The vaccination policy and the Code of Practice of the Joint Committee on Vaccination and Immunisation (JCVI): are they at odds?

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Introduction

No pharmaceutical drug is devoid of risks from adverse reactions and vaccines are no exception. According to the world's leading drug regulatory authority, the US Food and Drug Administration (FDA), vaccines represent a special category of drugs in that they are generally given to healthy individuals and often to prevent a disease to which an individual may never be exposed [1]. This, according to the FDA, places extra emphasis on vaccine safety. Universally, regulatory authorities are responsible for ensuring that new vaccines go through proper scientific evaluation before they are approved. An equal responsibility rests on the medical profession to promote vaccinations but only with those vaccines whose safety and efficacy has been demonstrated to be statistically significant. Furthermore, vaccination is a medical intervention and as such, it should be carried out with the full consent of those who are being subjected to it. This necessitates an objective disclosure of the known or foreseeable risks and benefits and, where applicable, a description of alternative courses of treatment. In cases where children and infants are involved, full consent with regards to vaccination should be given by the parents.

Deliberately concealing information from the parents for the sole purpose of getting them to comply with an "official" vaccination schedule could thus be considered as a form of ethical violation or misconduct. Official documents obtained from the UK Department of Health (DH) and the Joint Committee on Vaccination and Immunisation (JCVI) reveal that the British health authorities have been engaging in such practice for the last 30 years, apparently for the sole purpose of protecting the national vaccination program.

Here I present the documentation which appears to show that the JCVI made continuous efforts to withhold critical data on severe adverse reactions and contraindications to vaccinations to both parents and health practitioners in order to reach overall vaccination rates which they deemed were necessary for "herd immunity", a concept which with regards to vaccination, and contrary to prevalent beliefs, does not rest on solid scientific evidence as will be explained. As a result of such vaccination policy promoted by the JCVI and the DH, many children have been vaccinated without their parents being disclosed the critical information about demonstrated risks of serious adverse reactions, one that the JCVI appeared to have been fully aware of. It would also appear that, by withholding this information, the JCVI/DH neglected the right of individuals to make an informed consent concerning vaccination. By doing so, the JCVI/DH may have violated not only International Guidelines for Medical Ethics (i.e., Helsinki Declaration and the International Code of Medical Ethics) [2] but also, their own Code of Practice (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_115363.pdf).

The transcripts of the JCVI meetings also show that some of the Committee members had extensive ties to pharmaceutical companies and that the JCVI frequently co-operated with vaccine manufacturers on strategies aimed at boosting vaccine uptake. Some of the meetings at which such controversial items were discussed were not intended to be publicly available, as the transcripts were only released later, through the Freedom of Information Act (FOI). These particular meetings are denoted in the transcripts as "commercial in confidence", and reveal a clear and disturbing lack of transparency, as some of the information was removed from the text (i.e., the names of the participants) prior to transcript release under the FOI section at the JCVI website (for example, JCVI CSM/DH (Committee on the Safety of Medicines/Department of Health) Joint Committee on Adverse Reactions Minutes 1986-1992; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306).

Assertions

In summary, the transcripts of the JCVI/DH meetings from the period from 1983 to 2010 appear to show that:

1) Instead of reacting appropriately by re-examining existing vaccination policies when safety concerns over specific vaccines were identified by their own investigations, the JCVI either a) took no action, b) skewed or selectively removed unfavourable safety data from public reports and c) made intensive efforts to reassure both the public and the authorities in the safety of respective vaccines;

2) Significantly restricted contraindication to vaccination criteria in order to increase vaccination rates despite outstanding and unresolved safety issues;

3) On multiple occasions requested from vaccine manufacturers to make specific amendments to their data sheets, when these were in conflict with JCVI's official advices on immunisations;

4) Persistently relied on methodologically dubious studies, while dismissing independent research, to promote vaccine policies;

5) Persistently and categorically downplayed safety concerns while over-inflating vaccine benefits;

6) Promoted and elaborated a plan for introducing new vaccines of questionable efficacy and safety into the routine paediatric schedule, on the assumption that the licenses would eventually be granted;

7) Actively discouraged research on vaccine safety issues;

8) Deliberately took advantage of parents' trust and lack of relevant knowledge on vaccinations in order to promote a scientifically unsupported immunisation program which could put certain children at risk of severe long-term neurological damage;

Notably, all of these actions appear to violate the JCVI's own Code of Practice (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_115363.pdf).

Evidence

I here provide the evidence in support of each of the above assertions. (Note: emphasis added throughout the text as underlined are by the author unless otherwise indicated)

1) Instead of reacting appropriately by re-examining existing vaccination policies when safety concerns over specific vaccines were identified by their own investigations, the JCVI either a) took no action, b) skewed or selectively removed unfavourable safety data from public reports and/or c) made intensive efforts to reassure both the public and the authorities in the safety of respective vaccines.

As early as 1981, the JCVI had substantial documentation which associated the measles vaccine with serious adverse reactions including death and long-term adverse neurological outcomes. At the JCVI meeting held on 9th April 1981 (http://www.dh.gov.uk/ab/DH_095169), in discussing a paper that summarised all the reports of adverse reactions to the CSM, the following was noted:

(5.b.) Adverse Reactions to measles vaccine

"All reports since 1970 of encephalitis, encephalopathy or sudden death shortly after vaccination had been reviewed; 60 patients were involved of whom 8 had died, 36 had made an apparent complete recovery and 16 were left with permanent sequelae. The high proportion of deaths and patients with sequelae was surprising in comparison with the findings of the NCES [National Childhood Encephalopathy Study]."(5.b. Adverse Reactions to measles vaccine)

By 1983, the JCVI appeared to have had more evidence that the measles vaccine could cause encephalitis associated with "severe handicap" in a subset of vulnerable children. At the JCVI meeting on 17th of June 1983 (http://www.dh.gov.uk/ab/JCVI/DH_120115), the Committee on Safety of Medicines (CSM) received 66 reports of suspected adverse reactions to measles vaccines over the period January 1982 to April 1983. According to the transcript of the meeting:

(7. Suspected adverse reactions to measles vaccine: recent reports to the CSM)

"These included three cases of encephalitis; on follow-up, two of these patients were left one year later with severe handicap and the third patient, after a year, appeared to be developmentally normal."

By the end of 1981 serious safety concerns have also been raised with regards to another routine paediatric vaccine, the whooping cough vaccine. At the meeting held on 3rd November 1981 (http://www.dh.gov.uk/ab/DH_095169) in section 5 on Whooping Cough:

(5.d. Comments on Professor Stewart's letter)

"Professor Gilliatt observed that in the Meade Panel Study one-third of children with brain damage were not admitted to hospital. In both the Meade and Dudgeon studies there were examples of children who had a fit soon after vaccination which was followed by a fit at a later time and then followed by cessation of development. It was very difficult to assess this as a random event."

Furthermore:

"The Chairman concluded that much was not known about the natural history of brain damage in the young."

In spite of this, three years later, at the meeting on 25th of April 1986 (http://www.dh.gov.uk/ab/DH_095169), the JCVI concluded their discussion on suspected adverse

reactions for the period 19th September 1985 to 15th of January 1986 with the following statement:

(11.4)

"The Committee agreed to a suggestion from the Chairman that in future it would accept reports on adverse reactions as "for information" only." [their emphasis added-quotation marks]

It is somewhat perplexing why the JCVI adopted what appears to be a rather passive approach to vaccine safety, in light of the severe adverse reactions that were reported at that meeting. These included cot deaths, convulsions and anaphylaxis (11.4).

The JCVI appeared to have had other solutions for dealing with vaccine safety concerns. In a "commercial in confidence" CSM/JCVI/Joint Sub-Committee on Adverse Reactions to Vaccination and Immunisation (ARVI) meeting on 7th February 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), in a discussion about a surveillance study on adverse reactions to two measles vaccines, the members noted that:

"...results showed that 70 per cent of children were well after receiving Attenuvax and 61 per cent after receiving Rimevax. If children with mild general reactions were added to those who were apparently well then the numbers associated with Attenuvax were 85 per cent and those with Rimevax 80 per cent." (7.1 PHLS [Public Health Laboratory Service] surveillance of adverse reactions to two measles vaccine (Rimevax and Attenuvax))

In other words, even skewing the data by adding cases of mild reactions to those who were "apparently" well, did far from producing a reassuring statistic in favour of the safety of the measles vaccines, as it still implied a rate of 15-20% of vaccine-associated serious adverse reactions (as opposed to 30-39% of mild-to-serious adverse reactions in total). After further discussion on this topic:

"...it was agreed there was now enough information to stop the study."

While at the same time, there appeared to be no incentive to reconsider the current immunisation policy, in fact, it seemed more reasonable to conclude that some of the suspected adverse reactions to measles vaccine:

"...were unlikely to be associated with the use of measles vaccine and were more likely to be temper tantrums." (7.2 Suspected adverse reactions to measles vaccine: a summary of recent reports to the CS, June 1983 to September 1985)

The summary of suspected adverse reactions to DTP vaccine administered alone or with oral polio (OPV) during the period 19th September 1985 to 15th January 1986, presented at the same "confidential" meeting (CSM/JCVI/Joint Sub-Committee ARVI, 7th February 1986) were more difficult to ascribe to "temper tantrums":

(9.(1))

"Ninety such adverse reactions have been registered. These included six patients with convulsions, one a patient with abnormal fever following vaccination and one patient with apparent cerebral irritability; in addition two cot deaths were reported. (i) Case No. 154043 A three-month old boy who after his first dose of Trivax AD and OPV on 17 September 1985 was found dead 18 hours after immunisation....(ii) Case No. 154080 A three-month old girl who received her first dose of Trivax and OPV on the 19 September 1985 and was found dead on the night of 21/22 September 1985. No initial adverse reaction to vaccination was reported and the cause of death was stated as SIDS." [sudden infant death syndrome]

By mid to the late 1980s, the JCVI had become increasingly concerned about publicly associating the terms "death" and/or "brain damage" with the word "vaccine", because of the negative

repercussions they perceived this would have on vaccination policy (CSM/JCVI/Joint Sub-Committee ARVI meetings on 7th February 1986; 3rd October 1986; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306). Such concerns were also exacerbated by the increasing burden of litigations about pertussis vaccine-suspected injuries (JCVI meeting on 22nd April 1988; 20th October 1988; http://www.dh.gov.uk/ab/DH_095169), and the possibility that vaccination could be linked to some cases of SIDS, as evident from the Reports on Yellow Cards quoted above.

At the meeting on 22nd April 1988 (http://www.dh.gov.uk/ab/DH_095169), in an ongoing discussion about the Loveday v Renton litigation, the Chairman:

> "...reminded members that they had asked for a list of documents disclosed. JCVI (88)1 provided such a list, but it should not be made public. Dr Salisbury said that the Department's solicitors had advised that a part of the section on whooping cough in the revised Memorandum was in conflict with the judgement in the above-mentioned case. They had recommended that any statement on the risk of neurological reaction should avoid any estimate of the size of the risk of death or permanent brain damage. Dr Salisbury said that paragraph 3.4.1c of the section on whooping cough in the Memorandum had been modified accordingly and this modification was tabled. Professor Miller observed that the conclusion to be reached from the judgment of the Court and from the assessment of the scientific evidence of risk of neurological reactions and their consequences, were not necessarily the same. The legal judgement was that there is insufficient evidence, on the balance of probabilities that the vaccine causes permanent damage to allow any claim for damages to succeed. The JCVI was concerned with the implications of scientific assessment of the evidence for vaccine policy purposes. On this basis he was content to quote the figure for attributable risk of serious neurological illness without giving a figure for the risk of permanent damage, which was consistent with the conclusion of the NCES quoted in the Whooping Cough Report 1981."(Item 5, page 4 – Loveday v Renton)

The extent of the JCVI's concerns with the implications of scientific assessment of vaccine safety on vaccine policy explains why they were opposed to any long-term surveillance for severe neurological disorders following vaccination. In fact, as it will be shown below in greater detail, the CSM/JCVI/ARVI

considered such studies "unreasonable" and paradoxically, ARVI even "deprecated the use of the term 'brain damage'" (CSM/JCVI/Joint Sub-Committee ARVI meeting held on 7th February 1986; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306).

In 1989, 10 years prior to the "controversial" Lancet report by Wakefield et al. [3], the JCVI appeared to have been fully aware of the outcomes of the investigation carried out by the National Institute for Biological Standards and Control (NIBSC), which unequivocally established a link between the mumps component of the MMR vaccine (the Urabe-9 strain) and cases of vaccine-induced meningitis/encephalitis. In response to this, the JCVI appeared to have actively engaged in skewing and censoring data available to the public, continued to use the Urabe-9 containing MMR vaccines and made intensive efforts to reassure both the public and the authorities of the safety of all MMR vaccines.

According to the transcript of the JCVI meeting on 3rd November 1989 (http://www.dh.gov.uk/ab/DH_095169), the causal agent of vaccine-induced meningitis/encephalitis was unequivocally identified:

> **(9. ARVI Committee – Minutes of meeting 6 October 1989 (JCVI (89)25)**
>
> "Prof Collee expressed gratitude to the NIBSC for the progress it achieved in developing techniques to identify wild and vaccine virus strains. Dr Schild reported that NIBSC was now able to distinguish clearly the wild strains from each of the two vaccines, and isolates from CSF clearly showed Urabe in all three cases believed to be associated with vaccine-although it should not be assumed that Jeryl-Lynn is not capable of the same result. Professor Collee added that no mumps vaccine could be said to be void of risk. Dr Schild said NIBSC would be happy to continue analysing samples."

In the following meeting on 17th September 1990, the JCVI CSM/DH Joint Sub-Committee on Adverse Reactions (http://www.dh.gov.uk/ab/JCVI/DH_095294), on reviewing the adverse reactions to the MMR vaccine reported on Yellow Cards, applied the following criteria to the assessments:

(6.3.1.)

"Definite=Virus isolated from CSF [cerebrospinal fluid], time course of 14-28 days;

Possible/probable=Cells isolated from CSF, no virus in CSF, acceptable time course" [their emphasis added-underlined]

The transcript then states:

"It was noted that there were 10 definite cases of meningitis/encephalitis."

Both definite and probable cases were then discussed in some detail:

(6.3.4.)

"It was noted that the mumps viruses obtained from two out of three cases from Nottingham were sequenced and shown to be vaccine related. The patients had all been vaccinated from different batches and did not live close to each other."

At the 17th September 1990 meeting (http://www.dh.gov.uk/ab/JCVI/DH_095294), the JCVI CSM/DH Joint Sub-Committee on Adverse Reactions did recognize the need to do a follow-up analyses for long-term neurological outcomes in all cases of meningitis/encephalitis associated with the MMR vaccine. It was also recognized that the current avenues for adverse reactions reporting (via the Yellow Card, the British Paediatric Surveillance Unit (BPSU) scheme, directly to Communicable Disease Surveillance Centre (CDSC) and through Laboratory reports) were inadequate for detailed epidemiological evaluations. The JCVI CSM/DH Joint Sub-Committee then stated that:

(6.4)

"In order to further validate vaccine related illnesses, fuller studies would be required."

