking. Only 31 of the 5,000 studies were thought to "possibly fulfill their inclusion criteria".

The Cochrane Review is a significant piece of work because it actually exposes all the 5,000 related studies as being inadequate in some way, as all fail to find any link with long-term disability for which compensation has been paid or acknowledged by the vaccine manufacturers in their own product sheets.

Of course the MMR vaccine is responsible for long-term disability in some children. All drug products have the potential to cause both minor and serious adverse reactions one has only to read the manufacturers' product information sheets to be aware of this.

Vaccine damage, and in this case, MMR vaccine damage has been recognised by Governments, three examples are:

1. The US Government has a National Vaccine Injury Compensation Programme and 14% of all claims have been paid out to children damaged by MMR vaccination.

2. The Japanese authorities have paid out substantial compensation to parents of MMR vaccine damaged children after a successful court case in March 2004. (There is an on-going UK case.)

3. The UK Government has a Vaccine Damage Payment Unit which has paid out hundreds of thousands of pounds to children affected by childhood vaccines including MMR vaccine.

Many children who suffer adverse reactions are individually assessed by Government doctors panels. These panels determine the reported adverse event and association with vaccination (known to the manufacturers) and make recommendation for compensation for the individual. The criteria used is extremely high and compensation awards are not made lightly.

For the medical authorities now to conclude that this review gives the MMR vaccine a clean bill of health does a great injustice to all those children who have been awarded vaccine damage payments by ignoring their existence It will also bolster those that sustain the failed passive vaccine reaction surveillance system which continues to ensure very few reactions are put forward or recorded in medical data. It is this poor data that was used in many of the reports reviewed by Cochrane which they identified as inadequate. Therefore a continued cycle of failure by the medical authorities to identify and reduce vaccine adverse events in children will be assured. For the Department of Health to continue trying to convince parents, many of

whom have family and friends with children believed to have been affected by MMR vaccine, exposes them to being blind to the reality.

World Health Organisation (WHO) - Causality of Adverse Events:
"Since the inception of vaccination, it has been recognized that adverse events following immunization (AEFIs) will occur." (Ref. 2 below)

The WHO gives criteria to be considered when an adverse event is reported:
1. Consistency.
The association of a purported adverse event with the administration of a vaccine should be consistent, i.e. the findings should be replicable in different localities, by different investigators not unduly influencing one another, and by different methods of investigation, all leading to the same conclusion(s).
As already mentioned problems following MMR vaccination have been reported and accepted in Japan and the United States. A report from Finland described the immunization of 1.8 million individuals and gave rise to 173 potentially serious reactions claimed to have been caused by MMR vaccination. In all, 77 neurologic, 73 allergic and 22 miscellaneous reactions and 1 death were reported. (Ref. 3) Furthermore most of these cases were not followed up for more than a few weeks. And this Finnish study "did not examine the relationship of MMR and autistic spectrum disorders.....and does not therefore provide useful evidence on this point." Medical Research Council December 2001.

2. Strength of the association.
The association should be strong in the magnitude of the association (in an epidemiological sense), and in the dose-response relationship of the vaccine with the adverse effect.
JABS has been contacted by thousands of families who believe their children have suffered severe damage or died following the MMR/MR vaccination. In the main, doctors cannot give any other medical explanation for the child's deterioration or death. It must be remembered that many of the children have

been given the now withdrawn Urabe containing MMR vaccines which were known to cause inflammation of the brain. Furthermore, many of JABS children shared the same batches of MMR vaccine and subsequently suffered the same long term effects.

3. Specificity.

The association should be distinctive and the adverse event should be linked uniquely or specifically with the vaccine concerned, rather than its occurring frequently, spontaneously or commonly in association with other external stimuli or conditions. The three viruses, measles, mumps and rubella, are known to be linked with the children's conditions in their wild state. The vaccines contain the live viruses.

4. Temporal relation.

There should be a clear temporal relationship between the vaccine and the adverse event, in that receipt of the vaccine should precede the earliest manifestation of the event or a clear exacerbation of an ongoing condition. For example, an anaphylactic reaction seconds or minutes following immunization would be strongly suggestive of causality; such a reaction several weeks after vaccination would be less plausible evidence of a causal relation. A substantial proportion of the children had an immediate reaction to the vaccination, and the change which came over them dates directly from that reaction.

