A RESPONSE TO THE VETERINARY MEDICINES DIRECTORATE POSITION PAPER ON CANINE VACCINATION SCHEDULES

PART ONE

WHY WE SHOULD VACCINATE LESS FREQUENTLY

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INTRODUCTION

This document is prepared by Catherine O'Driscoll of Canine Health Concern (CHC). It is written in response to the Veterinary Medicine's Directorate's (VMD's) Position Paper on Canine Vaccine Schedules for Dogs, released on 31st March 2010.

The VMD's Position Paper was, in turn, prepared in response to a letter from Canine Health Concern and over a hundred vets and pet owners, asking for the VMD to withdraw licenses for one-year MLV (modified live virus) vaccines for pets, on the basis of the following principles:

Independent duration of immunity (DOI) studies have shown that immunity to viral disease in dogs persists for years or life.

Vaccines do not need to be repeated annually.

Annual vaccination is potentially harmful.

The American Veterinary Medical Association's position statement says:

> **"Unnecessary stimulation of the immune system does not necessarily result in enhanced disease resistance, and may increase the potential risk of post-vaccination adverse events".**

The American Animal Hospital Association (AAHA) Guidelines (http://www.leerburg.com/special—report.htm) state:

"Do Not Vaccinate Needlessly - Don't revaccinate more often than is needed and only with the vaccines that prevent diseases for which that animal is at risk." They also caution veterinarians: "Do not assume that vaccines cannot harm a patient. Vaccines are potent medically active agents and have the very real potential of producing adverse events."

The American Veterinary Medical Association's (AVMA's) Principles of Vaccination (http://www.avma.org/issues/vaccination/vaccination.asp) states that:

"Possible adverse events include failure to immunize, anaphylaxis, immunosuppression, autoimmune disorders, transient infections, and/or long-term infected carrier states. In addition, a causal association in cats between injection sites and the subsequent development of a malignant tumor is the subject of ongoing research."

THE VMD'S REPONSE

It should be noted that the VMD is an agency of the British government.

Although the VMD responded to CHC's request with a 37-page document, nowhere did it directly address the issue that one-year MLV vaccines need to be withdrawn. It merely stated what is happening now. The VMD response can be summarised as:

1. A history summary of vaccination – from Pasteur to current veterinary vaccines.
2. Diseases targeted by core canine vaccinates (disease descriptions plus UK authorised vaccines) .
3. Non-core UK vaccines authorised for use in dogs.
4. Other UK vaccines authorised for use in dogs.
5. Comments relating to the use of these vaccines and control of related diseases.
6. Requirements overview for the regulation of veterinary vaccines.
7. Public information and transparency.
8. Comparison of UK schedule with WSAVA guidelines.
9. Safety, adverse reactions and vaccine failures.
10. VPC report (2002).
11. Overview of POOCH study (2004).
12. Vaccines, immunology and duration of immunity.
13. Position of the BSAVA.
14. Animal boarding and vaccine requirements.
15. Promotion of vaccines and National Vaccination month.
16. Summary.
17. References.
18. Glossary.

Probably the most illuminating paragraph in the VMD's response is this:

> **For the majority of UK authorised dog vaccines the re-vaccination interval for the core vaccines canine distemper (CDV), canine parvovirus (CPV) and canine adenovirus (CAV) is at least every three years. These authorised re-vaccination schedules are in accord with the WSAVA Guidelines which state "not more often than every three years".**

With respect, there is some confusion in the VMD's response.

The VMD says we should vaccinate **at least** every three years, whereas the WSAVA (World Small Animal Veterinary Association) guidelines state that we should vaccinate **no more often than** every three years. Therefore the only element of the VMD statement that is shared with the WSAVA statement is the timeframe of three years. Materially, each stance is substantially different, and even diametrically opposed.

On the basis of the VMD's statement, veterinarians and pet owners in the UK might be led to conclude that companion animals should be vaccinated every year, every two years, or every three years – or, indeed, every five minutes.

On the basis of the WSAVA statement, it is quite clear that we do not need to vaccinate any more frequently than every three years. Further, the independent DOI studies clearly show that immunity against viral disease is probably lifelong in dogs.

This response from Canine Health Concern to the VMD therefore comes in two main parts and addresses:

1. **The reasons why we should stop over-vaccinating companion animals.**

2. **The reasons why the VMD might be reluctant to provide direction in this matter.**

This response is submitted to the VMD for one reason and one reason only:

We are over-vaccinating the animals.

All vaccines come with potential adverse effects,
and so we must vaccinate as infrequently as absolutely necessary.

In an article published in *The Veterinarian* in September 2009, entitled "Fur flies over small animal vaccination", Richard Squires, Associate Professor in Companion Animal Medicine at James Cook University, and a member of the World Small Animal Veterinary Association's Scientific Advisory Committee, stated:

> ***"There is strong and mounting evidence that most vaccinations administered to adult dogs and cats serve no beneficial immunological' purpose whatsoever."***

BACKGROUND

It has been known since Dr Ronald D Schultz conducted his independent duration of immunity (DOI) studies in the 1970s, that there is no scientific justification for the current revaccination schedules of dogs. As all vaccines come with a risk of severe and life-threatening adverse reactions, it makes sense to administer vaccines and drugs as infrequently as absolutely necessary in order to minimise any risks.

It is therefore difficult to understand why, after 16 years of campaigning on the part of Canine Health Concern, the British Veterinary Medicines Directorate, and the successive Ministers this government department has advised, should fail to reflect the known science, despite repeated requests, and despite repeated submissions of DOI data.

A PUZZLING RESPONSE FROM GOVERNMENT

Forgive me for presenting a potted history of Canine Health Concern's experiences over the past sixteen years, but we feel that a background such as this will explain our reasons for making a further request to the VMD, and for presenting it in this form. We feel that the dog owning public, and our elected representatives, need to see the bigger picture in order for change to be effected.

My late husband John Watt and I formed Canine Health Concern because our young Golden Retrievers had died at the ages of four, five and six, and our remaining young Golden Retrievers suffered from severe chronic illnesses. We noticed that our experiences were shared by many dog owners, and concluded that dogs of today were suffering from severe and debilitating chronic disease, and many were dying years before their time.

There was something dreadfully wrong with canine health.

Canine Health Concern is now run with the kind support of my husband Rob Ellis. Our mission remains to research the cause of ill health in the modern dog, and to share our findings with fellow dog lovers in order to alleviate suffering in the canine population.

A division between science and the people

The problem for the scientific community is that, although science tries to divorce itself from emotion, animals actually have personalities and souls. Anyone who has had a relationship with an animal knows that they are people. They cannot be dismissed as statistics and numbers. If someone harms our friends, we stand up and say, "No, you may not do that." This is a natural response.

Why are our dogs dying so young?

When discussing our dogs' ill health with other dog owners before the formation of Canine Health Concern, it became clear that our experiences weren't unique. Many dog lovers were reeling from the illness and deaths of their own young dogs. It just didn't make sense. Our ancestors would not have kept dogs if they were always sick and dying around them. Economics would not have allowed this. They couldn't carry passengers.

Why is it that, today, pet owners expect to be constantly at the vets, dealing with diarrhoea, skin problems, epilepsy, arthritis? Why are these chronic illnesses regarded as normal? Why are pet owners paying out thousands of pounds in veterinary costs as a matter of course?

Casualties are the expected risk of conventional veterinary medicine

After three of my young dogs died of vaccine-related illnesses during the 1990s, I began to research the vaccine issue in greater depth. I realised very quickly that annual vaccination is neither necessary nor without potential harm. And yet veterinarians were advocating and administering yearly vaccines against viral disease – when, from the 1970s, it was known that immunity against canine viral disease persists for years or even life. We actually don't need to vaccinate our pets every year.

This knowledge had come from independent researchers, Dr Tom R Phillips and Dr Ronald D Schultz. Dr Schultz, was head of pathobiology at Wisconsin University. He questioned why we were vaccinating dogs yearly when no-one was asking him to vaccinate his children every year. His research established a

scientific principle:

Immunity to canine viral disease,
once established, persists for years or life.

Diet is a cornerstone of health

We were also, before the start of Canine Health Concern, introduced to the concept of natural feeding. Our own experience with the natural diet for dogs prompted us to promote natural feeding to the dog world. We were not, of course, selling food for dogs, but sharing information.

Canine Health Concern members and countless natural rearers around the world are able to recount stories of sick dogs becoming healthier after their diets were changed to real food; many have also chosen not vaccinate their dogs every year.

Diet, and not repeated unnecessary vaccinations, is the basis for good health and immunity against disease. In addition to coming to this understanding through direct personal experience with our dogs, there are also many studies which support this claim.

The power of marketing

When you look at the simple fact that immunity against viral disease persists for years or life, and contrast this known fact with a practice that flies in the face of this fact (annual or even tri-annual vaccination), it doesn't take much intelligence to work out that over-vaccination has more to do with sales figures and profits than it has to do with health. The problem lies in persuading the people who are making the profits to let go of those profits.

