

The Urabe Farrago:

A Recent Historical Account of Corporations and Governments Hiding
Vaccine Damage for the Greater Good

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The Urabe Farrago

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The Urabe Farrago

A Recent Historical Account of Corporations and Governments Hiding Vaccine Damage for the Greater Good¹

*You must assume the liability for the collateral damage.
Vaccines have side effects. We demand informed consent.
We demand greener vaccines. We demand choice for our children²*

There are very powerful people in positions of great authority who have staked their reputations on the safety of MMR and they are willing to do almost anything to protect themselves.³

In the autumn of 1988, the British Department of Health (DH) introduced three brands of the second trivalent vaccination distributed in Britain,⁴ the Mumps, Measles and Rubella (MMR) vaccine. MMR was to take the place of the single Measles vaccine given in mass vaccination campaigns and by GPs, Rubella vaccination given on the basis of need to putatively pregnant women and mumps vaccine that was only rarely used and was becoming a loss leader for pharmaceutical companies. Four years after they were launched, in 1992, two of these newly introduced vaccines, Pluserix and Immravax⁵ both containing the Urabe strain of mumps virus, were withdrawn by the Chief Medical Officer. The announcement that coincided with the withdrawal suggested that after extensive research mainly at Queens Hospital Nottingham, where it was claimed British researchers had discovered that the two vaccines caused high levels of a slight illness, aseptic meningitis, in a few children.

¹ This essay should be read in conjunction with To Encourage the Others, my last essay published earlier this year and available from www.cryshame.com.

² Causecast: <http://www.causecast.org/search?q=vaccine+safety>

³ Dr Peter Fletcher. Sunday Express 15th July 2007. Dangers of the MMR jab 'covered up'. By Lucy Johnston, Health Editor.

⁴ DPT (Diphtheria, Pertussis and Tetanus) was first manufactured in 1947

⁵ Manufactured by the Merieux and by Smith Kline French (later to become Glaxo Smith Kline), respectively.

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At the time of his announcement, the Chief medical officer described aseptic meningitis as a slight problem from which children wholly recover. But aseptic meningitis is actually a far more serious illness than the government made out at the time. The condition begins with inflammation of the lining of the brain but can have continuing sequelae and be fatal. Acute symptoms of aseptic meningitis include, seizures, increased intracranial pressure and Subdural effusions, while chronic complications include, deafness and seizure disorders, that can lead to many serious conditions, behaviour disorders and mental retardation.

Contrary to the inconsequential problems highlighted by the DH on withdrawal of the Urabe containing brands of MMR, Lucy Johnston reported in 2002 on a number of very serious cases of vaccine induced aseptic meningitis;⁶ 'In 1995 the Government's vaccine damage tribunal paid £30,000 compensation to James Smith, of Gateshead, for brain damage after he was given MMR at the age of four. James died nine years later aged 13.' Johnston reported there were 300 legal actions against Pluserix brought by parents whose children were seriously damaged between 1988 and 1992. Other examples given by her included, the son of John and Faye Smith whose life had been transformed from that of a healthy, intelligent young boy to that of a child requiring constant round-the-clock care. It took them six years and four hearings, however, to persuade the vaccine damage tribunal of this.' Judith Dwyer, received a payment after her four-year-old daughter Chloe died following a 'booster' jab of Urabe containing MMR in 1989. 'Chloe first developed pins and needles in her legs, then paralysis and problems breathing. She was rushed to hospital but it was too late.'

The withdrawal of the two brands of MMR so early in the burgeoning combined vaccine programme, put the government, the DH and public health officials on the back foot. From 1992, in the face of criticism, mainly from Dr Andrew Wakefield, the DOH struggled on with their vaccination programme which initially included a Measles and Rubella (MR) vaccine and the only remaining licensed MMR

⁶ Were all of these children killed by the triple MMR jab? January 13 2002 *Sunday Express* Focus, Lucy Johnston Health Editor.

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vaccine in the UK, MMR II which contained the Jeryl Lynn strain of Mumps virus.⁷

Politically and precautionairily, perhaps the best course of action might have been to immediately withdraw the two Urabe containing vaccines when the first adverse indications were noted in 1989 and continue research, while returning to the well established practice of single vaccines for both measles and mumps. However, although these single vaccines were still licensed the government dissuaded parents from their use, manufacturers from their importation and distributors from their sales. Pushed by the vaccine establishment and daily more powerful drug companies, successive governments continued determinedly to promote the combined vaccine programme.

The advent of every new, especially combined vaccination used on children, is inevitably an experiment that has involved no long term testing and which produces a wide variety of low level, sometimes chronic and occasionally fatal, adverse reactions. With vaccination, the stakes are high for both the manufacturers, in relation to profit, the government in terms of political and scientific credibility and most especially the patient whose health is at stake. Consequently, wherever one looks in the world of vaccination, there is perfidy and intellectual dishonesty.

This essay looks in depth at the incidence of adverse reaction relating to the Urabe mumps virus strain containing MMR's and the role of the government, the vaccine establishment and its most prominent personnel; the Department of Immunisation, the Department for Health and the secretive regulatory bodies lodged in the DH but actually financed entirely by the drugs industry such as the MHRA, in covering up this crisis. A glimpse of how the vaccine and public health establishments dealt with Urabe gives us a picture of bungling incompetence and a deadly lack of care, that has never before been put before the public.

The essay looks particularly at the way that the Joint Committee on Vaccine and Immunology (JCVI) and the British government put the health of children in peril between 1988 and 1992, by refusing to heed international concerns about Urabe

⁷ This mumps viral strain was noted in a WHO Position statement on mumps vaccines published in November 2001.

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fearing it would lead to a fall in herd immunity and failings in the mass vaccination programme. The essay also raises questions about the use of Urabe containing MMR after its withdrawal in the UK and the British government's role in its continued use on children in developing countries.

Mumps Measles and Rubella: MMR

Some doctors in Britain who gave serious consideration to MMR, struggled to understand why the three vaccines with their concurrent dangers had been fused together. Some wanted to stay with the single vaccines thereby accomodating individual patients on the basis of medical need, rather than be involved in the mass vaccination programme.

When MMR was introduced, although there had been a single measles vaccine, which had it not been for the introduction of MMR, would probably have continued at a high rate of take-up; Rubella vaccination, that was only given on a specific case basis to women likely to become pregnant, while medically there was no recommendation to vaccinate against mumps.

Doctor Peter Mansfield an independent general practitioner had proceedings brought against him by the General Medical Council (GMC) in 2005, because he spoek out against MMR and promoted single vaccines. The GMC case against him was dropped during its preliminary stages. Although Dr Mansfield is generally considered a doyen of 'alternative' health care, his views on vaccination reveal a restrained, sensible and medically correct approach to vaccination. His views reflect those of a minority of scrupulous doctors who were, after 1988 to come under increasing attack from a government determined to bring in combined vaccines.

I had been a General Practitioner for 28 years before I left the NHS, in 1996. My attitude to vaccination was very selective. I took the view broadly speaking protection against infectious disease was sensible, providing that the disease was one which you were likely to catch and providing that the vaccination presented a lower bar for the child to jump than nature would have done.

Introducing vaccines after 6 months and keeping them voluntary was originally a sensible policy. But the arrival of Dr Salisbury in the vaccines unit at the Department of Health, in the mid eighties, changed all the conventional considerations on vaccination. It suddenly became a heresy not to have a vaccine and they were all brought forward. From 5 to 4 to 3 months to almost straight after birth, when the child is faced now with 15 or so challenges.⁸

I thought that there was some point in tetanus and some point in Polio, but certainly not diphtheria or Whooping cough by six months, because the damaging effects of whooping cough was on very small children and the only protection against this was to keep the child at home preferably being fed by it's mother. In the practice I ran, we had very little adverse reaction from the measles vaccine because we always vaccinated when the child and the mother were in good health. I thought that measles vaccination was useful. I thought that there was no reason at all to vaccinate for mumps, in fact I thought it was unethical. Mumps is a disease that is harmless until the onset of puberty, we used to organise parties to spread mumps around and I never recall one occasion in 30 years when we felt we had made a mistake. We would rather not administer Rubella until puberty and anyway it was licensed for girls only.⁹

The British government turned Mumps into a dangerous and notifiable disease, just so they could justify the inclusion of the vaccine into the MMR. The British National Formulary of 1986-88 read; 'since mumps and its complications are very rarely serious there is very little indication for the routine use of mumps vaccination'. It would appear that the re-classification of mumps took place in order to convince the public of the serious nature of all three conditions, 'treated' prophylactically by the MMR vaccine.

A decade after the launch of MMR, in February 2001, Yvette Cooper MP answered a commons question from Mrs Ewing MP, who asked the Secretary of State for Health, amongst other questions, how many single antigen mumps vaccines were administered in the United Kingdom in each year since 1979. The Secretary of State answered, ' Mumps vaccine has never been a part of the United Kingdom's routine immunisation programme and data on this were not collected'. Yet since October 1988 a mumps component had been incorporated into all three putative brands of MMR.

⁸ Children in Britain now face up to 35 vaccines before their teens.

⁹ Interview with the author 2007

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Support for the idea that mumps was an inconsequential illness not meriting inclusion in a mass vaccination campaign, came from the Scottish Health Services Planning Council, the Central Health Services Council and the JCVI who met together on December 11, 1974. In the minutes of this meeting it was recorded that 'in general discussion on the subject of reactions **Mr Redacted**¹⁰ said that in the view of the Ministry of Defence mumps vaccine was unnecessary because the complications from the disease were rare'.

There have been a number of MMRs' developed over the last thirty years, the majority of them differ in their constituents and the effects of these substances. Not only is scant attention paid by the GP to the idiosyncratic health or constitution of the baby or child, but rarely does any detailed information about the differences in chemical or biological make up of the vaccine passes between the manufacturer and the doctor or the doctor and the patient.

It is in light of this, that the parents of muslim children find that they have been given medications containing pork, that vegans are given inoculations the manufacture of which has involved chick embryo's and bovine material and that devout Christians are given vaccines that contain remnants of aborted foetuses. As if these assaults on the cultural and life-style diversity of the population were not enough, by far the worst and most dangerous arrogance of the pharmaceutical companies and the government is to dispense vaccines with abandon without considering each individual child's physiology and biological or even in some circumstances emotional make up.

Particularly with a combined vaccine, there are multiple chances of the vaccine creating an adverse reaction in a particular child, as well of course there is yet other opportunities for the separate constituent part of the vaccine to be affected by the other parts. In his ground breaking book *The hazards of Immunization*,¹¹ Graham

¹⁰ There are blacked out names and incidents in the minutes of the JCVI and other meetings, rather than put stars or blanks here I have decided on the convention of using the name **Mr Redacted** (the term used for censoring documents) in bold.

¹¹ Graham S. Wilson. *The hazards of Immunization*, University of London, The Athlone Press, London 1967

Wilson, a former Director of the Public Health Laboratory Services, spends a chapter breaking down the etiology of all vaccination adverse reactions. The book has 22 short chapters on the wide variety of adverse reactions caused by a variety of effects connected with vaccination. To these ideosyncratic problems has to be added the very real chance of industrial contamination in some batches.¹²

What is not widely understood, is that it is not always the case that new vaccinations go through clinical trials. To a litany of endless little differences, we have to add the widely fluctuating strengths and amounts of viral strain that appear in different batches of vaccine, seemingly changed at will by the manufacturer. The simple fact is that with combined vaccines and competitive capitalism, there is no independent standards regulation and little hope of consistent safety testing on a global scale.

MMR was not the first trivalent vaccine, diphtheria, pertussis and tetanus (DPT) vaccination,¹³ had been produced as early as 1947 and recommended for routine use in America. The first MMR vaccine was manufactured by Merck Sharpe and Dohme (MSD) in the US in 1967, it joined together three different single vaccine strains, Enders measles strain (brand name Attenuvax), Jeryl Lynn mumps strain (brand name Mumpsvax) and HPV77 Rubella strain (brand name Meruvax). Even with this early combined vaccine, the Rubella strain that was used, came in two different forms which used a different manufacturing processes, HPV-77 DK was attenuated from dog kidney's and HPV – 77 DE attenuated from duck embryo's. What generally happened with combined vaccines was that the companies which maybe years before had manufactured and had licensed single products simply put these single ingredients into one vial.