Despite these unresolved safety issues, the conclusion reached at the meeting was that:

(6.7)

"There should be no change in the present recommendations or supply of MMR vaccine on the evidence available to us at the present time."

Thus, instead of re-evaluating the vaccination policy, at least until safety concerns were fully evaluated, the JCVI choose to support the existing policy based on incomplete evidence that was available at that time.

Furthermore, at the 17th September 1990 meeting (http://www.dh.gov.uk/ab/JCVI/DH_095294), the JCVI appeared to have been fully aware of increasing numbers of cases of mumps vaccine-associated aseptic meningitis occurring in Japan, since at the time of the meeting, they had been presented with a draft of a study by Sugiura et al. [4]. The Japanese study found that among 630,157 recipients of the MMR vaccine containing the Urabe-9 mumps vaccine, there were at least 311 meningitis cases suspected to be vaccine-related. In 96 of these 311 cases, mumps virus related to the vaccine was isolated from the CSF. Sugiura et al. [4] noted that this was an unusually high incidence of vaccine-related adverse outcomes, which they had attributed in part to "adverse media publicity". Nonetheless, the fact that in almost one third of the cases, the vaccine strain had been isolated from the CSF of children, suggests that safety concerns over the MMR were warranted. Indeed, in 1993 the Japanese suspended the use of the MMR vaccines containing the Urabe strain due to it causing a high incidence of aseptic meningitis, and reverted to the use of monovalent measles, mumps and rubella vaccines. According to Japanese Health Authorities, the withdrawal of the MMR had not caused an increase in deaths from wild

measles infection. Noteworthy, in a BBC news report (http://news.bbc.co.uk/2/hi/asia-pacific/1808316.stm), a spokesperson for the Japan's Health Ministry stated that:

"...more children had died from the disease during the period when MMR was being used."

In reference to the Japanese study, the JCVI transcript specifically states:

(6.6)

"The paper confirmed information from Japan previously disclosed to ARVI."

This suggests that the JCVI knew for some time that the Urabe-9 vaccine was causing problems and yet, did not consider the possibility to temporarily suspend its use.

Furthermore, four months prior to the 17th September 1990 meeting, at the JCVI 4th May 1990 meeting (http://www.dh.gov.uk/ab/DH_095169), ARVI expressed concerns regarding the reports from Japan. The major reason for these concerns was not that the JCVI/ARVI were in favour of using the Urabe-9 vaccine which was now associated with increased risk of meningitis/encephalitis in children, but rather:

(9.1.)

"Professor Banatvala was concerned about the possibility of the Japanese experience being published widely in the UK, and urged the gathering of information on the various episodes from all MMR manufacturers."

ARVI also reached a rather surprising conclusion that:

"The Japanese experience may be due to different reporting/investigating criteria or other local factors."

However, if this were the case, "the Japanese experience" would have been an isolated event. That this was not the case can be clearly seen from further readings of the JCVI 4th May 1990 meeting transcript (http://www.dh.gov.uk/ab/DH_095169):

(9.3.a.)

"Dr Thores spoke to the letter, JCVI/90/10, from Dr McIntyre. He highlighted SHHD [Scottish Home and Health Department] concern about the Canadian decision not to use Urabe strain vaccine, the cases of neurological complications in Japan, the seeming bias of the UK adverse reactions towards Scotland, and the continued use of vaccine distribution figures as the denominator when calculating adverse reaction rates."

In spite of this, instead of re-evaluating or suspending the existing MMR vaccination policy due to safety concerns, the JCVI called for a specific and concentrated effort aimed at counteracting the growing public and health authorities' concern over the safety of the Urabe-9 MMR vaccines.

(9.3.c.)

"Professor Peckham told the Committee that she was aware of three districts changing from use of Urabe to Jeryl Lynn vaccine, and therefore the Committee needed to reassure authorities of the safety of all MMR vaccines."

Hence, it appears that the JCVI's solution to the growing problem regarding the MMR vaccine safety issues was to provide as little information as possible to health practitioners, in order to preserve the JCVI's vaccination policy. If this assumption is correct, does it suggest that the JCVI was more concerned about boosting vaccine uptake than child safety?

(9.3.e.)

"The Chairman asked the Committee if it thought necessary to draw up a statement about MMR."

(9.3.g.)

"Professor Hull suggested a simple sheet with ARVI's evaluation of the vaccines. This would let doctors know that an expert committee had looked at the situation and perhaps reassure them."

What appears to be a rather inadequate handling of the MMR safety concerns on behalf of the JCVI did not make the problem go away. Only a year later, at 1st November 1991 meeting (http://www.dh.gov.uk/ab/JCVI/DH_095050), unable to resolve the continuing MMR safety issues the JCVI turned to vaccine manufacturers for help:

(7.1 Report on MMR)

"On adverse reactions to the vaccine, the most worrying reports had been studies which showed problems with the Urabe vaccine, particularly Mumps Meningitis. Reports had also come from overseas countries, Canada being the most helpful….of 67 reported cases between October 1988 and August 1990, 38 children had definite or probable Aseptic Meningitis and one Encephalitis. Ten of these were definitely caused by the vaccine, and a further 29 were probably caused by the vaccine. Of these 39 children, 37 were followed up at 12 months. 33 (or 89%) were neuro-developmentally normal. Of the remaining four, two had neuro-developmental problems before being given MMR, one had behaviour problems and one had a cerebral astrocytoma. There had been eight reports of nerve deafness although one was pre-MMR; six needed further investigation. The over-all picture was that there were 3.7 cases per 100,000 doses of Urabe vaccine and no cases reported with the Jeryl Lynn vaccine. However, the MSD [Merck Sharp and Dohme] vaccine was generally not well accepted because of pain at the injection site. Urabe is the most reactogenic vaccine but some data suggested that it may also be the most immunogenic. It was impossible to make a firm decision about this until all information had been collected."

(Note: it ought to be asked why the UK health authorities thought it was appropriate to vaccinate children with neurodevelopmental problems and cerebral astrocytoma with a vaccine that had caused substantial worries to them over its association with adverse reactions affecting the brain).

(7.2 Discussions with Manufacturers)

"Dr Salisbury reported on his recent meetings with Merieux, MSD and SKB [Smithkline Beecham]. Information was shared and details of adverse events discussed. The manufacturers felt that the Department's line-that is, surveying adverse events and checking immunogenicity-was correct."

Again, the JCVI appeared to have adopted a passive approach to the problem and made no apparent efforts to identify specific sub-groups of children who may have been more prone to adverse reactions to the MMR. At the meeting that followed on 1st May 1992 (http://www.dh.gov.uk/ab/JCVI/DH_095050), the same conclusions were reiterated in light of the continuing MMR crisis, with an additional concern that the actual number of vaccine-associated aseptic meningitis cases might have been higher, due to suspected underreporting:

(7.4 Report of North Herts Immunogenicity Study (Dr Elizabeth Miller))

"The report of a cluster of CSF mumps virus positive cases in Nottingham had caused concern that national surveillance may have been underreporting the incidence of cases; a meeting had been held to discuss the Nottingham situation and the national data....In Nottingham all children with febrile convulsions were lumbar punctured, unlike some other areas from where reports had been received (Preston and Ashford) .The Committee agreed that no conclusion could be reached until the full immunogenicity results were available as well as the full analysis of the Nottingham and other data."

In the meantime, no changes were made to the immunisation policies. Would a seemingly passive approach to child health and safety, suggest that the JCVI in essence agreed to the fact that during the surveillance for the purposes of "for information only", some cases of

> suspected vaccine-induced convulsions, meningitis/encephalitis and deaths in children would just have to be tolerated?

Note also that for using the same technique of lumbar puncture, 18 years later, Dr Andrew Wakefield who investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder which appeared to have been linked to MMR vaccination, was charged and found unfit to practice medicine by the UK General Medical Council (GMC). According to the GMC hearing, lumbar puncture in children with MMR-suspected adverse neurological outcome was apparently "not clinically indicated" (http://www.gmc-uk.org/static/documents/content/Wakefield__Smith_Murch.pdf).

In July 1992, the data from Nottingham became available, nonetheless, it took another two months before the JCVI and the DH finally decided to take action, apparently not so much because of safety concerns but more so because of the legal advice given to the manufacturers by their lawyers in response to which the manufacturers decided to stop producing the Urabe-9 containing MMR vaccines. According to the transcript of the JCVI meeting on 6th November 1992 (http://www.dh.gov.uk/ab/JCVI/DH_095050):

> **(8.1 Report to Sub-Committee on SEAR/CSM: Dr David Salisbury)**
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> "In August, Department of Health officials met with MCA [Medicines Control Agency] and the manufacturers. At the end of August SKB, acting on the advice of their lawyers, decided to stop producing vaccine and advise licensing authorities world wide accordingly; the Department had, therefore, to act quickly."

Thus, only when the alarm was sounded by the manufacturers' lawyers did the DH sense that the matters regarding the safety of the MMR vaccine required some urgency. In addition, it appears that the principal preoccupation of the European Authorities was how to preserve global vaccine policies in face of the Urabe-9 scandal.

> "On the 3 and 4 September the Chief Medical Officers of European Community countries were advised in confidence of the situation at a routine meeting. ARGOS/SEAR [Sub-Committee on Safety, Efficiency (SEAR) and the Adverse Reaction Group of SEAR (ARGOS)] agreed on 4 September that no action would be taken to revoke the manufacturer's license as a change of purchasing policy was to be made by the Department; revoking the license would have caused a world-wide vaccine crisis."

The actual rate of aseptic meningitis after the MMR vaccination was discussed later on the JCVI 6th November 1992 meeting agenda (http://www.dh.gov.uk/ab/JCVI/DH_095050):

> **(8.7 Risk of aseptic meningitis after MMR vaccination in UK children: Dr Elizabeth Miller)**
>
> "The overall risk of this complication in the UK was 1 per 10,000 immunised children but, in Nottingham, this had increased to 1 in 4,000. Tests in Canada in 1989 had associated the Urabe vaccine with meningitis. The linking of laboratory records of CSE samples with district computer databases on immunisation had been very effective. The Committee was told that all the countries which had had a choice had switched from the Urabe to Jeryl Lynn;"

What is rather astonishing is that the four-year old Canadian concerns over the safety profile of the MMR vaccine (which had been confirmed in 1989), were apparently ignored by the JCVI or at least, not given much credence. While the Canadian Health Authorities suspended the use of the Urabe-9 MMR in 1988, the UK introduced it along with a vigorous promotional campaign. In a confidential meeting of the JCVI Working Party on the introduction of measles, mumps, rubella (MMR) vaccine on 11th February 1988 (http://www.dh.gov.uk/ab/JCVI/DH_095297):

> **(5. MMR vaccination in Canada)**
>
> "Members read a report of cases of mumps encephalitis which had been associated with MMR vaccine containing the URABE strain of the mumps virus. The Canadian authorities had suspended the licences of MMR vaccines containing the URABE strain, but Dr Salisbury considered that the data on which the decision had been based was slender."

The JCVI also had a specific plan to combat any adverse publicity in case any of this "confidential" information was to reach the public:

> "A statement would be prepared in anticipation of any adverse publicity which might arise."
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> **(7. Publicity)**
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> "A paper prepared by the MMR Publicity Group was presented, by Mr Flaherty and Mr Reid, for the Group to discuss and to approve the general approach it contained. Dr Ross considered that the priority was to get the message across to doctors, health visitors and nurses."

Finally, the JCVI also had a number of funding strategies in place to promote the introduction of the MMR:

> **(9. Funding situation)**
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> "£800,000 had been set aside for publicity and £1.4 million had been set aside to cover the period October 1988 - March 1989 to assist health authorities with increased vaccine costs, the education of professionals and for the re-programming of child computers. Members noted that the Statement of Fees and Allowances would need altering to include item of service payment for MMR."

This latter strategy was further refined on the JCVI Working Party on the introduction of MMR vaccine following meeting, on 17th May 1988 (http://www.dh.gov.uk/ab/JCVI/DH_095297):

> **(3. Matters Arising)**
>
> "Dr McGuiness suggested that instead of an item of service payment GPs might be paid according to their immunization rates."

In spite of carefully elaborated advertising and substantial investments, the JCVI did not entirely succeed in countering public concerns over vaccine safety, as on 6th October 1989 (http://www.dh.gov.uk/ab/JCVI/DH_095294):

> **(5.2.6)**
>
> "The meeting's further sadness was expressed over the press reports, which could have harmful implications and unnecessarily damage public confidence in vaccines."

Regrettably, similar sadness was apparently not expressed by the JCVI members over a report of a vaccine-suspected death of a 16 month old child, which was discussed at the same meeting. Rather:

> **(5.2.4)**
>
> "This was a fiscal case and as such was highly confidential. Doubts were expressed about the cause of death, and while it was not possible to give clear judgement, it was felt that there was unlikely to have been a causal relationship with the vaccine and that this was an unusual case."

Science should be based on facts and experimental evidence, not feelings.

As for the alleged "slender" Canadian data on safety hazards of the SKF (Smith Kline and French) Urabe MMR vaccine, in a confidential JCVI CSM/DH Joint Sub-committee on Adverse Reactions meeting on 7th March 1990 (http://www.dh.gov.uk/ab/JCVI/DH_095294) the following was disclosed:

> (6. Adverse reactions to MMR vaccine)
>
> "In Canada, the MSD vaccine had been used exclusively [Jeryl Lynn strain-containing MMR]. Following the introduction of SKF product, the cases of meningoencephalitis had been

> reported. When distribution of the SKF vaccine was halted, no further cases of meningoencephalitis were reported."

Yet, from this clear evidence, the JCVI derived a conclusion that somewhat seems to defy logic:

> "It was suggested that, due to different reaction criteria and methods of data collection, reporting in different countries should not be compared."

In summary, the JCVI endorsed and promoted a policy of vaccinating every child in the UK with the Urabe-9 MMR vaccine, in spite of the evidence that this would have caused a greater risk of encephalitis in children, when compared to the alternative Jeryl Lynn version of the MMR. It was only under pressure from a potential legal action that the JCVI and DH decided that it was due time "to act quickly" and withdraw the Urabe MMR from use in routine vaccinations.

2) Significantly restricted contraindication to vaccination criteria in order to increase vaccination rates despite outstanding and unresolved safety issues.

> Already in the early 1980s, the public confidence in the safety of the whooping cough (pertussis) vaccine has been eroded and since the uptake of the vaccine was relatively low, the JCVI sought ways to improve immunisation rates. According to Sir Charles Stuart-Harris, at the JCVI meeting on 3rd November 1981 (http://www.dh.gov.uk/ab/DH_095169) in section 5 on Whooping Cough:
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> **(5.c. Whooping Cough Vaccination Campaign)**
>
> "...a 40% uptake of the vaccine ensured continuance of the disease; the uptake rate had to be improved."

