second draft

MORE MOTIVES REVIEWED…..MMR.

Hilary Butler. 6TH February, 2001.

George Bernard Shaw counseled against allowing a doctor a financial interest in cutting off your leg. The wisdom of that principle is unassailable. (32)

As many of you who followed the Liam Holloway case will know, the two oncologists from Dunedin hospital took an alternative practitioner to the Health and Disciplinary Tribunal, because he used "unproven" treatments on the child. As you also know, if you don't agree with doctors, and your child is under 16, the doctors can apply to court to have custody removed, so that they can use their "proven" treatments on your child. Which is what they tried to do to Liam, and which is why his parents went into hiding.

As parents it is our right to know that the accuracy of medical studies is very low, with only around 15% of medical interventions supported by solid scientific evidence (26). And that what is given to our children either vaccines, or drugs is safe, effective and proven..

Trouble is, it isn't:

"Studies throughout Europe have shown that health professionals are forced to use medicines that are either not licensed for use in children or used at a different do, for a different indication, bor by an alterative route from that recommended (off-label) Two third of children in hospital and 90% of sick newborn infants receive medicines that are unlicensed or off label. Little information is available about the risk of such prescribing, but one study has suggested that there is an increased risk of toxicity."

"*The pharmaceutical industry has been reluctant to study medicines in children for various reasons. These include the limited fianacial returns, the difficulty of organizing clinical trials in children, and concerns about possible toxicity."*(27)

Does not this strike you as a contradiction…"We're worried about toxicity in trials, so we'll just use it anyway." And why those concerns? A clue comes from Dr David Wendler (31) a bioethicist who said:

"*For a long time, the prevailing ethical view was the research is dangerous and people have to be protected from it. People were worried about exposing kids to potential risks. Now a lot of*

concern focuses on the placebo group, because they may be denied possible beneficial treatment."

This view is still held by many doctors, like Dr Hirschfeld (31) who said placebo trials are essential because "Children are not only very susceptible to their own expectations,.. They are very susceptible to their parents' expectations".

Another doctor, Dr Charles Weijer (31) said it was wrong to submit children to risks while providing them no immediate benefit, and challenged the scientific value of placebos. "*the unethical use of placebo controls in clinical trials is the most widespread problem in medical research today,"* he said.

Interestingly enough, this is discussed in Dr Jerome Groopman's book called "Second Opinions" because one of his main job is Phase I, II and III drug trials in adults. These are performed after the drugs show benefit in animals. And he describes how by around Phase III, most of them turn out to be useless in humans.

The use of untested drugs, or vaccines that don't work has plenty of precedent, one of which you already know. In the Senate records (28) is stated that " for decades, USA vaccine manufacturers sold to the public at huge profits 32 vaccines which "*were either of little value or perhaps even harmful… to people who felt they were being protected.*" One of those was the manufacturer of the current MMR vaccine, Merck Sharp and Dohme. Their five useless vaccines were Vacagen tablets, Brucellin antigen, Staphylo-strepto serobacterin vaccine, Catarrhalis serobacterin vaccine mixed and Sensitized bacterial vaccine H. influenzae Serobacterin in vaccine mixed. The records also state that the manufacturers made hundreds of millions, for profit, for nothing.

The problem here is for us as parents, because with anything, a vaccine or a drug it is so easy for doctors to put pressure on you as a parent, but say nothing about the validity of their own treatments. Not only is that somewhat hypocritical, it could actually be dangerous, a facet of the issue which the New York Times (29) picked up on shortly after the BMJ editorial was published. They pointed out that doctors knew way back in the 60's that adult antibiotics that were just fine an adults could kill babies, because their livers couldn't break them down, proving that:

"when it comes to medicine, children are not just "little adults." Despite that lesson four decades ago, pediatricians remain in the dark about how most medicines affect their patients. Only about a fourth of all drugs have been tested in children, leaving doctors at times guessing at the best treatments."

How they managed to keep this hidden for so long - goodness only knows. When parents whose children were on Ritalin found out that it had not been tested in under-sixes (30) , there were not pleased, especially as many reported problems had been rubbished. When you find out that there are estimated to be 150,000 – 200,000 children in USA between the ages of 2 – 4 yrs receiving Ritalin this raises a few problems. Not least of which are legal issues.