Combined vaccines were hailed as a great breakthrough; a child only got one jab instead of three, they were so much more convenient. In 1972 the MMR

¹² See Martin J Walker, *The Ghost Lobby*, Published on the internet or available from www.slingshotpublications.com and Janine Roberts, *Fear of the Invisible: How scared should we be of viruses and vaccines, HIV and AIDS?* Impact Investigative media Productions. Bristol, UK. 2009

¹³ One of the great books about vaccine and adverse reactions was written about DPT. Harrison L. Coulter, Barbara Leo Fisher. *DPT A Shot in the Dark*. Harcourt Brace Jovanovich, New York. 1985.

manufactured by MSD was licensed in Britain but not marketed. However the HPV - 77 single rubella vaccine, particularly the DK variant, that was a constituent part of this triple vaccine became associated with an unacceptable level of arthritis and arthropathy and was withdrawn. By January 1979 the HPV-77 strain had been removed and replaced by the Wistar RA 27/3 strain in the USA. Now, the brand names included in this MMR product read as follows; Enders measles, (brand name Attenuvax) Jeryl lynn mumps (Mumpsvax) and Wistar RA 27/3(Meruvax II). This concoction became known as MMR II. At this time all other existing rubella vaccine were discontinued in the USA.¹⁴

Enter Urabe

Most countries have at some time, been exposed to Urabe either in single, monovalent form, or as part of the trivalent vaccine, MMR.¹⁵ Urabe in it's monovalent form is not generally associated with a high level of adverse reactions and especially not aseptic meningitis. In the Summary of Product Characteristics for Pariorix, the 1983, UK mumps single vaccine Licence for GSK, a Urabe Am 9 containing mumps vaccine, encephalitis is recorded as a possible 'undesirable effect'.

¹⁴ In February 2009, notice was given by Merck that they were to discontinue the single mumps vaccine in Britain and the USA.

¹⁵ **Urabe containing vaccines. Orevax:** Contents, Injection: Live attenuated virus vaccine against mumps, Urabe AM-9 strain, prepared by culture in embryonated hen eggs: Mumps vaccine. manufacturer, Aventis Pasteur. **Pariorix:** Contents, Injection: Monodose vial: Lyophilized preparation of the highly attenuated Urabe Am 9 strain of mumps virus, obtained by propagation of the virus in chick embryo tissue cultures. Mumps vaccine. Manufacturer, SmithKline Beecham. **Vaxipar:** Contents, Injection: Live attenuated virus vaccine against mumps, Urabe AM-9 strain, prepared by culture in embryonated hen eggs: Mumps vaccine. Manufacturers, Amson. **Trimovax:** Contents, Injection: Live attenuated virus vaccine against measles, (Schwarz strain), prepared on primary chicken embryo cells, against mumps, (Urabe AM-9 strain), prepared by culture in embryonated hen eggs, and against rubella, (Wistar RA 27/3M strain), cultured on human diploid cells. (Measles, Mumps & Rubella vaccine). Single dose vial+syringe of 0.5 ml. diluent. MMR vaccine. Manufacturers, Aventis Pasteur

The peculiar state of affairs in relation to the regulation of amounts of dosage of mumps strain virus in vaccines, was revealed by a paper on mumps virus published some time after the British launch of MMR. This study of available data for numerous Urabe containing vaccines highlights the huge differences in the amounts of Urabe virus included in past preparations.¹⁶ WHO requirements do not specify the minimum amount of vaccine virus that one human dose should contain; rather, this is determined by the national control authority of the country where the vaccine is produced (34). Most countries use at least 1000 CCID50 of attenuated mumps virus per dose, but many vaccines contain higher amounts.¹⁷

In their paper on Urabe, also written after the launch of MMR in Britain, Andre and Peetermans¹⁸, say that when the dose of Urabe virus previously included in a monovalent vaccine is included in a bivalent or trivalent product, it results in reduced rates of seroconversion against mumps. In the first stages of MMR production, this was resolved by increasing the dosage of Mumps virus in the trivalent vaccines. However, because these decisions were made 'on the hoof' without clinical trials we have no way of knowing their impact.

In June 1988 GSK were granted a licence for Pluserix MMR containing the Urabe mumps strain followed by the licensing of Immravax in September 1989, another Urabe containing MMR manufactured by Merieux, a French company.

Concerns about cocktails

If proof were required, of how the immunisation take-up rates dominated all decisions made by the Joint Committee for Vaccine and Immunology (JCVI) about

¹⁶ Mumps and a Mumps vaccine, a global review by A.M.Galazka, S.E.Robertson, and A Kraigher in the Bulletin of the World Health Organisation 1999, 77(1)

¹⁷ For example: Pluserix contained not less than 20,000 TCID50 of Urabe mumps strain. Trimovax contained 5,000 TCID50 of Urabe mumps strain. Immravax contained greater than or equal to 5,000 TCID50 of urabe mumps strain. Morupar contained 5,000 TCID50 of urabe mumps strain

¹⁸ Andre and Peetermans Effect of simultaneous administration of live measles vaccine on the "take rate" of live mumps vaccine. *Dev Biol Stand.* 1986;65:101-7.

susceptibility indicators or sub-group safety, we need look no further than the way in which contraindications, for vaccines were quickly changed with the advent of MMR.

With the introduction of combined vaccines, there was one eerie concern which had not been addressed and that was waiting in the wings ready to make an entrance. From the earliest beginnings of the scientific understanding of vaccination, it had always been understood that the effect of a vaccine virus on another virus present in the body at that time, could cause serious adverse reactions. It was for this reason that for the last thirty years one of the contraindications enquired about by doctors from parents, prior to vaccination was any kind of contemporary infection or infectious illness.

With the combination of three vaccines, it was always possible that instant adverse reactions might be created in specific individuals. When it was recognised that it was Urabe mumps strain that was creating aseptic meningitis, some investigators were confused by the fact that these adverse reactions only seemed to occur when the strain was mixed in a combined vaccine.

The concerns about the administration of three live vaccines in one inoculation was dismissed with MMR. The idea of administering a combination vaccine had been debated as far back as 1974 when in the Minutes of the Central Health Services Council, the Scottish Health Services Planning Council and the Joint Committee on Vaccination and Immunisation,¹⁹ at item 11 headed 'Simultaneous Administration of live Vaccines' we read the following:

Mr Redacted referred 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 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

¹⁹ 11th December 1974 (CHSC(VI) (74) 14)

MSD could be given with live poliovirus vaccine. **Mr Redacted** and **A.N. Other Redacted** 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 administration of any 2 live vaccines whichever came first.

If proof were required, of how the immunisation up-take rates dominated all decisions made by the JCVI about susceptibility indicators and contraindication we need look no further than the way in which the most important contraindication pre-MMR was changed, without the slightest scientific information that the contraindication was no longer valid.

By 2003 there had been an even further, slightly lunatic change in the perception of risk and multiple vaccination. An NHS publication in 2003²⁰ *MMR Information sheet 2*, suggests that a baby could, in theory, respond to around 10,000 vaccines at any one time!

A baby's immune system has an enormous capacity to fight thousands of bacteria, viruses and other pathogens that it is bombarded with every day. A Study from America shows quite clearly that even babies who are poorly can still produce protective immune responses to vaccines. This study also shows that a baby could, in theory, respond to around 10,000 vaccines at any one time. If for example, 11 vaccines were given to a baby at one time, this might only use about a thousandth of the immune system. In providing protection vaccines prevent "weakening" of the immune system.

Of course all such talk was nothing but rank stupidity; the historical results of vaccination of all kinds, showed clearly that different sub groups of children, affected by different risk factors and subtle juxtapositions of viruses and antigens, might be radically and adversely affected even with the use of single vaccines let alone any combination more than this.

Strains of a Different Kind

²⁰ MMR Information sheet 2, to be found at www.immunisation.nhs.uk

Amongst those who deny that there can be vaccine damage from MMR, there is an absolute unwillingness to understand, put forward, or even analyse even the crude science involved in vaccine manufacture. The government, the vaccine industry and the medical and paediatric establishment, discuss vaccines as if they were aeroplanes or automobiles that occasionally crash in odd circumstances; vaccines are not aeroplanes or automobiles. There are many variables of degeneration, toxicity and corruption associated with live viruses manufactured in combination with other viruses and then injected into the human blood stream.

The Urabe Am 9 vaccine was produced from a 1967 Japanese isolate at The Research Foundation for Microbial Diseases of Osaka University in Japan. It involved the use of quail embryos and chick amniotic cavities.²¹ Osaka University filed a Patent for Urabe in the United States in 1979, it was manufactured by the Biken Company as a single vaccine. At the same time Urabe appeared in Germany in a bivalent measles/mumps vaccine under the label of Rimparix.

From the inception of its production in 1979, this monovalent Urabe vaccine by comparison with the bivalent and trivalent products incorporating it rarely produced any adverse reactions. The World Health Organisation (WHO) records that by 1985, 5 million doses of Urabe vaccine had been given.²² Given the size of this cohort it seems reasonable to deduce that had large scale outbreaks of adverse reactions been occurring they would be easily identified. In 1983 a single Urabe mumps vaccine, Pariorix was produced by Wellcome²³ and put on the UK market. By the mid nineteen eighties Urabe appeared in Canada as part of an MMR vaccine called Trivirix by SmithKline and French laboratories and in 1988 and 1989, in the two Urabe containing MMR vaccines offered in Britain.

²¹ M. Flynn & B.P. Mahon Chapter 6: *Immune Response to Mumps Viruses Recent Research Developments in Virology*, 5 (2003):97-115 ISBN:81-7895-094-4

²²

http://www.who.int/biologicals/publications/trs/areas/vaccines/mumps/who_trs_760_A7_Mumps.pdf

²³ Wellcome was later taken over by Glaxo and after various metamorphoses eventually became GlaxoSmithKline, (GSK) which is the company that I shall refer to throughout the rest of this essay

MMR II the third MMR vaccine licensed in Britain contained the Jeryl Lynn mumps virus - named after the child from whom the virus was isolated. The Jeryl Lynn strain was not compromised when included in the combination vaccine. On the down side it made MMR II much more expensive than the Urabe containing MMR's.²⁴ In the US MMR was only produced with Jeryl Lynn.

First Plans: the Introduction

On the 17th December 1987, Tony Newton the then Minister for Health, announced in a Press release that a one- dose combined measles, mumps, and rubella vaccination was to be introduced into the UK immunisation Programme in October 1988.²⁵ It was, he suggested, to be the 'biggest change in British immunisation policy for over 20 years, and should lead to the virtual disappearance of measles, mumps and rubella.' According to Minutes of the JCVI, the original intention had been to announce the launch of MMR on World Health Day, April 1987.²⁶

As with all mass vaccination campaigns, considerable funds, in this case totalling £1.4 million were earmarked to cover the first six months of the campaign; 'to assist health authorities with increased vaccine costs'. According to the minutes of the JCVI Working Party of February 1988 the license for the Merck Sharpe and Dome 1972 (MSD) MMR product had lapsed by the late eighties and it was not available for the grand launch of this mass vaccination campaign. The government was then led to licensing two other MMR brands, quickly in order to carry out their campaign.

²⁴ JCVI minutes and all other available data recorded how MMR II was 3-4 times more costly than Pluserix but the new releases identify the MMR II product at £1 in the early catch up phase going up to £2 after that whereas the supply agreement for Pluserix records the cost of Pluserix at £3.80 plus vat.

²⁵ Despite it being said at the launch of MMR that the vaccine gave a life-long safeguard, some time later, the DH gave up on this and introduced a booster.

²⁶ JCVI Friday 7th November 1986

That the oddly unlicensed MMR manufactured by MSD was the product originally intended for the UK market in 1988 is supported by the fact that the JCVI had sourced and relied upon data from Sweden, USA and Finland to bolster their suggestion that it be introduced into the UK. However, there was one big difference between this well studied MMR product, already used in the USA and Scandinavia and two of the MMR vaccines which were finally introduced into the UK. Neither of the new combined vaccinations contained the Jeryl Lynn strain of mumps contained in the MMR product manufactured by MSD. The two new vaccines licensed for use in the UK, Pluserix MMR and Immravax MMR, which would ultimately secure 87% of the UK market contained the Urabe mumps strain making data from the USA and Scandinavia on safety efficacy and efficiency totally irrelevant.