The transcripts of the JCVI meetings from 1981 to 1986 indicate that the Committee did not know what was the risk/benefit balance of whooping cough vaccination in children who were potentially more at risk of vaccine associated-adverse outcomes. In spite of this, the JCVI went on with restricting contraindication criteria so that more children could be vaccinated. The JCVI also seemed to have been more preoccupied with protecting the "reputation of the vaccine" rather than protecting potentially vulnerable individuals, as the former served a basis for defining certain contraindication criteria.

> In 1981, a Working Group on Contra-indications to Whooping Cough Vaccination had been set up because ARVI, which had been asked by the JCVI to consider contraindication to whooping cough vaccine, had not been able to reach an appropriate agreement on this issue. At a beginning of the meeting of this Working Group on 1st May 1981 (http://www.dh.gov.uk/ab/JCVI/DH_120115), it was noted that:
>
> "It was extremely important that the present meeting should reach an agreed conclusion because the reports on whooping cough were to be published on the 12 May, and it was desirable for any new contra-indications to be ready as soon as possible after this date."
>
> and:
>
> "When considering the question of contraindications, the general principle to be borne in mind was that the right balance had to be struck between the need to keep acceptance rates for vaccination as high as possible and the need to protect groups of children who had an increased risk of adverse reaction to vaccination."
>
> Assuming that the whooping cough vaccine is effective in preventing whooping cough, this principle indeed appears to be sound. Curiously however, one of the first items to be discussed under this agenda was that of respiratory illnesses and whether these should be regarded as a contraindication to whooping cough vaccination. Some members thought that respiratory illnesses ought to be deleted from the list of contraindications. Others however:

"...thought that the reference to respiratory disease was not really a contra-indication; rather it was a move to protect the reputation of whooping cough vaccination by avoiding an association between vaccination and SIDS."

Since apparently:

"Respiratory illness was often associated with SIDS, and therefore the reference to respiratory disease was a wise precaution to prevent SIDS and whooping cough vaccination being associated."

Next:

"Professor Miller stressed the need to maintain public confidence in the vaccine and said there was a need to prevent children with epilepsy being vaccinated in order to avoid an apparent association between vaccination and fits."

In addition:

"The Chairman asked members to consider "History of seizures, convulsions, or cerebral irritation in the neonatal period". Professor Hull said that this contra-indication would include children with disguised brain damage; this was good for the reputation of the vaccine in that it prevented an apparent association between vaccination and the discovery of brain damage."

It is somewhat perplexing why in discussing contraindication to whooping cough vaccination, the Working Group members entrusted with an "extremely important" task to reach a prompt agreement on this issue, appeared to have been more concerned about the reputation of the whooping cough vaccine, rather than the risk/benefit balance of whooping cough vaccination in children who were potentially more at risk of vaccine associated-adverse outcomes, especially since:

"It was agreed that the risk/benefit balance in this group of children was not known."

Nonetheless, Dr Griffiths in referring to a paper from the US, in which children with a history of convulsions were immunised against whooping cough and then followed up noted that:

"...this data did show a slightly increased risk of convulsions following vaccination in children with a previous history of convulsions."

In the ensuing discussion, members also considered whether a family history of epilepsy or other diseases of the central nervous system should be regarded as a contraindication to whooping cough vaccination and:

"There was general agreement that including other diseases of the central nervous system was unnecessarily restrictive, and that this particular contra-indication should be deleted."

Whether such contraindications were indeed "unnecessarily restrictive" and whether the need to rush an agreement on this issue was justified in the light of the data available at that time, remains questionable following the observations made by Professor Gilliatt at the subsequent meeting held on 3rd November 1981 (http://www.dh.gov.uk/ab/DH_095169):

(5.d. Comments on Professor Stewart's letter)

"In both the Meade and Dudgeon studies there were examples of children who had a fit soon after vaccination which was followed by a fit at a later time and then followed by cessation of development. It was very difficult to assess this as a random event...The Chairman concluded that much was not known about the natural history of brain damage in the young."

On 30th January 1986 at the Joint Working Party of the British Paediatric Association (BPA) and the JCVI Liaison group meeting (http://www.dh.gov.uk/ab/JCVI/DH_120115), concerns

were expressed over the low rates of whooping cough vaccination due to contraindications which may have exempted children who had a family history of seizures. In discussing cases in whom whooping cough vaccination is not absolutely contraindicated but who require special consideration as to its advisability (item 4.8):

"Professor Gillliatt said that there had been a paper published recently in America, History of convulsions and the use of pertussis vaccine. Harrison C Stetler et al. Journal of Pediatrics 1985; vol 107; pages 175-179

which indicated that there was a quite high incidence of a family history of convulsions among the first degree relatives of children who had febrile convulsions. Members observed that changing this recommendation might decrease the number of children available for vaccination against whooping cough."

By November 1986, the JCVI had a quite remarkable solution to deal with the "problem" of reduced uptake of the pertussis vaccine: the suggestion was to alter the advice on contraindication criteria.

According to the transcript of the 7th November 1986 JCVI meeting (section 3.5.2a; http://www.dh.gov.uk/ab/DH_095169), the groups of children in whom the advisability of Whooping Cough vaccination required special consideration included:

i) Children with a documented history of cerebral damage in the neonatal period.

ii) Children with a personal history of convulsions.

iii) Children whose parents or siblings have a history of idiopathic epilepsy.

iv) Children with developmental delay thought to be due to a neurological defect.

v) Children with neurological disease.

It is further noted in the same transcript that:

"There was considerable discussion on 3.5.2(a)"

the details of which had not been given but:

"it was finally agreed that for (iii), it should be stressed that the risk was very slight and that (iv) and (v) should be combined under "children with neurological conditions which are stable" and "not a contraindication", ie in 3.5.4." [their emphasis added-underlined]

Based on no apparent scientific evidence the JCVI claimed that neurodevelopmental delays or neurological disorders were in fact stable conditions and as such, unlikely to be exacerbated by vaccinations. It would appear that the sole purpose of this potentially misleading claim was to reassure parents, who otherwise might have been deterred from vaccinating their child against pertussis, of the safety of pertussis vaccination. The same would apply to the JCVI statement regarding the alleged "very slight" risk of adverse reactions in children with family history of idiopathic epilepsy.

One has to wonder whether the notes of the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting on 3rd October 1986, later obtained through FOI (which discussed among other "not be disclosed" items, suspected adverse reactions to DTP vaccines given alone or with OPV; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), would have had the same "reassuring" effect on parents had they been made publicly available at that time, or promoted with the same vigour as the vaccination campaigns:

"During the current period [13th May 1986 to the 11th September 1986] 95 suspected adverse reactions were reported. These included:

*i)*Death 151828. A 16 month old girl who two days after her first dose of DTP in mid-July 1985 was found to have a fever and a possible respiratory tract infection. Two days later

> she had a major fit and was admitted to hospital where further convulsions occurred. Further fits occurred at the end of July 1985 and she died on the 1st of August probably from pneumococcal septicaemia. This patient had a family history of idiopathic epilepsy." This case has been reported to previous meetings of ARVI.
>
> *ii)*There were 8 reports of convulsions following vaccination including 165236, a patient who was in status epilepticus within hours of receiving her third dose of triple vaccine." (7. Summary of Suspected Adverse Reactions to Vaccines, a.)

It should be noted that the adverse reactions from OPV alone were no less severe and in fact more easily specifically attributed to the polio vaccine:

> "A six month old girl who developed recipient vaccine-associated poliomyelitis 30 days after receiving her first dose of oral polio vaccine." (7. Summary of Suspected Adverse Reactions to Vaccines, c.)

At the same meeting, the CSM/JCVI/Joint Sub-Committee ARVI discussed the results of a National Childhood Encephalopathy Study (NCES) as these were the subject of court proceedings on pertussis vaccine-related injury that were ongoing at that time:

> **(5.1.1.)**
>
> "The working party had established that the final number of cases in the NCES was 1,167. 39 cases had received triple vaccine in the week prior to the onset of their neurological illness (9 with infantile spasms, 18 with convulsions, and 12 with encephalopathies). These vaccine-associated cases included 5 patients (4 with convulsions and 1 with infantile spasms) who had a history of neurological events before immunisation which indicates possible prior abnormality."

Again, one has to wonder whether these five patients also fitted in the JCVI's criteria of "stable" neurological conditions. The apparently lenient attitude with regards to vaccine safety on behalf of the JCVI is perplexing, particularly in light of their admission which followed the brief discussion about the significance of the NCES findings the CSM/JCVI/Joint Sub-Committee ARVI:

> **(5.1.3.c.)**
>
> "From the above there is reason to believe that the increased relative risk of prolonged convulsions after DTP was a real one."

Is this supposed to be a reassuring statement for all those children with prior family history of epilepsy or those suffering from "stable" neurological disorders, who as a result of the JCVI's decision to shrink the contraindication criteria, no longer had a choice to opt out from pertussis vaccination? In further "reassurance", the following was noted in the transcript of the CSM/JCVI/ Joint Sub-Committee ARVI meeting on 3rd October 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

> **(5.1.5.)**
>
> "Queries had been raised with regard to long-term sequelae after vaccine-associated encephalopathy...Among 12 children with encephalopathy there were 2 deaths, and 5 children with impairment of varying severity at 1 year. The relative risk for an acute vaccine-associated illness (convulsions or encephalopathy) was 3.3, and was similar irrespective of degree of impairment."

Thus, according to the JCVI's own admission, not only was the risk of DTP-associated neurological complications a real one, it also appeared to be a relatively high risk.

A somewhat lenient approach to contraindication criteria was also used with vaccines other than DTP in order to boost vaccination rates.

> **(12. BPA/JCVI Working Group)**

"In the matter of alleged egg allergy and measles vaccine, it was noted that although it was possible to amend the advice contained in the Memorandum 'Immunisation against Infectious Disease', it was also desirable to encourage manufacturers to change the advice in their data sheets." (Meeting on 25 April 1986; http://www.dh.gov.uk/ab/DH_095169)

In other words, the JCVI appeared to be rather unwilling to change their own advice in the Memorandum and instead suggested that manufacturers should be "encouraged" to do so. The following Section (3) indicates that the JCVI elaborated a very simple solution for boosting vaccine uptake in face of impediments posed by contraindication criteria: restrict the contraindication criteria, rewrite information in the Memorandum and ask the pharmaceutical companies to change their data sheets as to "avoid confusion" and possible legal action.

3) On multiple occasions requested from vaccine manufacturers to make specific amendments to their data sheets, when these were in conflict with the JCVI's official advice on immunisations.

That boosting vaccine uptake appeared to be the major force driving the JCVI's decision process, can be inferred from their request to the manufacturer of the MMR vaccine Merieux to modify the data sheet information related to contraindication to adverse effects, at the 1st May 1987 meeting (http://www.dh.gov.uk/ab/DH_095169). Apparently, it was not sufficient to amend existing information on immunisation in their Memorandum to Infectious Diseases, it was also necessary to make that information concordant with the advices stated on manufacturer's data sheets:

(7.2 Report of the meeting of the Working Party held on 25 February 1987)

"It was also noted that the data sheet for the Merieux MMR vaccine contra-indicated the use of the vaccine in children with a past or family history of convulsions. Medicines Division would be asked to approach Merieux to ascertain whether they would be willing to adopt appropriate modification to this data sheet."

At a later meeting on 23rd October 1987 (http://www.dh.gov.uk/ab/DH_095169), the JCVI also pressed for a change in the pertussis vaccine licensing details from the manufacturers, in spite of a pertussis vaccine-suspected injury litigation that was ongoing at that time. The Chairman of the JCVI approached the Association of British Pharmaceutical Industries to resolve this issue. The notes on this meeting state that:

(15.2)

"The meeting considered revised contra-indications to pertussis vaccine in parallel with those at present published; ARVI was aware of the potential difficulties in relaxing the contra-indications to pertussis vaccine and suggested that the papers be sent to the CSM and also to the manufacturers. The latter, in a written response, replied that it was not possible at present to change the product license details whilst litigation was in progress."

The "potential difficulties" that ARVI was concerned about were related to the ongoing pertussis litigation (this becomes more evident from the notes of a confidential meeting on 6th July 1987 cited further below). Unable to get the manufacturers to comply with their request, the JCVI turned to the Solicitors Branch in the Department of Health and Social Security (DHSS), to seek advice over:

"...the difficulty of reconciling revised contra-indications to pertussis vaccine with advice issued by the manufacturers."(18. Meeting of the Chairman of the JCVI and the Association of British Pharmaceutical Industries; JCVI meeting 23rd October 1987; http://www.dh.gov.uk/ab/DH_095169)

The advice from the Solicitors was that:

"...such a discrepancy was not a problem for the JCVI whose function was to give advice to medical profession in the light of the best available knowledge."(19. Memorandum "Immunisation Against Infectious Disease; JCVI meeting 23rd October 1987; http://www.dh.gov.uk/ab/DH_095169)

Notably, the "difficulty of reconciling revised contra-indications to pertussis vaccine" had been previously discussed by the CSM/JCVI/Joint Sub-Committee ARVI, on 6th July 1987, in yet another meeting that was noted as "commercial" and "in confidence".

According to this transcript which has been obtained through FOI (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

"The Chairman reminded members that the proceedings, papers, and information before them were confidential and should not be disclosed."

The same transcript also reveals the reason why the JCVI made great efforts to obtain the manufacturers' compliance to their request to amend the data sheets on the pertussis vaccine and why, failing that, they sought help from the DHSS Solicitors. It was not necessarily because their policy was ethically and scientifically sound, but possibly because they were anxious about potential legal repercussions.

(Note that the names of the participants have been redacted from the transcript prior to its release under the FOI section at the JCVI website, so that the comments made are un-attributable to particular members):

(6.4 JCVI's revised contra-indications to pertussis vaccine)

"The Chairman stated that JCVI had produced more permissive guidance on contra-indications to pertussis immunisation and that the revised contra-indications, shortly to appear in the next version of the Memorandum 'Immunisation against Infectious Disease' would not conform with the manufacturers data sheet. This might lead to confusion for general practitioners and other vaccinators and there might be legal problems. _____ commented that both the JCVI and the JCVI/BPA Working Party had tried to improve guidelines to give specific contra-indications but an attempt should be made to reconcile these with data sheets and product licenses. Delay in the new Memorandum might be worthwhile in order to obtain manufacturers agreement to changes in data sheets and also to give the BNF [British National Formulary] the opportunity to change its advice. _____ agreed with _____ and welcomed the clearer advice from JCVI on pertussis contraindications which he endorsed."