The FDA in its wisdom, must have seen this coming, because despite the outcry from many doctors who don't see the need to study children, over the last three years, Congress has been giving pharmaceutical companies financial incentives to study pediatric drugs (33). Take Merck, for instance. They have been given an incentive of $ US 290 million to make sure a drug called Pepcid is safe. It was about to lose its patent protection but as a rewards for conducting the first formal studies of Pepcid in infants, the federal government has also given them an extra half-year protection from generics. Some paediatricians are delighted with the results and are lobbying to extend the law past its finish date, December 2001. But as Zimmerman says:

" …a closer look at the law shows that it is also producing an unintended consequence: a drug-industry financial bonanza…the studies required to gain six more months of marketing exclusivity are relatively small and inexpensive, costing anywhere from $200,000 to $3 million. But the extended exclusivity that results can be vary valuable. It will boost drug-campany sales by more than $4 billion dollars."

Now just how did they achieve that? In November Public Citizen, a congress watchdog group published a paper which showed that in the lead up to the election:

"The prescription drug industry is spending approximately $230 million this election cycle on lobbying, campaign contributions and issue ads as it tries to shape public policy in the face of increasing public hostility to its price-gouging and profiteering." Which included:

$170 million for lobbying,
$15 million in direct campaign contributions
at least $35 million in campaign ads
at least $10 million to the US Chamber of Commerce for pro-drug industry campaign.

Would there be a link here? If so, it paid off handsomely.

Kimmelman goes on to quote Ian Spatz, Merck's executive director of public policy as saying: "I don't deny it's been a win for industry, but it's also been a win for kids."

Tell me, if their motives for producing the drugs were totally altruistic, and they wanted "a win for the kids" right from the start, why do they need and "incentive" to study them? Because 20 years ago when FDA tried to force the drug makers to submit substantial safety and efficacy evidence, they refused. Instead they put on labels to say that effectiveness in children had not been established. The Dean of Yale Medical School admitted:

"We were stuck. We had tried everything possible, every kind of other incentive, and nothing worked."

But that's not where that story ends. The manufacturers initially wanted not 6 months, but five extra years exclusivity, then two years, and then one year – finally agreeing to six months. What's worse, the law'd critics say it has loopholes that undermine a laudable intent, such as

allowing a financial benefit for studies that would probably have been done anyway. For instance, Eli Lilly gains six months more selling time for Prozac, worth an estimated $831 million. Just by submitting a clinical study that had already been completed in 1995, two years before the law was passed, and results of three studies that had already been initiated. Lilly spokesman, however, admitted that the final decision to proceed with them came only after the "financial incentive" was confirmed.

But a really big problem is that companies are using the law to extend their exclusivity on existing drugs, and not testing hundres of other drugs, on patent and off, that need to be tested in certain age groups.

Which is certainly not a "win for the kids" or their parents. At the FDA, Dr Murphy acknowledges that drug manufacturers will make "quite a lot of money on this." But, she says, "that's the price you pay."

So what for us as parents, is the price we pay, when we want to do it our way? Or when we don't want to vaccinate our children? It seems, that if Merck has their way – a considerable price.

On 31 January, the New Zealand Doctor ran an article on page 9, by Penny St John, called ***Mandatory jabs short cut to increasing rates***. Merck had sponsored a "briefing" for Journalists in the Asia?Pacific Regions.

And why push compulsory vaccination to only JOURNALISTS?

Amongst all the bad press that American journalists can dish out, vaccine manufacturers, along with the World Health Organisation, recognize that the best way to alter opinion, and condition society is "the media." They alone, have the power to change people's views.

We know too, that there is a "Plan" (25), because, in a 1997 World Health Organization publication (14) they clearly spelled out why an "on-side" media is vital to them. WHO was planning the first of many regular summits on vaccination at the time of publication, and they see the role of the WHO and the vaccine manufacturers to undertake a multi-pronged campaign:

Pg 90: *"the recruitment of those people who are able to back scientific declarations with political commitment for action: heads of state, or other high-level government officials such as prime ministers, governors or senators; national policy-makers from both the health and finance sectors; directors of international organizations; and directors of agencies from the donor assistance community.* ***A third group of participants in the meeting would be media representatives from as broad a spectrum as possible. It is essential that the public be informed, and continually reminded, that vaccines an immunization are one of the most cost-effective health interventions to day, and that they save the lives of millions of children every year****."*

Why?