In June 1988 a Product Licence was fast tracked for the SKF (SKB), MMR product named Pluserix, it contained the Urabe Am 9 strain of mumps virus. Evidence that the licensing of Pluserix was fast tracked while it's specifications were based upon the data from the well tested MSD MMR used in other countries comes from the following statement in MMR Working Party Minutes of 1987:

SmithKline and French were intending to apply for Clinical trials certificate and Product Licence; SKF had data from experience of MMR from elsewhere. **Mr Redaction** felt that that respectable data from other countries would be acceptable to the Committee on the Safety of Medicines(without new trials), it might be possible in this way to move directly towards Product Licence application stage.²⁷

No evidence of 'respectable data' from other countries which would allow Pluserix to exclude the need for Clinical Trials and move directly to Product licensing was produced at this meeting.

The Working Party set up to implement the introduction of MMR, first met in January 1987 some 22 months before the actual introduction. Even earlier discussions on the projected introduction of MMR can be found as far back as the JCVI minutes of the 7th November 1986. With such a lengthy period of 'forward planning' why did

²⁷ MMR Working Party Minutes 23 January 1987

the need arise for any product to be fast tracked? One answer might lie in the fact that the earlier licensed MMR was licensed to MSD and was an American product, while SKB was one of the biggest British companies very close to the government.²⁸

Most curious was the announcement by Mr Horam MP²⁹ to the House Of Commons on the 20th March 1987 that the JCVI had given positive endorsement to the introduction of the new MMR into the Childhood Immunisation Programme. He advises the House that positive data from Sweden, USA and Finland had been instrumental in helping the JCVI to reach this decision. Hearing this, it would be fair to assume that the children of the UK were to be given the same product as had been used in Sweden and other countries. It seems inconceivable that the authorities in the UK would have been swayed by data from other countries about the healthy safety record of an entirely different vaccine into the UK Programme.

A letter obtained at a latter date under FOI dated March 1987, containing the advice submitted to Ministers by Officials recommending the introduction of the new MMR in the UK, also commented on the use of MMR in other countries:

The combined MMR vaccine has been introduced in other countries , notably USA and Scandinavia, with encouraging results.

The experiences in other countries involving one MMR vaccine appears to have been used to entice Ministers to think favourably about the introduction of another MMR vaccine into the UK. In an 'outline of statement' to be made at functions on the 7th April 1987, World Health Day,³⁰ information for speakers tells them that; *'The JCVI has considered evidence now available from other countries and has advised that significant benefit would flow from changing over to combined MMR in infancy'*.

²⁸ A number of FOI request between 1988 and 1998 resulted in blank refusals or an apparent lack of knowledge.

²⁹ John Horam MP, Member of Parliament for Orpington since 1992. Minister of Health in the last Conservative Government and before a Minister in the Cabinet Office. From 1997 - 2004 Chairman of the House of Commons Environmental Audit Select Committee, presently a member of the Foreign Affairs Select Committee.

³⁰ Information obtained under FOI

By September 1987 a *Policy for the Implementation of the MMR Vaccine* was being circulated advising that two types of MMR Pluserix and Immravax vaccine were to be made available on the 1st October 1988. The inclusion of MMR II occurred some time after this launch when a direct approach was made by Wellcome requesting to be included in the MMR market. The JCVI Working Party Minutes of February 1988 state that ' **Redaction 1 Ltd** and **Redaction 2 Ltd** had both submitted applications for Product Licences. **Redaction 2 Ltd** had now been granted a licence which had previously lapsed; it's vaccine contains a different strain of mumps virus (Jeryl Lynn)'

Seemingly without any discussion of the viruses used, regulation of their amounts or the consequence of their combination, without any kind of trials involving the new strain of virus, two new versions of MMR were to be released onto the British market.

The Launch

As the introduction of MMR approached, the JCVI spent some time discussing the issues surrounding the introduction. In the early stages of planning, 'there was some resistance' to the trivalent vaccination, however, as time went by this seems to have been weeded out.³¹ That issue was replaced by such things as how to explain contraindications and risks and what could be done about parents who refused the new vaccine. The answer to this last question was easy: 'for a limited period' they would be offered the single measles vaccine. But after that limited period, MMR was to be almost compulsory and children starting nursery or primary school, who had not received the vaccination would have to show, either: a documented record of MMR vaccination; *a valid contraindication*. parental refusal or laboratory evidenced immunity to measles, mumps and rubella.

³¹ Minutes of a meeting of the Joint Working Party Of The British Paediatric Association and The JCVI. 26 June 1986.

Of the three brands of MMR launched in October 1988, Only the Urabe containing Pluserix by GSK, was actually licensed and available in October. Immravax by Merieux was brought in September 1989, and MMR II by MSD was re-licensed by November 1988.

Pluserix had been licensed in numerous countries prior to 1988³² but unbeknown to the British public, far from Pluserix having a good record in these countries, the vaccine *had already been withdrawn in Canada*, where it was marketed as Trivirix following the discovery of an adverse reaction of aseptic meningitis. And so it was, that in the Autumn of 1988, Edwina Currie, the then Tory Health Minister shared with an assembled gathering of health officials and media personnel, information regarding what was to be one of the most profound changes in the child immunisation programme in the UK. A triple MMR vaccine, two brands of which containing Urabe mumps vaccine that had had no clinical trials, but was said to offer 'life-long protection with a single jab' was launched in Britain. Ms Currie failed to tell her audience that a brand of this revolutionary new vaccine had already been withdrawn in Canada.

News from Canada

The MMR Trivirix with the Urabe strain AM-9 containing Mumps virus, was introduced in Quebec, Canada to replace MMR I in 1986. However, within months, in 1987 public health specialists and Canadian doctors became suspicious that there appeared to be a problem with the vaccine. By early 1988, over six months before

³² MMR II was licensed in the UK but according to contemporaneous minutes from the JCVI, the vaccine was not expected to be brought into the campaign until the end of November of that year and the licence for Immravax the third of the UK campaign vaccines, was not be granted for a further 18 months. The supply of Pluserix from 1988 was managed by SmithKline and associated companies which were about to be swalled up by Glaxo and incorporated with Wellcome.

Urabe containing vaccines were licensed in Britain and while the British were just about to launch MMR, the Canadian government acted swiftly to withdraw all MMR vaccines containing the Urabe strain of mumps virus.

On July 18, 1988, Dr Richard Schabas, Director of the Public Health Branch and Chief Medical Officer of Health at the Ontario Ministry of Health, issued a memo to all physicians instructing that remaining stocks of Trivirix vaccine be returned and that MMR II manufactured by MSD be the only triple vaccine used to immunise children against measles mumps and rubella.

If any thing should have acted as a very early warning to the British government it was the Canadian experience; why didn't the British government call off the launch of their two Urabe containing vaccines?

Setting aside the very obvious and acknowledged failings of the adverse reactions surveillance by the British Paediatric Surveillance Unit (BPSU) in the UK, other indications that all was not well were clearly swept aside. In March 1988, the following passage appears in the Minutes of the Joint Sub Committee on Adverse Reactions to Vaccinations and Immunisations (ARVI):

Five cases of mumps encephalitis following MMR have been reported from Canada. Four of these cases definitely followed the use of vaccine containing Urabe Am 9 mumps virus and the fifth probably did.

The members of the JCVI Working Party on MMR also debated the Canadian situation, noting that a decision had not been made by the Canadian authorities to suspend the licenses of MMR vaccines containing the Urabe strain and concluding that 'the data on which the decision had been based was *slender*.'

Damage and Feet Dragging, Japan

Between 1987 and 1992, the JCVI and other Department of Health committees intimately related to the vaccine industry, talked secretly about the damage that Urabe strain mumps virus might be doing in the combined MMR vaccination. But even faced with information from Canada and then Japan, the British government failed to take seriously the dangers of the vaccine.

In the case of MMR, Japan is not perhaps the best example of how to use the precautionary principle or even how to act speedily against vaccine adverse reaction. However, the massive and most honourable distinction, that sets the Japanese government aside in this situation is the fact that they moved with alacrity admitting cases of vaccine damage and bringing them to court to award parents compensation. In the considerable lack of interest and scepticism shown by the British in the face of the developing disaster in Japan one is able to gauge the mind set of the British civil servant; the protect your back while doing as little as possible, approach.

Urabe AM-9 containing MMR was introduced in Japan in March 1989 and within six months, in September 1989 the first post vaccine cases of aseptic meningitis, were reported to the Japanese Public Health Council.³³ A few months later in 1990, when MMR had already been distributed in Britain for two years, the matter of data of serious adverse reactions in Japan was discussed at a May JCVI meeting, under item 9.1b. The records report:

Of special concern to the ARVI (adverse reactions vaccination and Immunization) were the reports from, Japan, of a high level of meningoencephalitis associated with the administration of MMR. However, ARVI concluded that the Japanese experience may be due to different reporting/investigating criteria or other local factors.

And these people call themselves scientists! '*ARVI concluded*' and '*may be due to*' and '*other local factors*', these are off-the-cuff remarks inside a secret meeting. There is

³³ see <http://www.nih.go.jp/JJID/55/101.pdf>.

no sense or logic or rationale to these statements, there is no evidence presented, there is only an evident and complete desire to dismiss the reports from Japan.

Five years after the Urabe containing MMR had been withdrawn in Britain, in 1997, one persistent MP ³⁴ asked the Secretary of State for Health for a break down of health concerns relating to different MMR vaccines;

If the secretary of state will list for each of the nine MMR vaccines for which the product licence has been cancelled, the date on which the product licence was granted; whether the licensing of the vaccines was on the advice of the Committee for the Safety of Medicines; on what date each cancellation took place; what safety concerns had been identified for each vaccine by the Medicines Control Agency and under whose direction the licence was withdrawn.

With the answer below the Minister made it clear that the manufacturing companies commercial competitiveness was considered more important than the health or public knowledge of the British citizens or even the power of their member of parliament.

Information regarding the cancellation of product licences is commercially confidential. The recommendations of the Committee on Safety of Medicines are confidential. ³⁵

³⁴ Mr Llew Smith MP 20th March 1997 column 805

³⁴ Response from Mr Malone 29th March 1997, column 805 Hansard

³⁴ The MHRA came into existence in 2003. While it might appear, superficially, that the MHRA is a department of the DoH, or even perhaps an independent agency linked to the DoH, it is in fact a Government trading fund. This might as well be called a business or a corporation, for a trading fund is an almost entirely separate economic entity, which earns money by the provision of services, and, like any kind of company, has to balance the books at the end of each year. A trading fund is a government department, or an executive agency, or part of the department, which has been established as such by means of a Trading Fund Order made under the Government Trading Funds Act 1973. However, unlike a number of other Government Trading Funds, which provide services, earn money and accept fees from diverse 'beyond government' sources, the whole of the MHRA income is provided by one funder – the pharmaceutical industry. Further, a percentage of staff and executives of the agency have come into it from the pharmaceutical industry. It is, therefore, not surprising that, funded and partly staffed by the industry, its policies are shaped to please this sector. The MHRA, has the largest policing and enforcement department in Europe, a part of the Enforcement & Intelligence Division (E&ID) of the Agency. The group is now dealing with an increasing volume of cases of alleged non-compliance with medicines legislation, and offences under the 1968 Medicines Act and more recent European regulations. Extract *The Fate of a Good Man: The Investigation, Prosecution and Trial of Jim Wright by the MHRA*, Martin J Walker. E book Slingshot Publications (www.slingshotpublications.com) London. 2007

This is the inevitable consequence of having a medicines regulatory body, disguised as part of government, inside the DH (the MCA or the more contemporary MHRA) that is entirely funded by the pharmaceutical industry.³⁶

Although Japan, began listening to the reports of Urabe vaccine damage with more alacrity than the British, they acted upon these reports at more or less the same time. The Japanese began using the MMR in April 1989 but while doctors were warning of side effects by July, the Japanese government chose not to act on these warnings until 1993 when the vaccine was eventually withdrawn. By this time, some 1,000 Japanese people had suffered adverse reactions and three children had died.³⁷

The Japanese were so concerned initially as to the numbers of cases of aseptic meningitis post immunisation with Urabe containing MMR, that on the 1st November 1989, only months after MMR was introduced, approaches were made to their counterparts in USA, Canada West Germany and the UK.