John Watt held a Masters degree in systems analysis and operational research. He had worked as a researcher, statistician and business consultant for many of the world's largest corporations. I worked as a public relations consultant, also for many of the world's largest corporations.

As business consultants, we naturally understood that wealthy organisations within the multi-billion pet product industry would be forging relationships with legislators, politicians, academia and veterinarians. These relationships would be cultivated and oiled with the aid of money. This would be in the form of funding for political parties, for veterinary teaching establishments, for animal charities, and for vets in practice.

All businesses, in order to sell their products and services, forge relationships with the 'supply chain'. A supply chain is a network of interconnected businesses involved in the provision of a product or service to customers. This is not considered to be an evil in the business world. We had advised our own clients to do much the same. It's part of the sales process.

Similarly, governments understand that in order for society to thrive, it relies upon the economic presence of employers and tax paying corporations.

Grieving, as we were, for our beloved dogs, we looked at normal practice and realised that the food our vets recommend, and the yearly jabs our vets recommend, might be the norm simply because these practices had been marketed effectively.

You can have a useless product and make a fortune out of it if you have the money to market it effectively. Similarly, you could have a cure for cancer but no-one will ever hear of it unless you have the money to get it to market.

Therefore, we reasoned, even if annual vaccination is making our dogs ill, and pet food is making our dogs ill, no-one will ever know this. The Ancient Yoga Vasishtha stated that the world is an illusion created by the mind. What we think dictates who we think we are. We believe what we believe largely because everyone else believes it. This is the power of marketing.

As a PR and marketing professional myself, I know that if you shout loudly enough and often enough (which, in this modern world is very much about how much money you throw at it), then people will believe what you say – whether or not you speak the truth.

Of course, there are laws which are supposed to ensure that all advertising and marketing is ethical and above board. But laws are devised in order to protect the system in which the lawmaker believes.

Independent research

We decided to conduct a survey – by dog owners for dogs – free from commercial bias. We would not be looking for sponsorship from big business; we would remain independent from commercial bias. We, the dog owners, would fund the research ourselves. Naively, we estimated that this research would take about six months, we would release our findings, the world would listen, and the dogs would stop dying years before their time. Importantly, we would go back to our day jobs.

As any researcher will understand, this sort of research requires funding. Our solution was to invite dog owners to complete a 26-page questionnaire and, at the same time, contribute £5 towards the research costs. In return, they would receive a copy of our findings. This seemed reasonable to us. We human beings frequently mistakenly believe that, if we think a certain way, others will too. I honestly believed that dog lovers would jump at the chance to take part in the research and help the dogs to live longer and healthier lives.

But before the research had even started, a UK dog magazine, *Dog World*, published a defamatory news item about a “couple who were working from a post

office box and who stood to make thousands of pounds from a 'survey'". The editor subsequently printed a retraction.

The Canine Health Census was launched in another pet magazine: *Pet Dogs*. We had reasoned that if we didn't attract at least 2,000 of the 30,000 readers to participate in the survey, then it was unlikely to get off the ground and we would abandon the project. In the event, just over 200 readers took part. However, the editor, Paula Shires, urged us to carry on and promised to keep publicising the initiative. Sadly, Paula was killed and the magazine was sold off and later ceased publication.

Meanwhile, we struggled to attract the participation of dog lovers in our survey. The first problem was that, in the 90s, dog owners firmly believed in the benefits of annual vaccination, and they did not want to hear negative messages about the pet food they relied upon. Also, most pet owners trust and like their vets. They were uncomfortable to hear veterinary advice being questioned. We struggled to get enough dog owners to complete our questionnaire in order to arrive at meaningful statistical conclusions.

It soon became apparent that it was necessary to get the dog world talking about the health problems we were seeing, and their causes. Once the issues were out in the open, we felt, dog owners would understand the need for the survey, and the health of dogs would subsequently improve.

We approached a number of veterinary colleges in the UK and asked them if they would be prepared to cooperate with our research; we were turned away. We wrote to many of the UK's animal charities. Again, we were turned away.

We also approached a number of 'maverick' veterinarians who had, themselves, raised questions about modern canine husbandry. Many of these joined our panel of experts, and Canine Health Concern was born. Dog lovers from around the world also became members of Canine Health Concern. Hundreds of these members have stayed with us to this day.

After corresponding in the dog press and having a few articles published, I was invited to speak at dog club events. I would usually ask the audience to raise their hands if they vaccinated every year and fed pet food. Mostly every hand in the room would go up. I was also routinely heckled and dog owners would leave the room in protest. I realised that the vaccine issue was almost like a religion, with very high passions on both sides of the debate. It was commonplace to receive letters and phone calls accusing us of scamming the pet owning public in order to make away with their £5s. Amongst the veterinary profession, I was referred to as "that awful woman".

I also received letters and phone calls warning me that if we were successful and jeopardised the profits of big business, then we would be publicly discredited and

even ‘bumped off’. This was echoed by the advice of a senior civil servant within the VMD: “I fear for you if you carry on, Catherine. I fear for you.” I wasn’t sure whether this was a threat or a kindly warning. I will not mention his name – he will know who he is.

It is worth noting here that I have always avoided mentioning names in a negative context, as we have never sought to attack any individual. Canine Health Concern exists to help alleviate suffering, and not to cause it.

Research

In an effort to understand the vaccine issue, and also to share what I had learnt with fellow dog lovers, I started to research and write a book about canine vaccination. It was a self-published book called, *“What Vets Don’t Tell You About Vaccines*”, published initially in 1997. The book is now published by Dogwise in America and has been reprinted on numerous occasions. It has been followed-up by a second book, *Shock to the System* which has also been reprinted many times.

Before *What Vets* was published, I was warned that it would go straight to the veterinary vaccine company legal departments, and I would be sued and lose everything. This of course has not happened, presumably because one cannot be sued for telling the truth (and you can’t lose everything if you don’t have much to lose in the first place).

Also, despite the warnings that I would be killed if my work was successful, I am still, so far, alive and well. If it is true that big business bumps people off if they threaten profitability, then I must thank the veterinary vaccine and pet food industries for their gentlemanly behaviour towards me.

Unwitting introduction to the VMD

As I was writing the manuscript for the book, I became involved in public correspondence with Steve Dean, now head of the VMD. Mr Dean has for many years enjoyed a column within *Dog World* under the banner of “A Vet’s View”. I had no idea that Professor Dean was a member of the Veterinary Medicines Directorate, nor that he had spent 17 years as a marketing manager with a pharmaceutical company, and had subsequently been a pharmaceutical industry consultant.

I apologise to Steve for naming this, but this information is fairly crucial for any dog lover who seeks to understand why most vets in the UK advocate annual vaccinations when immunity against viral disease, once established, remains for years or life.

It must be noted that the government knew of Steve Dean's background before he was appointed. And it must be concluded that the British government actively sought out an individual to head its veterinary licensing authority who would be sympathetic to the veterinary pharmaceutical industry's aims.

In *Dog World*, Steve Dean frequently minimised claims of vaccine damage and championed annual vaccination. Although I viewed Steve as a vet ("A Vet's View"), I also felt that the tone of his columns, and the nuggets of information he shared, indicated that this was a man who knew far more than the average vet did about vaccines.

Vaccine survey

In response to Steve Dean's column in *Dog World*, John and I decided to conduct a vaccine-specific survey. This was designed with the aid of the vets Christopher Day and Dr Jean Dodds. Canine Health Concern members participated in the survey and, in order to minimise any bias, members also invited their dog-owning friends and neighbours to participate. The questionnaire was also published in *Dog World* (we paid the going advertising rate). The reason for this expenditure was to ensure as much impartiality as possible.

The vaccine survey was designed to test Christopher Day's theory that, when a vaccine date is known, 80% of illnesses in animals occur within three months of that vaccine event. On a personal note, I vowed that if the survey did not support the message conveyed by the manuscript I had written (*What Vets Don't Tell You About Vaccines*), then the manuscript would be shredded. My aim was to help dogs, and not to make a name or money for myself.

It transpired that our survey did indeed support Christopher Day's observations in practice. We found that, overall, 67% of illnesses in dogs occurred within three months of a vaccine event. If vaccines had no role in the creation of illness, then you would expect to see an even 25% of illnesses starting in each yearly quarter. The study is detailed, illness by illness, in What *Vets Don't Tell You About Vaccines*.

Please note that the survey was not looking at the number of reactions in a particular pet population (as tested by the later industry-funded POOCH survey), but was seeking to ascertain whether, if the dog was ill, there was any correlation between that illness and a vaccine event.

The government responds

Before the POOCH survey was announced, the Veterinary Medicines Directorate contacted Canine Health Concern and asked to conduct a review of the CHC vaccine survey. At the time, the head of the VMD was Professor JM Rutter.