The discussion that followed seems to indicate that ARVI was indeed nervous about potential legal implications, as apparently, they tried to evade having any responsibility on this matter:

"_____ commented there was no need for JCVI advice to change but there should be awareness of the implications of change. _____ suggested a meeting with the manufacturers to discuss the changes in an attempt to seek common ground. _____ commented that it was not ARVI's responsibility to dismantle other groups instructions. _____ noted that ARVI had responsibilities to both JCVI and CSM and asked that pertussis section of the revised Memorandum should be submitted to the CSM for endorsement and then to the Licensing Authority to discuss with manufacturers so that the data sheets and the Memorandum would be compatible. _____ suggested that advice should be followed and that members should submit their comments in writing to the Chairman. _____ hoped that there could be informal discussion with the manufacturers of areas of agreement or debate and _____ noted that the new pertussis guidelines would be produced at a time of a continuing pertussis litigation._____ asked if there was likely to be a change in pertussis vaccine in the near future as this might promote difficulties if the contra-indications were also to change._____ agreed that the pertussis section should be sent to CSM...."

The following "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting held on 2nd October 1987 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), reveals how the CSM dealt with the burden of responsibility over the revised pertussis contraindications issue:

(6.4 JCVI's Revised Contra-indications to Pertussis Vaccine)

"_____reported that the discrepancy between JCVI recommendations and manufacturers product licenses had been discussed at CSM who had upheld JCVI's right to issue advice to the profession."

"_____reported that a meeting was shortly to be held with the Pharmaceutical Industry to find common ground on issues such as this. _____stated that DHSS Solicitors views of this discrepancy had been sought and had been advised that there was no obligation on JCVI's views to conform with the manufacturers product licenses when those views represented the advice of expert medical opinion."

We see here that unlike the manufacturers, the CSM had endorsed the proposed revisions of contraindications to pertussis vaccine and their view was held by the DHSS Solicitors as superior to that of the vaccine Licensing Authority. This indeed is the case, since in the UK licensing process when applying for a licence, the pharmaceutical company will first submit a file to the Medicines and Healthcare products Regulatory Agency (MHRA) and the CSM within the MHRA will then review the application and produce an independent assessment. Following that, the CSM will issue a recommendation to the Licensing Authority that a licence is granted (http://www.ukmi.nhs.uk/Med_info/licensing_process.pdf).

The CSM's competence as a body of medical experts and the reliability of their advice can be assessed from the notes of the preceding "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting, held on 6th July 1987 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

(6.1 Whooping cough)

"In conjunction with Tabled Paper 1 and an unnumbered agenda paper the Secretary summarised the present position regarding the Loveday litigation for the benefit of new members. He explained that in February the CSM had called for ARVI's advice about updating the statement made in the 1981 report on Whooping Cough (HMSO) about a possible link between DTP immunisation and serious neurological illness. It had been hoped that by this means 'discovery' of all the relevant JCVI, CSM and ARVI documentation on whooping cough vaccine could be avoided. However, by the time _____ could report a revised statement to CSM (see minutes of February 1987 meeting) it was already clear that nothing could be done to avoid 'discovery'. Subsequently, the Chairman of CSM asked ARVI to keep a watching brief on the situation, and to let the Main Committee know if at any time it was thought possible to modify further the statement."

The contents of the controversial statement that the CSM appeared to be eager to modify, in order to avoid potential legal consequences, have been disclosed to the JCVI/Joint Sub-Committee ARVI members on "commercial in confidence" meeting on 6th February 1987 obtained through FOI (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

The notes of that meeting in the section "7.1 Whooping cough vaccine –CSM advice" read:

"No scientifically unassailable link has been established between DTP immunisation and serious neurological illness but we have come to conclusion, on the basis of all present evidence, that there is a prima facie case that such a link may exist. We would also agree that the evidence suggests that the vaccine causes convulsions in some children."

Thus, the "best available knowledge" on which the CSM "upheld the JCVI's right to issue advice to the profession on restricting contraindication to pertussis vaccination can be summarized as follows:

Both the CSM and the JCVI/Joint Sub-Committee ARVI seemed to have been fully aware of the fact that the pertussis vaccine could cause convulsions and adverse serious neurological outcomes in a sub-set of children. Apparently, the CSM and the JCVI/Joint Sub-Committee ARVI have then attempted to avoid "'discovery' of all the relevant JCVI, CSM and ARVI documentation". Does this suggest that the top UK authorities responsible for sound vaccination policies were not as much concerned about putting certain children at risk of serious vaccine-induced neurological harm, as they were of legal repercussions that might have followed in the event that any of the "relevant" documents were to reach the public?

Finally, rather than being in line with public health interests, those responsible for the safety of medicines and sound vaccination practices appeared to have been more aligned with the interests of vaccine manufacturers. This is implied by the following discussion from the transcript of the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting held on 6th June 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), at which members of the US Centers for Disease Control (CDC) were also present. In discussing the significance of the NCES report on pertussis vaccine injury it was noted:

(6. Litigation and pertussis vaccination)

"6.1_____ referred to the June issue of the American Journal of Diseases of Childhood. He said that between 18 and 22 million doses of DPT were manufactured annually in the United States prior to the difficulties concerning whooping cough vaccine and litigation... Since 1985, the price of the vaccine has risen from 40 cents per dose to $ [unreadable] per dose in 1986 and it is expected to rise to $11 per dose. Litigation claims per year have risen from virtually nil in 1978/79 to over 219 in 1985, claiming [unreadable] billion US dollars, and litigation suits follow a similar pattern. The total amount claimed has likewise increased greatly."

"6.2_____said that out of court settlements had not been included in these figures. It was difficult to protect manufacturers against such heavy compensation claims. The situation had been aggravated by an organisation called 'Dissatisfied Parents Together'. The Hawkins Congressional Commission suggested that claimants might go into a system with a Panel and if accepted would be given an award of $1 million or alternatively accept court settlement. There was also a Bill before the American Government which suggested that punitive damage be done away with and that damages for pain and suffering only be awarded."

Over the subsequent years the trend of restricting contraindications criteria by the JCVI in order to increase vaccination rates continued. On 20th October 1988 (http://www.dh.gov.uk/ab/DH_095169):

(6.2 Health Education Authority (HEA) publications on MMR)

"Members pointed out that the Data Sheet for MMR vaccine suggested that it should not be given before the age of 15 months and also that the vaccine should be given subcutaneously (and not by deep subcutaneous or intramuscular injection as suggested in the Memorandum). The difficulties of changing the Data Sheets to agree with the advice in the Memorandum "Immunisation Against Infectious Disease" were discussed."

What also continued is the JCVI's confidential meetings with vaccine manufacturers, which appeared to be focused on vaccine policy and business rather than child health and safety. In reference to the meeting of the Chairman of the JCVI and the Association of British Pharmaceutical Industries, the transcript of the JCVI meeting on 23rd October 1987 (http://www.dh.gov.uk/ab/DH_095169) states:

"Also discussed was the availability of scarce vaccines and the introduction of new vaccines into more regular use. The question of financial support for training members of the health

service in immunisation was also discussed." (18. Meeting of the Chairman of the JCVI and the Association of British Pharmaceutical Industries)

It ought to be asked why the Chairman of the JCVI deemed as appropriate for members of health services to be financially supported by the vaccine manufacturers.

On further relations between the JCVI and vaccine manufacturers, the transcript of the JCVI meeting on 4th May 1990 (http://www.dh.gov.uk/ab/DH_095169) reveals that:

(2. iv.)

"The Chairman said that Departmental officials had recently met vaccine manufacturers who were keen to be informed, in confidence, of the outcome of JCVI discussions which might affect their own plans. Agreement was sought from the committee on the appropriateness of a summary of such discussions, cleared by the Chairman, being provided to manufacturers. The Committee agreed to this. In connection with this Professor Hull brought to the Committee's attention a recent letter he had received from a GP, the contents of which indicated, and the Chairman and committee agreed, a continuing communication problem on the relationship between JCVI advice and manufacturer's data sheets. Dr Salisbury said he was aware of this particular correspondence."

Incidentally, this is the same Professor Hull who, 8 years later, on 6th July 1998, was prompted to write to Professor Zuckerman at the Royal Free Hospital in London, to express his concern about the work of Dr Andrew Wakefield, who investigated the histories of 12 children with regressive autism and gastrointestinal symptoms that appeared to be linked to the MMR vaccine (http://www.circare.org/autism/hull_zuckerman_19980706.pdf).

In summary, by making persistent efforts in restricting vaccination contraindication criteria, so that more children could be vaccinated, the JCVI appeared to have prioritized vaccination policy over vaccine safety. In doing so, both the JCVI and the CSM (which actively supported the JCVI's amendments) may have shown a disregard for the safety of children. Furthermore, together with ARVI and the CSM, the JCVI attempted to avoid "'discovery' of all the relevant documentation" and thus perhaps evade potential legal repercussions. By seemingly siding with vaccine manufacturers rather than public health interests, the CSM/JCVI appear to have signally failed their fiduciary duty to protect individuals from vaccines of questionable safety and thus possibly shown incompetence in their role in the public health service.

4) Persistently relied on methodologically dubious studies, while dismissing independent research, to promote vaccine policies.

Over the years, the JCVI has consistently promoted the MMR vaccine as safe, based on studies that have proven to be either irrelevant, inconclusive, or methodologically questionable. There was also a marked tendency by the JCVI to rely on epidemiological work to support the MMR policy. For example, in a discussion of a population-based study by Fombonne and Chakrabarti [5], which found no link between the MMR vaccine and autism, at the JCVI meeting on 2nd November 2001 (http://www.dh.gov.uk/ab/JCVI/DH_095044):

(7.1)

"The Committee agreed that this data from Dr Fombonne was persuasive and indicated that the frequency of regressive autism appeared not to have increased."

The problem with epidemiological studies is that they only test for "association" and not "causation", thus providing unreliable estimates of true risks. Regarding the alleged safety of the MMR vaccine, the most comprehensive independent evaluation done on this subject, by the Cochrane Review (October 2005, http://www2.cochrane.org/reviews/en/ab004407.html), is hardly reassuring.

Although the Cochrane Review found no significant evidence of an involvement of the MMR with either autism or Crohn's disease, none of the 31 studies included in the review met the Cochrane Collaboration's methodological criteria.

In fact, one of the major conclusions from the Cochrane's 2005 MMR review was:

> "The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."

More specifically, referring to the 2001 Fombonne and Chakrabarti study which the JCVI regarded as "persuasive" in disproving the link between the MMR vaccine and autism, the Cochrane review made the following remark:

> "The number and possible impact of biases in this study was so high that interpretation of the results is impossible."

While historically, the JCVI tended to be quick in accepting those studies which dismissed safety concerns over the MMR or other vaccines, it was inert in accepting those which indicated that concerns were warranted. At the JCVI meeting on 1st November 2002 (http://www.dh.gov.uk/ab/JCVI/DH_095044), the members discussed recent scientific research on the MMR where:

> "The Committee was provided with recent research published on the safety of MMR, in particular the link with inflammatory bowel disease and autism. The following papers had undergone review by experts:
>
> 1. "Neuro-immunopathogenesis in Autism" V Singh. New Foundation of Biology 2001, 447-458.
>
> 2. Abnormal measles-mumps-rubella antibodies and CNS auto-immunity in children with autism. V Singh et al. Biomedical Science 2002; 9; 359-364
>
> 3. Small intestinal enteropathy with epithelial IgG and complement deposition in children with regressive autism. Torrente et al. Molecular Psychiatry 2002; 7(4);375-382
>
> 4. Development of an "allelic discrimination" type assay to differentiate between the strain origin of measles virus detected in intestinal tissue of children with ileocolonic lymphonodular hyperplasia and concomitant development disorder. O Sheils et al. Abstract presented at the Pathological Society of Great Britain and Ireland in July 2002.
>
> 5. Review article: the concept of entero-colonic encephalopathy, autism and opioid receptor ligand. A Wakefield et al. Alimentary Pharmacology and Theraputics 2002; 16: 663-674." (10.2 Recent scientific research)

The conclusions were:

> "that this new evidence did not alter the CSM view: there was no evidence to support a causal link between MMR vaccine and autism and bowel disease. JCVI found the papers helpful and expressed its strong support for the conclusion reached by the CSM."

As it will be evident from Section 8), the JCVI attitude towards vaccine safety, particularly the MMR, has not changed and to this day, the Committee still regards it as safe. On the other hand, independent research is accumulating to suggest otherwise. Only a year after the 1st November 2002 JCVI meeting, Singh and Jensen found more evidence to support an aetiological role of the measles virus component of the MMR vaccine in autism [6]. Using enzyme-linked immunosorbent assay, Singh and Jensen found that children with autism, unlike their siblings or normal children, had significantly elevated levels of measles antibodies in their sera. Antibodies against rubella and mumps did not significantly differ between these groups of children, however, immunoblotting screen against measles vaccine virus (source Merck&Co) showed that 43 out of 52 (83%) autistic children, but none of the 30 normal children or 15 siblings of autistic children, had antibodies against the measles vaccine virus. Since none of the children in Singh and Jensen study had any prior history of measles rash or wild type measles infection, but they all have had their immunisation with the MMR, the authors concluded [6]:

> "This vaccine in a small population of genetically predisposed children may perhaps manifest an atypical measles infection that does not yield a clinical rash but produces neurologic symptoms similar to those seen in children with autism."

and

> "Although more research is necessary to uncover the etiology of autism, the hyperimmune response to measles virus might indicate virus reactivation that triggers a misguided humoral immune response in children with the disorder."

Finally, far from being "discredited" and "flawed" as suggested in latest editorials published in the BMJ [7], the "Wakefield's hypothesis", which indicates that there is "a pattern of colitis and ileal-lymphoidnodular hyperplasia in children with developmental disorders" [3], is now supported by more independent research [8-12]. Notably, several respectable publications suggest that the principal findings of the Wakefield's 1998 Lancet study should not be discarded nor ignored. For example:

Quigley and Hurley [13]:

> "Wakefield et al. are to be congratulated on opening yet another window onto the ever-broadening spectrum of gut/brain interactions. Their findings raise many challenging questions that should provoke further much-needed research in this area, research that may provide true grounds for optimism for affected patients and their families."

Most recently, at the meeting on 2nd February 2011 (http://www.dh.gov.uk/ab/JCVI/DH_123529), the JCVI dismissed the relevance of a paper by world-renowned autoimmunologists Professor Yehuda Shoenfeld and Nancy Agmon-Levin [14], which raised serious concerns about the role of vaccine adjuvants in vaccine-related autoimmune conditions.

> **(XII. Papers for information and any other business, 61.)**
>
> "The committee discussed a review paper by Shoenfeld and Agmon-Levin (2010)[3] on autoimmune/inflammatory syndrome induced by adjuvants, in particular on the role of adjuvants in the pathogenesis of four conditions: siliconosis, the Gulf war syndrome (GWS), the macrophagic myofasciitis syndrome (MMF) and post-vaccination phenomena. The committee considered that the paper did not provide convincing data on the role of adjuvants in these four 'enigmatic' medical conditions and that the review did not raise safety concerns about the use of adjuvants."