On 26th of the same month, the Director-General of the Pharmaceutical Affairs Bureau, the Ministry of Welfare verbally instructed vaccine manufactures such as RIMD to investigate cases and literature, etc. and as of 1st November of the same year, requested Japanese diplomatic establishments in the U.S.A., Canada, the U. K. and West Germany to investigate the matter, through the North American Affairs Bureau and the European and Asian Affairs Bureau of the Ministry of Foreign Affairs, in order to find out the rate of occurrence of aseptic meningitis after the MMR vaccination and mumps vaccination in other countries.³⁸

Interestingly, Professor Salisbury, Head of Immunisation at the Department of Health despite initiating a search, in answer to a parent researcher noted some years later in a letter 'we have no record of receiving a request from the Japanese Government and no diary entry of an appointment'.³⁹ Professor Salisbury could not say for certain that a

³⁷Bonnie Estridge *Daily Mail* 18 May 2004

³⁸ Transcript of the Japanese MMR Litigation 2003

³⁹ e-mail from Professor Salisbury to parent of a vaccine damaged child.

meeting did not take place but that he had 'no recollection of such a meeting eighteen years ago' and that the DOH had 'no correspondence requesting such a meeting'.

The Committee on the Safety of Medicines met on the 28th September 1989⁴⁰ with the attendance of the French minister of health, six or seven months before the decision was made in Canada to withdraw the Urabe containing MMR permanently, two months before the Japanese had relayed their experience of aseptic meningitis to the British in November 1989⁴¹. These Minutes, at 14.2 record how by September of 1989, two months before the Japanese alert, ten cases of mumps meningitis following MMR vaccination, had come to light; the veritable top-of-the-iceburgh. So even before the Japanese findings were made known, the UK authorities had picked up on ten cases of aseptic/mumps meningitis which were played down against the 2.5 m doses of MMR given in the UK. At the time of the Japanese alert and afterwards everyone became slightly hysterical as they tried to play down the significance of the Japanese experience. This hyperdenial was based it seems on the fact that everyone believed that the superior surveillance system in the UK would immediately pick-up such a problem here if there was one.

Two days after the Japanese raised the alarm on Urabe, on November 3 1989,⁴² at a meeting of the JCVI, Minutes of a ARVI meeting in October are tabled and it is recorded⁴³ that the National Institute for Biological Standards and Control (NIBSC) had been able to define the vaccine strains and identify that all cases tested by them were of the Urabe strain consistent with the vaccine which had been administered.

At the meeting of the JCVI on Friday the 4th of May 1990 when the Japanese situation was again discussed, no mention was made of the ten cases of Mumps meningitis identified in the UK. This is especially concerning given that two people, Professor Breckenridge (chairman of the ARVI) and Dr Rotblat, of the DH were

⁴⁰ Minutes of the CSM meeting 28th September 1989

⁴¹ In an email exchange between Salisbury and a parent of a vaccine damaged child, Salisbury does not to remember any meeting taking place with the Japanese.

⁴² Transcript of Japanese MMR litigation 2003

⁴³ ARVI Minutes October 6th 1989

present at both meetings. The truth was that irrespective of the statistics, the UK had experienced exactly the same type of reaction as that uncovered in Japan.

Concerns highlighted by the Japanese compelled a representative of the Scottish Home and Health department (SHHD), expressing its independent intelligence, to write on the 9th April 1990 to the Department of Health requesting reassurance as to the safety of Urabe containing MMR's.⁴⁴

Direct questions were placed before the DH with a request that they be tabled at the forthcoming May meeting of the JCVI. Among other things, the representative of the SHHD asks if there was any justification for changing to the MMR vaccine which used the Jeryl Lynn strain of mumps virus. At this same meeting huge concerns regarding the Japanese situation were tabled but not quite in the same vein as those expressed by the SHHD. Whereas the shared concerns by the SHHD emanated from alarm as to the safety of the Urabe containing MMR's by stark comparison **Mr Redacted** was more "concerned about the possibility of the Japanese experience being published widely in the UK". It must have come as a huge relief to the assembled gathering when a little further on **Mr Redacted** noted how "the Japanese had withdrawn a letter sent to the Lancet".

Although Japan eventually withdrew the Urabe containing MMR after the UK decision to switch entirely to the safer MMR II product, some individual areas of Japan actually stopped using the vaccine on the 1st November 1989, the very day when Japan is recorded as having made approaches to Canada, USA, West Germany and the UK.

The transcript of the Japanese Court case⁴⁵ in which seven claimants, (four claimants were mother and father of two dead children, one was a damaged child and the final two were his mother and father) tells us that on the 1st November, Takatsuki

⁴⁴ Received from JCVI minutes under FOI.

⁴⁵ Transcript of Japanese MMR litigation 2003.

City decided to suspend the use of the Urabe containing MMR and that on the following day, Toyonaka city followed suit.

In 1992 sadly too late for the many children who suffered side effects in Britain members of the JCVI were forced to admit that *'many lessons had been learnt from MMR. It was agreed that better surveillance was needed as well as a consideration of how adverse events were followed up'*⁴⁶

Questions must be raised as to how, faced with the data from Japan in 1990, the UK authorities considered the surveillance system for detecting such reactions within the UK, was adequate. It has been known for years, that the Yellow card system, only picks up on around 10% of adverse reactions and general doctors are notoriously ignorant of the side effects suffered by patients to the drugs they prescribe.

Worryingly, also, while the British JCVI/ARVI seemed to confuse the situation in Japan by describing the majority of cases of illness as meningoencephalitis, while it was actually cases of aseptic meningitis that had been highlighted by the Japanese authorities. It was known by this time that such cases were directly linked to the Urabe mumps component of MMR and were primarily viral in origin.

Concerning aseptic meningitis following the MMR vaccination, about 630,000 children were vaccinated with the MMR vaccine between 1st April 1989 and 31st October of the same year ; among them 311 recipients were clinically diagnosed with aseptic meningitis after the MMR vaccination; the cerebrospinal fluid was collected from 302 of them; the mumps virus isolation test was carried out with the cerebrospinal fluid of 222 individuals; the viruses were isolated from the fluid of 79 cases; it was determined that that the virus came from the vaccine in 67 cases using the PCR method.⁴⁷

The material contained in the JCVI minutes on this subject is misleading in that it generalises the problem from Japan to be that of meningoencephalitis while in fact

⁴⁶ Minutes of meeting Friday 6th November 1992,

⁴⁷ Transcript of Japanese MMR litigation 2003

Japan also had numerous cases of aseptic meningitis, the majority of which were identified as vaccine induced and more specifically yet, associated with the Urabe mumps strain.

Members at the JCVI meeting, quoted above, were also concerned about two further matters; whether or not there was a possibility that the 'Japanese experience' might be widely and detrimentally publicised within the UK and the need to 'gather information on the various episodes from all the MMR manufacturers'.⁴⁸ At the same meeting it was mentioned by one participant that three health districts had changed from the use of Urabe containing MMR's to the Jeryl Lynn product.

Irrespective of the status of the Surveillance system in place in the UK, which seemed to obsess some JCVI members, other indicators were emerging which should have suggested that there were serious problems concerning the Urabe containing MMR.

Collapse of Stout Party: Britain

The DH and UK government were well aware of the problems occurring with the Urabe strain of mumps vaccine not only before the vaccine was given to millions of children in this country, but even before the vaccine was approved for licence in June 1988. Concerns were referred to in the Minutes of the Joint Sub-Committee on Adverse Reactions to Vaccination and Immunisation, (ARVI) in March 1988.

Following the launch of MMR late in 1988, reports of aseptic meningitis began to circulate. In October 1989 two letters appear in the *Lancet*⁴⁹ Burns concerning a 3 year old girl who had presented with aseptic meningitis after a period of 21 days post immunisation with the MMR. The isolated virus was identified as

⁴⁸ This is an interesting suggestion and gives credence to the fact that large pharmaceutical companies actually spend millions of pounds on post-prescription surveillance that they do not share with national health care systems or national governments for reasons of commercial competitiveness.

⁴⁹ James A. Gray and Sheila M. Burns (correspondence), *The Lancet* (14 Oct 1989): 981989

mumps by fluorescent-antibody tests. Soon afterwards the virus was identified by nucleotide sequencing analysis as the Urabe strain. The child concerned exhibited lethargy, vomiting, headache, dry cough, fever, irritability, and meningeal irritation. There had been no known exposure to measles, mumps or rubella in their natural forms. No other infections were identified either bacterial or viral.

In the August 12th edition of the *Lancet* a further letter appears, this time from a doctor in West Germany, who had identified a two-year-old boy with mumps meningitis 21 days post MMR vaccination. This vaccine differed from that in the previous case involving the 3 year old girl identified by Gray and Burns. Again there was no exposure to natural mumps and the author of this letter wrote 'The incubation period for mumps is about 21 days. In some patients, time-lag between immunisation and manifestation of meningitis was very close to three weeks, without known previous mumps contacts. These facts strongly suggest that some patients may have had vaccine mumps meningitis and not wild mumps infection'. A month later two British doctors reported two sixteen month boys with mumps meningitis with hospital admission, 18 and 19 days respectively following MMR vaccination.

Worryingly in 1989, the Committee on the Development of Vaccines and Immunisation Procedures (CDVIP) openly question the figures for mumps meningitis placed before them and in their meeting in November 1989⁵⁰ record that:

Information available at the present time suggested that mumps vaccine caused clinical meningitis in approximately 1: 200,000 doses individuals; this was probably at least ten fold less than that associated with natural infection. Members of the CDVIP were sceptical of this figure since the data collection had not been based on objective studies: they suggested that in future the data should be examined with reference to defined clinical state, virus isolation and serological tests."

By May 1990 members of the JCVI were noting their concerns regarding the fact that Canada have stopped the use of Urabe containing MMR's. The Japanese situation

⁵⁰ Committee on the Development of Vaccines and Immunisation Procedures (CDVIP) meeting in Tuesday 28th November 1989

clearly affected some members of the committee and there is also the concern that three Health Districts in Britain have stopped using Pluserix and Immravax.

At the conclusion of the November 1989 the JCVI committee meeting a member spoke of the 'risk to the MMR programme of adverse publicity and said that vigilance by all was a essential'. This tends to infer that members should at all times and above all considerations consider the risk to the MMR campaign when reviewing adverse reactions which had the public been aware of them, might have had a very detrimental effect on vaccine uptake. Such pressure is bound to have spread reluctance among members to deal appropriately with adverse reactions to the MMR vaccines. The presence of a constant reminder of the importance of the entire MMR vaccine programme could obviously create an under evaluation of any issue which threatened the programme.

By January 1991, The Rt Hon Jack Ashley, who had been at the forefront of the campaign to gain recognition for victims of DTP and whooping cough vaccine⁵¹ wrote to Virginia Bottomley JP MP, the then Minister for Health. Ashley expressed his surprise on being told that new vaccines were not to be subject to surveillance by Dr Iman's Unit at Southampton University. He requested details of the Surveillance systems in place other than the Yellow Cards System, all adverse reaction reports to vaccines received in the last year and a breakdown of the vaccines to which they apply.

In her reply Ms Bottomley supplies the fact that 748 adverse reactions were received in 1990 through the Yellow Card System. Commenting on the other Surveillance systems in place in the UK she said:

A number of advisory bodies including the joint Sub Committee on Adverse Reactions and Immunological Products (ARVI) which reports both to the CSM and to the Joint Committee on Vaccination and Immunisation (JCVI) , regularly review the safety of vaccines taking account of information from both the spontaneous ADR reporting schemes and from special studies and surveillance

⁵¹ Rosemary Fox, *Helen's Story* John Blake, London 2006

programmes undertaken in relation to specific vaccines. One such programme relating to surveillance of MMR vaccines has been set up under the British Paediatric Surveillance Unit to identify neurological reactions occurring after vaccination. Under this scheme, all Consultant paediatricians in the UK are asked, monthly to report any such cases which are then systematically followed up to obtain comprehensive information. The programme is funded by the Department.

That the surveillance system described by Ms Bottomley set up to monitor adverse reactions to MMR was funded by the Department of Health must surely have afforded them some embarrassment when, on the withdrawal of the two Urabe MMRs the JCVI subsequently acknowledge that 'a better surveillance system was needed'.

A further damning comment came in respect of the inadequacies of the Yellow Card System when P.O.S.T the Parliamentary Office of Science and Technology⁵² later acknowledged that 'The Urabe experience was exacerbated by the failure of the Yellow Card Surveillance System to detect the scale of the problem'.

Lord Ashley in a further communication requests figures for the number of aseptic meningitis cases, within the reported 748, which were likely to be permanently damaged, a breakdown of how many case of death or serious damage followed a triple vaccination and how many post MMR. Ms Bottomley advises him that a total of 199 reactions graded as "serious" were reported in 1990 of which 45 were in relation to an MMR vaccine. Included in the 199 were 7 deaths which were further broken down to ; 2 deaths which were considered not to be as a consequence of the adverse reaction, 3 deaths where the cause of death was uncertain; and 2 deaths which were considered to be due to the administration of a triple vaccine.