5. Biological plausibility.

The association should be coherent; that is, plausible and explicable biologically according to known facts in the natural history and biology of the disease. The viruses are known to be linked with the health problems when caught as the wild diseases. The vaccine manufacturers' acknowledge this by recording these problems as the 'rare' adverse events associated with their products. Many of the children have had a variety of medical tests and examinations to rule out other causes.

The WHO continues with:

a. The requirement for biological plausibility should not unduly influence negatively a consideration of causality. Biological plausibility is a less robust criterion than the others described. If an adverse event does not fit into known facts and the preconceived understanding of the adverse event or the vaccine under consideration, it clearly does not necessarily follow that new or hitherto unexpected events are improbable. Biological plausibility is most helpful when it is positive; it is less so when negative.
This is an important statement as it makes it quite clear that just because something has not been recognized as linked with the vaccine in the past doesn't mean it isn't linked. This supports our concern that with the failure of the post-vaccination adverse event surveillance system to collect data on unexpected reactions and therefore a failure to investigate them could be allowing a serious problem to go undetected. This could lead to a catch 22 system; because the problem hasn't been linked with MMR vaccine before, further reports of the same problem are not put forward because they are not known to be linked with the MMR vaccine.

b. Consideration of whether the vaccine is serving as a trigger (trigger in this context is an agent that causes an event to happen which would have happened some time later anyway). When acting as a trigger, the vaccine may expose an underlying or pre-existing condition or illness. An example of the latter would be an auto-immune condition triggered non-specifically by the immune stimulus of the vaccine.
This is an interesting point. Many of the parents report that their child's health problems are not known in the family's medical history but they have been told by their medical practitioner that the vaccine acted as a trigger to reveal the underlying condition. What is particularly worrying is that the child usually has more than one, supposedly, rare condition that started at the same time e.g.

autism and bowel problems, epilepsy and loss of speech and communication and a failure to move on mentally from the point of vaccination. Some children developed health problems when vaccinated at four years of age or ten years of age or sixteen years of age after many years of good health and development progress.

c. In the case of live attenuated vaccines, if the adverse event may be attributable to the pathogenicity of the attenuated vaccine microorganism and thus not be distinguishable (except, perhaps, in severity) from the disease against which the vaccine is being administered, a causal connection is more plausible. Identification of the vaccine organism in diseased
tissue and/or in the body fluids of the patient in such a situation would add weight to causality. There are exceptions to both these above points. Measles virus has been found in the spinal fluid - and therefore the brain - in three of the six children at the centre of the huge UK high court battle over the safety of the vaccine. It has also been found in 18 children in the United States who developed autism after receiving MMR.

Financial cost:

Letter submitted to the Lancet (Spring 2004) by David Thrower
Sir,
AUTISM
As one of the parents who, through enforced circumstance, has become involved in the controversy surrounding the causes and consequences of autism, I wish to respond to your commentary (1).
As you imply, the 2002 UK autism research funding of $2.75m was lamentably inadequate, and should be set against the very considerable economic costs of autism. It has previously been estimated that just one severe case of autism will cost the community up to £3m over that person's lifetime. The degree of severity and consequent precise costings could be debated at length. Costs include special needs education, home-to-school

taxiing, escorts, daily respite care, overnight respite breaks, transport, health care, attendance and disability allowances, carer's allowance, and loss of tax revenues from the parent who has to cease work to become the child's carer. From age 16, you can add-on independent living fund payments and incapacity benefit. From age 19, schooling costs cease, but most of the other costs continue for life, and you also have to add in the lost tax revenue from the autistic person. In these circumstances, the estimate of £3m for the costs of a severe case of autism may well be an underestimate. But let us stay with £3m, for the sake of simplicity. So the 2002 autism research grant, for the UK, was actually less than the lifetime cost of just one severe case of autism. And then you can try to estimate the numbers of UK cases. The recent unsuccessful UK High Court action alone involved 1,300 families. There have been many attempts at trying to gauge the numbers of UK autism cases. But hard State-collected data from the US Individuals With Disabilities Education Act database points to there being 120,000 children and young people ages 6-21 in full time education in the US with a primary diagnosis of autism, so a pro-rata application of those figures to the UK would give around 35,000 cases in the UK within that age-band. Obviously, not all cases are severe, but a reasonable estimate would be that an assumed 35,000 cases would cost the taxpayer somewhere between £35 billion and £100 billion over the next seven decades, or between £500m and £1.4 billion per annum. This of course, excludes any future cases that enter the autistic population over that time, plus the present existing small numbers of autistic adults. If autistic children continue to emerge at the rate now being recorded across the US, then the UK taxpayer could be facing an immense autism bill of several billion pounds per annum, within a couple of decades. On those terms, even your sought-after £12.5m for autism research therefore seems grossly inadequate to research a condition that is clearly already creating an economic burden, and one that seems set to increase. And these future autism costs will apply wholly irrespective of the current controversy about autism's actual detailed causes. The children already exist now, today, for whatever reason. The economic stakes over seeking