We readily agreed to have our research scrutinised, providing that the analysis was conducted by a truly independent expert. We suggested that the VMD approach a professional body involved with statistical analysis. The VMD declined to do this, and instead put forward a Professor Gettingby, who was at the time a vaccine industry consultant. We declined to submit our data to an individual with known industry bias and again asked the VMD to nominate an independent third party. The VMD declined.

The message was clear - to us, anyway: the government body charged with the task of ensuring the safety of veterinary medical products was hostile towards any evidence linking vaccines with death and disease in the pet population.

TV coverage

Shortly after publication of *What Vets*, I met, by chance, a TV producer. The result of that meeting was a World in Action TV documentary which exposed some of the problems associated with over-vaccination and pet food. Millions of people watched the programme and I understand that vets were subsequently spending an inordinate amount of time with clients, persuading them that their dogs did, indeed, need vaccinating every year.

The veterinary vaccine industry, alerted to the programme in advance, sent crib sheets to every veterinary practice in the UK, coaching them on the answers they should give if clients had seen the programme. This document, circulated on headed paper from the National Office of Animal Health Limited (the trade association representing the veterinary pharmaceutical industry), said:

- Certain autoimmune disease syndromes are being more commonly recognised as a result of better diagnosis and awareness by vets and specialists, but there is little scientifically-proven evidence linking such disorders with routine vaccination. It may be true that the actual prevalence of certain autoimmune or immune-mediated disorders is increasing due to in-breeding in various breeds with a relatively small genetic pool.

- There is little scientifically-proven evidence linking such disorders with routine vaccination. Although there has been one publication from the States suggesting a possible temporal association with vaccination and the onset of AIHA in dogs, a more detailed study recently reported from the UK has found *no evidence of any increased risk of developing either AIHA or IMT as a result of vaccination*. However it has been suggested by some workers that vaccination may simply be acting as an 'antigenic load' triggering the onset of immune-mediated disease in a very small number of 'genetically pre-disposed' individuals in the same way that tumours and infectious disease have sometimes been implicated.

- Serious side-effects following vaccination are very rare indeed.

- … it is impossible to ever guarantee that any product will be 100% safe and effective in every individual case. There is always the risk of an unusual

idiosyncratic or allergic reaction in a susceptible individual which cannot be predicted in advance.

- Where there are known side effects or specific contra-indications related to the use of a particular product (eg its use during pregnancy), these are clearly listed by the manufacturer on the Data Sheet.

- To enable the immune system to respond optimally to the vaccine, it is important that the animal is in full 'immunological health' (ie, not suffering from any immune suppressive disorder or on such medication) and that the immune system is not 'otherwise engaged' fighting some acute disease condition.

- Whilst our principal concern, therefore, would be the likely efficacy of the vaccine in unhealthy dogs, it would be wrong to discount the possibility that an acutely sick animal may be more likely to respond adversely to vaccination.

It should be noted that the - now discredited - detailed study which found "*no evidence of any increased risk of developing either AIHA or IMT as a result of vaccination"* (referred to above, and circulated within the NOAH document to veterinarians in the UK) was commissioned by the veterinary vaccine industry and conducted by the Animal Health Trust. Similarly, the POOCH survey was paid for by the veterinary vaccine industry and conducted by the Animal Health Trust (which listed itself in one of its report and accounts as a 'vaccine developer').

It does not pass our notice that the VMD is overly ready to call the POOCH survey 'independent'. How can a study that has been paid for by the veterinary pharmaceutical industry, and conducted by a vaccine developer, ever be regarded as independent? And what business does a government department have in calling it independent?

Surely the VMD is aware that drug companies are renowned for pointing to studies that demonstrate the effectiveness of their drugs in the hope of selling more drugs, and that most of these studies are paid for by the drug company, which influences the outcome?

A recent study – and one that wasn't funded by a drug company – has discovered that "most drug studies will conclude that the remedy is effective, if the research has been paid for by the manufacturer. The study sponsor influences the result in a variety of ways". This study was led by Professor Wolf-Dieter Ludwig, chairman of the drug commission of the German Medical Association. "Aside from directly paying for the study, the drug company may also have direct, or indirect, financial links with the authors, and this could include payments for lectures, air travel to exotic locations, and the like." The results aren't the only thing open to bias. The all-important conclusion – the summary that most people focus on – "is also open to interpretation, and can even differ from the actual results". (*Deutsches Aerzteblatt International*, 2010; 107: 279-85).

Working group looking into canine and feline vaccines

Shortly after the World in Action documentary, the government, under the auspices of the Veterinary Medicines Directorate, commissioned a working group to look into canine and feline vaccination. The working group concluded that we should essentially leave things as they are, which meant we should continue to vaccinate our dogs and cats annually. This is referred to and leaned upon in the VMD position paper in response to our call for the VMD to withdraw one-year MLV vaccines from the market.

At the time, I wrote, in all, some 13 letters via my MP to the then Minister, complaining that the working group was comprised of individuals with ties to the veterinary vaccine industry.

Register of interest details at the time of the report (2002) showed that Professor Rosalind Gaskell (working group chairman) was an Intervet shareholder and in receipt of research grant and support for studentship from Intervet. Professor George Gettingby worked as a consultant to Intervet's sister company Organon, Hoechst Animal Health and Pitman-Moore. Mr David Skilton BVSc, MRCVS was listed c/o the Veterinary Defence Society Limited. None of these three were, then, independent as claimed. The fourth member of the working group was Mrs Sheila Graham BSc, a lay member of the VPC. This information is in our files, courtesy of R Anderson, Director of Policy, VMD, and extracted from the VPC Annual Reports of 1994, '95, '06, and '07, and published in the Medicines Act 1968 Advisory Bodies Annual Reports.

Additionally, I sent the Minister copious documentation, including independent duration of immunity studies, to show, scientifically, that once a dog is immune to viral disease, he is immune for years or life. The response from the Minister was to say that vaccines are rigorously tested and safe, and the working group members were individuals of the highest integrity.

The problem, of course, is that had the working group been comprised of individuals with no ties to the veterinary vaccine industry, we all would have been confident that their advice was impartial. Importantly, these individuals of the highest integrity curiously failed to reflect the scientific principle that once a dog, and cat, is immune to viral disease, he is immune for years or life.

Why would a succession of government Ministers support annual vaccination by failing to give clear guidance in the face of the known science?

Steady stream of vaccine tragedies

Meanwhile, we continue to receive emails, letters and phone calls from people whose dogs became ill or died shortly after a vaccine event. Invariably, the vet suspects no link, denies any link, and no adverse event reports are submitted to the Veterinary Products Committee for assessment.

Today, for example, I have received two phone calls from dog owners who believe that their dogs have been damaged by vaccines. The first was from a lady, Mrs Hewins, whose dog's personality changed after he received his puppy shots. She described her dog as 'autistic'.

"He was a normal dog before he had his puppy shots," she said. "Then he became hyperactive, aggressive and uncontrollable. His eyes are dead. He shrieks for no apparent reason, throws his body in the air, and grabs your clothing. After a few minutes this passes and he is back to normal. We haven't had one day in the last 7½ years without tantrums."

The second caller phoned in tears. Her 14 year old dog was given the Leptospirosis vaccine a few days ago and she has lost the use of her legs. She was staring into space, and seemingly frightened. This lady took her dog back to the vet fearing vaccine damage, but the vet discounted any vaccine involvement and told the caller not to worry.

As this document aims to illustrate, there are many consequences of unnecessary vaccines that are never recorded or quantified. We shall be supplying scientific evidence to substantiate such claims.

We are not here for the fun of it

Running Canine Health Concern is very hard. We have no funding except that provided by membership subscriptions, lecture fees and book sales. Without the support of our members, CHC simply couldn't survive. Although the house we live in is very nice, it is rented and we struggle to pay the rent. Sometimes we cannot afford to heat our home, and we worry about how we shall pay for everyday necessities such as haircuts and washing powder.

And yet we carry on because the dogs (and other species) do not deserve to be sacrificed upon the alter of science – science which has been corrupted by the dictates and profit expectations of an international multi-billion industry.

Annual vaccination is neither necessary nor without risk. There is no scientific justification for annual vaccination. It should cease now.

Who invented annual vaccination for pets?

> *"When I first qualified as a vet in the early 70s, it was accepted that we vaccinate only once for distemper, and that would be that. Then we were approached by the veterinary vaccine industry. They said that annual shots would do no harm, and we'd get a chance to do an annual checkup. We knew it was fraud at the time, but we all went along with it. Now annual vaccination has been accepted into the mythology."*
>
> A telephone conversation with a vet

Whose idea was it that dogs and cats needed to be vaccinated annually back in the '70s? Where was the science to support this idea? Colorado State University announced in the '90s that annual vaccination is so unscientific that we may as well vaccinate every full moon!