On 17th September 1990, the ARVI minutes refer to reports of emerging cases of meningitis in Crawley, Cambridge, Kidderminster and Nottingham, with clusters of cases in the latter three locations. 25 cases were reported spontaneously between February and September 1990.

⁵² Parliamentary Office of Science and Technology. Summary Report of July 1995

It is clear that irrespective of the failures of the surveillance systems in the UK to detect the scale of the problem, there were many wasted opportunities along the way to investigate mounting evidence that there was a problem with the MMR vaccine. A sustained and blatant refusal by those in authority to address the rising concerns and re evaluate the cases of serious side effects, resulted in thousands of children in the UK being exposed to two vaccines which, before they even entered the UK market and throughout their time in it, were enmeshed in uncertainties involving adverse reactions.

* * *

Why was it that despite well aired concerns, members of the JCVI, ARVI and the MCA, still doggedly relied on the worse than useless yellow card system of Surveillance to highlight serious adverse reactions to the MMR vaccine? Why was it that given the information coming before them at Committee meetings no one questioned the abilities of the systems in place to accurately determine figures of adverse reactions? Was there pressure on members to consider the outcome for the MMR immunisation programme if they reported worries over the safety of the vaccines?

A little known piece of information might well go some way to explaining why it was that alarm bells concerning Urabe went unheard and we find that in the JCVI minutes of the 13th Nov 1996, item 8.1:

there was no statutory duty for the MCA to advise the JCVI of problems with vaccine safety, and in effect the MCA decided which information they passed to the JCVI.

This is most alarming given that on the 20th march 1997, Mr Horam in the House in response to questions by a Mr Smith advises him that

The Joint Committee on Vaccination and Immunisation decided at it's meeting of the 7th November 1986 to recommend to Ministers that a combined measles

mumps and rubella vaccine be introduced into the United Kingdom childhood Immunisation Programme as a replacement for single antigen measles vaccine.

It appears that the JCVI have the power to make recommendations to Government Ministers as to the introduction of vaccines but in 1996 we learn that there was no statutory duty for the MCA to advise the JCVI of any problems of vaccine safety. How then could the JCVI be certain that the product they were endorsing and advocating to Ministers was safe?

Based on a catalogue of early warning signs that all was not well with the Urabe containing MMR's why did it take until September 1992 to have them withdrawn. According to Mr Sackville⁵³ in response to questioning from Mr Smith,

As soon as data were available confirming the extent of the risk, showing that an alternative vaccine did not have this level of risk and was equally effective, and adequate alternative supplies were available, the Urabe vaccines were replaced. This occurred in September 1992.

In fact this was a clever bit of politicking by Sackville, who, with his misrepresentation, seemed to delay even further the simple continuance of the MMR II vaccination. What Sackville refers to as an 'alternative vaccine' creating the impression that it would have to be sought out and tested, was in fact, none other than the MMR II vaccine which had been used alongside both the withdrawn vaccines since Nov 1988. Essentially all that happened was that MMR II which previously had 15% of the UK market had to suddenly expand sales to cover 100%. Further more since MMR II had been on the market in the UK since 1988, 4 years worth of usage in the UK together with the years that it had been on the market in the US had shown it didn't have the same level of risk.

This answer smacks of the idea that the DH was actually experimenting on children and had there not been an alternative available they would have gone on with the Urabe containing MMR. In a recent letter to a parent, Kent Woods the present CEO of the MHRA had the following to say about the possible future use of Urabe containing Immavax and Pluserix:

⁵³ Holding answer 31 October 1995

However, as use of Urabe-containing MMR vaccine had already ceased in the UK and as it was considered that there would be a place for use of Immravax and Pluserix should the supply of MMR-II be compromised at any time, it was considered that no licensing action was required at the time for the two MMRs that contained the Urabe strain.⁵⁴

Department of Health officials met with the MCA and the manufacturers Smith Kline Beecham (SKB) at the end of August 1992, and the drug company acting on the advice of their lawyers, decided to stop producing vaccine and advise licensing authorities world wide, accordingly, the department felt, it had therefore to act quickly for fear of suddenly being short of stocks. On the 3rd and 4th of September the CMOs of European Community countries were advised *in confidence* of the situation at a routine meeting.

The Committee for the Safety of Medicines (CSM) Sub-Committee on Safety, Efficiency (SEAR) and the Adverse Reaction Group of SEAR. (ARGOS) agreed on September 4 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 licence would have caused a world-wide vaccine crisis; effectively the British government gave the green light to continue damaging children any other part of the world. (see page 38 -)

The DH then requested an increased supply of MMRII from MSD from 200K to 800K doses per year. This was initially agreed by Wellcome but when the actions of the Government became clear, extra demand for the vaccine was demanded and DH officials had an all expenses paid trip to Philadelphia to the MSD factory where they negotiated a supply of extra amounts of MMRII.

Regional and District pharmacists were advised on September 9 to expect delivery of un-requisitioned supplies of MMRII. However, this information was leaked to the press by a pharmacist and published on September 15 pre-empting the Department's plans for an 'orderly release of information'. This leak precipitated a letter from the CMO which was then issued on that day and a press release sent out.

⁵⁴ Email sent by Kent Woods CEO of the MHRA to a parent.

At the date of the JCVI meeting, 35K doses were being made available each week.

When the withdrawal of the vaccine was announced by Professor Calman, Chief Medical Officer at the Department of Health, he went to some lengths to claim that the withdrawal had nothing to do with previously received data from Japan or Canada.

Part of the government sponsored review of aseptic meningitis cases entailed research from Queens Medical Centre Nottingham, which looked at children with aseptic meningitis who had been vaccinated in the Nottingham area. When the withdrawal of the vaccine was announced by Professor Calman, Chief Medical Officer at the Department of Health, he went to some lengths to claim that the withdrawal had nothing to do with previously received data from Japan and Canada, stating that the Nottingham University team, had tested the spinal fluid of all children admitted to Nottingham Health Authority hospitals after vaccination to check for meningitis and after this study had found a number of cases of aseptic meningitis, the

The results of this review brought down adverse reactions to one in 3,800 vaccinated children, a much higher ratio than any other previous research had reported. The authors of this paper had moved to publish it in *The Lancet*, but came under considerable pressure not to do this. When it did appear in the *Lancet*. It cast a new more public light on the adverse reactions.

Withdrawn, Destroyed, Taken Off the Market, Dead, This is a Deceased Vaccine! Or is it?⁵⁵

⁵⁵ With apologies to John Cleese and his 'Dead Parrot sketch': Mr. Praline: 'E's not pinin!' 'E's passed on! This parrot is no more! He has ceased to be! 'E's expired and gone to meet 'is maker! 'E's a stiff! Bereft of life, 'e rests in peace! If you hadn't nailed 'im to the perch 'e'd be pushing up the daisies! 'Is metabolic processes are now 'istory! 'E's off the twig! 'E's kicked the bucket, 'e's shuffled off 'is mortal coil, run down the curtain and joined the bleedin' choir invisibile!! THIS IS AN EX-PARROT!! Monty Pythons Flying Circus first series 'Full Frontal Nudity', 7 December 1969. <http://www.youtube.com/watch?v=4vuW6tQ0218>

The statement concerning the 'withdrawal' of the two Urabe MMR vaccinations Pluserix (SmithKline Beecham) and Immravax came from the Chief medical officer on 14 September 1992. The confusion however was spectacular, like a retreating army reorganising itself and beginning new strategic onslaughts, without any overall plan.

Kent Woods, for instance in his summary quoted above, explains how the chances of vaccinated children getting aseptic meningitis, was so small that it was considered acceptable to continue with the use of the vaccine use in the future *if this was necessary*; this conclusion is reached, we should remember, for the use of a mumps vaccination that some doctors considered at the best unnecessary and at the worst unethical.

Most ordinary citizens would think that when a drug proves to be a danger to people, it is taken off the market, recalled, like a faulty automobile or a child's toy that has a metal spike running through it, this however is not always the case and it was not the case with Urabe strain MMR. We have several descriptions on the demise of the Urabe containing MMR vaccines but until relatively recently it was nigh on impossible to determine the status of Pluserix the vaccine manufactured by Smith Kline Beecham and Immravax by Merieux in September 1992. The company used every trick in the book to keep the vaccine afloat and claw back their development investment.

There was no 'worldwide withdrawal' of Pluserix in 1991. The Canadian regulatory authority cancelled the Pluserix licence in 1990 and Malaysia the Philippines and Singapore followed Canada. In Britain, however, the manufacturer 'suspended distribution of the vaccine', the DOH stopped 'purchasing' it, but there was no product recall initiated for it and in the JCVI Minutes of 6th November 1992 item 8.1 tells us that 'no action would be taken to revoke the manufacturer's license'.

What actually happened in Britain was this; the Department of Health issued a 'Dear Doctor' letter on 14th September 1992 advising all Health Care Professionals that, from September 14th 1992, Pluserix (SmithKline Beecham) and Immravax

(Merieux) would no longer be supplied 'following reports of generally *mild transient meningitis* caused by the mumps vaccine virus in some children who recently received the Urabe mumps vaccine containing products'.⁵⁶

Perhaps the most insidious untruth perpetrated throughout the distribution and then withdrawal of the two vaccines, is embedded in this explanation given by Kent Woods. He reports the words of the Chief Medical Officer, describing the adverse effects of aseptic meningitis as 'mild transient meningitis'; just some slight discomfort that passes almost immediately.

On one hand the identified numbers of cases of aseptic meningitis were sufficiently high to warrant instructions by the manufacturer to stop using it immediately, and the Chief Medical Officer (CMO) 'ordered' pharmacists to remove the vaccines from their shelves. On the other hand the UK licensing authorities did not consider the situation grave enough to merit the issuing of a formal Product Recall and were quite content to permit the licence to remain live.

What was the reasoning behind allowing the two companies to keep their license. It seems to have been two fold, on the one hand always willing to make a quick buck and not afraid of making the children of developing countries ill, Smith Kline Beecham wanted to continue selling the vaccine. The other reason was equally logical, the British government thought it best not to dispose of vaccine stocks or it's license, just in case it was needed some time in the future.

However, as use of Urabe-containing MMR vaccine had already ceased in the UK and as it was considered that there would be a place for use of Immravax and Pluserix should the supply of MMR-II be compromised at any time, it was considered that no licensing action was required at the time for the two MMRs that contained the Urabe strain as the overall benefit to risk balance remained positive when compared with the risk of meningo-encephalitis associated with naturally-acquired mumps infection.⁵⁷

By permitting the manufacturers to keep their Product Licences , the UK authorities

⁵⁶ Kent Woods CEO of the MHRA

⁵⁷ Kent Woods CEO of the MHRA

paved the way for the vaccines to be marketed in other EU countries and further afield despite having been removed from use in the UK on safety issues.

The situation regarding the status of the Pluserix vaccine in 1992 is made quite clear in this Freedom of Information (FOI) release to a parent.

I can inform you that there was no formal recall of Pluserix. In September 1992, a decision was taken by Department of Health not to purchase any further Urabe based MMR vaccines (Pluserix and Immravax). MMR2 was issued as a replacement but there was no formal action taken against the Urabe-containing products.⁵⁸

In an article in the Pharmaceutical Journal on the 19th September 1992 the demise of pluserix is glossed over with the announcement that future purchasing of the MMR vaccine is to be 'restricted' to that of MMR II only.

The Department of Health restricted future purchasing of mumps, measles and rubella vaccine to MMR-II which is marketed by Wellcome Medical Division and contains the Jeryl Lynn (B level) strain of the mumps virus.⁵⁹

The only communication to practitioners in the UK on the subject of the withdrawal of Immravax and Pluserix was the letter by the Chief Medical Officer Sir Kenneth Calman, advising that as of the 14th September 1992 only MMR II was to be supplied by the NHS.

This raises a number of questions. Why if SmithKline Beecham issued an urgent letter to all practitioners in New Zealand advising them to stop using the Pluserix vaccine *immediately* on the 11th September 1992, did the same thing not happen here? When asked to clarify that the CMO's letter was the only communication sent out in the UK Dr Salisbury answered, 'From memory, that is correct.'⁶⁰

It seems that the government were forced to act against Immravax and Pluserix, despite their inclination to keep the whole story of the adverse reactions

⁵⁸ FOI release from Jill Moorcroft Freedom of Information Unit, Department of Health,

⁵⁹ (GBRPHJ) The Pharmaceutical Journal, 358, 19 Sep 1992

⁶⁰ Private email from Professor Salisbury to a parent dated 30/04/07

under wraps. On the one hand an ongoing argument developed between the Chief medical Officer and Professor Salisbury about the publication of the results of research commissioned by the DH into Urabe and adverse reactions. On the other hand, someone leaked the facts about the government orders sent out to pharmacists about the withdrawal of the two vaccines.