5) Persistently and categorically downplayed safety concerns while overinflating vaccine benefits.

The sharp increase in litigation claims over pertussis vaccine injury between 1978/79-1985, presented an additional challenge for the CSM/JCVI/Joint Sub-Committee ARVI, as increased efforts were now needed to reassure the public in the safety of the pertussis vaccine.

> In the transcript of the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting held on 7th February 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), ARVI made the following comments on a confidential paper:
>
> (Item 5.1 ARVI's comments on _____ paper "Whooping cough disease, vaccination, vaccine damage")
>
> "_____ deprecated the use of the term 'brain damage' which the public might consider as a permanent entity. The public may not also understand the significance of febrile convulsions."

> Are we to assume that ARVI had not been aware of a certain controversial statement made by the CSM in the 1981 in a report on Whooping Cough about a possible link between DTP immunisation and serious neurological illness?:
>
> "No scientifically unassailable link has been established between DTP immunisation and serious neurological illness but we have come to conclusion, on the basis of all present evidence, that there is a prima facie case that such a link may exist." (JCVI/Joint Sub-Committee ARVI "commercial in confidence" meeting on 6th February 1987, section "7.1 Whooping cough vaccine –CSM advice"; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306)

Perhaps the reason why ARVI "deprecated the use of brain damage" is because of their firm belief that vaccines could not be associated with such events. Apparently, the possibility that vaccination could cause permanent brain damage must have been considered as an outrageous assertion, so much so that it did not even deserve scientific scrutiny. In fact, following a discussion on a proposal for the surveillance of severe neurological disorders in infancy and their relationship to pertussis vaccine on 7th February 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), CSM/JCVI/Joint Sub-Committee ARVI jointly concluded that:

> **(6.5.1)**
>
> "It was considered unreasonable to ask paediatricians to report for a period of six years."

Under the same agenda, the CSM/JCVI/Joint Sub-Committee ARVI also decided that:

> **(6.5.1)**
>
> "No attempt would be made to study serious neurological disease arising from pertussis and other infectious diseases."

Obviously without such a standard, it would have been quite impossible to assess whether vaccination against pertussis caused more severe brain damage than natural pertussis infection. If concerns about pertussis vaccination were indeed unsupported and only a product of an inexpert "perception of the public" as ARVI's statements would led us to believe, then surely such a study would have just reinforced the notion that vaccines are safe. However, it appears that according to the CSM/JCVI/Joint Sub-Committee ARVI's problem-solving rationale, instead of encouraging further research, it seemed more acceptable to downplay safety concerns over possible vaccine-injury, which then justified their decision to take no further investigation into the matter. Unwillingness to carry out this specific research is perplexing indeed, in light of what was noted at the 3rd November 1981 meeting (http://www.dh.gov.uk/ab/DH_095169) in section 5 on Whooping Cough:

> **(5.d. Comments on Professor Stewart's letter)**
>
> "Professor Gilliatt observed that in the Meade Panel Study one-third of children with brain damage were not admitted to hospital. In both the Meade and Dudgeon studies there were examples of children who had a fit soon after vaccination which was followed by a fit at a later time and then followed by cessation of development. It was very difficult to assess this as a random event...The Chairman concluded that much was not known about the natural history of brain damage in the young."

Are we meant to believe that "cessation of development" following episodes of vaccine-associated fits does not fit into the category of "permanent entity" and/or "brain damage"?

> As for the public's alleged misunderstanding on the significance of febrile convulsions, the transcript notes of the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting held on 6th June 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306) are particularly enlightening:
>
> In discussing the significance of the NCES report on pertussis vaccine injury:
>
> **(5.2 Encephalopathy)**

> "The report used the NCES estimation of relative risk of 3:1, it was estimated that one third of such cases have permanent handicap one year from their onset (as derived from the NCES)."
>
> **(5.3 Complex Febrile Convulsions)**
>
> "These were defined as being of more than 10 minutes in duration, or repetitive over 24 hours...Vaccine could cause such seizures and it was believed that 10 per cent of such complex seizures could result in permanent handicap..."

Perhaps the public would have been better acquainted with the significance of febrile convulsions and the fact that pertussis vaccine could cause them, had not:

> "The Chairman reminded members that the proceedings, papers and information before them [were] confidential and should not be disclosed."

Paradoxically, at the prior meeting on 7th February 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), at which ARVI stated it "deprecated the use of the term brain damage", the CSM/JCVI/Joint Sub-Committee ARVI acknowledged:

> **(6.5.1)**
>
> "that the NCES may have missed cases of severe neurological disease which progressed to handicap among children who were not admitted to hospital."

Going back to the meeting that followed, on 6th June 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

> **(5.7)**
>
> "In the general discussion which followed, some members of the Committee felt that the report [referring to the American Medical Association (AMA) panel report on Pertussis Vaccine Injury, published in JAMA 1985; vol 254, pages 3083-3084] not only accepted the fact that vaccine damage was a real phenomenon but implied (by the way it was written) that it was commoner than was believed to be the case in the UK."
>
> Notably, according to the notes of the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting on 3rd October 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306), the AMA panel report had been prepared:
>
> **(5.2)**
>
> "...with the particular intention of providing information for legislators as to what type of vaccine-associated event might require compensation, if Federal compensation for presumed vaccine injury were to be introduced."
>
> Perhaps it is because of this that the CSM/JCVI/Joint Sub-Committee ARVI:
>
> **(5.2)**
>
> "...agreed that the document contained a number of assertions which could not be accepted."
>
> One has to wonder whether such assertions unacceptable to the CSM/JCVI/Joint Sub-Committee ARVI include:
>
> "...the fact that vaccine damage was real a phenomenon" and "commoner than was believed to be the case in the UK." (CSM/JCVI/Joint Sub-Committee ARVI meeting on 6th June 1986; item 5.7; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306)

Other than perceiving health hazards associated with certain vaccines as a danger to overall routine immunisations, the JCVI felt that certain health professionals were also negatively affecting the vaccination policy by exercising more caution with regards to contraindication criteria than the JCVI deemed appropriate (for a remainder of the JCVI's position with regards to contraindication criteria refer back to Sections 2) and 3)). In a Summary Report on an investigation of failure to reach a measles immunisation uptake in the Maidstone Health Authority, at the Joint Working Party of the BPA and the JCVI Liaison group meeting on 30th September 1986 (FOI release, 86/3rd meeting; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4140335), the member whose name was erased from the transcript commented that:

(7.)

"...the paper described a position which was still bedevilled by false contra-indications to measles vaccination."

Apparently,

"_____ commented that often parents wanted the vaccine given but were dissuaded by health service staff. _____ stressed the need for training of health professionals and the Chairman considered that the 'responsible person' in each district (quoted in previous circulars) should organise such a training." (7. Measles vaccination: Summary Report on an investigation of failure to reach a measles immunisation uptake in the Maidstone Health Authority)

In a later meeting (JCVI 7th November 1986; http://www.dh.gov.uk/ab/DH_095169):

(9. BPA/JCVI Working Group)

"Members agreed that the most disturbing feature was that a minority of health professionals could exert a disproportionally bad effect on a campaign."

What the JCVI's perception of a "responsible person" might be, is perhaps best understood in the light of their bewildering leniency towards vaccine safety and a seeming tendency to align with the manufacturers' interests more than those of public health.

By 18th November, the JCVI had an elaborate strategy to improve measles vaccine uptake (as documented in the transcript of the JCVI meeting on 1st May 1987; http://www.dh.gov.uk/ab/DH_095169), which included:

(discussion about a PHLS meeting on 18th November on the uptake of measles vaccine)

"GP clinics where immunisations were given should be more attractive and use every opportunity of attendance at clinics to offer immunisation; this is especially important for deprived families."

It was also recommended that:

"Regional and District Health Authorities (DHAs) should be accountable for their vaccination performance."

Since:

"All the members agreed that accountability with regard to immunisation was most important. The Chairman is summing up said that immunisation was a most important NHS Policy and that recommendation before them, after editing, should be put to the NHS Management Board and then promulgated to the NHS with a separate copy to the nominated persons in the districts."

That "immunisation was a most important NHS Policy" is also implied in a discussion on whooping cough at the JCVI meeting on 3rd November 1981 (http://www.dh.gov.uk/ab/DH_095169):

(5.d. Comments on Professor Stewart's letter)

"The meeting then considered Professor Stewart's paper on deaths from whooping cough in Great Britain (JCVI(81)12). Dr Williams, referring to page 5 of the paper, said that deaths from whooping cough tended to be under-notified...On the other hand, at times of outbreaks of whooping cough the disease tended to be over-notified; this had the effect of lowering fatality ratio."

In the ensuing discussion:

"The Chairman concluded that it would probably not be wise for the Committee to make a formal reply to this paper. (Members also thought that controversial replies to correspondence to the medical journals might not add support to the whooping cough vaccination campaign.)"

In the following years, the members of ARVI continued to "express anxieties" over eroding confidence of the public in pertussis and other vaccines. In a Joint Sub-Committee ARVI meeting on 8th March 1988, the members recommended that a monitoring system for vaccine reactions should be set up, which would cope with any vaccine related "adverse publicity" (item 7, Adverse Reactions Surveillance; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306; note that this meeting was incorrectly noted as March 1998 rather than March 1988).

While the public appeared to have lost the confidence in the safety of the pertussis vaccine by the mid 80s, in 1989, the JCVI was still debating on whether or not the pertussis vaccine caused permanent brain damage. Referring to the NCES report it was generally accepted by the JCVI that if the vaccine led to severe neurological outcomes, it did so very rarely (JCVI meeting on 3rd November 1989; http://www.dh.gov.uk/ab/DH_095169). Finally, it was agreed that the statistical data of attributable risk should be removed from the Memorandum since, according to Dr Salisbury:

"If the public was given a risk ratio — any ratio — they would still see it as a scientifically proven risk. It was therefore preferable not to use insecure figures if possible but to stress the benefits from vaccination." (12.1 Whooping cough – article by Dr A H Griffith in Vaccine etc JCVI (89)32)

Regarding the alleged overall "benefits from vaccination", it is worth mentioning that in a discussion about Diphtheria outbreaks in immunised populations on 22nd April 1988 (http://www.dh.gov.uk/ab/DH_095169), the JCVI acknowledged that these do in fact:

(16.1)

"occur in well-immunised populations..."

In addition, the decision to include mumps in the routine vaccination schedule with the introduction of the MMR in 1988 goes against JCVI's own past advice, as evidenced by a discussion about the usefulness of the mumps vaccine in the JCVI meeting on 11th December 1974 (http://www.dh.gov.uk/ab/JCVI/DH_095052):

(10.)

"The Committee agreed that there was no need to introduce routine vaccination against mumps."

because

"complications from the disease were rare."

Granted, opinions can change with time as new scientific evidence becomes available. Even so, the arguments are against routine mumps vaccination. Mumps in adults but not in children can cause mumps orchitis, a serious condition which may result in male sterility. Mumps outbreaks in older

individuals increased in frequency since the introduction of the MMR into the routine schedule, most likely because of the poor effectiveness of the mumps component of the vaccine.

In a comprehensive assessment on mumps orchitis in the post-vaccine era, which included epidemiologic, clinical, therapeutic, and follow-up studies and outcomes of 609 patients, Ternavasio-de la Vega et al. [15] reported:

> "Mumps orchitis is the most common complication of mumps infection in young postpubertal males. Testicular compromise is characterized by an abrupt onset of unilateral or bilateral marked scrotal swelling and pain, accompanied by constitutional symptoms and fever. Immunization programs against mumps have reduced the number of reported cases and influenced their age distribution. Since the introduction of mumps vaccine in 1967 (the year the first mumps vaccine was licensed in the United States), a shift in the age of peak incidence of mumps from children aged 5-9 years, in the prevaccine era, to children and young adults aged 10-24 years has been observed. Serious complications have appeared as a consequence because of the higher rate of sequelae among the older age-group. The principal complication of acute mumps orchitis is the atrophy of germinal epithelium with spermatogenesis arrest, which in turns leads to male sterility."

The evidence for the poor effectiveness of the mumps vaccine has recently been reported by Castilla et al. [16]:

> "This study adds to the literature showing moderate effectiveness of the mumps vaccine containing the Jeryl Lynn strain, which seems to be related with early and progressive waning immunity. This effect, seen in children vaccinated with both one and two doses, makes it difficult to control the disease even when high vaccination coverage is achieved, and leaves open the possibility that outbreaks will occur when the infection is reintroduced."
>
> "Our results indicate that this effect of waning immunity begins early, as seen in the fact that 3 or more years after the second dose of MMR vaccine, the risk of mumps was 10 times higher. This increased risk does not appear to be linear, but rather is accentuated over time."

Hence, routine mumps vaccination has shifted a childhood disease to adolescents and young adults, groups with a higher incidence of adverse long-term complications and sequelae. By contrast, the benefits of naturally acquired immunity against mumps in early childhood are life-long protection against mumps and its serious complications later in life.

Curiously, at the meeting held on 17th September 1990 (http://www.dh.gov.uk/ab/JCVI/DH_095294), the JCVI also acknowledged the consequences of shifting mumps infections to older age groups:

> **(6.5)**
>
> "It was noted that the introduction of mumps immunisation could in theory shift the age specific infection rates to the older age groups in whom the complications were greater;"

However, the Committee concluded:

> "...nevertheless, the gains from the progressive reduction in mumps illnesses outweigh such concerns."

It would appear that in following the JCVI's line of reasoning, one must conclude that the alleged benefit of eradicating mumps in young males where the illness is mild and "complications are rare", outweighs the risk of male sterility.

Similar to mumps, the complications from rubella early in childhood are minimal, hence it may be argued that vaccination against both rubella and mumps are of little clinical benefit to a child. Serious complications from rubella may occur in a developing foetus of a pregnant woman who has contracted rubella during her first trimester. In such cases a child may be born with congenital rubella syndrome (CRS), involving multiple congenital abnormalities. The risk of CRS can be reduced either by making sure all women have caught rubella as children or by vaccinating those

who have not prior to puberty. Hence, the current JCVI's policy of vaccinating every child, male and female, against rubella does not appear to be justified.

Finally, apart from "no need to introduce routine vaccination against mumps" , the decision to introduce the MMR into a routine schedule was in conflict with the JCVI's past concerns about risks associated with simultaneous administration of multiple live vaccines. Curiously, the MMR vaccine developed by MSD was first licensed in the UK in 1972, but not marketed until 1988. An indication as to why it took 16 years to introduce it in to a schedule may be found in the same meeting which discussed the usefulness of the mumps vaccine (JCVI meeting, 11th December 1974; http://www.dh.gov.uk/ab/JCVI/DH_095052):

> **(11 Simultaneous administration of live vaccines (CHCS(VI)14))**
>
> "The Chairman refereed to the 3 vaccines which had been licensed for Merck Sharp and Dohme and asked for comments on the company's claim that these could be administered simultaneously with live poliovirus vaccine. This use of the vaccine appeared to conflict with the Committee's published advice and they had to consider (a) whether this advice should be changed and (b) if the vaccine concerned viz MMR, Biavax and Measles and Rubella virus vaccine and live MSD could be given with live poliovirus vaccine. Professor Dick and Dr Warin pointed out that an interval in the administration of live vaccines had been advocated in view of the probability of adverse reactions and because of the recent publicity surrounding adverse reactions. The Committee agreed that it would be inopportune to change the guidance that an interval of at least 3 weeks should be allowed to elapse between the administration of any 2 live vaccines whichever came first."