Pg 16*: "2.3 To create and expand demand for vaccines:*

- *inform the public and decision makers on the value of disease prevention and the role of vaccination as a cost-effective health intervention."*

Pg 43: "*The concept and practice of immunization needs to be integrated into the "health consciousness" of people and thus, to their daily lives. Media, local leaders and other partners need to be used to reach this objective."*

So, as WHO write, they need to:

Summary chart on pg 75*: "4.2.5 develop active information campaigns for the public on immunization programmes, vaccines and the risks of infectious diseases."*

Pg 75 summarises earlier information on pg 20 under a heading ***"Fostering a culture of prevention through advocacy for vaccines"*** which discusses action to maintain local and political commitment to vaccines:

"*This can be done only through active efforts which inform the public of the benefits and risks of vaccination, the real risks of infectious diseases in their community and the impact of these problems on society as well as the individual. Similar efforts must also be directed at opinion leaders and those who provide resources so that support to immunization efforts can be dramatically expanded to provide better protection."*

Risks and benefits according to who? Studies performed by who? Financed by who? For the benefit of who? Or, are they even studied properly at all?

And how does WHO propose to do this? Firstly, they want to do: *"Social and behaviour research on attitudes and access to immunization… to guide the process of expanding protection."*

Sure enough, about 2 years ago, the CDC in America starting doing a study, and were appealing to parents who didn't vaccinate to contact them and tell them why. I have a copy of the fax sent out. WHO also need to *"Help countries identify where to acquire vaccines; how to acquire them; how to assure their quality; and how to finance vaccines as costs rise and resources diminish"* (Pg 59)

Note that. "**AS COSTS RISE AND RESOURCES DIMINISH**" What does this mean? Costs can only rise if countries choose to diminish their resources by making vaccine companies the biggest money heap in the universe. WHO could succeed,- if they get enough media onside, to spew out free information often enough to make people scared enough, so that they want everything WHO has to offer. And WHO has identified the way to do this:

- *"Promote the use of mass media sources, such as internet, to address the value of immunization and vaccines*
- *Identify community leaders to act as advocates for immunization programmes and vaccines"*

And these four aims, scattered in different places of the book:

- *"establish a clear agenda of action for decision makers including ascertaining that vaccine supplies, immunization infrastructure finance and support systems (such as training; education and communication materials; and monitoring systems) are adequate …"*
- *develop recommendations that encourage all countries to implement the widest practical range of vaccination activities…."*
- *create , or strengthen National Control Authorities responsible for vaccines*
- *"inform decision makers on the benefits of immunization and vaccines to their communities."*

Is this just about disease prevention?

Consider this,… that Global expenditure on vaccines in 1994, with only the more basic vaccines was a mere estimate of $ USA 10 billion dollars (pg 48). In the context of how much vaccine manufacturer's earn today, that is a pittance. Let's not forget that SmithKlineBeecham's Engerix B vaccine sales alone exceeded $1 billion dollars in 1995(15). The estimated figures now are staggering with sums you can't even imagine. We are talking hundreds of billions here. As Dr Hilleman is quoted as saying(21): "this is the golden Era of vaccine research." In the very next breath Duke University's Dr Samuel Katz enthuses:

"Spell it "b-o-o-m". Protection from frivolous lawsuits has given large companies increased freedom to stay in the vaccine business, which biotech companies are turning out wonderful new scientific advances."

The new "now" research is centred on how to get the most dollars. Unfortunately, that is not by developing the older type vaccines. As Signals Magazine put it:

"A killed virus yields little hope for broad patent protection, but identifying a critical subunit protein to use in a vaccine offers prophylaxis, patentability and the promise of fatter profits."

"Some of these new products will be plenty pricey."

A good example was the Hepatitis B vaccine, which when first introduced was made from pooled human blood from American homosexuals, because this contained huge amounts of antigen. But ran into both professional and consumer resistance. In 1986, the first recombinant viral subunit vaccine by Merck came out, and like Smith Kline's version, is, according to Signals Magazine, "a billion-dollar-a-year item". The other way to do it is proprietary vaccine combinations, which Merck has right up its sleeve….

A conclusion in the WHO book on pg 42 puts this in a larger context as they see it:

"There have been significant new developments at the early stages of the vaccine continuum. Much of this has, however, only been applied in industrialized countries, and even there incompletely. The pace of innovation is increasing. This highlights the need for concerted action so that the potential for public health benefits in all areas of the world is accelerated and maximized."

But to continue with WHO's adoption of the media as the key to success:

Pg 91 *To increase advocacy for vaccines and immunization through widespread inclusion of the media in the summit, preparations for the Summit, and follow-up activities.

A fourth group of participants in such forums are:

" 4) consumers of vaccines, including doctors and national immunization program managers."