autism's causes are therefore extremely high.

I would also strongly support the efforts of Dr. Tom Jefferson in bringing adverse event surveillance out of the nineteenth century and into the twenty-first (2). But I would ask, how genuinely keen is our Department of Health, and government departments in other countries, to actively seek out every potential case of vaccine damage, and to analyse the data proactively?

There seems to have been a marked lack of enthusiasm to date. The Medicines & Healthcare Products Regulatory Agency's existing Yellow Card system has been admitted by its predecessor, the Medicines Control Agency, to record only 10%-15% of even serious adverse events, yet the Agency seems quite content to live with that. In other areas of life, it is very difficult to imagine (say) the Vehicle Inspectorate being content with such a poor system for vehicle inspections, so why is medicine's Yellow Card scheme's inadequacy tolerated so readily? Perhaps the Agency lacks the determination that parents of damaged children have to investigate adverse outcomes.

Finally, as you rightly point out, "the discovery of a possible link between bowel disease and autism is a serious scientific idea.....and one that deserves further investigation." The original Royal Free team paper was in February 1998. It is now Spring 2004. It is the continued abject failure to fund clinical research in this area, based upon the detailed examination of regressive-autism cases, that is the least acceptable aspect of the autism controversy, and I would welcome some candid explanation from the relevant authority, the Medical Research Council, as to what it has - or has not - been doing over the past six years.

David Thrower , Stockton Heath, Warrington, Cheshire WA4 2DZ

References:

(1) Commentary, The Lessons of MMR, Lancet, 2004, 363

(2) Jefferson T, Price D, Demicheli V et al. Unintended events following

immunisation with MMR: a systematic review. Vaccine 2003; 21: 3954-60 (PubMed)

Summary:

In our opinion the current Government has failed in its duty of care. At the meeting in 1997 the Health Minister should have instigated a scientific study of the children believed to have been damaged to discover why the children's lives changed so dramatically within such a short time of MMR/MR vaccine being given. Since that meeting the reports of MMR/MR damaged children to JABS has greatly increased.

The issue of safety surrounding the MMR vaccine has not yet been resolved. The Department of Health have relied on epidemiological studies as their basis for stating the vaccine is safe. These studies are not designed to collect data on 'rare' events.

The Department of Health has failed to adopt the precautionary principle. Until the question of MMR safety is resolved the option of single dose vaccines should be made available for parents who have lost confidence in the combined vaccine.

A question that must be asked of the present Health Minister is: if the drug companies have informed the Department of Health's doctors of the known vaccine problems and parents have informed the doctors that these problems are occurring. Why is the Department of Health denying the problems and ignoring the parents?

It could be argued that the vaccine manufacturers have a duty to provide compensation, as they have to in the United States by contributing to the US National Vaccine Injury Programme. The pharmaceutical industry profits from the supply of vaccines to the UK and also, ironically, from the victims because they produce the anti-convulsants, pain killers and other medical products these children need. At the moment however, in the UK, they do not contribute financially in any way to the vaccine damage payment scheme.

The UK Vaccine Damage Payment Act 1979 has gone some way to address the issue. Unfortunately, because the criteria are so strict most families cannot access justice for their children through this Government scheme and therefore it is relatively ineffective. Until a compensation programme similar to the US scheme is implemented in the UK, parents will seek redress through the courts and for this reason families need the support of legal aid to pursue justice. Legal aid should be re-instated.
Critics of the JABS group must think of this: If our members had been anti-vaccine lobbyists our children would not have been taken for vaccines and subsequently damaged. We are parents who put our faith in the UK healthcare system; our children have reacted usually in the time frame known to the manufacturer and, in the main, are living with long term problems also known to the manufacturer. We want the children to be recognised and compensated and clinically investigated to help develop a screening programme to improve vaccine safety.