Perhaps unknown to most lay people as well as medical professionals is the issue of vaccine contaminants which is somewhat inherent to the vaccine production process. In this regard, one particular item discussed under the section 3.4. Ruminant and Human Materials used in Vaccine Manufacture, at the JCVI meeting on 4th May 2001 (http://www.dh.gov.uk/ab/JCVI/DH_095044), deserves special emphasis:

> **(3.4.1)**
>
> "This report was provided for information. The Committee asked by which date the vaccines already distributed would no longer include any whose production process may have involved the use of potentially BSE [Bovine spongiform encephalopathy] infected Category 1 or 2 material. The Committee was told that Category 1 material was only used at the master seed/working seed stage of the manufacture of a very few vaccines, not in routine vaccine production itself. Many vaccines are produced from master seeds which were manufactured many years ago...Master seed material often antedated the BSE epidemic in the UK, and was diluted many fold to the extent that any exposure to infected material, if ever present, would be remote."

How many people would feel comfortable with taking medicinal products derived from potentially BSE-contaminated material? As to why such vaccines continued to be used:

> **(3.4.1)**
>
> "There is reluctance to establish new master seeds for vaccines which have long history of use because such a change could possibly change the vaccine characteristics which may adversely impact safety and efficacy."

Indeed, removing sources of possible BSE contamination from vaccine manufacture would have no doubt "impacted safety"; it would have made vaccines safer.

Curiously, when asked by the JCVI:

> **(3.4.3)**
>
> "...to consider whether it would be possible to put the information it had summarised on vaccine manufacturing and excipients in vaccines into the public domain; the MCA would consult their lawyers on this point."

If there was no risk of contracting BSE from a vaccine, then why did the MCA have to consult their lawyers "on this point"?

At the same meeting, on 4th May 2001 (http://www.dh.gov.uk/ab/JCVI/DH_095044), the Committee discussed:

> **(4.5.1)**
>
> "... suspected adverse reactions categorised as serious to DTP/Hib, polio, BCG, hepatitis A and B vaccines over the last three years. The data was based on Yellow Card reports received by the MCA."

and it showed the following:

> "i. DTP/Hib - the overall pattern and type of suspected reactions in 2000 were similar to previous years, with the exception of an increase in the number of respiratory reactions. Most of the increase appeared to be due to an increase in number of SIDS (5) and apnoea type reactions (14) being reported.
>
> ii. Polio - The types of suspected reactions reported in 2000 were on the whole similar to previous years. The only differences appeared to be an increase in the number of cardiovascular, eye and respiratory reactions reported.
>
> iii. BCG - Overall the types of suspected reactions reported were similar with the exception of an increase in number of cardiovascular reactions in 1999 and musculo-skeletal reactions in 2000.
>
> iv. Hepatitis B - The types of suspected reactions reported on the whole had been similar, with a notable decrease in the number of serious cardiovascular, eye, immune system, musculo-skeletal and neurological reactions being reported.
>
> v. Hepatitis A - The types of suspected reactions being reported were on the whole fairly similar. However, there were three notable differences: a significant increase in the number of cardiovascular and musculo-skeletal reactions reported in 2000, and a significant increase in the number of immune system disorder reactions reported in 1999. All these type of reactions were recognised side effects of this vaccine."
>
> **(4.5.2)**
>
> "Overall, there were no new safety issues identified."

Perhaps these were not new issues, just old persisting ones. Nonetheless, in all but one case (Hepatitis B), the number of serious adverse reactions appeared to have increased and in some cases this was not only significant but also a "recognised side effect of this vaccine" (Hepatitis A). In spite of this:

> **(4.5.2)**
>
> "The Committee was not persuaded given all the inherent uncertainties of spontaneous reporting that there were significant problems developing."

If anything, the Committee previously appeared to have acknowledged that there were problems with underreporting of adverse reactions to vaccines. In a Report of North Herts Immunogenicity Study on the 1st May 1992 meeting (http://www.dh.gov.uk/ab/JCVI/DH_095050), it was noted that "the report of a cluster of CSF mumps virus positive cases in Nottingham had caused concern that national surveillance may have been underreporting the incidence of cases..."

As noted in the following Section (6), the Yellow Cards are a passive surveillance system, not routinely used by the GPs and hence, data on adverse reactions obtained through Yellow Card reports are likely to be an underestimate of the true rate of these events.

Finally, since the principal rationale for shaping vaccine recommendations and policies according to the JCVI was to keep vaccination rates as high as possible so that presumably, "herd immunity"

would be achieved, it would seem fair at this point to question exactly how well has this concept been established? The theory behind vaccine-mediated "herd immunity" appears sound, it maintains that vaccination of a significant portion of a population (herd), will provide a measure of protection for individuals who have not developed immunity. Obviously, transmission of a disease to the point where it would reach an epidemic is expected to be countered in a population where most individuals are thought to be immune. However, the concept of vaccine-mediated "herd immunity" is based on the assumption that vaccines are effective in conferring immunity to the individual. If this were so, then how does one explain outbreaks of infectious diseases in populations where over 95% of individuals have been vaccinated?

> Gustafson et al. [17] "An outbreak of measles occurred among adolescents in Corpus Christi, Texas, in the spring of 1985, even though vaccination requirements for school attendance had been thoroughly enforced. Serum samples from 1806 students at two secondary schools were obtained eight days after the onset of the first case. Only 4.1 % of these students (74 of 1806) lacked detectable antibody to measles according to enzyme-linked immunosorbent assay, and more than 99 % had records of vaccination with live measles vaccine...After the survey, none of the 1732 seropositive students contracted measles. Fourteen of 74 seronegative students, all of whom had been vaccinated, contracted measles. In addition, three seronegative students seroconverted without experiencing any symptoms. We conclude that outbreaks of measles can occur in secondary schools, even when more than 99 percent of the students have been vaccinated and more than 95 percent are immune"

(Note that if the measles vaccine was effective in providing herd-protection, then the <5% of children in this study who did not seroconvert would still have had protection from contracting measles. The whole premise on achieving high vaccination rates rest on the assumption that the herd will protect those vulnerable individuals who have not been vaccinated, or do not seroconvert.)

> Hersh et al. [18] "In early 1988 an outbreak of 84 measles cases occurred at a college in Colorado in which over 98 percent of students had documentation of adequate measles immunity (physician diagnosed measles, receipt of live measles vaccine on or after the first birthday, or serologic evidence of immunity) due to an immunization requirement effect since 1986."

> Tugwell et al. [19] "A chickenpox outbreak occurred in a school in which 97% of students without a prior history of chickenpox were vaccinated. Students vaccinated >5 years before the outbreak were at risk for breakthrough disease."

It would thus appear that these vaccines only provide waning immunity, not herd immunity, as already well established in the case of the mumps vaccine by Castilla et al. [16] This often has the effect of shifting a relatively mild childhood disease to older age groups of children or young adults, in whom complications and sequelae from the disease are much more severe [15].

6) Promoted and elaborated a plan for introducing new vaccines of questionable efficacy and safety into the routine paediatric schedule, on the assumption that the licenses would eventually be granted.

> On 7th May1999 (http://www.dh.gov.uk/ab/JCVI/DH_095050), the JCVI met to discuss the use of the new conjugate Group C meningococcal vaccines. At the beginning of the meeting, Professor Hull, the Chairman:
>
> "...reminded members that the minutes and proceedings of the JCVI were confidential. Politically and clinically sensitive material was dealt with by the Committee..."
>
> It was further emphasised:
>
> **(8. Meningococcal meningitis, i.)**

"This was the main agenda item for the meeting. Much information had been made available and important decisions were required of the Committee, particularly about the introduction of meningococcal Group C conjugate vaccine, of which three brands would soon become available. Any decision would be dependent on the granting of product licenses and the wording of those licenses and, during the discussion, the Committee had to act on the assumption that licenses would be granted. The MCA was responsible for the safety, efficacy and quality of vaccines. The question for consideration by the Committee was how it would recommend that the vaccine should be introduced."

The Committee members were also once again:

"...reminded that this issue, and the papers presented, was extremely sensitive, commercially and politically. It was requested that confidentiality be maintained."

The Chairman had then asked for any declarations of interest:

"Professor Cartwright was involved in manufacturers' studies on the vaccines, including health trials. Dr Goldblatt was involved in one company-sponsored study and had provided a clinical expert report to the MCA for one manufacturer. Dr Jones was involved in trials for two of the companies involved. Dr Schild said that NIBSC was evaluating the vaccines."

In spite of these substantial conflicts of interests:

"There were no objections to these members continuing to take part in the meeting and it was agreed that they would be able to provide a valuable input to the discussion in common interest."

We are only left to speculate as to what such "common interest" might have been, between the JCVI and the pharmaceutical industry, bearing in mind several past instances where the Chairman of the JCVI met with the Association of British Pharmaceutical Industries to discuss:

"...the availability of scarce vaccines and the introduction of new vaccines into more regular use. The question of financial support for training members of the health service in immunisation was also discussed." (18. Meeting of the Chairman of the JCVI and the Association of British Pharmaceutical Industries, JCVI meeting on 23rd October 1987; http://www.dh.gov.uk/ab/DH_095169)

or where:

"The Chairman said that Departmental officials had recently met vaccine manufacturers who were keen to be informed, in confidence, of the outcome of JCVI discussions which might affect their own plans." (2.iv. JCVI meeting on 4th May 1990 (http://www.dh.gov.uk/ab/DH_095169)

The apparent close ties between the pharmaceutical industry, JCVI and the DH perhaps explain why the DH funded studies were not adequately designed to detect long-term vaccine-related adverse outcomes. In discussing 8.4.1 Meningococcal C Conjugate (MCC) Vaccine Evaluation Programme, at the 7th May1999 JCVI meeting (http://www.dh.gov.uk/ab/JCVI/DH_095050), Dr Elizabeth Miller reported:

(i.)

"Papers providing data on the new vaccines' safety and efficacy and data from the Department of Health funded studies were looked at; no other country had conducted similar studies. The Medicines Control Agency had also gathered lots of information and NIBSC was evaluating the vaccines. The data provided to the Committee related to the Wyeth product, which would be the first to become available. All available ADR [adverse reactions] data was included; the follow-up of ADRs had been up to the end of 4 to 6 weeks."

It should be obvious that long-term adverse reactions cannot be identified if a study is not designed to detect them (and quite predictably there were none, since the DH funded

studies showed that the MCC vaccines were well tolerated, section 8.4.1. vii., 7th May1999 JCVI meeting; http://www.dh.gov.uk/ab/JCVI/DH_095050). The reason for such omissions in study design are bewildering, given the past safety issues with the measles vaccine, where several children "were left one year later with severe handicap." (7. Suspected adverse reactions to measles vaccine: recent reports to the CSM, JCVI meeting on 17th of June 1983; http://www.dh.gov.uk/ab/JCVI/DH_120115)

Not only did the safety of the new, soon-to-be introduced MCC vaccine remain questionable, but also:

(ii.)

"There was no good evidence for the efficacy of the meningococcal Group C conjugate vaccine, only the surrogate of antibodies compared with those known to be protective against invasive disease. To actually test the efficacy on the conjugate vaccine it would be necessary to introduce the vaccine and then conduct a Phase III or Phase IV study to test efficacy; this would be very difficult to do and would delay introduction by 3-5 years."

In the ensuing discussion we are told that the JCVI:

(iii.)

"...felt that it was important to plan the programme now and confirmation that the vaccines were equally effective could follow."

In other words, the JCVI and the DH were actively working on a plan to introduce a vaccine with no demonstrable safety or efficacy into a routine paediatric schedule. Apparently, those responsible for sound safe and effective immunisation policies concluded that it was "very difficult" to conduct the necessary trials and they felt that this would unnecessarily delay the introduction of the MCC vaccine into a routine immunisation schedule.

What should have been considered by the JCVI is that vaccines represent a special category of drugs, generally given to healthy individuals and often to prevent a disease to which an individual may never be exposed [1]. Because of this, according to the US FDA, significant emphasis should be placed on vaccine safety [1]. Thus, If there are uncertain benefits from a vaccine, only a small level of risk of adverse effects may be acceptable. If the benefits are certain, then a greater risk of side effects may be tolerated. However, neither of these two points would have applied in the case of the MCC introduction programme, since there is absolutely no clinical benefit to a child from a vaccine that has neither been proven to be safe nor effective. The only "benefit" from such a programme would have been more in line with certain "common interests" rather than public health.

What followed at the 7th May 1999 meeting (http://www.dh.gov.uk/ab/JCVI/DH_095050), was a discussion on priority groups to whom the MCC vaccine should be offered, in which Dr Smithson made a following remark:

(ix.)

"...there was very little to chose between the priority age groups but suggested that infants were easier to target."

Finally, the Committee concluded that:

(x.)

"...if sufficient vaccine was available, all children should have it..."

In the following meeting, held on 21st January 2000 (http://www.dh.gov.uk/ab/JCVI/DH_095050), in section 6.4 Meningococcal C Conjugate (MCC) Vaccine Evaluation Programme, Dr Elizabeth Miller reported that several safety studies indicated that the new vaccine was not a cause for concern. Although,

(6.4.4)

"... headache, particularly if it was associated with muscle stiffness inevitably raised fears of actual meningitis, although the vaccine could not cause this."

Furthermore:

(6.4.6)

"The Committee noted that this information would not have been available without the co-operation of the manufacturers. This had given everyone much more confidence in the vaccine programme and was a unique co-operation."

In the following meeting, on 9th October 2000 (http://www.dh.gov.uk/ab/JCVI/DH_095050), the Committee was given an update on the safety profile of the MCC vaccine:

(7.6.2)

"The Working Party had received data available and had concluded that an association between MenC vaccine and seizures had not been proven. There had been 14 deaths reported. (2 further deaths had since been reported: 7 of the deaths were SIDS, 2 were meningitis B, 3 were in children with underlying conditions 1 was pneumococcal septicaemia, 1 was infantile encephalitis, 1 bronchiolitis and 1 child collapsed one month after immunisation with no cause of death being found).The Working Party believed that the deaths were all explained by other causes and that the vaccine was most unlikely to be implicated. By 21 September 2000, there had been 8.300 reports of 17,000 ADRs (1 ADR per 2,000 doses). The profiles were the same for each brand of vaccine."