And when you read this book, you cannot help but notice, that NOWHERE does this book mention the concerns of the lay consumers who include the people that vaccines are given to – parents, people – old, young, babies. What would we know?

They only want to involve those critical to the success of the fulfillment of the stated goals:

Pg *91 "Participants critical to the success of the meeting will be selected by the Summit Steering Committee and will be financially supported."*

This document was written around the time that a medical journal (16) described what they call "United States Vaccine Research: A Delicate Fabric of Public and Private Collaboration." On pages 1015 – 1016 the article read:

"To achieve the full promise of modern science and technology …America's cooperative and collaborative relationships in vaccine research and development are interwoven into a fabric of innovation. This must be maintained and strengthened. It is important to understand the nature of these relationships to prevent inadvertent damage to this ***delicate fabric****."* (author's emphasis)

More about this "delicate fabric" a little later… but on page 1018 the article continues:

"This delicate fabric of partnerships is highly sensitive to environmental changes, including changes in policy and market opportunities. A squeeze on funding in one area will have an adverse impact on discovery and development across the board…. Reductions in federal funding for vaccine research and development will have a secondary effect in academia and thereby on the United States capacity to engage in vaccine research."

"If the regulatory climate becomes cumbersome, regulation itself can become a hurdle, making it more difficult for new companies to enter the vaccine research and development area."

"Price controls are a source of concern… because investors fear the potential profits will be compromised."

"Collaboration and cooperation of government agencies, such as NIH, CDC, FDA, USAID< DOD, large vaccine companies, small research companies and academia are essential to continue success and fulfill the promise of recent advances in science and technology."

"Threats to any part of the delicate vaccine research and development network jeopardize the rapid development and supply of new… vaccines for the American people….These National Vaccine Advisory Committee recommendations will help to ensure that public policies take into consideration this research and development network, and foster and sustain it to facilitate the timely introduction and supply of new vaccines."

To the point where drug manufacturer's not only contributed hugely to Bush's campaign, they funded Bush's inauguration (17) to the tune of $1.7 million US dollars. What goes around, comes around.

And clearly a roundabout which the WHO is delighted to participate fully in, by a 1998 comment in one of their newsletters in which Dr Jong Wook Lee, Executive Secretary of the Children's Vaccine Initiative talks about the fact that:

"…to people outside the international vaccine community… new syndromes…. like prion diseases, viral haemorrhagic fevers like Ebola, Marburg, hantavirus, Lassa, dengue or tick-borne diseases, or a new kind of flu, not to speak of Aids … are bad news."

He goes on:

"To people like me and my GPV colleagues, its good news. All right, we have a daunting task. And maybe we won't win in the end. Maybe as vaccine researcher and developer Stanley Plotkin said, prevention by vaccination ***is*** *"the El Dorado of research in infectious diseases.".*

"Maybe. But for me it's good news mainly because, unlike El Dorado, vaccines are for real….they are already preventing more than 3 million deaths every year and could prevent another 9 million if we make new and better vaccines and find ways of ensuring they are fully used. And there's no reason why we shouldn't succeed: Just 3 years ago, there were "only" about 150 vaccine candidates in development; today, only 4 years after GPV was created, there are about 240.

"Yes, indeed, the news for us in the vaccine business is good."

"And yes, we're human beings and have got to eat, and the continual emergence of new diseases means our jobs aren't likely to disappear in the near future."

If there were 240 candidates in 1998, four years after there were 150, how many are there now? And **who** are they aimed at?

Dr Stanley Plotkin, by the way, is now a executive-wig with vaccine manufacturer Aventis Pasteur (Merck), USA. His colleague amongst the early vaccine "greats", Dr Maurice Hilleman, is also well looked after by Merck..

The promise of El Dorado, that Plotkin says is vaccines, was, in the late 80's under threat, as court cases swept USA and UK, threatening to cause all vaccine companies to fold. Fortunately, with considerable help from the medical professionals and other misguided individuals, the USA congress passed legislation which shielded vaccine producers from all financial and legal responsibility for vaccines, not related to manufacturing error (20). Which is the basis for the present b-o-o-m in vaccine research and sales. Without this legislation, vaccines as an industry was "dead-duck" country.

Now we have a meticulously orchestrated, "delicate fabric of partnership" which wants the media to educate you into seeing every day in the New Zealand Herald, the next, newest, greatest magic bullet. So that you will trust and buy. And not question.