Where is the science to prove that annual vaccination is necessary? We are being fobbed off with reverse logic by the VMD, telling us that manufacturers must prove duration of immunity for every vaccine product, and accepting one-year efficacy data. This turns the Veterinary Medicines Directorate into the sales arm of the veterinary vaccine industry. It is not acceptable. Neither is it good science.

> *Me, on a plane to fellow passenger who is reading a book about childhood immunisation: "Hello, I notice you're reading a book about childhood immunisation. Are you a doctor?"*
>
> *Fellow passenger (squirming slightly in his seat): "Yes, I'm just going back into general practice and reading up on this."*
>
> *Me: "That's interesting, only I've just been presenting a lecture about the unwanted effects of annual dog vaccination."*
>
> *Doctor (taking about two seconds to respond): "They vaccinate dogs annually? But that's terrible. It would destroy their immune systems."*

Diverse side effects hide the real problem

The problem with vaccines is that their unwanted effects are diverse. It's not like pricking your finger with a needle and you bleed. Vaccines can cause havoc in any system of the body. They do not always cause immediate effects. Many of the unwanted effects of vaccines develop slowly over months or years. There is copious science to support this statement, some of which will be presented shortly.

Few pet owners are trained immunologists, pathologists or virologists. They cannot argue the science, but must be able to trust their vets. The diversity of adverse effects from vaccines is precisely why it is difficult to argue with a veterinarian or vaccine manufacturer when they call our dead dogs anecdotes and dismiss them.

But many of us – many of us – are asking questions when our dogs become epileptic within hours, days or weeks of a shot. Many of us question when our dogs become aggressive after a shot. We question the coincidence when our dogs' personalities change and they look brain dead after a shot. We question when our dogs develop skin problems, or arthritis, or thyroid disease, or cancer or leukaemia after a shot. We ask the questions, and we are dismissed.

Vaccinators expect adverse reactions

The British government and the Veterinary Medicines Directorate rightly place a great deal of emphasis upon the vaccine approval and licensing procedures, and upon the legislation that is in place to ensure that approved veterinary vaccines undergo rigorous safety and efficacy tests.

However, herein lies the veterinary vaccine Achilles heel.

Vaccine adverse effects usually come to light ***after*** they have been approved and placed on the market.

The vaccine process, itself, is expected to cause adverse effects in a proportion of the vaccinated population – whether human or animal. The balancing act for the veterinary vaccine industry, veterinarians and legislators lies in how many adverse reactions can be expected, and how many are acceptable. Only after adverse effects reach unacceptable limits (in the eyes of manufacturers and legislators), are vaccines withdrawn from the market.

The SARSS Scheme is a failure

The Veterinary Medicines Directorate acknowledges in its position document that adverse events to vaccines are under-reported. In fact, the adverse event reporting scheme does not work. It has failed. Veterinarians are not trained to recognise vaccine reactions; they rarely submit adverse event reports to the Veterinary Products Committee because they have very little idea of what a vaccine reaction looks like. This is not necessarily the fault of individual vets. The training is at fault.

Dr Jean Dodds has said:

> Some veterinarians today still tell their clients there is no scientific evidence linking vaccinations with adverse effects and serious illness. This is ignorance, and confuses an impressionable client. (Abstract of presentation: Compliance or resistance to current vaccine guidelines?. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.)

Dr Dodds also stated:

> The veterinary profession and vaccine industry have traditionally emphasized the importance of giving a series of vaccinations to young animals to prevent infectious diseases, to the extent that this practice is considered routine and is generally safe for the majority of animals. Few clinicians are prepared, therefore, for encountering an adverse event and may overlook or even deny the possibility. (Dodds, W.J. 2001. Vaccination Protocols for Dogs Predisposed to Vaccine Reactions. *Journal of the American Animal Hospital.* May/June 2001, Vol. 37, 211-214.)

Dr Ronald Schultz also says that:

> "there is a reluctance to report reactions, even those that lead to the death of an animal". (Schultz, R.D. 1998. Current and future canine and feline vaccination programs. *Veterinary Medicine*. March 1998, 233-254.)

Denial and dismissal

When pet owners witness their pets becoming ill shortly after they are vaccinated, they often raise questions about the coincidence with their veterinarians. Time and time again, grieving pet owners are told that there is no link. No adverse event report is submitted.

And yet if anyone takes the time and trouble to examine the science, vaccine damage patterns become clearly visible. We are able to see that any allergic, inflammatory or immune-mediated disease can have a vaccine event as its cause – no matter whether it occurred within hours or days of a vaccine event, or within several years.

There is no justification for current canine or feline vaccine practices. We need to vaccinate no more frequently than is absolutely necessary. Duration of immunity to canine and feline viral disease has been shown to persist for years, and probably for life.

However, in its position paper, the VMD made it clear that they did not consider that there is enough science to support the cessation of annual vaccination. They left it to vets and their clients to overturn the established norm. Once again, we refer the VMD to a selection of published papers regarding duration of immunity and vaccine adverse effects, and ask the VMD for any single shred of evidence to show, scientifically, that annual vaccination or even three-yearly vaccination is required. We ask the VMD to demonstrate scientifically that once dogs or cats are immune to viral disease, boosters are necessary.

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DURATION OF IMMUNITY – A SCIENTIFIC PRINCIPLE

The Frequency of Pet Vaccination

The VMD stated in the introduction to its position statement:

> **A healthy debate of the pros and cons of vaccination is valuable as it is entirely possible that a disease can become so rare that risks associated with vaccination can outweigh the risk of contracting the illness.**

We are grateful to the VMD for making this observation, although we would wish the VMD to note that we are not debating vaccination per se, but the frequency with which dogs, cats, horses and other animals are vaccinated in the UK.

Clearly, we appreciate that the VMD comes from the position that vaccination is instrumental in preventing infectious disease.

No pet owner would want their dog to die of a disease that could be prevented. We do not wish to argue this point, but merely call upon the VMD to bring to a halt the unnecessary and unscientific practices concerning over-vaccination of animals in the UK.

A scientific principle has been established by independent duration of immunity studies in dogs (and also in cats), viz., that it is not necessary to repeat vaccinations against the core canine diseases (distemper, parvovirus, adenovirus) every year. Neither is it necessary to repeatedly vaccinate cats against core feline diseases (feline parvovirus, feline calicivirus and feline herpesvirus). Essentially, once immune to viral disease, animals are immune for years or life – which is why we don't vaccinate children against viral disease every year.

It should also be noted that no vaccine can ever be guaranteed as safe. All vaccines come with potential adverse effects. When we vaccinate both humans and animals, we are trading the desire to reduce infectious disease against the known and unknown potential side-effects of vaccines. These side effects range from skin disease and arthritis, through allergies, organ failure and autoimmune disease, to death.

In addition to concern surrounding the frequency with which dogs (and cats, rabbits, and horses) are routinely vaccinated in the UK against 'core' viral disease, we also express concern about, and the need for moderation, with regard to vaccines for 'non-core' diseases such as Leptospirosis and Kennel Cough.

The following extract is taken from a paper by the **pro**-vaccinator Dr Ronald D Schultz who is arguably the world expert with regard to canine vaccines and duration of immunity against viral disease.

> Vaccination can provide an immune response that is similar in duration to that following a natural infection. In general, adaptive immunity to viruses develops earliest and is highly effective. Such anti-viral immune responses often result in the development of sterile immunity and the duration of immunity (DOI) is often lifelong.
>
> In contrast, adaptive immunity to bacteria, fungi or parasites develops more slowly and the DOI is generally short compared with most systemic viral infections. Sterile immunity to these infectious agents is less commonly engendered.
>
> Old dogs and cats rarely die from vaccine-preventable infectious disease, especially when they have been vaccinated and immunized as young adults (i.e. between 16 weeks and 1 year of age). However, young animals do die, often because vaccines were either not given or not given at an appropriate age (e.g. too early in life in the presence of maternally derived antibody [MDA]). More animals need to be vaccinated to increase herd (population) immunity.
>
> The present study examines the DOI for core viral vaccines in dogs that had not been revaccinated for as long as 9 years. These animals had serum antibody to canine distemper virus (CDV), canine parvovirus type 2 (CPV-2) and canine adenovirus type-1 (CAV-1) at levels considered protective and when challenged with these viruses, the dogs resisted infection and/or disease. Thus, even a single dose of modified live virus (MLV) canine core vaccines (against CDV, cav-2 and cpv-2) or MLV feline core vaccines (against feline parvovirus [FPV], feline calicivirus [FCV] and feline herpesvirus [FHV]), when administered at 16 weeks or older, could provide long-term immunity in a very high percentage of animals, while also increasing herd immunity.
>
> Studies on immunosenescence in the dog and cat have suggested a decline in the immune system with age, but the significance of the decline with regard to increased susceptibility, especially to infectious agents, has not been shown ([Schultz, 1984], [Schultz and Conklin, 1998], Campbell et al., 2004 D.J. Campbell, J.M. Rawlings, S. Koelsch, J. Wallace and J.J. Strain et al., Age-related differences in parameters of feline immune status, *Veterinary Immunology and Immunopathology* 100 (2004), pp. 73–80.)
>
> It is likely that an effective MLV vaccine will provide a DOI similar to that following natural infection, but it is very unlikely that a vaccine will provide a longer DOI than would be achieved following natural infection. The DOI may persist via immunological memory involving B and T lymphocytes, long-lived plasma cells that continue to produce antibodies for several years (‘memory effector B cells’) and possibly long-lived ‘memory effector T cells’ (Schultz and Conklin, 1998).
>
> When dogs recover from natural infection/disease due to CDV, CAV-1 or CPV-2, they develop life-long immunity to these diseases. Long-term immunity also

develops in cats that have recovered from infection by FPV. Although immunity to the other core feline viruses (FCV and FHV) is less effective (no sterile immunity), immunity from severe disease does persist in most pet cats for years after vaccination (Scott and Geissinger, 1999; Schultz, 1998).