Just how the DH planned to deal with the building crisis is unclear but the Minutes of the JCVI 6th November 1992 record how any opportunity of an orderly, controlled release of information was denied them when information was leaked to the press by a pharmacist forcing an immediate release of the letter from the CMO and subsequent formal press releases. The actions of the pharmacist and the publication by the newspaper at least ensured swift and decisive action by the DOH.

Pluserix and Immravax went on to ensnare lucrative contracts for Immunisation Programmes all over the World. As had been the case with other drugs withdrawn in Britain previously, these two vaccines merely adopted new names and started anew. At a meeting of the JCVI on the 6th November 1992 it is recorded that a conscious decision not to revoke the manufacturers licence had been taken as this may have caused 'a worldwide vaccine crisis.'

As part of the hard sell of the MMR, leaflets encouraging the use of the vaccine were distributed. In answer to the question 'Is it safe?' the answer was a resounding and unequivocal 'yes'. Sadly these leaflets made no reference to the meningitis risk.

The Global 'Withdrawal'

However seriously the Urabe containing vaccines were taken in the developed world, when it came to a continuing life of profit their manufacturers were happy to palm off damaging goods on the developing world. The WHO was also happy to act as a mouthpiece for the manufacturing companies, reassuring the people of various countries that aseptic meningitis was a simple transitory illness little different from a

cold. The WHO recommended that vaccines containing the Urabe mumps strain could be used in countries where vaccines containing an alternative mumps virus strain were not available.

Mumps, measles and rubella vaccine is a mixed preparation containing live attenuated strains of the measles, mumps and rubella virus. There are different strains of the mumps virus and it is suggested that meningitis *may occur marginally more frequently with vaccine containing the Urabe Am 9 strain of the mumps virus than the Jeryl Lynn strain*. However, a number of regulatory authorities still accept the Urabe Am 9 strain of the mumps virus on the grounds *that no permanent damage arises from the aseptic meningitis*.⁶¹

Professor Woods CEO of the MHRA, the drug company funded department of the Department of Health, suggested a more humane explanation for the WHO's promotion of Urabe MMR in developing countries, this was possible he said; *'in countries where vaccines containing an alternative mumps virus strain were not available*.'⁶² This of course sounds more reasonable than the deception quoted above.

The authorities in the UK clearly had difficulty in making a definitive decision regarding any aspects of licensing relating to Pluserix after it was identified in the Nottingham data as being hugely problematic in relation to aseptic meningitis. Cyprus did not have the same problems. By the 23rd October 1992 the Cypriots had taken steps to ensure that their children would be safe from Urabe by completely removing the Cypriot licences. The Drug Council in Cyprus withdrew the marketing licence for Smith Kline Beecham triple vaccine Pluserix, the mumps/measles vaccine Rimparix, the mumps vaccine Pariorix and two other MMR vaccines, Trimovax and Imovax manufactured by Pasteur Merieux.⁶³

To add to our understanding of what happened to Pluserix and Immravax, after their withdrawal in Britain, Japan and Canada it is useful to look at the global situation. Of course, it wouldn't really do for a Pharmaceutical company to produce a

⁶¹ <http://www.who.int/medicinedocs/es/d/Js4902e/4.1.409.html> (accessed February 2009)

⁶² Letter from Kent Woods CEO of MHRA

⁶³ Reference: (CYPPS) Pharmaceutical Services, Ministry of Health, 23 Oct 1992

drug that had immediately to be recalled and not distributed. Pharmaceutical manufacturers have strategies for continually spinning out the life of dangerous drugs and vaccines by changing their names, rebranding and redistributing, especially to countries where there is even less medicine safety than in Britain, difficult though that might be.

In fact, two decades after their distribution in Britain, there can be very few countries which have not used a Urabe containing vaccine in some shape or form and a very distinctive pattern emerges. It appears that once the product has been associated with problems in a specific country, it is removed from use but subsequently appears at a later date in another country and with a new name. To date, Urabe containing products can be identified as Pariorix, Trivirix, Pluserix, Immravax, Rimparix, Morupar, Vaxipar, Trimovax and Orevax.

An example of this is the Chiron Corporation MMR vaccine. In March 2006, biotech company Chiron Corporation recalled and withdrew their vaccine Morupar, that it had mostly supplied to Italy and various developing nations such as Syria, Jordan, and a variety of smaller countries that received the drug through the United Nation's Children's Fund and Pan American Health Organization.

Perhaps the most alarming issue pertaining to the withdrawal of Morupar comes in the paragraph below. Having decided to withdraw their product due to adverse reactions, Chiron then became party to a risk benefit analysis⁶⁴ with the WHO in respect of their vaccine to determine whether or not it would be appropriate for a proportion of their stocks to be utilised in current health programs such as those conducted by UNICEF and PAHO.

Chiron has been in communication with the relevant health authorities and informed them of its actions in order to enable them to find replacement supplies of MMR vaccine. Chiron will work closely with the World Health

⁶⁴ Such risk benefit analyses are fraught with problems and the often favour pharmaceutical companies in a most illogical manner. Assuming that vaccination completely rids a country of a disease, they then move on to say, and so if the vaccine kills 20 people, this is a lesser number than those that would have died from the wild illness. Ipso facto we should introduce the vaccine. This is as faulty as arguing that as we know the death sentence deters people from committing murder, we should keep it however many murderers we have to execute.

Organization (WHO) to assist it in conducting a thorough risk-benefit analysis of MORUPAR vaccine to determine whether it is appropriate for a limited quantity of the existing inventory to remain available for current public health programs such as those conducted by UNICEF and PAHO.⁶⁵

In 1995, Pluserix was identified as the vaccine used in a mass immunisation programme in Brazil resulting in a huge outbreak of aseptic meningitis (see below). In the minutes from the Legislative Council we note that Hong Kong used Urabe within their MMR until it was changed in 1997. Korean, Croatian, Bulgarian, French, Malaysian, Australian and New Zealand children are also reported to have been given Urabe preparations.

In January 2003 Urabe appears again as part of an MMR called Trimovax by Pasteur Merieux-France in Saudi Arabia, and cases of aseptic meningitis were recorded.

Immrvax like Pluserix despite being dropped from use by the Department of Health in September 1992 appears to have progressed under different names to encompass the globe. By 2003, in the Eastern Mediterranean Health journal Volume 9 Nos1/2, January 2003 in an article 'Effect of Gender on Reporting of MMR Adverse Events In Saudi Arabia' the vaccine identified is Trimovax by Pasteur Merieux, France, containing Urabe Am 9 mumps strain, Schwarz measles strain and Wistar RA27/3 rubella strain the identical components as Immrvax some 11 years earlier. Immrvax mutated into Trimovax for the Saudi Arabia market. Outbreaks of unacceptable levels of adverse reactions follow in the wake of Urabe containing MMR vaccines yet they reappear, post withdrawal from the markets, revamped with a new name and packaging and reappear in different countries.

A Couple of Ethical Chickens Coming Home to Roost

⁶⁵ <http://www.pslgroup.com/dg/258BFA.htm> Chiron Recalls and Withdraws Morupar(R) MMR Vaccine from Italian and Developing World Markets

When, in November 1994, the editor of the *Bulletin of Medical Ethics*, Dr Richard Nicholson entered the fray over MMR, accusing the vaccine establishment of drumming up a storm over an imminent measles epidemic and charging them with experimenting on the child population, while also suggesting that the Department of Health was misleading the public by providing inadequate information on the side effects of the vaccine, the response was predictable.⁶⁶

The Health Department keeps saying that they will be closely observing the effects of this mass vaccination on our children, that is part of a research programme. The health department has a bad record in interesting itself in the ethics of research on humans. Now it appears to be breaching its own and accepted international guidelines to carry out research on our children.⁶⁷

Nicholson spoke out about the mass vaccination for a year, before publishing a paper in *The Bulletin of Medical Ethics*. At a meeting of the JCVI in November 1995, item 11, the article by Dr Nicholson was described as 'deeply offensive' to all those involved in the Measles Rubella (MR) campaign. It was suggested that Dr Nicholson had interpreted matters 'in his own way' (implying there was only one way information could be interpreted) giving a 'superficial view' 'failing to understand many of the issues involved.' It was also noted that much of his theory was presented without empirical evidence. Dr Nicholson was further charged in his absence with referring to the MR campaign as an 'experiment' and that he had suggested 'impropriety in vaccine purchase', it was noted that his article had not been peer reviewed.

The Committee acknowledged that 'dealing with *this matter* was very difficult'. Interestingly the *Health Visitors Journal* had promoted the article and considerable media attention had been generated through it. To counter balance the

⁶⁶ Dr Richard Nicholson, *The Bulletin of Medical Ethics*. August 1995

⁶⁷ Child vaccine 'breaches rules on research', Victoria Macdonald. *The Sunday Telegraph* 6 November 1994. Dr Nicholson is quoted here at the time of the mass vaccination programme carried out by the DH.

effect, the PHLS had prepared a detailed response to Dr Nicholson's criticisms in the *CDR Review*.⁶⁸

Dr Elizabeth Miller wrote the rebuttal article with N J Gay. It begins with a superb piece of reasoning which reminded me of the joke about the man who looking over his garden hedge sees his neighbour stalking round his garden with a shotgun, 'What are you doing?' he says, 'Me?', says the man with the shotgun, 'I'm ridding my garden of polar bears', the neighbour frowns, 'But there aren't any polar bears in your garden', 'I know, done a good job haven't I?' the man with the gun says before stalking off.

The aim of the national vaccination campaign was to prevent an epidemic of measles that had been predicted to occur in 1995. The incidence of measles has fallen considerably [*there was no epidemic*] since the campaign, providing evidence of it's success⁶⁹

The great measles epidemic that was supposedly going to sweep Britain in 1994 was never going to happen, Nicholson argued, it had been dreamed up to sell vaccines. A £20m national immunisation programme went ahead without an epidemic, and at least 300 children were claiming they have been permanently damaged during the mass vaccination, with a vaccine that government officials and doctors assured parents had no major side effects.⁷⁰

Finally, Dr Nicholson described the campaign as 'a gift horse' for the two drug companies, which still had vaccines in stock intended for use with the combined measles-mumps-rubella (MMR) jab.

Elizabeth Miller and the Boys from Brazil

⁶⁸ The *Communicable Disease Report Weekly (CDR Weekly)* is the national public health bulletin for England and Wales. Published every Thursday,

⁶⁹ N J Gay, E Miller, Was a measles epidemic imminent, *CDR Review*: Volume 5, Number 13, 8 December 1995.

⁷⁰ *What Doctors Don't Tell You* magazine, Nov 1995

However hard you look on the internet for an exacting description of Salvador, one of the principal cities in Northeast Brazil, you will probably find that everything is covered by a glossy tourist language that gilts everything from human rights, to beautiful beaches, from modern architecture to Marde Grase. It's only if you fall upon an off-beat writer and traveller such as Galen R. Frysinger Sheboygan a retired scientist from Wisconsin USA,⁷¹ who now spends most of his time traveling to interesting places, that you come across statements such as 'Northeastern Brazil is one of the country's most impoverished regions and it is characterized by high birth and infant mortality rates. Many of Salvador's residents are extremely poor and the city suffers from high levels of unemployment and crime'.

Inevitably, few writers go as far as the Scripps analyst, who described Brazil as the gateway to the world pharmaceutical market, but if there is one country in the world that is receptive to buying British pharmaceuticals and also contains wide US influence, it's Brazil, and just like Africa and the newly democratised East European countries, it has become a fertile land for pharmaceutical human experimentation. There are good reasons for this, some 40 - 50% of the Brazilian population cannot obtain any pharmaceuticals because of what the industry calls 'financial constraints' and what a more literate observers call poverty.⁷²

Despite the fact that there are 370 indigenous pharmaceutical companies in Brazil, with about 80% of them being national, foreign firms from the US and Europe supply 70% of the market, without taking into account direct sales to the government. For these reasons and others, Brazil is a drug pushers paradise, both for generics and for the sophisticated and highly specialised sales to the government of things like HIV drugs, and vaccines.