Note that the Working Party "believed" that the vaccine was not implicated. An even firmer belief in MCC vaccine safety was held by the JCVI:

(7.6.3)

"The Committee did feel that the MCA statement that there was "no evidence that the vaccine caused meningitis" was far too light: the vaccine categorically did not cause meningitis. The MCA Meningitis Working Party would consider this issue further..."

How the JCVI could claim with such definite certainty that the newly introduced and poorly tested MCC vaccine could not cause meningitis is not clear from the transcript. Amongst those who did not share similar views with regards to vaccine safety are Alexander Harris Injury and Accident Solicitors and their clients, families whose children appear to have suffered severe long-term health problems following MCC vaccination. From their website (http://www.alexanderharris.co.uk/OurWork/ProductLiability/MeningitisCVaccine/Pages/default.aspx), we learn that safety concerns about MCC vaccine were first raised by the media (and not the UK health authorities) and that:

"Some 16,527 adverse reactions from 7,742 patients had been reported by GPs to the Medicines Control Agency through the Yellow Card reporting system. As well as reactions at the site of the injection such as swelling and soreness were other long-term reports which included seizures and 12 deaths."

This appears to be consistent with the data reported at the JCVI 9th October 2000 meeting. Further, the Solicitors made an important observation:

"The Yellow card reporting system is not routinely used by most GPs and healthcare professionals and as such the figures for adverse reactions are likely to be an underestimate. Despite the known under-reporting, the number of adverse reactions reported for Meningitis C vaccine is the highest for any vaccine within the UK immunisation programme."

7)

8) Actively discouraged research on vaccine safety issues.

On 14th October 1985 a letter was issued to Dr Derek Zutshi (DHSS), from a member affiliated with the London School of Hygiene and Tropical Medicine at the University of London, whose name was erased from the copy of the letter prior its FOI release (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4140359.pdf):

> "Dear Derek
>
> Enclosed are comments on the estimates of vaccination-associated SIDS as presented at the recent ARVI meeting. I hope they prove helpful.
>
> Let me add that this is a complicated problem, but one that I would be interested to pursue in the future."

In three pages, the author of the letter made several comments on "Tabled Paper 1, (Appendix to ARVI/85/34)", titled "Note on the estimation of sudden infant deaths expected to occur by chance after immunization", authored by Paul EM Fine from the London School of Hygiene and Tropical Medicine. A balanced critical overview was given on three key points relevant to Paul EM Fine's estimation of SIDS: "method used", "data used" and "assumptions made", outlining both strengths and limitations. In a final note, the author concluded:

> "These brief comments indicate a number of problems which arise in estimating the number of SIDS deaths expected to arise by chance, within 24 hours of vaccination, if there were no causal association between them. Some of these problems favour overestimation and others favour underestimation by the methods used in the DHSS note. Given the nature and direction of the biases, it is probable that the estimates presented in the DHSS note are of the correct order of magnitude. On the other hand, given the importance of the subject, a more thorough examination of the subject seems appropriate."

Copies of this letter appear to have been forwarded to Dr M Graveney (DHSS) and Professor RW Gilliatt (JCVI).

Two months later, on 13th December 1985, on the University of Nottingham, Department of Child Health's letterhead, a member whose name was erased from the copy of the letter released under FOI (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4140362.pdf), also wrote to Dr Derek Zutshi, to express his grave concerns about potential further investigations into the relation between vaccination and SIDS:

> "Dear Derek
>
> I showed the Tabled Paper 1, (Appendix to ARVI/85/34) to Richard Madeley [Department of Community Medicine and Epidemiology, University of Nottingham Medical School] and he kindly prepared the enclosed observations. I agree with everything that he has said. As you know, at the meeting I had grave misgivings about the exercise and of the assumptions that were made."

In the following section, "Re: Note on the estimation of sudden infant deaths expected to occur by chance after immunisation", apparently from the author of the "enclosed observations", Richard Madeley, several reasons are given for his own misgivings "about the exercise", some of which appear to be sound, such as:

> **(3. The hypothesis that immunisation may cause SIDS)**
>
> "c. Most deaths from SIDS occur before the age of four months[2], when first immunisation takes place."

(note, this still does not exclude the possibility that some cases of SIDS may be vaccine-related)

while others appear not as sound:

> "d. There is no foolproof method of discrediting the hypothesis by statistical or epidemiological methods. On the contrary, there is a danger of getting drawn into a lengthy

> argument about numbers which neither side could win, thus giving more credibility to the hypothesis than it deserves."

(it ought to be noted that in the realm of science, a hypothesis can only be proven or disproven by experimental evidence and not by personal opinions)

In his "Final Comments and Conclusions" the author stated:

> "For those reasons, I think it would be extremely unwise for the DHSS to get involved in any type of epidemiological work on this hypothesis. The hypothesis seems most unlikely on grounds of basic scientific reasoning, and such evidence as already exists points in the opposite direction."
>
> "To go ahead in these circumstances would endow upon the hypothesis a respectability which it does not deserve. It is impossible to disprove through numbers. To try to do so, using flawed assumptions, as in the memorandum of the DHSS Statistics Division, weakens the position."

Indeed, epidemiological work would not be the most appropriate way to address the possibility that SIDS could be causally related to vaccination given that epidemiological studies only test for "association" and not "causation". However, case control studies as well as post-mortem lab analysis should have been considered as viable alternatives to further research. Such as:

> Ottaviani et al. [20] "Herein we report the case of a 3-month-old female infant dying suddenly and unexpectedly shortly after being given a hexavalent vaccination. Examination of the brainstem on serial sections revealed bilateral hypoplasia of the arcuate nucleus. The cardiac conduction system presented persistent fetal dispersion and resorptive degeneration. This case offers a unique insight into the possible role of hexavalent vaccine in triggering a lethal outcome in a vulnerable baby. Any case of sudden unexpected death occurring perinatally and in infancy, especially soon after a vaccination, should always undergo a full necropsy study according to our guidelines."
>
> "The identification of a possible pathological basis of reflexogenic mechanisms in sudden, unexpected infant death necessarily requires examination of the brainstem nuclei and of the cardiac conduction system on serial sections."

The senior author of this study, Professor Luigi Matturri is a member of the European Medicines Agency (EMEA) Pathologists Panel for evaluation of SUD (sudden unexpected death) cases reported for hexavalent vaccines. In a review by EMEA cited in the Introduction of the study, of five reports of unexplained deaths in children which occurred within 24 hours of vaccination with a hexavalent vaccine, panels of experts (including pathologists with the experience in the field of vaccines and SIDS), investigated whether there might have been a link between the vaccines and the deaths observed:

> "The EMEA's conclusions were that the causes of death remained unexplained. SIDS, viral infection, metabolic disorders, allergic reactions or airway obstruction were plausible but were not definitely proven to have been the cause of death [4]. However, to the best of our knowledge, during the mentioned post-mortem investigations, little, if any, attention was paid to examination of the brainstem and the cardiacconduction systems on serial sections, nor was the possibility of a triggering role of the vaccine in the lethal outcome considered."

In addition, in responding to numerous criticisms of their study Unexplained cases of sudden infant death shortly after hexavalent vaccination [21] Zinka et al. noted [22]:

> "(ad 6) The main problem is that vaccination specialists have failed for decades to establish any tests or other criteria to find out if adverse events are linked to vaccinations or not. To our knowledge they did not even try hard—why?!"
>
> "(1) A precise description of the mechanism leading to serious adverse events after hexavalent vaccination is not the task of forensic pathology. This would be the job of vaccination specialists, and actually this job should have been done before phase 1 and phase 2 studies in order to get valid data on the drug safety."

In summary, it may be inferred from here that the real reason why causality is rarely (if ever) established by scientific investigations into vaccine-related serious adverse outcomes is because it is assumed that: a) they don't happen and b) the study is not designed to detect them. This may further suggest that vaccines are not proven to be safe but are only assumed to be safe. Indeed, according to the US FDA "Historically, the non-clinical safety assessment for preventive vaccines has often not included toxicity studies in animal models. This is because vaccines have not been viewed as inherently toxic" [1].

9) Deliberately took advantage of parent's trust and lack of relevant knowledge on vaccinations in order to promote a scientifically unsupported immunisation program which could put certain children at risk of severe long-term neurological damage.

Recently the DH announced that there would be a significant change in the current UK immunisation schedule, following the October 2010 meeting at which the JCVI recommended that children be vaccinated against six diseases at the same time. This would be through receiving three vaccines (Hib/MenC, MMR and pneumococcal) in one visit rather than getting the first vaccine at 12 months of age and the second two at 13 months of age. According to a letter sent by the Chief Medical Officer Professor Dame Sally Davies to local GPs (http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_121748), this new "simplified" immunisation policy is to be implemented "as soon as practicable". Furthermore, according to a BBC news report on 22nd November 2010 (http://www.bbc.co.uk/news/health-11809967), the purpose for vaccinating against 6 diseases at one single appointment is "to boost vaccine uptake", which has apparently been low ever since safety concerns regarding the MMR vaccine had been raised in public following the study of Wakefield et al. in 1998 [3]. Despite continued public concerns on the overall safety of the MMR and its possible link to autistic regression and other severe neurological outcomes, the DH spokesperson stated (http://www.dh.gov.uk/en/MediaCentre/Statements/DH_122026):

> "Independent scientific research has shown that providing these vaccines at the same time is safe, effective and more convenient for parents."

I have requested from the UK DH to show me these independent data. The request was granted, and much more than that. First to the independent data: they are not independent.

The study by Miller et al. [23], referenced by the DH states in the acknowledgments:

> "This is an independent report funded by the Policy Research Programme in the Department of Health, UK, grant 039/031."

As for the safety assessment:

> "For safety, proportions of children with erythema, swelling or tenderness at site of injection, or fever or other systemic symptoms for 7 days after immunization were compared between regimens. No adverse consequences for either safety or immunogenicity were demonstrated when MCC/Hib was given concomitantly with
>
> PCV and MMR at 12 months of age or separately at 12 and 13 months of age."

Thus the vaccine was "demonstrated safe" based on a 7 day follow-up and monitoring for largely local reactions. Not only is this an appalling example of a vaccine safety study, it is the only study quoted by the DH and JCVI in support of their decision to implement a new vaccine schedule. This is evident from a Possible simplification of the childhood vaccination schedule report (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_121799.pdf), issued by the JCVI Secretariat in October 2010, which states:

> **(4.)**

> "In June 2009, JCVI considered a pre-publication clinical trial paper from Miller et. al. that showed that co-administration did not adversely affect the immune response elicited by the vaccines. In addition, no safety concerns around co-administration were identified."

The JCVI report further states:

> **(Annex A, Background)**
>
> "In June 2009 the Joint Committee on Vaccination and Immunisation concluded that there is no scientific reason to keep the combined Hib and Meningitis C vaccine (currently given at 12 months) and the MMR and pneumococcal vaccines (given at 13 months) separate."

The "no scientific reason" is grossly misleading. Once again, it should be obvious that safety concerns cannot be identified if the study is not designed to detect them. Autistic regression is known to occur gradually over periods of weeks to many months. In spite of this, the vast majority of studies which are presumed to provide conclusive evidence on the safety of vaccines, have short follow ups and focus almost exclusively upon acute near-immediate events [23-29].

In addition, the fact that in 2008 The US federal Advisory Committee on Immunization Practices (ACIP) voted to withdraw their initial recommendation for the use of measles, mumps, rubella, and varicella vaccine (MMRV, marketed by Merck & Co., Inc. as ProQuad) as the vaccine of choice for vaccination of infants, because it was associated with double the risk of febrile seizures when compared to the MMR, shows that there is indeed solid reason for concern over simultaneous administration of multiple vaccines. Proquad contains only four vaccines in combination, not six. The research from The Vaccine Safety Datalink (VSD), considered by the ACIP, evaluated the incidence of febrile seizures in 43,000 children between the ages of 12 and 23 months who had been vaccinated with ProQuad and 315,000 who had received two separate MMR and varicella vaccines. Within 7 to 10 days after vaccination, those given ProQuad suffered twice as many seizures (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5710a3.htm):

> "The preliminary results indicated a rate of febrile seizure of nine per 10,000 vaccinations among MMRV vaccine recipients compared with four per 10,000 vaccinations among MMR vaccine and varicella vaccine recipients."

The multivalent vaccine Hexavac was also recently withdrawn following a recommendation from the EMEA (http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/12/WC500017695.pdf) "as a precautionary measure", due to its poor effectiveness. Safety concerns have also been raised over administration of hexavalent vaccines by Ottaviani et al. [20] and Zinka et al. [21] the latter, following five cases of infant deaths in Germany in 2005 (all occurring within 48 hrs of vaccination). The post-mortem analysis of six children aged 4-17 months (5 of whom were vaccinated with Hexavac and one with another hexavalent vaccine, Infanrix Hexa) reported by Zinka et al. [21], revealed abnormal pathologic findings particularly affecting the nervous system. Although there is no conclusive proof that these deaths were directly caused by vaccination, the authors felt it was:

> "...important to inform vaccinating physicians and pediatricians as well as parents about such possibly fatal complications after application of hexavalent vaccines."

In spite of these relevant findings, no mention of these two studies is found in the DH and the JCVI reports regarding the introduction of the new "simplified" and "improved" schedule.

Other than the paper by Miller et al. [23], the DH also provided me with the official report on their research on parents' attitudes to the possibility of administering the Hib/MenC, PCV and MMR vaccines on a single occasion. Following their initial consideration of the draft paper by Miller et al., in 2009, the JCVI did recognize the need to seek parent's opinion on the proposed "6 in 1" program before making any changes to the current schedule. In February 2010, the DH initiated this research and subsequently published it in a document **Childhood immunisation programme: Attitudinal research into combining 12 and 13 month immunisations** which is now available on the DH website at:

http://www.dh.gov.uk/en/Publichealth/Immunisation/Marketresearch/index.htm

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122329.pdf

What the Attitudinal research found was that parent's knowledge on childhood's current immunisation timetable, particularly around 12 and 13 months, was generally low and apparently, the DH and the JCVI are content with keeping it that way, in order to preserve the national vaccination program. The DH and the JCVI concluded that informing parents of the changes would be "unwise" because it would create unnecessary panic. In order to prevent this, the health officials need to be instructed on how to "reassure" parents in the safety of vaccines, especially the MMR.

According to the Attitudinal research report, parents generally trusted the schedule and the NHS, however, some had reservations about the MMR, particularly if it was to be combined with other vaccines. Specifically, the Research Management Summary on Behalf of the DH from a Possible simplification of the childhood vaccination schedule report (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_121799.pdf), issued by the JCVI Secretariat, states that:

> "While the principle of combining vaccinations and/or giving more than one at the same time appeared largely to be accepted, if one of these is MMR, views can change." (Conclusions and Recommendations: 2.)