In the light of all this, the enthusiastic "reportage" which flowed from St John's pen about Merck's "briefing" was to be expected

Dr Thomas Vernon, the vice president of public health and vaccine medical affairs for Merck Vaccine Division's opening shot in the article was:

"New Zealand should consider mandatory vaccination for children as a way of quickly raising the country's low immunization rates."

He went on to say that vaccine preventable deaths are not justifiable in New Zealand and that:

"*New Zealand has laws requiring children to wear seatbelts and questions why this form of protection is not extended to include vaccination."*

He also said:

"*the UK system of assigning each child to a GP and giving* ***financial incentives*** *for GP's who achieve high rates of vaccination has resulted in high levels of vaccination without mandate."*

Let's look at what this meant, for GP's in England. In a magazine called Financial Pulse, dated 8/2/97, there were two articles about this. The first was by a GP in Radlett, Herts, called "the Problem" In this, Dr Jan Gold teels us that they analysed their accounts, and found their

earnings from vaccinations and immunizations were well below the national average, and "should represent between 5 – 10% of item-of-service income…It is therefore an important source of earnings."

She goes on to detail the two levels of target payments – one at 70% vaccination rates (5,790 pounds), and a higher one at 90% coverage (at the lower level plus 11,580 pounds). She considers that improving her income by 17,370 pounds is worth the effort, and sets out not only how to do this. Some memorable quotes are:

"There is no item-of-service fee for some public policy immunizations, for example influenza, pneumococcus and hepatitis B. It is still worth generating income from these through the reimbursement scheme. This practice could generate up to 3,700 pounds from an effective annual influenza vaccination campaign if it immunized 10% of the practice"

and immunizing 5% of "targeted" patients would bring in 3,000 pounds.

"Many practices are finding this (foreign travel) a growth area, so it could be costly to ignore… the GPs in this practice should consider starting a travel clinic, run by the practice nurse. They should first direct this at their own patients, but there might be scope later to expand it to a private service for patients registered with other practices."

"Good marketing is the secret of increasing uptake in this area…."

The other article is by Dr Mike Townsend, and is entitled "Travel vaccines – broaden your earnings," where he explains how GPs can take advantage of patients' trips to exotic destinations….

This is what Dr Vernon is suggesteding, to get more of his products into your child.

Like all vaccine protagonists, Dr Vernon does not understand the difference between his money making products which go ***INSIDE*** a body, and an inert restraint which goes **around** part of a body in a car – or like helmets, on the head. Or steel-capped boots which prevent foresters from chain-sawing their toes off – on the foot. Except when it comes to trials, which might then show that a vaccine or drug is not quite like a seatbelt.

> Seatbelts, helmets and capped boots do not cause any changing in the immune system of the body.

We have seen Jenny Shipley fly the "Compulsory vaccination" kite, as have many others. And it seems to me that the general public is so relaxed about the issue of informed consent, and if the issue of "financial incentives" is as attractive to N.Z. doctors as it has beguiled UK doctors, we just might have a fight on our hands to retain the democratic right of freedom to chose. Already, in terms of cancer therapy and treatments of chronic conditions, by law, it just isn't there.

So lets look at another "Merck" issue, which is hot news overseas, but about which we are hearing zilch here. Unless you have internet at home, you won't know that the subject of the safety of MMR vaccine has absolutely exploded in the United Kingdom, and that the USA vaccine protagonists are gearing up for immediate "Risk Management" in the wake of a combination of media coverage, a hurriedly called Institute of Medicine Vaccine Safety Review, and some new American research about to published about the dangers of MMR which will greatly annoy Merck.

The sparking point of current debate was a medical article stating that the safety studies for the MMR vaccine were inadequate. (1) One of the two authors was Dr Andrew J. Wakefield which guaranteed that this article was always going to receive special risk management attention, because Dr Andrew Wakefield views that the MMR vaccine is causing Autism in some children has implications which go further than the ripples from a dropped stone into a large pond.

Naturally enough, the UK Health Department was "furious" over the medical article, and went public saying that Dr Wakefield was wrong, (10) and that most trials were for four to six weeks, one particular trial monitored them for six to nine weeks, and a minority of children in the trials were followed up for a year, and though they didn't state numbers, they inferred that was irrelevant, because with all the millions of doses given, its "safety" record proved itself. They also went into risk management mode, putting up on their website a "rebuttal"(6), prepared by a committee of 12. Of whom 8 were on Merck's "payroll".