In our studies (Schultz 2006) we have examined the persistence of antibodies in vaccinated dogs kept in natural as well as virus-free environments. The longest period of time after initial vaccination that dogs were sampled and that antibody was found to persist was 14 years for CDV (vaccination with MLV), 14 years for CAV-1 (MLV against CAV-1 or CAV-2) and 10 years for CPV-2 (MLV) (Table 1). Similar studies have been reported in the cat (Scott and Geissinger, 1999).

Thus, all studies based on persistence of antibody as well as challenge show that immunity to CDV, CPV-2 and CAV-1 persists for a lifetime after vaccination, similar to the persistence of immunity after natural infection (Schultz, 2006).

In view of the number of variants of canine parvovirus that are now described, the question arises as to whether older dogs vaccinated at an early age maintain protective immunity to all the variants of CPV-2 that are currently circulating (CPV-2a, b, c). Our studies have shown that vaccination with any one of these variants provides cross-protection against the others. Dogs that were vaccinated with CDV and CPV-2 or CPV-2a and then challenged 4–9 years later with both CDV (by intravenous injection) and CPV-2c or -2b (by administration intranasally and per os) showed 100% protection (Table 2). This study indicates that the CPV-2 variant used to vaccinate does not affect the minimum DOI (Larson and Schultz, 2008).

Conclusions

Based on experimental studies that have been ongoing since the 1970s, in which large numbers of vaccinated animals were challenged and/or tested for the titre of serum antibody, in addition to observations in the field, in particular in animal shelters experiencing outbreaks of CDV and/or CPV-2, it may be concluded that:

• Old dogs and cats do not die from vaccine-preventable infectious diseases. It is rare to see an old dog die from distemper, canine parvovirus or infectious canine hepatitis (CAV-1), unless it has never been vaccinated.

• Unlike elderly people, who often die from respiratory disease complex (i.e. pneumonia), old dogs and cats rarely die from canine/feline respiratory disease complex.

• In contrast to old dogs and cats, many younger dogs and cats do die from vaccine-preventable disease because they are not vaccinated or were not vaccinated at an appropriate age (i.e. at or after 16 weeks of age) or with effective vaccines.

• Only one dose of the modified-live canine ‘core’ vaccine (against CDV, CAV-2 and CPV-2) or modified-live feline ‘core’ vaccine (against FPV, FCV and FHV), when administered at 16 weeks or older, will provide long lasting (many years to

a lifetime) immunity in a very high percentage of animals ([Schultz, 1998], [Schultz, 2000] and [Schultz, 2006]).

> **Age and Long-term Protective Immunity in Dogs and Cats**
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We add a recent statement from the Indian Council for Medical Research, which is pertinent to the over-vaccination of companion animals:

> http://www.pharmabiz.com/article/detnews.asp?articleid=55415&sectionid=
>
> ***"Vaccination should be need-based and all vaccines are deemed non-universal, unless specified otherwise based on scientific evidence. The mere availability of a safe and efficacious or even affordable vaccine cannot be a good enough justification for its widespread use. Vaccines are not consumer goods and should not be given or taken, unless their necessity is proven based on the scientific principles of public health.***
>
> **"Vaccines outside the UIP should not be unethically promoted through direct or surrogate advertising, advocacy by individuals, groups or aid agencies, on their own or funded directly or indirectly by the vaccine industry."**

The paragraph quoted immediately above is explored at length in relation to animal vaccines in Part Two of this document.

In Part One, we look at the VMD's assertion that vaccine reactions are very rare. We understand that governments might accept the sacrifice of individuals to vaccine adverse effects when the wider population is being protected from infectious disease.

However, we do not accept that individuals should be sacrificed to vaccines which they do not need.

PART ONE

ANIMAL VACCINE SAFETY

Running Canine Health Concern for the past sixteen years, we have been contacted by hundreds of dog owners who tell us that their dogs became ill within a few hours, days or weeks of a vaccine event. Indeed, Catherine O'Driscoll formed Canine Health Concern after three of her own young dogs died of illnesses that were vaccine related.

However, bodies such as the Veterinary Medicines Directorate maintain that vaccine reactions are very rare, although it is known in medical and veterinary fields that adverse events are vastly under-reported.

It is a fact that many dogs have died of vaccine-induced illnesses without their vets or guardians ever suspecting a link. Can this be proven scientifically in every single case? No. Can the known science point us towards this conclusion? Definitely yes.

There is much that science does not know about the sequelae to vaccination, but there is also much that is now becoming visible.

Canine Health Concern is aware that animals who die as a result of their vaccinations are viewed in scientific circles as 'anecdotes', and that grieving pet owners are viewed with scepticism and discounted on the same basis – that their dogs' suffering and deaths are simply stories without any scientific basis as to cause.

However, we are able to view the accepted published science and understand that specific sequelae to vaccine events are known to occur. These specific sequelae, such as brain damage, autoimmune diseases, skin problems, organ failure, paralysis and allergies, are seen in dogs far more frequently than the VMD appears willing to acknowledge.

Before looking into the science of these known vaccine-associated conditions, however, we would like to challenge the VMD's claim that:

> **vaccines are manufactured to a consistent and acceptable quality using high grade materials and are uncontaminated with potentially harmful infectious agents or other toxic substances**

*"**Guidance for Industry, Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications**"*, recently produced by the American FDA states:

Potential Sources of Contamination

It is important that you identify and examine all potential sources of contamination of your product. For example, a viral seed could be exposed to the following potential sources of contamination: the person or animal from which it was isolated; the cells and raw materials (e.g., serum or trypsin) used in its isolation and attenuation; materials used in banking and propagation of cells for viral seed growth; and other materials used during production and filling of the seed.

You should also consider the species of origin of your cell substrates, viral seeds, and other biological starting materials in selecting your tests to ensure the absence of contaminants. Furthermore, you should consider any infectious viruses (including those that infect nonhuman species) as potential contaminants if there is the possibility of contact with your product or cell substrate at any time during development or production.

Retroviruses may be either endogeneous (i.e., encoded by the cell substrate genome) or exogenously acquired. Retrovirus testing should address the possibility that either type of retrovirus could contaminate a product. Finally, you should consider the possibility of contamination from unusual sources, as exemplified by the reported presence of minute virus of mice (MVM) in some lots of recombinant proteins (Ref. 5). The susceptibility of the cell substrate to infection by agents of potential concern can influence the tests needed to assure absence of contamination.

Use of qualified raw materials can reduce the risk of introducing adventitious agents. For example, inactivation of viruses by irradiation of serum could provide additional assurance regarding the purity of the final product.

Live virus vaccines always come with the risk of contamination.

UK Veterinary Vaccine Screening Failure

As recently as April this year, *The Journal of Virology* reported that two independent laboratories had isolated a feline virus in both dog and cat vaccines in the UK and Japan. The authors stated: "the current methods used for screening human vaccines for retroviral contaminants include extremely sensitive PCR-based RT assays (**not required for veterinary vaccines**) that are much more sensitive than conventional RT assays".

> ***Isolation of an Infectious Endogenous Retrovirus in a Proportion of Live Attenuated Vaccines for Pets,*** *Journal of Virology, April 2010, p. 3690-3694, Vol. 84, No. 7.* http://jvi.asm.org/cgi/content/full/84/7/3690

The authors stated:

In this study, we isolated a feline infectious ERV (RD-114) in a proportion of live attenuated vaccines for pets. Isolation of RD-114 was made in two independent laboratories using different detection strategies and using vaccines for both cats and dogs commercially available in Japan or the United Kingdom. This study shows that the methods currently employed to screen veterinary vaccines for retroviruses should be re-evaluated.

Overall, it is possible that our data under-represent the number of vaccines from which RD-114 can be isolated….

Collectively, our data show unequivocally that RD-114 is present in live attenuated vaccines commonly used in dogs and cats from different continents and produced by three different manufacturers. Future studies will be necessary to determine whether RD-114 has any negative impact in cats or dogs….