In 1997 in the wake of the national immunisation programme in Salvador, a team of epidemiologists scoured the hospitals looking for cases of aseptic meningitis. Oddly this team was not just made up of Brazilians, one of the project participants was Patrick Faringdon, a statistician at the Public health Laboratory Service (PHLS)

⁷¹ http://www.galenfrysinger.com/salvador_bahia_lower.h

⁷² Pharmaceuticals January 2005. Brazil, top US Export prospects

Communicable Disease Surveillance Centre, in London. One of his seniors was Dr Elizabeth Miller, one of Britain's generals of the campaign for mass vaccinations and most determined defender of MMR. Miller was also involved in writing up the paper,⁷³ that grew up out of the project.

The paper that was written following the mass vaccination campaign using Urabe containing MMR was published in 2000, and concluded 'that there was *an outbreak* of aseptic meningitis' following the mass vaccination programme. It would be charitable to think, that Faringdon and Miller had been called in to track down the source of the outbreak and stop it, this however unlikely as it was SKB, the manufacturer of the Urabe containing MMR that had sold the vaccine to the Brazilian's. Not wanting to be accused of cynicism, it might be best if one didn't suggest that the British immunological establishment was engaged in experimentation on poor, powerless, Brazilian children. One of the reasons, the Urabe strain MMR was used in this round of mass vaccination in Brazil was, the government suggested, that the vaccine was cheaper than its counterparts.⁷⁴

It might be suggested by some that the British government, the MHRA and even the pharmaceutical companies acted heartlessly in reselling stocks of Urabe containing MMR to developing countries and then researching the resultant adverse reactions. There is however, a much warmer and consoling interpretation, not only were the dangerous vaccines sold cheaply, but the research on the children of developing countries could obviously be used to great advantage if at any time in the future the Urabe containing vaccines were to be used again in Britain.

⁷³ Outbreak of Aseptic Meningitis associated with Mass Vaccination with a Urabe-containing Measles-Mumps-Rubella Vaccine Implications for Immunization Programs. Ines Dourado *et al.* American Journal of Epidemiology Vol. 151, No. 5: 524-530

⁷⁴ Unfortunately, the events in 1997 with MMR were not the last problems involving vaccines and Brazil, or even MMR and Brazil, by any means. In 2004, just a couple of months after Brian Deer published his expose in the Sunday Times about Dr Wakefield, the New York Times reported, that Chiron's MMR vaccination had caused adverse reactions in a large number of children who had received the vaccine in an ongoing mass immunisation programme. The reactions included rashes and anaphylactic shock, a potentially fatal allergic condition. At least 125 children experienced the reactions.⁷⁴

Conclusions: Not in Our Name

It's February 2009 in London, England and the trial before the General Medical Council (GMC) of three doctors, charges with over 100 offences before a GMC Fitness to Practice Panel, is after two years, almost due to bring in a verdict. The trial began in June 2007 with a suggested time frame for completion of four months.⁷⁵

Perhaps the most serious charges against Dr Andrew Wakefield and his two co-defendants, Professor Walker-Smith and Professor Simon Murch, who had, the GMC states, suggested that the MMR vaccination could cause inflammatory bowel disease and regressive autism in vulnerable children, is that they carried out experimental procedures on autistic children with the intention of proving, for financial gain, serious adverse reactions to the MMR vaccination. The truth is that faced with an undiagnosed illness amongst seriously ill young children brought to them by many parents, these doctors and others at the Royal Free Hospital, worked hard to come up with a diagnostic protocol that would lead to the treatment of these children.

While doctors Wakefield, Murch and Walker-Smith stand accused of experimenting on children, the fact is that with vaccination, even more regularly than with other pharmaceutical treatments, pharmaceutical medicine continuously experiments on populations of healthy people. Most of the treatments devised by pharmaceutical research are never tested for long or even medium length adverse reactions, while a number of pharmaceutical products that have been on the market for many years have had no clinical trials at all.⁷⁶

In no area of society other than public health, apart from the military and states of warfare, are the interests and messages of public good, corporate profit and ideology so greatly and deliberately confused. In fact not surprisingly in times of biological, toxic and germ warfare, the two areas often use the same personnel, and

⁷⁵ For an ongoing account of this hearing see www.cryshame.com and a number of essays by this author.

⁷⁶ Aspirin is a good example.

plant. It isn't just coincidence that, despite having a lovely picture of sheep and rural tranquility on its home page, one of the main centers of the Health Protection Agency is based at Porton Down, where as late as 2002 the military and medical establishments were still testing deadly Sarin gas on unwary soldiers in the name of public health.⁷⁷

As Marshall McLuhan⁷⁸ said in the late sixties, *the medium is the message* and this is especially true in terms of public health, the image of which has to present an unblemished facade. However, unlike many areas of industry public relations crisis management, such as airplane crashes or automobile accidents, in the area of vaccines only a small percentage of the public is even vaguely aware that there is a serious conflict between external appearance and hidden dangers. In the case of vaccination a world of jiggery-pokery exists behind the reassuring scenes propagated by an apparently benign government. Nevertheless such shenanigans, dirty tricks and duplicity are there and the operators of these dysfunctional public health systems have learnt without shame from the military and Public Relations establishments, to placating the public with a peaceful vision of rural idylls and urban progress.

There is inevitably a moral dimension to the economic and health conundrum presented in the GMC trial of doctor Wakefield. In a democracy, regulatory oversight should be at a high level, in the area of pharmaceutical especially risk in all its detail should be explained to patients, by doctors not associated with the industry. In the area of vaccines, alternatives should be available to children in danger of adverse reactions and finally, support systems of all kinds, medical and financial should be in place for any child that suffers any kind of adverse reaction in a State organised programme. In this regard the social, regulatory and governmental problems relating to vaccination are the same as those that relate to the adverse effects of all pharmaceuticals. The construction of such policies should be one of the first

⁷⁷ An interesting, if irrelevant aside. The Centre for Applied Microbiology & Research, Britain's research establishment for weapons of mass destruction, which describes itself as 'An independent public sector body providing expertise and resources for Government and the biopharmaceutical industries worldwide', has six non executive directors, and nine executive managers, all of whom are men. Should we assume from this that the writ of equal opportunities does not run in independent agencies, or simply that most women wouldn't touch the work with a barge pole?

⁷⁸ Herbert Marshall McLuhan 1911 - 1980, was perhaps the greatest modern thinker about post industrial media and communications. His best known book was *The Medium is the Message*.

considerations of an honest government answerable to the people and not to industry.

However, the modern citizen knows next to nothing, in many areas, about the objectives and methods of modern government. The separation between the rulers and the ruled has always been there, it is doubtful for instance whether the feudal serf knew anything about the plans of his more powerful masters. What is singularly different, today however, is that while the serf was expected to honour and obey his master following some vaguely religious belief in how society was ordered, today the citizen expects and believes that they have a more intimate involvement in the workings of society. It comes as something of a shock to the laity when they find that they are being hoodwinked and manipulated by well organised cabals within government.

* * *

Until relatively recently, a constant argument flowed through Japanese society about the use of research carried out on prisoners in Japanese prisoner of war camps. Simplified, the argument when like this, if the experiments carried out on prisoners were 'unethical', such as those which looked at the point at which people died if they were frozen, was it possible to use the resultant information thirty years later, for example, in school text books.

This discourse did not go on to the same extent in Germany because as soon as the war was over the most important scientists, engineers and technicians of the Third Reich were given a safe haven in the United States where they worked on, such things as, the new US Space programme and the atomic bomb. As well, many leading figures in the Nazi regime, who proclaimed themselves liberals and democrats to the new four power administration that took over Germany, were whisked away to 'schools' in Britain and America where they were 're-educated' to take up positions of power in post-war Europe.

However, it is known to be the case that experiments on women prisoners in Auschwitz, conducted with the intention of finding out how whole societies could be made infertile and how others might reproduce only arian peoples, considerably aided

the development of Hormone Replacement Therapy by I G Farben's subsidiary companies after the war.

While these experiments fuelled xenophobic ideological ideas about Japan and Germany, the allies came out of the second world war, in relation to scientific ethics, 'smelling of roses'. That is, until it was revealed that after the war, experimentation on citizens was rampant, especially in America, the final disclosure of the MK ULRA programme, proved how people had been experimented on without their knowledge using psychiatry, hypnosis and mind altering drugs. While the *Final Report of the Advisory Committee on Human Radiation Experiments*, published in 1996, reported after sitting for a year and a half that American military and security personnel had experimented on children, prisoners, mental patients and other hospital inmates, in North America and Europe with radioactive substances in one experiment sprinkling the material on the breakfasts child orphans.⁷⁹

The idea of finding out what will damage the enemy and how the enemy might damage us, or how populations might be controlled are now firmly intertwined with the exploration of human health. So it has happened that the field of vaccination has become subject not only to the double-speak portrayed so well by George Orwell in *1984*,⁸⁰ but also to similar ideas about government control that tend to determine all relations between the government and the people in areas of high security.

The question of what citizens know about vaccines, of what they are told about their effects and the responsibility taken by governments for damage caused by them, in both mass vaccination campaigns and more esoteric areas such as the use of anthrax vaccine in Gulf War soldiers,⁸¹ lies at the very centre of contemporary 'democracy'. No scientific project apart from such things as the development of the atomic bomb have every argued more succinctly for the participation of the whole population, personal choice, the complete disclosure of information and the taking of responsibility for collateral damage, than vaccination.

⁷⁹ *Final report of the Advisory Committee on Human Radiation Experiments*: Oxford University Press. New York. 1996

⁸⁰ Orwell, George (1949). *Nineteen Eighty-Four. A novel*. London: Secker & Warburg.

⁸¹ Gary Matsumoto, *Vaccine A: The covert government experiment that's killing our soldiers and why GI's are only the first victims*. Basic Books, USA. 2004.

Meanwhile getting any kind of compensation out of the British government, is like trying to squeeze blood from a stone. While Japan had settled all its Urabe victim cases, and even America has begun settling its MMR cases, the British government remains obdurate, they will principally protect the pharmaceutical companies and the long roll call of discredited civil servants, politicians, academics and health officials rather than act with empathy and honesty towards the citizen parents of vaccine damaged children. These victims have been the collateral casualties of an internal war waged not between the forces of scientific health and dangerous diseases, but between the pharmaceutical companies, their profit and respectability and the British people suffering an onslaught of poor, sometimes experimental, misguided and sometimes untruthful health advice from government.

* * *

Because of the secret government run through the regulatory agencies by the drugs companies and embedded in the Department of Health, the real discourse around death and medicine never reaches the public arena and even if they do, a peculiar kind of reasoning sets in that allows the participants to escape any discipline for their crimes and misdemeanours. Although superficially, the arguments of the pharmaceutical companies has changed since the 1960s and thalidomide, the peculiar resentment of the pharmaceutical industry that has always appeared odd in a democracy is still there. In their excellent book ⁸² published in 1972 about the power of the drug companies, following the Thalidomide scandal, Henning Sjostrom and Robert Nilsson say:

It seems, in principle, self evident that no free enterprise can expect only to share the profit of their products without also taking responsibility for any damage caused by them. It was very surprising to hear Astra's argument during the thalidomide trial, that society i.e. the Swedish state, should pay compensation for the damage caused by Astra's products, Neurosedyn and Noxodyn. It is preposterous to assume that the drug industry can be allowed to

⁸² Henning Sjostrom and Robert Nilsson, *Thalidomide and the Power of the Drug Companies*. A Penguin Special, England 1972.

prosper when their results are positive, but refrain from paying damages and pass the burden of responsibility on to society when something goes wrong with their products.

One argument put forward by the pharmaceutical industry against any application of strict liability is that the drug industry is working for the benefit of mankind in a unique way and cannot be compared with other types of industrial enterprise. It seems that the pharmaceutical industry does not wish to recognise the fact that the main impetus for the running of the pharmaceutical industry, like any other type of industry in the West, is profit.

While the language has changed, the same sly insinuation that the world owes Big Pharma a living is still there based on the fictitious idea that they do everything they do for the sake of world health.

In the area of vaccination, since its inception, the public have paid a price for an illusory peace of mind. There have been, almost without exception, serious adverse reactions to every vaccine that has been produced. The price paid for 'herd immunity', is for some individuals and their families, very high. Given this, the risk, spread, damage and pain of personal injury consequent upon vaccination has for generations been hidden from the public. This conjuncture, disclosed or not is at the very centre of the social contract, its meaning and construction. Do you tell citizens that in order to keep society healthy they might have to turn a blind eye or be struck dumb over the deaths and illnesses of their loved ones? Further what does society owe to those who are sacrificed in such a manner?