The "delicate fabric" of cooperation had swung into action. In the context of this "action" you as parents should know that:

1) Scientists do not know how vaccines work (2)

2) The current New Zealand MMR manufacturer's information provided to doctors (3) says, under Clinical Pharmacology, that this is based on the:

> "*Clinical studies of 279 triple seronegative children, 11 months to 7 years of age, demonstrated that MMR II is highly immunogenic and generally well tolerated."*

The actual documented rate of autism in the UK, USA and Canada has exploded in a way never seen before. On Friday March 31, 2000, PRNewswire New York ran a story called:

"A panel of Scientific Experts Asserts that Autism and Other Pediatric Special Needs Classifications may not be Developmental Disorders, but are Likely Medical Disease Processes that are Beginning to Overwhelm Our Country."

This was the results of a statistical study done my an organization dedicated to researching Autism, which showed that autism has increased at least twenty-fold in the last decade.

Dr Michael Goldberg, a pediatrician with an interest in Autism said:

"If autism were purely behavioural or genetic, we would not be witnessing this dramatic rise in the number of cases, particularly those children that experience a period of normal development prior to the emergence of symptoms. It is scientifically impossible ***to have*** *an epidemic of a developmental or genetic disorder of any type. Clearly something is very wrong here."*

These doctors are staying away from the MMR issue. What they are saying is that "There is strong anecdotal evidence that a large subset of children with "acquired" autism (which MMR/autism cases fall into – in fact, most acquired autism falls into) suffer from a disease process that "elevates their immune system to a dysfunctional level" which they call NIDS or Neuro-Immune Dysfunction Syndrome.

DrJeffrey Galpin, Associate Professor at the University of Southern California and Infectious Disease specialist says:

"It is time to recognize that these children may be suffering from a potentially treatable medical disease and need our clinical research efforts now".

The aims of MAT, (Medicine for Autism Today), is to fund studies to evaluate the efficacy of immune modulating agents in the treatment of this acquired autism, and apparently there are several interested pharmaceutical companies lined up.

I have reservations about this research, because Dr Goldberg was once a staunch opponent of Chronic Fatigue Syndrome, ….until his wife got it. Now, he wants to treat these children – and who doesn't – but wants to stay away from the one thing that most of these parents say caused their children's autism in the first place? But like WHO's Dr Jong Wook Lee, he too, is "only human."

What is responsible for the present increase in Autism in New Zealand? We have no idea, even thought the Autistic Society seems to be inundated with large numbers, because there are no autism experts in this country. They are currently being "trained up" by American and Australian experts who, up to last year, came over here twice a year to attend to the needs of this previous neglected group. The fact is, most family GP's without a specific interest wouldn't have a clue as to what are the disorders which fit within the huge spectrum that is loosely termed autism.

In the past, the first thing that happened with parents of autistic children was that their parents were sent for psychiatric evaluation. Even now such is the emphasis on child abuse, and ignorance of such things as Asperger's syndrome, that some parents have been "investigated" for Munchausens,.

That parents are being harassed in this way is not surprising, since over 200 families in the UK who alleged their children were damaged by the MMR vaccine, have lost their children after being accused of Munchausen's syndrome by proxy. (13) Doctors involved alleged that Munchausen's is now being used as a cover-up over the suspected link between MMR and autism. Said Dr Shattock:

"It's down to pride. The medical establishment can't admit to being wrong."

Because Dr Wakefield has seen so many of these children he firmly believes that MMR can affect some children> It seems that he wanted answers to the following logical questions:

"On what basis was this vaccine licensed, … were those studies adequate, and large enough to prove that MMR was safe?

The first warning anyone had that this study was coming out was a news item (4) in Scotland, which stated that the studies had too few participants, were too short, and inadequate, thereby leaving unanswered questions regarding the safety of the MMR. The article also published the views of the peer reviewers. Dr Peter Fletcher, who was a senior professional medical officer in the Department of Health in the early 80's said "Being extremely generous, evidence on safety was very thin, being realistic there were too few patients followed up for sufficient time. Three weeks is not enough, neither is four weeks." Professor Duncan Vere, a clinical pharmacologist and former member of the Committee on the Safety of Medicines said: "***In almost every case, observation periods were too short to include the time on onset of delayed neurological or other adverse events. Interactions between vaccines had not been considered adequately in children with multiple vaccinations and potentially ill-developed immune system.***"

The reaction was predictable and swift (5). Dr Ian Jones, director of the Scottish Centre for Infection and Environmental Health, wrote to the editor of the medical journal demanding that the paper be withdrawn, claiming that it was normal practice for a scientific journal not to publish a paper if it appears in the medical before the planned issue date, and a few other pointed comments. Naturally, the editor of the journal was furious at what he interpreted as a threat, and stated that "…***putting pressure on us not to publish is despicable***".