Infectious ERVs have the same biological properties and pathogenic potential of exogenous horizontally transmitted retroviruses, once the co-evolutionary mechanisms that have shaped the interaction with their natural hosts cease to exist. In this regard, the large-scale exposure to RD-114, particularly of the dog population, may have effects that are impossible to predict even if successful RD-114 transmission was an extremely rare event.

Millions of puppies are vaccinated annually worldwide, and they may be more susceptible to RD-114 infection than cats as the dog genome does not harbor RD-114. Also wild cats do not harbor RD-114, and they are regularly vaccinated in zoos with the same vaccines used for pets. These vaccines have been used extensively for many years without major acute effects on vaccinated animals, but retroviruses rarely induce acute diseases.

Therefore, it is impossible to rule out chronic effects, especially as we were able to grow RD-114 very efficiently in dog cell lines (data not shown), confirming older published studies….

A recently identified novel human retrovirus (xenotropic murine leukemia virus-related retrovirus [XMRV]) has been found in some forms of prostate cancers and chronic fatigue syndrome in humans, although causal association has not been proven yet. XMRV is almost undistinguishable from an ERV present in mice, and it will be important to investigate how this virus passed into the human population, regardless of its pathogenic potential.

Interestingly, the current methods used for screening human vaccines for retroviral contaminants include extremely sensitive PCR-based RT assays (not required for veterinary vaccines) that are much more sensitive than conventional RT assays. Thus, contamination of human vaccines with XMRV would not pass undetected with the currently available technology, although this may not be necessarily true for vaccines produced in previous decades.

Finally, although the risks posed by RD-114 are seemingly small, it would be appropriate to produce live attenuated vaccines in cells that do not express this endogenous retrovirus. To this end, cells of dog origin may be better suited to produce pet vaccines than cat cell lines, although not all cat cell lines express

RD-114. Contamination of subunit or inactivated vaccines by infectious agents in general (including ERVs) is obviously less of a concern.

The implications of this study should not be under-estimated, and they should especially not be under-estimated by the VMD, which is a government body charged with the task of assuring the safety of veterinary products. The study concluded that:

- Future studies will be necessary to determine whether RD-114 has any negative impact in cats or dogs….
- A recently identified novel human retrovirus (xenotropic murine leukemia virus-related retrovirus [XMRV]) has been found in some forms of prostate cancers and chronic fatigue syndrome in humans
- sensitive PCR-based RT assays [as used in this study] are not required for veterinary vaccines

Writing in US *Dog World*, March, 1995, Dr Jean W Dodds stated:

> "Immune–suppressant viruses of the retrovirus and parvovirus classes have recently been implicated as causes of bone marrow failure, immune-mediated blood diseases, haematologic malignancies (lymphoma and leukaemia), dysregulation of humoral and cell-mediated immunity, organ failure (liver, kidney) and autoimmune endocrine disorders – especially of the thyroid gland (thyroiditis), adrenal gland (Addison's disease) and pancreas (diabetes). Viral disease and recent vaccination with single or combination modified live virus vaccines, especially those containing distemper, adenovirus 1 or 2 and parvovirus, are increasingly recognised contributors to immune-mediated blood diseases, bone marrow failure and organ dysfunction."

According to Kennel Club research, one in four dogs in the UK can be expected to die of cancer. Retroviruses are implicated in this scenario.

> **Retroviruses and cancer** *CURRENT SCIENCE, VOL. 81, NO. 5, 10 SEPTEMBER 2001* http://www.ias.ac.in/currsci/sep102001/528.pdf - quote:
>
> Indeed, the study of retroviruses in relation to cancer has been recognized in the award of three separate sets of Nobel Prizes: to Peyton Rous in 1966 for the discovery of his eponymous sarcoma virus in chickens; to David Baltimore and Howard M. Temin in 1975 for their discovery in 1970 of reverse transcriptase; and to J. Michael Bishop and Harold E. Varmus in 1989 for their demonstration in 1976 that retroviral oncogenes originate from cellular genes in the host. Retroviruses were first associated with malignant disease in animals more than ninety years ago. In 1908 the Danish veterinarians Ellerman and Bang observed that erythroleukaemia is infectiously transmissible in chickens. Then in 1911, Rous in USA and in 1914, Fujinami in Japan showed that some avian sarcomas could be transmitted by inoculation of cell-free filtrates.

> On many occasions during vertebrate evolution, retroviruses have infected cells of the host's germ-line, destined to become the eggs and sperm. In this way the integrated DNA provirus can be passed on to the next generation without undergoing further viral replication. Such genetically transmitted retroviral genomes are called endogenous retroviruses (ERV) to distinguish them from exogenous, infectiously transmitted retroviruses.

It is therefore somewhat astounding that the team involved in the *Journal of Virology, April 2010 study* should comment that *"* the risks posed by RD-114 are seemingly small". The word 'seemingly' is a worrying word to use when, historically, such errors are evaluated retrospectively, after they have caused ill health and death in vaccinees.

We are actually talking about cancer being potentially passed to subsequent generations via the vaccine needle.

The authors also stated that, "Overall, it is possible that our data under-represent the number of vaccines from which RD-114 can be isolated…"

The Veterinary Medicines Directorate has therefore failed in one of its primary aims, which robs this government agency of the right to support unnecessary revaccination through lax governance - when that revaccination is known to be unnecessary

In its position paper, the VMD asserts that it seeks to ensure that:

> **vaccines are safe to be administered to young and older animals where relevant, and pose no risk to the owner, their families or other animals and persons coming in contact with vaccinated animals. Where necessary, specific warnings are added to the product literature to minimise any risk of an adverse reaction following administration of the product**

Within this document, we seek to explain to the VMD, veterinarians, our elected political representative and the wider dog owning public that no vaccine can ever be considered to be completely safe.

The VMD is right to '**seek** to ensure safety', since it cannot guarantee to do so, although elsewhere in its document the VMD goes so far as to state:

> **The seed materials are grown in cultures using a variety of biological materials, often sourced from animal tissues and, therefore, the risks of a vaccine containing an extraneous agent (unwelcome contaminant) are high. To prevent this, the manufacture of products according to the principles of Good Manufacturing Practice (GMP), the application of quality control tests on every batch and pre-authorisation tests on seed materials are the principle controls to ensure the quality of authorised veterinary vaccines and the exclusion of extraneous agents.**

It is clear that the VMD has failed.

It is also clear that both inflammatory and immune-mediated illnesses – developing immediately after a vaccine event and within months or years - need to be assessed in relation to previous vaccine events if the full sequelae to vaccines are to be understood.

Vaccine safety is <u>not</u> assured at the point of license. It cannot be.

The unwanted effects of vaccines are seen in the field, after humans and animals have been vaccinated; after they are forced to live with vaccine-induced illness, and after vaccines have killed the people and animals they were purported to help.

We must examine the wider picture of vaccine adverse effects – both long- and short-term – and assess revaccination schedules with the animals in mind, rather than having industry profits in mind.

Independent duration of immunity studies exist, using different vaccine brands, to establish the

principle

that **"once immunity to viral disease exists, it persists for years or life".**

There is no scientific reason, basis or justification – in view of the potential adverse reactions – to continue with the annual vaccination, or even three-yearly vaccination, of companion animals.

The government must act to put a stop to this general practice.

Excuses from the VMD

It should be noted that the current practice in the UK, with few exceptions, is that pet owners are encouraged to vaccinate their dogs annually for both core and non-core diseases. This situation exists through established practice, and because there is a lack of clarity and direction regarding the known and current science. The VMD states in its position paper:

> **The DOI established through research is a minimum period of duration and the actual DOI may be much longer. However to establish the maximum duration of immunity that might be applied across the wide range of husbandry systems would require animals to be isolated for very long periods of time and this raises considerable concerns about animal**

welfare, veterinary ethics and cost. Any scientific research should only be conducted where the benefit to the wider population of animals can be justified. Therefore, extending any laboratory studies to derive DOI beyond 3-4 years poses significant questions as to the value of such studies and the benefit they would offer to the wider population of pet animals.

In response:

1. There is no need for further studies to establish the principle that once immune, dogs and cats remain immune for years or life. This work has been done, and which vaccine product used is irrelevant. Once immune, they are immune.

2. Veterinary vaccine companies are international. What is good in one country should be good in another. If this is not the case, why is the UK accepting sub-standard vaccines?

3. The VMD is only able to infer that the benefit of DOI studies cannot be justified because the SARSS scheme is a failure. Were the true picture of vaccine adverse effects acknowledged, the VMD would have to conclude that annual vaccination cannot be justified.

4. "DOI studies beyond 3-4 years pose significant questions" regarding the value it would offer to the veterinary vaccine industry, rather than the VMD's assertion that it would pose questions with regard to value and benefit to pets.