* * *

Who did or didn't want the triple vaccine, MMR, who thought they might lose money and who thought they would gain 'health' credibility with it, are serious questions when we come to ask whether or not and in what manner the government underwrote the production of the Urabe containing MMR vaccine.

The matter of indemnity, or the underwriting of corporate pharmaceutical losses, either by legal claims for damages, withdrawal of products or simple failure of efficacy, is discussed briefly here, despite the fact that it didn't come to the surface until 2006, when the Urabe farago appeared to be over.⁸³ Since the seventies, concurrent governments had been digging the hole into which they might crawl on the instigation of a serious claim for damages over a vaccine product. On the other hand, pharmaceutical companies have worried that a political policy might result in the failure or the withdrawal of a vaccine that has taken millions to produce. Realising that the manufacturing companies could gain considerably by producing with governments, the pharmaceutical companies have done their best to draw governments into a manufacturing partnership.

The developing Corporatism in Britain ensured that governments increasingly take risks on behalf of corporations. Taxpayers money has been used to support high risk and inefficient ventures and rather than governments stand clear of corporations, making them pay for their own mistakes, they have been hoodwinked into bearing corporation loses. As far as pharmaceutical companies are concerned, this is as it should be: Big pharma has always argued that their costs and liabilities should be shared with government on account of the altruistic work they do on behalf of the nation's health. Nowhere more than in the pharmaceutical industry have corporations hoodwinked governments into accepting both their policies and their liability for their mistakes and loses.

In order to realise the relevance of the indemnity issue we have to move forward from the introduction of the Urabe containing vaccines to the years between 2003 and 2006, because it was only then that the fact and the meaning of indemnity was placed on the table. In the autumn of 2003, pushed by some secret mechanism inside the New Labour government, the Legal Services Commission withdrew the legal aid that had been provided to claimant parents over the previous ten years. The

⁸³ Whether or not this need by the pharmaceutical companies to have liability covered by the government has anything to do with MMR lying unused in Britain between 1972 and 1988, we might never know. It seems more than probable, however, that the intrinsic dangers of combining vaccines could have deterred drug companies historically from acting on MMR in Britain.

parents had been bringing a case against Merck, their British distributors and associated manufacturers GSK and the French company Merieux. The appeal against the withdrawal of legal aid was lost.⁸⁴

By the summer of 2004, the hopes of thousands of parents and their vaccine damaged children had been dashed. The parents had been deprived of a voice only months before their case came to trial. As far as the pharmaceutical companies were concerned they had won a major strategic victory, with the threat of a hearing for the parents in court removed, with all the claimants documents in the hands of the pharmaceutical company lawyers, and with it the contempt hazard present while the case was ongoing now lifted, the defendant pharmaceutical companies could begin the sprint to next base. Their central strategy was to turn the tables on Dr Wakefield and the parents, to put them in the dock in their place.

We will probably not know for some considerable time, who had most to gain from underwriting the Urabe brands of MMR that were to do so much damage to British children. However, we can be fairly certain that the pharmaceutical companies and the government sought solace in each others arms and organised their campaign against the parents and Dr Wakefield with equally exacting determination.

When it came later to explaining any indemnity offered by the DoH to UK vaccine manufacturers, the matter was never simply explained. Professor Salisbury has both denied and acknowledged its existence. In September 2006, Professor Salisbury stated: 'as has been stated on innumerable occasions, there was no immunity/indemnity given to MMR manufacturers.'⁸⁵

In March 2007, however, he stated: 'We have found that North East Thames District Health Authority (that no longer exists) agreed with at least one MMR vaccine manufacturer to indemnify them against outcomes that were consequences of

⁸⁴ Was ruled on by a judge whose brother was a non-executive director of GSK, and also happened to be Dr Horton's on line manager at *The Lancet*.

⁸⁵ An email exchange with a concerned parent

failure. We can find no further evidence of any other indemnification with regard to MMR vaccine made by North East Thames District Health Authority.⁸⁶

In an email sent on the 3rd April 2007 Professor Salisbury said: 'In the contract between NHS Procurement Directorate, acting by its agent NETRHA, and Smith Kline & French (SKF), there is a paragraph on indemnity to SK&F:'

NHS shall indemnify SK&F against any proven loss which SK&F shall suffer as a result of any act or omission of the Nominated Distributor in connection with the performance or non performance of this Agreement where such act or omission appears to be within the scope of the Nominated Distributor's authority as agent of NHS provided that SK&F shall immediately notify NHS of any claim under the provisions of this clause.

This indemnity is an 'all cause' indemnity. Clearly the JCVI and the UK government understood at least one of the MMR manufacturers to be indemnified when marketing their MMR product. This is confirmed in the unambiguous JCVI minutes of May 7th 1993: 'SKB continued to sell the Urabe strain vaccine without liability.'

David Salisbury seems also to have denied knowledge of a deal with the UK government, indemnifying the manufacturers of this vaccine against any potential claims from damaged children in the UK. As well, he appears to have ignored consistent evidence to suggest that the effects observed in countries where the vaccine had been withdrawn were beginning to appear, identically, in UK children soon after the vaccine had been introduced. These devastating adverse effects were acknowledged long before the public were made aware, and even longer before the vaccine was withdrawn and distributed to developing countries.

The developing corporatism of British government has meant that in part the taxpayer, as well as suffering the consequence of bad vaccines and mass vaccination policy, has somehow shouldered the financial burden for drug company losses when

⁸⁶ Ibid.

Urabe mumps virus MMR was discontinued in Britain. Throughout all the battles, to defend vaccine policy, the pharmaceutical companies have stood shoulder to shoulder with government. The evident solidarity of the two parties was illustrated clearly when in 2004, Brian Deer's vaccine industry 'expose' of Dr Andrew Wakefield in the Sunday Times, was supported three days later by no lesser person than the Prime Minister Tony Blair, who commented that Deer's article had now revealed the truth and neither Dr Wakefield or his research were what they appeared.

* * *

In January 2002, exactly a decade after the Urabe MMR debacle, Liam Donaldson, the Chief Medical Officer at that time, published *Getting Ahead of the Curve – A strategy for infectious diseases*.⁸⁷ This report set the agenda for 'modernization' of the structures which deal with infectious diseases and, incidentally, research into bio-warfare agents. The report led to the winding up of the Public Health Laboratory Service (PHLS), which had muddled along in an on-off relationship making vaccines with Wyeth Pharmaceuticals and other drug companies. The new Health Protection Agency (HPA) was set up and joined with the Centre for Applied Microbiology & Research, a part of the Microbiological Research Authority, which reports to the Department of Health.

The Health Protection Agency, like many of the other free standing agencies set up under New Labour, has a commercial section which now, rather than muddling through, provides contracted services for pharmaceutical companies as well as developing drugs and vaccines with them.⁸⁸ The HPA is very American in its concept of an agency in the vanguard of the battle, on behalf of the community against

⁸⁷ As a piece of academic work, this report is often lacking. The introductory section which looks briefly at compromised immunity begins with the words 'Advances in medical treatment, particularly in the fields of cancer therapy and transplantation, have resulted in increased numbers of people living with impaired immunity.' Despite the fact that drugs and chemotherapy mainly consist of chemicals, Donaldson completely avoids any reference specifically to chemicals in the contemporary phenomena of depleted immunity. The section of the report on vaccines is full of the evasive, confused uses of English e.g. 'Fifty years ago, in this country, there were measles epidemics every year. Hundreds of thousands of children were affected. *Even in the second half of the twentieth century, there were more than 100 deaths associated with many such epidemics.*' (Author's italics.)

⁸⁸ It was the Centre for Applied Microbiology & Research which supplied the armed forces with anthrax vaccine during the Gulf War and the occupation of Iraq. Who passed this vaccine for safety ?

infectious disease and terrorist use of agents of bio-warfare.⁸⁹

Perhaps more worrying than any of this, is that the HPA, also has a committee completely dedicated to risk management of those putative threats to public health that it explores. In the field of mobile phones, vaccination and such things as dioxins industry arguments are supported and promoted for public consumption.

Donaldson's report laid considerable stress on vaccination, which he clearly saw as the future of 'cost-effective health strategy'.⁹⁰ He commits himself and New Labour to an accelerating pace 'of new vaccines'. Which will not only be new 'but many will be combined'. Inevitably, as a modernizer bent on governing in partnership with industry, Donaldson makes it clear in his report that 'Harnessing this change will require a carefully managed relationship with the research community and the vaccine industry'.⁹¹ From the time of *Getting Ahead of the Curve*, the British Government entered into a business partnership with the pharmaceutical industry to accelerate the production of 'cost-effective combined vaccines'. Although the public was not informed, another major novelty would be that many future vaccines would be based upon genetically engineered material.

There is no mention in this report of any public safeguards or support mechanisms for vaccine damaged children. We can only assume that while the combined vaccine programme is to be accelerated, the responsibilities of government and the pharmaceutical industry are to be completely curtailed.

The Urabe Farago, is a little history of secret government in contemporary

⁸⁹ The fight against infectious diseases and terrorism are closely linked in Donaldson's Report. This is yet another way in which the discussion of environmentally induced aspects of public health are avoided.

⁹⁰ Quoting from the 1993 World Bank Report *Investing in Health*.

⁹¹ The vaccine industry consists of those companies who regularly produce vaccines and are represented within the ABPI, by being an especially named group: The UK Vaccine Industry Group (UVIG), made up of Aventis Pasteur which is owned by Merck & Co., Baxter healthcare, Chiron vaccines, GlaxoSmithKline, Solvay Healthcare and Wyeth. Above the UVIG is the European Federation of Pharmaceutical Industries and Associations body EVM. Both the UK Vaccines Industry Group and the European Vaccine Manufacturers Group have the same basic goals: to sell as much vaccine as possible, or in the words of the EVM, to 'promote a favourable climate for expanded vaccine protection and improve vaccine coverage in Europe, and to help sustain the innovative R&D capabilities of vaccine manufacturers in Europe'.

Britain, it prefigures the drawn out assault on Dr Wakefield that began around 1994. Both the secret way in which the British government and the pharmaceutical backed agencies, responded to the Urabe crisis and the manner in which the made light of vaccine damage to large numbers of children, laid the basis for the programme of vaccine damage denial that has accompanied the deprofessionalisation and public humiliation of Dr Wakefield.

Vaccine damage denialist, might want to push the Urabe phenomena into the background, but it was an apparently 'accidental' training ground - competitive tendering for the DH vaccine, lack of proper trials, unpublished swapping of viral strains, serious adverse reactions to be dismissed, campaigns to stop media publicity - for fighting the more contemporary problems that were to accompany MMR and other combined vaccines.

It also has to be remembered that Dr Wakefield and his colleagues began seeing adverse reaction cases of MMR at the Royal Free Hospital, from the first years of the 1990s. There can be no doubt that some of these early cases that turned up at the Royal Free Hospital were cases of children that had been badly effected by Urabe Mumps strain vaccine. It is hardly surprising therefore, given the colossal health destroying error of the British Government in partnering Galxo Smith Kline in the distribution of the dangerous Urabe mumps strain virus, that Dr Wakefield was initially concerned about the adverse reactions of MMR. This concern showed itself long before the legal case of the parents of vaccine damaged children gained legal aid and around 6 years before he and ten other authors published their paper on other side effects of the remaining brand of MMR.

Perhaps just as important in it's effect upon the conflict that has developed between Dr Wakefield and the British government is the fact that having had to make a strategic retreat over two of the three brands of combined MMR vaccine launched by the DH, there could be no doubt that the government would hang on for dear life in the face of any criticism of their one remaining vaccine. In some ways Dr Wakefield attracted not only the hatred, contempt and political knives of the present NHS encumbants, but also the vengeful ghosts of another previous mistake made by their

predecessors over MMR,

The arguments of vaccine damage denialists, that vaccines are completely free of adverse reactions, actually disguise not just simple information about vaccination but whole areas of inadequacy in British post industrial democracy. Corporate governance in which the pharmaceutical industry buys its way into partnership with elected representatives, is a basic threat to British and North American democracy, it creates an area of government that seems to always escape responsibility for the damage that it does to children and adults and it is an phenomena that is growing daily. We have to ask ourselves repeatedly, when industry takes over the governance of society who will defend, protect and safeguard the health of citizens.

END