So then came the flood of information rebutting Dr Wakefield's claim, which interestingly enough, all sort of read the same. There was one mistake, which even more suspiciously, was repeated in each major rebuttal. These rebuttals were the news item about the Health Department being furious, an editorial in the BMJ dated 27th January, The Department of Health rebuttal, and medical information released to all and sundry around UK with the suggestions that it should be liberally spread around to enable "colleagues" to rebut these claims.

As mentioned earlier, 8 out of twelve of the committee who defended MMR have financial links with the MMR manufacturers. (7). Five of them hold shares in the drug companies, or are paid consultants, while another seven have received grants or sponsorship from them to fund

academic studies or clinical trials. This is similar to a situation in America which is called "the Grantsmanship" game (8) which goes something like this.

A doctor might be working at the National Institutes studying something, which he sees might have commercial application. In order to research it thoroughly he needs funding. As an esteemed government employee, he is eligible to government funding. So since he works for the "the good of the state" he applies for money, and gets it. This fictitious doctor realizes the financial potential of this product, so on the side, sets up his own company called, say, Immunofantastic. His work progresses, and as time comes near, the "company" he has set up, agrees to pay royalties to him and take the contract to develop and market the product. He gets, three ways. Public money for the research, royalties from his own company, and the profits from his own company.

He might decide to leave the Government institution so he can have even greater freedom, but this restricts his ability to obtain public money. So what he does is to set up a nonprofit organization at the same industrial park complex that is "Immunofantastic". This arrangement means that he can combine academic-style "intellectual freedom" with the ability to usher his inventions to market and the possibility of a further financial payoff. He still gets his no-strings attached (without interest required, don't have to pay it back) public funding, is "paid" by his company for "rights" and gets the profits from the products his own company makes for him. We might call this "triple-dipping". Those in the medical world who don't do it, call it "intellectual prostitution". But all the medical people who were happy to walk the Wall Street Journal through their buildings, and openly reveal their multi-millionaires financial gains, can see nothing wrong with it. It is their right. One of the examples in this article was worth $115 million with his company trading at around $17.38 on the Nasdaq, and his family and other companies he owns held another 10%. He admitted that if there was not this non-profit/profit arrangement that he "would have to make alternative arrangement… which could significantly delay and increase expenses in the testing of his own potential pharmaceuticals".

In a previous article I listed some of the American doctors who advise the world on vaccines, whose relationship reflects similar "intellectual prostitution." One of these was Dr Paul Offit, who holds a patent on a rotavirus vaccine, and received a grant from Merck to develop this vaccine. The vaccine companies also pay him to travel around the USA teaching doctors that vaccines are safe. He was a member of the CDC's advisory committee and voted on three rotavirus issues, including the adding of his vaccine to the vaccine schedule.(11) Also listed and detailed were the financial conflict of interests of other US CDC members. But it gets worse.

It also turns out that 54% of Government employed FDA advisers who advise the Government on safey and effectiveness of medicines have direct financial interests in the drug (vaccine) or topic of their interest which they are advising on, which usually involve stock ownership, consulting fees or research grants. (9) What is even more interesting is that the FDA has kept all details secret since 1992. However, Dennis Cauchon, the journalist, was able to prove from records that from January 1, 1998 to June 2000:

- ✓ At 92% of meetings, at least one member had a financial conflict of interest.

- ✓ At 55% of meetings, half or more of the FDA advisers had conflicts of interest.

- ✓ At the 102 meetings dealing with the fate of a specific drug, 33% of the experts had a financial conflict.

It is not surprising that so many drugs are now being removed from the market, and that even with those that are considered "safe", the numbers of deaths each years in USA from harmful drug reactions is over 100,000 every year, and results in medical bills of $136 billion dollars. (12) This article is even more interesting, in that it gives an explanation as to why so much safety research is probably totally meaningless. For instance, one of many problems is that drugs do not stay at constant levels in the body "Those peaks can sometimes be toxic and the valleys totally ineffective". Another problem, as stated in the NIH's Recorder, years ago, is that depending on your genetic make-up, or your ethnicity, drugs can have totally unpredictable reactions. What is worse, a reasonable dose for one person might be ineffective or toxic for another.