In light of this explicit concern, the DH report noted:

> "The combined schedule at 12 and 13 months was regarded with mixed feelings; if it is introduced, the way in which it is communicated will have a significant impact on how it is received. Given low awareness of the immunisation schedule, parents are unlikely to notice the change until informed about it." [their emphasis added-italicised] (Conclusions and Recommendations: 3.)

They further elaborated on this particular finding:

> "When the combined schedule was presented to parents first (before seeing the current schedule), very few identified the appointment at a year of age as different or worthy of comment. Parents' problems and worries only came to the surface when the combined option was explicitly presented as a change to the schedule. Those in areas where the combined schedule is apparently already being given accepted it without question. When parents were told that the new schedule involves giving MMR and PCV at the same time as another vaccine, some changed their views, including some of those who were otherwise accepting of MMR." (Conclusions and Recommendations: 4.)

On the basis of the above observations the DH concluded that it is best to keep parents ignorant of the proposed changes, in order to avoid what they deemed as "unwarranted anxiety", as this would most likely lead to reduced immunisation rates:

> "Offering parents a choice between the two schedules could generate more questions than answers, and seems unwise. It might also risk compromising current understanding of the vaccination schedule as 'just what happens', and reframing it as optional, which could reduce vaccine uptake." (Conclusions and Recommendations: 5.)
>
> Consistent with their past legacy that apparently puts priority on the preservation of the vaccination program rather than the safety of an individual, the British Health Authorities consider it "unwise" that parents should have a choice as to how immunisations are to be carried out. So much so that special action is needed to assure that their efforts in promoting vaccination are not hampered. In particular, to the DH it "seems sensible" to, somehow, camouflage the change in the vaccination schedule in order to prevent what they deem as "unwarranted anxiety".
>
> "It is also clear that offering parents detailed information, and flagging up changes, can generate anxiety where it is not warranted. In light of this, it seems sensible to introduce the combined schedule as far as possible without announcing it explicitly as a change." (Conclusions and Recommendations: 6.)

Indeed, the DH offers an elaborate strategy for addressing parental concerns about the "improved" and "simplified" vaccination program:

> "If the combined immunisation is introduced, some parents will have questions about it, and health professionals, especially health visitors and practice nurses, will be their first port of call for information. Health professionals will have an important part to play in informing and reassuring parents, and they will need to provide consistent answers; any variation between what they say is likely to create a sense of unease among parents." (Conclusions and Recommendations: 7.)

In revealing further details on how the health staff should approach those parents who may have concerns over the safety of the MMR vaccine, the DH advises:

> "Health professionals will need to be ready to reassure parents that…
>
> • combining vaccinations into one appointment and giving three at a time is entirely safe
>
> • the fact that MMR is one of these makes no difference, because MMR is safe
>
> • there is a good reason for the change: though the current system is effective and safe, changing it will be an improvement
>
> • there are significant benefits to baby and parent in having one fewer appointment and reduced distress"

It should be obvious that any a priori exclusion of possible adverse effects from vaccines which is not based on valid scientific evidence but rather, a belief system is not by definition scientific. Rather, it reflects a disturbing trend to view anything associated with vaccines and vaccine policy as sacred and beyond scientific scrutiny. The need to protect the UK government-mandated vaccination program against any reasonable doubt, in the absence of any truly independent scientific evidence and despite a) CSM/JCVI/ARVI's own records discussed under Sections 1)-3) & 5) which show that vaccines, including measles and the MMR are not "entirely safe" and b) the government's own concession that the MMR can in fact cause permanent brain damage (in the case of Robert Fletcher who in August 2010 received £90,000 payout for epilepsy and severe mental retardation that he suffered following the MMR jab; http://www.bbc.co.uk/news/uk-england-merseyside-11125343), is even more disturbing.

If vaccines are indeed entirely safe as the DH and the JCVI claim, why do they feel they need to hide information from parents and health professionals?

Perhaps "combining vaccinations into one appointment and giving three at a time is" not "entirely safe"

As a reminder (JCVI meeting, 11th December 1974; http://www.dh.gov.uk/ab/JCVI/DH_095052):

> **(11 Simultaneous administration of live vaccines (CHCS(VI)14))**
>
> "Professor Dick and Dr Warin pointed out that an interval in the administration of live vaccines had been advocated in view of the probability of adverse reactions and because of the recent publicity surrounding adverse reactions. The Committee agreed that it would be inopportune to change the guidance that an interval of at least 3 weeks should be allowed to elapse between the administration of any 2 live vaccines whichever came first."

The above would explain the need to censor certain information as well as why the JCVI went to great lengths in devising a special strategy with which such a task would be achieved:

> "Given continued sensitivity about MMR, any negative news coverage will have a significant impact. Health professionals will be the front line in combating this, and will need to be kept fully informed on the latest information from JCVI and DH to prevent any contradictions or confusion, and to ensure that they are equipped to reassure parents." (Conclusions and Recommendations: 9.)

The choice of words is rather peculiar here, it appears as if the DH and the JCVI are preparing for war. Their choice of weapons includes "educating" health professionals with what appears to be highly censored information, since numerous truly independent studies which raised safety concerns in the scientific community (particularly about the MMR vaccine), were simply dismissed by the JCVI (see Section 4). Both the JCVI and the DH opted instead for the methodologically dubious study by Miller et al. [23] as their only evidence to promote the new "improved" and "simplified" immunisation program. This obvious information bias is to be promulgated by the JCVI/ DH to the health profession.

Furthermore, according to the DH, it is not only important to censor information given to both parents and health professionals, the way in which this information is to be communicated is also very important.

> "It is important that the information given by health professionals is pitched at the right level. The JCVI information prompted questions among many respondents, but was useful for reassuring some, particularly those with a more pragmatic view of immunisation. Information at this level needs to be carefully tailored by health professionals according to the attitudes of individual parents."

The corresponding section from the Attitudinal research report (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122329.pdf) adds:

> "If in doubt, we would suggest keeping it simple, as outlined above." (D Conclusions; 3. Dealing with questions about the change to a combined schedule)

Since some disclosure to the parents on adverse events associated with the combined schedule is necessary, it is further regarded that in spite of some:

> "...diverging views on when the sheet should be given to parents; on balance it seems wise to hand it out immediately before vaccination, so that parents feel they have been given advance warning, but do not dwell on the content to the extent that they begin to worry." (D Conclusions; 4. The tear-off sheet on side effects)

The idea of "keeping it simple" was also welcomed by the health professionals. Indeed, as already discussed in Section 5), the public may not understand correctly the significance of febrile convulsions. Nor would anyone want the public to dwell extensively on associations between the words "vaccine" and "death" or "permanent brain damage".

One has to wonder whether parents who to this day continue to trust the British Health Authorities on matters of immunisation, would still have the same opinion if crucial facts on vaccine-associated adverse events discussed in "commercial" and "in confidence" CSM/JCVI/Joint Sub-Committee ARVI meetings were fully disclosed to them:

From the Attitudinal research report (pg 22):

> "To my eyes these things have all been tried and tested, the medical people studied for years, they tried all of this stuff. They obviously know getting these things correctly so my trust is in their hands really at the end of the day."

From a discussion on a proposal for the surveillance of severe neurological disorders in infancy and their relationship to pertussis vaccine, 7th February 1986, CSM/JCVI/Joint Sub-Committee ARVI (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

> **(6.5.1)**
>
> "It was considered unreasonable to ask paediatricians to report for a period of six years."
>
> "No attempt would be made to study serious neurological disease arising from pertussis and other infectious diseases."

From Miller et al. [23]

"For safety, proportions of children with erythema, swelling or tenderness at site of injection, or fever or other systemic symptoms for 7 days after immunization were compared between regimens."

From the JCVI meeting held on 3rd November 1981 (http://www.dh.gov.uk/ab/DH_095169):

(5.d. Comments on Professor Stewart's letter)

"Professor Gilliatt observed that in the Meade Panel Study one-third of children with brain damage were not admitted to hospital. In both the Meade and Dudgeon studies there were examples of children who had a fit soon after vaccination which was followed by a fit at a later time and then followed by cessation of development. It was very difficult to assess this as a random event...The Chairman concluded that much was not known about the natural history of brain damage in the young."

From the Attitudinal research report (pg 22):

"...the diseases must be serious and pose a risk – 'the NHS wouldn't put children through it [so young] if it wasn't necessary."

From the JCVI meeting on 11th December 1974 (http://www.dh.gov.uk/ab/JCVI/DH_095052):

(10.)

"...mumps vaccine was unnecessary because complications from the disease were rare. The Committee agreed that there was no need to introduce routine vaccination against mumps."

From a discussion on a proposal for the surveillance of severe neurological disorders in infancy and their relationship to pertussis vaccine, 7th February 1986, CSM/JCVI/Joint Sub-Committee ARVI (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

(6.5.1)

"No attempt would be made to study serious neurological disease arising from pertussis and other infectious diseases."

From the Attitudinal research report (pg 23):

"They're in the book and they say you should do them, I think if I don't do them then that's wrong. They know what they're doing."

From the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting, held on 5th October 1984 (http://www.dh.gov.uk/ab/JCVI/DH_095294):

(9.)

"Fetal damage after accidental polio vaccination of an immune mother. Barton AE et al. Journal of the RCGP 1984: 34: p. 390-394

Dr Smith observed that the termination of the pregnancy at 20 weeks in this case report was not related to the administration of oral poliovaccine (OPV)."

Note: how such conclusion could be reached remains unclear since:

"However, the foetus was reported to have signs of infection with poliovirus in the nervous system although no similar event had been previously seen after vaccination."

From the Attitudinal research report (pg 23):

"I don't think they would put something into a child that is not good for them."

> "I put my hands in the medical profession and they do a good enough job for me and I trust them."
>
> "Surely they wouldn't give these injections if they felt they would harm?"
>
> "I do think it's a good thing. You want to try and protect your children so if that's what they're suggesting they have to have done you should trust your health professionals."
>
> "Because they're recommended you kind of trust the doctors to guide you."

From the "commercial in confidence" CSM/JCVI/Joint Sub-Committee ARVI meeting, held on 6th July 1987 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

(6.1 Whooping cough)

"He explained that in February the CSM had called for ARVI's advice about updating the statement made in the 1981 report on Whooping Cough (HMSO) about a possible link between DTP immunisation and serious neurological illness. It had been hoped that by this means 'discovery' of all the relevant JCVI, CSM and ARVI documentation on whooping cough vaccine could be avoided."

From the JCVI/Joint Sub-Committee ARVI "commercial in confidence" meeting on 6th February 1987,

section "7.1 Whooping cough vaccine –CSM advice" (contents of the statement that CSM wished to modify; http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

"No scientifically unassailable link has been established between DTP immunisation and serious neurological illness but we have come to conclusion, on the basis of all present evidence, that there is a prima facie case that such a link may exist. We would also agree that the evidence suggests that the vaccine causes convulsions in some children."

From the CSM/JCVI/Joint Sub-Committee ARVI "commercial in confidence meeting on 3rd October 1986 (http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_4135306):

(5.1.3.c.)

"From the above there is reason to believe that the increased relative risk of prolonged convulsions after DTP was a real one."

From the JCVI meeting on 3rd November 1989 (http://www.dh.gov.uk/ab/DH_095169):

(9. ARVI Committee – Minutes of meeting 6 October 1989 (JCVI (89)25)

"Dr Schild reported that NIBSC was now able to distinguish clearly the wild strains from each of the two vaccines, and isolates from CSF clearly showed Urabe in all three cases believed to be associated with vaccine-although it should not be assumed that Jeryl-Lynn is not capable of the same result."

From the JCVI meeting on 7th May 1999 (http://www.dh.gov.uk/ab/JCVI/DH_095050):

(8. Meningococcal meningitis, i.)

"Committee members were reminded that this issue, and the papers presented, was extremely sensitive, commercially and politically. It was requested that confidentiality be maintained. The Chairman asked for any declarations of interest. Professor Cartwright was involved in manufacturers' studies on the vaccines, including health trials. Dr Goldblatt was

involved in one company-sponsored study and had provided a clinical expert report to the MCA for one manufacturer. Dr Jones was involved in trials for two of the companies involved. Dr Schild said that NIBSC was evaluating the vaccines.

"There were no objections to these members continuing to take part in the meeting and it was agreed that they would be able to provide a valuable input to the discussion in common interest."

From a discussion of the 8.4.1 Meningococcal C Conjugate (MCC) Vaccine Evaluation Programme, at the 7th May1999 JCVI meeting (http://www.dh.gov.uk/ab/JCVI/DH_095050):

(ii.)

"There was no good evidence for the efficacy of the meningococcal Group C conjugate vaccine, only the surrogate of antibodies compared with those known to be protective against invasive disease. To actually test the efficacy on the conjugate vaccine it would be necessary to introduce the vaccine and then conduct a Phase III or Phase IV study to test efficacy; this would be very difficult to do and would delay introduction by 3-5 years."

(iii.)

"It was felt that it was important to plan the programme now and confirmation that the vaccines were equally effective could follow."

Standards of Conduct

Finally, a reader may wish to assess the presented data on JCVI vaccination policies against the JCVI's own Code of Practice (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_115363.pdf) which states:

(Responsibilities of Committee and Sub-committee members):

(30)"All members of the Committee and its Sub-committees ('members') must demonstrate high standards of conduct."

(31)"In exercising their duties, members must observe the 'Seven Principles of Public Life' set out by the Committee on Standards in Public Life (the Nolan Committee):

Selflessness: Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends

Integrity: Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity: In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability: Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness: Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty: Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership: Holders of public office should promote and support these principles by leadership and example."

(Conflicts of Interests)

(39) Personal pecuniary[8] interest

"If a member has in the last 12 months received, or plans to receive a financial payment or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI or a Sub-committee including:

• holding a directorship, or other paid position

• carrying out consultancy or fee paid work

• having shareholdings or other beneficial interests

• receiving expenses (e.g. travel to, or registration for, conferences) and hospitality

the member must declare this interest.

If this interest is specific to an agenda item and the payment or other benefit is connected specifically with the product under consideration, the member will be required to absent him/herself from the discussion and any subsequent vote."

Summary

In conclusion, by apparently prioritizing vaccination policy over vaccine safety, the JCVI, the DH and the Committee on Safety of Medicines (CSM) may have shown a disregard for the safety of children. Through selective data reporting, the JCVI in conjunction with the DH, has promulgated information relating to vaccine safety that may be inaccurate and potentially misleading, thereby making it impossible for the parents to make a fully informed consent regarding vaccination. Furthermore, by 1) apparently misleading patients about the true risks of adverse reactions as to gain their consent for the administration of the treatment and 2) seemingly siding with vaccine manufacturers rather than public health interests, the JCVI and the CSM appear to have signally failed their fiduciary duty to protect individuals from vaccines of questionable safety. If these provisional conclusions are indeed correct, then the information presented here may help us in understanding the UK government's and the JCVI's official position on vaccine damage, that is, one of persistent denial.

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