JABS believes in a safe vaccination programme but the emphasis is on safe and reducing risk wherever possible.

Acknowledgements:
We are extremely grateful to:-
David Thrower for his input and to Parents who submitted the JABS questionnaire.

References:

Ref. 1:
MMR and Acquired Autism (Autistic Enterocolitis) - A Briefing Note by David Thrower March 2006
http://www.jabs.org.uk/pages/Autism_Review.pdf
Relevant Extracts:
93. Paper by Uhlmann, Sheils et al, Measles Virus In Reactive Lympho-Nodular Hyperplasia and Ileo-Colitis of Children, (publication date

not known), Department of Pathology, Coombe Womens' Hospital, Dublin, Trinity College Dublin and Royal Free Hospital London.
This paper noted that measles virus nucleoprotein (N antigen) had been detected in association with follicular dendritic cells (FDC) in patients, and sought molecular confirmation of this result. It found that:
* Solution phase RT PCR yielded specific MV N gene amplification in affected children (10/10).
* Distinct measles virus genome was identified in FDC reactive follicular centres by in-cell RNA amplification
* None of the normal controls showed any evidence of measles virus genome
* The data highlighted a possible causal link between measles virus infection and ileo-colonic lymphoid nodular hyperplasia in affected children
96. Paper Presented to US Congressional Oversight Committee on Autism and Immunisation, Professor John O'Leary, Dublin Womens Hospital, April 2000. This paper reported a study using biopsy material from children examined at the Royal Free in London. Dr. Wakefield at the Royal Free had posed three questions to the O'Leary team,
(1) was measles virus present in gut biopsies of affected children?
(2) where was measles virus located in the gut biopsies of the affected children?
(3) how much virus was present?
* The O'Leary team used in-situ hybridisation (with/without tyramide signal amplification), in-cell PCR, solution-phase PCR, TaqMan quantitative PCR and DNA sequencing to determine the answers to these questions.
* Using TaqMan PCR the team was able to quantify the measles virus copy number per 1,000 mucosal cells using gene dosage correction formulations. The copy number of measles virus in gut biopsies from children with autistic enterocolitis was low, at approx. 30-50 measles virus genomes per 2,000 mucosal cells (inc. Gut, epithelial, lymphoid and dendritic cells).
* Confirmation of the presence of measles virus genomes was achieved using positive and negative strand sequencing of cDNA measles amplicons.
* The results were that 24 out of 25 (96%) of the autistic children were

positive for measles virus, including 2 children from the USA who were included in this analysis:

* In the controls, only 1 of the 15 children (6.6%) was positive for measles virus.
* The study therefore localised, quantified and sequenced measles virus genomes in gut biopsies of children with autistic enterocolitis. The study team then posed the question, "how did it get there?".

97. Paper by Kawashima, Takayuki et al, Detection and Sequencing of Measles Virus from Peripheral Mononuclear Cells from Patients with Inflammatory Bowel Disease and Autism, Digestive Diseases & Sciences Vol. 45, No. 4, April 2000, pp723-729

Following reports that measles virus might be present in the intestines of children with Crohn's Disease, a new syndrome was reported in children with autism who exhibited developmental regression and gastrointestinal symptoms(autistic enterocolitis), in some cases after MMR vaccine, was reported

(see papers by Wakefield et al). It was not known whether the virus, if confirmed as present in these patients, derived from wild strain or vaccine strain.

This study carried out the detection of measles genomic RNA in peripheral mononuclear cells (PBMC) in 8 patients with CD, 3 patients with UC and 9 patients with autistic enterocolitis. As controls, the study used 8 cases of either healthy children or children with SSPE, SLE or HIV-1. The results were:

* 1/8 patients with CD, 1/3 with UC and 3/9 with autism were positive. Controls were all negative
*The sequences from patients with CD shared the characteristics with wild-strain virus.
*Sequences from patients with UC and children with autism were consistent with vaccine strain measles.
*These results were consistent with the exposure history of the patient.