The most interesting thing about the Time article was **not** the message that these drugs might be inherently dangerous, but the wonderful new patentable research that was going in to promoting new methods of delivery to try to avoid some of the side effects, like skin patches, or pre-loaded straws for those who can't swallow pills, which you just sip your fruit juice through, to get your fix. For those of you really into the high-tech, there is the microchip to be swallowed which contains up to 1,000 tiny reservoirs of chemicals released in the proper quantity and sequence when the chip is prompted by certain voltages.

What has this got to do with MMR. Plenty. Because what the UK public reads is dictated by people such as these, giving their views to the MEDIA. Only a few of them can see that there could be another, very serious side to the proclamations that MMR is safe, effective, properly tested and causes no problems. By and large, the MEDIA have little idea of the "delicate fabric of co-operation."

The question New Zealanders should be asking is – does it happen here? Yes, It is part of the medical "culture".

As Catherine D. DeAngelis (22) said in a recent article:

"The enticement begins very early in a physician's career: for my classmates and me, it started with black bags. Dr Kassirer's colleague is not along in remembering which pharmaceutical company provided the. The timing of presenting the black bags early in our first year was wonderfully strategic, as was the inscription of our names on each….Subsequently, offers came for "free" lunches, dinners, and tickets to various events followed by offers to serve as an "expert" with the usual lineup of speaking engagements and serving on advisory panels and hoards, for an "honorarium" of course. There should be little question about the expected effects of accepting free food, tickets, and even black bags. It has been shown that clinicians' decisions are affected by their interactions with pharmaceutical companies. This is no

revelation; why else would anyone provide these "free" gifts except ultimately in the selling of a product? The public is well aware of this problem, and it has become a favorite subject of recent newspaper articles."

What was really interesting about Kassirer's article (23) was that when he started to talk to the medical students and house officers, the response was initially stunned silence. Once the audiences started to respond, most said there was nothing wrong with it all. He then says:

"By the end of the hour-long session, many in the audience seemed to "get it" which became apparent by the questions they asked….It is reasonable to presume that nearly all of those present at this conference went into medicine with high-minded motives and that financial gain was only a secondary consideration. …Yet the culture in academic medical centers becomes a major determinant of professional behavious once students enter the clinical years and later when they become house officers. Some of this acculturation is promoted by faculty members who themselves are exploiting their academic status for financial gain. But much of it, I suspect, is a consequence simply of inattention."

"Students and residents first acquire a tastet for the largesse of the pharmaceutical industry in the halls and conference rooms of academic medical centers and later at lavish dinners at company sponsored symposia. Some resist, but others develop a sense of entitlement….Where professionalism is concerned, they must teach that there is no free lunch. No free dinner. Or textbooks. Or even a ballpoint pen."

But the key to understanding about mandating vaccines, financial incentives and defending one's product vehemently could lie in something they are not telling you.

Aventis Pasteur MSD has brought out a new vaccine called Hexavax which "protects" against diphtheria, tetanus, pertussis, polio, hepatitis B and Haemophilus influenzae B. They funded the study, and stated that the vaccine did cause a few more mild side effects after the first dose than two other of their vaccines, Hepatitis B and Pentavac (against 5 others). They also found that while the antibodies to hepatitis B and Hib rose more slowly with Hexavac, this should not affect the child's immunity. The study said:

The vaccine *"will also make it easier for countries that have not yet incorporated all these into their national immunization programs to adopt these vaccine recommendations more widely."*

But this is not the real crunch. That came in the New Zealand Doctor 31 January 2001, page 9, which said that Merck (the same company as Aventis Pasteur MSD actually) has registered another vaccine which incorporates Dtap, Hep B, Hib, IPV, and MMRV. Just to add that all up, that is ten vaccines. Same as Heptavac, but with measles, mumps, Rubella and Chickenpox as well.

The next part said: "There is no scientific evidence showing combination vaccines cause more adverse reactions than individual vaccines."

And here we have the crux of it all. Two phrases. "Scientific Evidence," And Combination Vaccines.

The repeated "one mistake", and other irreconcilable differences with the studies quoted by Dr Wakefile didn't make sense, until a very kind concerned professional, sent me "THE FAX".

The information in the 9th January fax seemed to follow the pattern, and contained the one mistake which formed the basis of the UK defence against Dr Wakefield. I was written by Dr Mike Watson, Medical Director, Aventis Pasteur MSD.

Now, why do you think Merck want New Zealand to make vaccination compulsory to increase the "compliance" rate?

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