The VMD stated in its position paper:

> **Serology is used extensively in human medicines to assess DOI of some vaccines where protective levels of antibody are known, as it is not possible for ethical reasons to conduct challenge studies.**

If it is not ethical to conduct challenge studies on humans, and if science accepts serology studies in order to license human vaccines, then the same logic should be applied to dog and cat vaccines, particularly since DOI studies have already been conducted by Schultz and others. Humans are thought by the majority to be more important than humans, are they not? The requirements laid upon veterinary vaccines should not be more onerous, seeming to have the effect of boosting sales with the support of spurious arguments.

The VMD also states:

> **In the veterinary field DOI is usually established by challenge; the "gold standard" for demonstrating protection from infectious disease. Unfortunately, there are no international standards or prescribed serological tests for most of the canine diseases. Tests vary considerably between laboratories and are difficult to standardise. Diagnostic**

> **laboratories must validate their own in-house tests and establish thresholds for re-vaccination based on their expertise and scientific opinion. In the absence of clearly defined protective titres, interpretation of serological tests must be treated with care and advice sought on equivocal results. Whilst the WSAVA Guidelines suggest any measurable titre in an actively immune vaccinated animal is correlated with protection, the evidence to support such conclusions appears weak.**

Do these problems not apply to the acceptable DOI studies for human vaccines? And yet we are not vaccinating humans every year … Indeed, the arguments postulated above in defence of over-vaccination appear themselves to be very weak. If the veterinary vaccine industry and the veterinary legislators cannot sort their act out, do not expect the animals to pay for it.

Serology (Titre) Tests

The VMD also states:

> **The conclusion has to be that serology provides useful additional information on the immune status of an animal but should not be treated in isolation to other determinants for deciding upon re-vaccination. The fact that a particular titre may be well correlated with protection does not ensure the animal is protected. The application of statistical correlations to the individual will, by the very nature of statistics, expose some to the risks of disease. The risks of over-vaccination are arguably relatively small compared to the risks of exposing susceptible animals to life-threatening infections.**

The operative word in the above paragraph is 'arguably' relatively small. It assumes that the SARSS scheme actually reflects the real picture of vaccine damage in the canine population, and yet the VMD acknowledges that adverse events are under-reported. This argument will not wash with the people whose dogs were killed by a vaccine they didn't need, against a disease to which they were already immune.

This argument also contravenes the EU's required Precautionary Principle.

Serology (titre) tests represent the precautionary approach and should be advocated firmly by the government licensing body. Here, the word 'should' is the operative one, and it comes with a question mark as to why titre testing is brushed aside – especially considering the recommend-ations of world veterinary bodies that titre testing is preferred to blanket revaccination.

The VMD Abdicates Responsibility

In its position paper, the VMD states:

> **The fact that both immediate and longer term adverse events may occur make the benefits of vaccination for a healthy animal more difficult to assess especially as the prevalence of a disease against which a vaccine will protect may not be measurable with any degree of certainty. In such cases a decision regarding vaccination of a healthy dog is largely a matter of judgement on the part of the owner following advice from their veterinary surgeon. It is acknowledged that more information is needed on the prevalence of canine diseases in the UK to enable veterinary surgeons and their clients to make more meaningful benefit/risk assessments on whether to vaccinate an individual animal.**

To make the above paragraph clearer, the VMD is saying:

- we don't know the risk, or prevalence, of canine disease in the UK
- let the vet decide vaccine schedules and advise the owners accordingly
- we'll see if we can get some data to justify frequent re-vaccination

Admission of vaccine reactions, but no idea how prevalent these are

With regard to adverse reactions, the VMD kindly tells us:

> **Vaccine-induced auto-immune disease**
>
> **34.1 Immune mediated diseases and the association with vaccine reactions have been reviewed by Day (1999, 2006), Pedersen (1999) and the VPC Working Group (2002). Vaccine reactions are generally classified into one of four recognised categories: Type I-IV. The immunological theories behind such reactions would suggest that such adverse events should only occur following an immunological reaction to a previously exposed vaccine antigen, adjuvant, excipient or other production remnants such as bovine serum. However, immune mediated reactions can also follow the administration of a primary dose of vaccine and the exact mechanisms for such a reaction are unknown.**
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> **34.2 Type I hypersensitivity reactions involve an immune mediated reaction that releases potent inflammatory mediators and other chemicals that trigger an anaphylactic reaction in the affected animal. The reactions are usually acute, with the clinical signs appearing within minutes or hours of vaccination. Typical signs reported are facial oedema, shock, lethargy, respiratory distress and diarrhoea. Severe anaphylactic reactions may result in death. Urticaria (hives), facial oedema and anaphylactic shock are specific clinical manifestations of Type I hypersensitivities.**

34.3 Type II hypersensitivity reactions involve the binding of the animal's own antibodies to cells or a cell matrix. The formation of auto-immune antibodies is thought to involve a number of complex immunological mechanisms. Secondary immune mediated haemolytic anaemia (IMHA) has been associated with vaccination but may also occur following infection, neoplasia or administration of medications. In this condition, auto-antibodies are produced against the animal's own red blood cells but the immunological mechanism by which vaccines may produce such a response is not yet established. Confirmation of IMHA is dependent on the demonstration of auto-antibodies and, therefore, not all reports of such adverse events can be recorded accurately if confirmatory diagnostic tests have not been performed. For the period 2005-2010, 57 suspect adverse reaction reports of immune mediated reactions were submitted to the VMD. Subsequently only 25 of these reports were attributed to immune mediated reactions. Other clinical manifestations of Type II disease include immune mediated thrombocytopenia (IMTP) (autoantibodies to blood platelets) myasthenia gravis (autoantibodies to muscle nerve receptors) and pemphigus (foliaceous & vulgaris) (auto-antibodies to epidermal proteins).

34.4 Type III hypersensitivity reactions result from the formation of circulating complexes of antigen and antibody that deposit in certain organs or tissues in the body leading to inflammatory reactions and destruction of cells and associated matrix. The deposition of immune complexes usually results in inflammation of the blood vessels. The reaction is dependent on the continued presence of both antibody and antigen with the latter being derived from infection, vaccination, medication or exposure of 'self-antigens' through disease. Infections will inevitably result in the formation of immune-complexes as the body aims to rid itself of a foreign invader. Some examples of well known immune-complexes provide clinical signs such as:

(i) 'Blue Eye' is a well documented manifestation of a Type III reaction following infection with CAV-1 and or administration of some of the early CAV-1 vaccines. Replacement of CAV-1 by CAV-2 vaccines have minimised the risk of such adverse events with just six reports of 'blue eye' reported to the VMD during the period 2005-2010.

(ii) Reactions involving type III immune mediated mechanisms have also been demonstrated following rabies virus vaccination.

(iii) Systemic lupus erythematosus (SLE), a disease characterised by the development of antinuclear antibodies (ANAs).

(iv) Drug-induced arthritis has been reported as a Type III reaction but the evidence of similar vaccine associated immune-mediated syndrome is sparse. The VMD has received two reports of pemphigus associated with vaccination during the last five years.

34.5 Type IV hypersensitivity reactions or "delayed-type hypersensitivity" are cell, rather than antibody, mediated. These diseases are usually

relatively slow to develop and are dependent on the cell-mediated arm of the immune system.

Perhaps we can help …

In addition to viewing the immediate inflammatory and immune-mediated illnesses in proximity to vaccine events, we must also consider longer-term effects of repeated vaccination. The known science points the way towards caution in vaccine re-administration.

VACCINE DAMAGE IN THE DOG – THE LONG- AND SHORT-TERM RISKS

Contra-indications

Perhaps this is the best place to start, as datasheets for animal vaccines, approved by the VMD, state that vaccines are for use in healthy animals only; this is a licensing requirement – although it is common practice in the UK for veterinarians to vaccinate unhealthy animals.

Intervet's datasheet for Nobivac DHPPi states: "Immunocompetence [the ability of the body to develop an immune response in the presence of a disease-causing agent antigen] of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress."

This refers to certain animals being unable to mount an immune response to the vaccine challenge, in which case frank disease may follow. This means that if you vaccinate an animal, or a human, with a modified live virus (MLV) vaccine, and they are not well, malnourished, stressed, or genetically compromised, you may give them the disease you are vaccinating them against. This may also explain why disease outbreaks occur in heavily vaccinated, stressed and malnourished dogs in rescue centres. But there is more to it.

The Merck Manual (sixteenth edition) (1) states: "Children with known or suspected immunodeficiency disease should not receive any live virus vaccines, since they could initiate a severe or fatal infection… Patients with either B or T cell immunodeficiencies should not be given live vaccines because of the risk of vaccine-induced illness." (Immunodeficiency disease is the inability, either inborn or acquired, of the body to produce an adequate immune response to fight disease.)