This study is obviously particularly important because it points to infection with

vaccine-strain measles virus
Detection of Measles Virus Genomic RNA in Cerebrospinal Fluid of Children with Regressive Autism: a Report of Three Children J.J. Bradstreet, MD., J. El Dahr, MD; A.Anthony MB, PhD; J.J.Kartzinel, M.D; A.J.Wakefield, MD.

Ref. 2:
World Health Organisation
http://www.who.int/vaccine_safety/causality/en/
Causality assessment of adverse events following immunization

Since the inception of vaccination, it has been recognized that adverse events following immunization (AEFIs) will occur. The frequency of AEFIs is directly related to the number of vaccine doses administered. AEFIs can be causally related to the inherent properties of the vaccine, linked to errors in the administration, quality, storage and transport of the vaccine (programmatic errors), but it must be recognized that when large populations are vaccinated, some serious events that occur rarely with or without vaccination will be observed coincidentally following vaccination. Thus, investigating causality of AEFIs, particularly those that are most serious, is challenging.
The clearest and most reliable way to determine whether an adverse event is causally related to vaccination is by comparing rates of the event in a vaccinated and non-vaccinated group in a randomized clinical trial. Such trials, however, can never be large enough to assess very rare events, and postmarketing surveillance systems are required to identify events potentially related to vaccination. Postmarketing surveillance capability is improving; more countries now have AEFI monitoring systems, and more importance is attached to the reporting of suspected links between vaccination and adverse events. These systems have been successful in bringing to light serious AEFIs after vaccines have been marketed. A recent example is in tussusception after administration of reassortant rhesus rotavirus vaccine. Assessments of whether a given vaccine causes a

particular adverse
reaction vary from the casual observation to the carefully controlled study. The majority of individuals are not trained in interpreting such studies and are unlikely to understand the enormous difference in significance between these two extremes. Nonetheless, the public frequently forms a decision about a vaccines safety based on the information available to them is often a report based on unscientific observations or analyses that fail to stand the scrutiny of rigorous scientific investigation. Certain reports of AEFIs published in the medical literature over the past few years have resulted in controversy. The studies on which these reports are based, while generating provocative hypotheses, have generally not fulfilled the criteria that would be needed to be able to draw conclusions about vaccine safety with any degree of certainty. Yet these reports have had a major influence on public debate and opinion-making. When this debate spills over to the political arena, to policy-making and to determining the public acceptance of a vaccine by balancing the known benefits against possible but unverified risks, it is clear that a correct assessment of causality is vital. Submitting a study to a scientific process rather than to partially informed opinion is crucial in determining whether a vaccine actually causes a
given reaction. If undertaken carelessly or without scientific rigour, the study results will be inconclusive at best, may result in the inappropriate withdrawal of a valuable vaccine from use, or at worst may result in the exposure of a population to a dangerous vaccine. In 1999, WHO launched the Immunization Safety Priority Project to establish a comprehensive system to ensure the safety of all immunizations given in national immunization programmes. The development of mechanisms to respond promptly and effectively to vaccine safety concerns is a major area of focus of this project. As part of this effort, the Global Advisory Committee on Vaccine Safety (GACVS) was constituted by WHO in September 1999. The Committee's mandate is to enable WHO to respond promptly, efficiently and with scientific rigour to vaccine safety issues of potential global importance.
1. Consistency. The association of a purported adverse event with the

administration of a vaccine should be consistent, i.e. the findings should be replicable in different localities, by different investigators not unduly influencing one another, and by different methods of investigation, all leading to the same conclusion(s).

2. Strength of the association. The association should be strong in the magnitude of the association (in an epidemiological sense), and in the dose-response relationship of the vaccine with the adverse effect.

3. Specificity. The association should be distinctive ñ the adverse event should be linked uniquely or specifically with the vaccine concerned, rather than its occurring frequently, spontaneously or commonly in association with other external stimuli or conditions.

4. Temporal relation. There should be a clear temporal relationship between the vaccine and the adverse event, in that receipt of the vaccine should precede the earliest manifestation of the event or a clear exacerbation of an ongoing condition. For example, an anaphylactic reaction seconds or minutes following immunization would be strongly suggestive of causality; such a reaction several weeks after vaccination would be less plausible evidence of a causal relation.

5. Biological plausibility. The association should be coherent; that is, plausible and explicable biologically according to known facts in the natural history and biology of the disease.

Building on the seminal work on determining causality of the Surgeon General is Advisory Committee on Smoking and Health (1964),3 the generally established criteria underpinning vaccine adverse event causality assessment that the GACVS uses may be summarized as follows:

a. The requirement for biological plausibility should not unduly influence negatively a consideration of causality. Biological plausibility is a less robust criterion than the others described. If an adverse event does not fit into known facts and the preconceived understanding of the adverse event or the vaccine under consideration, it clearly does not necessarily follow that new or hitherto unexpected events are improbable. Biological plausibility is most helpful when it is positive; it is less so when

negative.
b. Consideration of whether the vaccine is serving as a trigger (trigger in this context is an agent that causes an event to happen which would have happened some time later anyway). When acting as a trigger, the vaccine may expose an underlying or pre-existing condition or illness. An example of the latter would be an auto-immune condition triggered non-specifically by the immune stimulus of the vaccine.
c. In the case of live attenuated vaccines, if the adverse event may be attributable to the pathogenicity of the attenuated vaccine microorganism and thus not be distinguishable (except, perhaps, in severity) from the disease against which the vaccine is being administered, a causal connection is more plausible. Identification of the vaccine organism in diseased tissue and/or in the body fluids of the patient in such a situation would add weight to causality. There are exceptions to both these above points.
Clearly, not all these criteria need to be present, and neither does each carry equal weight for a causal relationship between an adverse event and the vaccine to be determined. In addition to the general principles mentioned above, there are a number of provisos or considerations that need to be applied for determining causality in the special field of vaccine safety. They are:
1. Well-conducted human studies that demonstrate a clear association in a study design that is determined a priori for testing the hypothesis of such association. Such studies will normally be one of the following, in descending order of probability of achieving the objective of the study: randomized controlled clinical trials, cohort studies, and casecontrol studies and controlled case-series analyses. Case reports, however numerous and complete, do not fulfil the requirements for testing hypotheses, although on occasion such reports can be compelling if there are clear biological markers of the association, as is the case for vaccine-associated paralytic poliomyelitis.
2. An association that is demonstrated in more than one human study and

consistent among the studies. The studies would need to have been well conducted, by different investigators, in different populations, with results that are consistent, despite different study designs. Demonstrable association in the studies between dose and the purported adverse effect (either the dose or the number of doses administered, or both) will, in many cases, strengthen the causal association between the vaccine and the adverse event. This is not always the case, especially if there is an immunological relationship.

3. A strong similarity of the adverse event to the infection the vaccine is intended to prevent, and there is a non-random temporal relationship between administration and the adverse incident.

An association between vaccine administration and an adverse event is most likely to be considered strong when the evidence is based on:

It is important that there should be a strict definition of the adverse event in clinical, pathological and biochemical terms, as far as that is achievable. The frequency in the nonimmunized population of the adverse event should be substantially different from that in the immunized population in which the event is described, and there would not normally be obvious alternative reasons for its occurrence that are unrelated to immunization.

An adverse event may be caused by a vaccine adjuvant or excipient, rather than by the active component of the vaccine. In this case, it might spuriously influence the specificity of the association between vaccine and adverse event. As far as possible, safety issues should be clarified in premarketing controlled clinical studies, with attention being given in such studies to safety issues and their monitoring, although with extremely rare unexpected events, this may not be achievable because of the need for extremely large sample sizes to detect them.

When adverse events are attributable to a vaccine, it is important to determine whether there is a predisposed set of subjects (by age, population, genetic, immunological, environmental, ethnic, sociological or underlying disease conditions) for any particular reaction. Such

predisposition is most likely to be identified in case-controlled studies.
A systematic effort should always be made to exclude confounding programmatic errors and variability and aberrations in vaccine manufacture.
The latter quality issues are most likely to be revealed by careful attention to batch and lot testing.
Since observational studies are not randomized and since individuals who are ill are generally less likely to be immunized (but more likely to have an adverse outcome), epidemiological studies on vaccine safety need to pay special attention to contraindications as potentially confounding factors.
The consequences of this bias may be false-negative studies.
Ref. 3: > Serious adverse events after measles-mumps-rubella vaccination during a 14 year prospective follow up. Pediatr Infec. Dis J. 2000;19:1127_34
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