How can we tell if our dogs had B and/or T cell immuno-deficiencies, and are therefore contra-indicated? Merck states:

"Associated features of B cell deficiencies include respiratory or food allergies; features of T cell deficiencies include heart disease; and features of combined T and B cell deficiencies include dermatitis, neurological deterioration and eczema." This profile represents a wide percentage of the dog population.

Many vets believe that we should vaccinate animals who exhibit chronic illness, as they may be more at risk from viral disease. However, individuals exhibiting features of B and T cell immunodeficiencies might be more at risk of vaccine-induced illness or fatality. Indeed, Merck – a vaccine manufacturer – states in its manual that we should not vaccinate individuals who suffer from immuno-

deficiency disease, because they could die. They could also be the seed bed for epidemics.

In December 1988, *DVM magazine* published a round table debate in which eminent pro-vaccine experts discussed the pros and cons of vaccine use.(2)

Dr Ronald Schultz stated: "We have had the idea for years that vaccines, if they don't do any good, won't cause harm. I think that's another concept the veterinarian has to get away from because whether it be modified live or non-infectious, there is the potential to cause harm."

Immunosuppression

In the same debate, Dr Ian Tizard stated: "In making a modified live vaccine you make it for an animal that you assume is immunologically normal… There will be a proportion of any population that is not immunologically 100 percent. This can immediately tilt an animal towards disease susceptibility. In addition, a vaccine may not cause frank disease itself. It may cause mild immunosuppression."

But what are the implications of immunosuppression? The first, of course, is that individuals are more open to infection. One study, for example, showed chicks with a decreased resistance to E coli infection post-vaccination.(3) (Marek's disease vaccines cause temporary U-lymphocyte dysfunction and reduced resistance to infection in chicks" *Avian Pathology*, Vol 21, issue 4, Dec 1992, pages 621-631.)

Another involved a fatal outbreak of salmonellosis in a breeding cattery post-vaccination, and concluded that MLV vaccines, particularly those containing panleucopaenia virus, may cause transient immunosuppression and should be used with caution because of the possibility of activating sub-clinical opportunist infection. (4) (*JAVMA* Vol 214, No 1, January 1,1999)

Vaccines and cancer

Cancer is, however, another potential sequel to immunosuppression. One paper stated: "Recent events in the field of cancer research have stressed the importance of immune factors in the development and progression of certain cancers. Tumour-specific antigens have been demonstrated in a variety of experimental human neoplasms, and the ability of a host to repress neoplastic growth appears to depend on its immunological competence." (5) (*Cancer Research* 30, October 1970, 'Spontaneous Development of Mammary Adenocarcinoma following Prolonged Immunosuppression in the Dog')

Another paper stated, "live attenuated rubella vaccine inoculation may cause sustained immunosuppression including defective lymphocyte response to mitogene and impaired cytokine production. The signs of immunosuppression

may persist for at least 1 month after vaccination". (6) (Cytokine profile after rubella vaccine inoculation: evidence of the immunosuppressive effect of vaccination, *Mediators of Inflammation*, 12(4), 203-207 (August 2003)).

Mrs E Smith wrote to me to share her 'anecdote'. Her five-year-old Doberman was given a full puppy series as her vaccine had not been boosted in three years. Two weeks later she was presented to the vet with swollen lymph glands. Lymphoma was eventually diagnosed. The vaccine company naturally said that the cancer was underlying and nothing to do with the vaccine.

However, the FDA is mindful of cancer-generating properties within vaccines. In ***"Guidance for Industry, Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications"*** it states:

> Use of tumorigenic and tumor-derived cells for vaccine production is associated with additional issues. This document does not provide guidance on a pathway for licensure of live-attenuated or minimally purified vaccine produced in these cells. You should perform additional testing if your cell lines are tumorigenic or derived from a tumor. You should assess cell lines that are tumorigenic or tumor-derived for potential oncogenic viruses and oncogenic substances (including nucleic acids), which could be associated with induction of a neoplastic process in a vaccine recipient. Test strategies for potential oncogenic viruses or oncogenic substances may be determined case-by-case, depending on the tissue type, source species, passage history, and extent of knowledge about the transforming event(s).
>
> …If your vaccine is manufactured in a cell substrate that was derived from a tumor, or that has a tumorigenic phenotype through an unknown mechanism, it might carry a higher theoretical risk of containing oncogenic [tumour forming] substances.

It seems that the American FDA is seeking to guide vaccine manufacturers to make vaccines less capable of causing cancer, which of course implies that it is known that vaccines can cause cancer.

An alternative view is that individuals routinely develop and shed cancer cells, and that they only express frank disease if the body's natural healing is interrupted, which vaccines might do through immunosuppression. Searching for 'cancer and spontaneous regression or remission' in the database PubMed retrieves about 10,000 publications.

Another study concluded that, "when canine distemper virus was combined with canine adenovirus type 1 or canine adenovirus type 2, significant suppression in lymphocyte responsiveness to mitogen occurred. The results indicate that interactions between canine distemper virus and canine adenovirus type 1 or canine adenovirus type 2 are responsible for the polyvalent vaccine induced suppression of lymphocyte responsiveness". (*Effects of Vaccines on the Canine*

Immune System, Tom R. Phillips, Jean L. Jensen, Michael J. Rubino, Wen C. Yang and Ronald D. Schultz, *Can J Vet Res* 1989; 53: 154-160) (7)

We are talking about cancer again, since lymphocytes attack infected and cancerous cells, and vaccines are shown to disable lymphocytes.

It is of course accepted that cats develop vaccine-site sarcomas. Dr Dennis W Macy, stated, "I estimate there are about 22,000 cases of [feline] vaccine-associated tumours per year… it is likely that the more vaccines given in a particular site, and the more vaccines given over time, the higher the chance of sarcoma development." (8) (*JAVMA*, Vol 207, No 4, August 15, 1995)

"The most significant problems associated with feline vaccines have been injection-associated sarcoma. Previously, this problem seemed most apparent in cats administered adjuvanted rabies virus and feline leukaemia virus vaccines. However, recent information suggests that injection site sarcomas can occur with any type of vaccine. For example, in the United Kingdom in 2005, 23 of 39 injection site sarcomas reported in cats occurred at the site a live vaccine (non-adjuvanted) was administered" (Dyer *et al*, 2007).

Research grants were awarded so that the scientists could discover which vaccine(s) might be responsible for these feline cancers, and which cats might be susceptible. Meanwhile, cat owners were advised to continue vaccinating, and American veterinarians took to vaccinating cats in the tail and leg so they could amputate when cancer appeared.

An Italian study has shown that vaccine-site sarcomas also occur in dogs. (9) (*JFM Series A*, August 2003, vol 50, no 6, pp 286-291)

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Autoantibody production – long term vaccine risks exposed

The Vaccine Research Group at Purdue University School of Veterinary Medicine conducted several studies to determine if vaccines cause changes in the immune system of dogs that might lead to immune mediated diseases. Their paper was presented to the International Veterinary Vaccines and Diagnostics Conference hosted by the University of Wisconsin, July 27-31, 1997. Other papers on vaccine-induced autoimmunity are referenced below. (10, 11)

In the Purdue study, a group of Beagles was routinely vaccinated and closely followed for three years with blood and other tests at regular intervals. The blood of all the vaccinated dogs were seen to contain significantly elevated concentrations of antibodies directed against proteins that are present in commercial vaccines as contaminants of the production process. None of the unvaccinated control dogs had similar increases in these antibodies. The contaminated proteins were typically of bovine origin, since foetal calf serum is used as a component in the growth media used to grow viruses for vaccine production.

Dog and cow protein are very similar in structure, and the Purdue team felt that antibodies produced by the vaccinated dogs might have cross-reacted with the dogs' own tissue proteins in a process similar to autoimmunity. The team added that experiments in other animal species suggested that the antibodies might eventually cause disease in the vaccinated animals.

The biochemicals seen to be under attack in this study included fibronectin, laminin, DNA, albumin, Cytochrome C, cardiolipin and collagen. But what is the significance of these autoantibodies?

Fibronectin is an extra cellular adhesion molecule involved in tissue repair, embryogenesis; blood clotting; and cell migration/adhesion. Laminin surrounds muscles, nerves and fat, and is involved in may cellular activities, including the adhesion, spreading, differentiation, polarisation, proliferation and movement of cells. This indicates that the vaccine process scrambles the innate intelligence of cells and threatens tissues and organs, as well as reproduction.

Albumin is a protein manufactured by the liver which enables fluid to remain in the bloodstream rather than leak into tissues. If albumin gets low, fluid builds up and inflammation can occur in the body. Importantly, fatty acids are carried with the aid of albumin to cells in the body. Fatty acids are the building blocks for lipids, which form all of the membranes around and inside cells. Fatty acids are essential for life, and albumin is essential for their distribution.

Antibodies against Cardiolipin were also found in the Purdue study. Anti-Cardiolipin autoantibodies (ACA) are frequently found in patients with systemic lupus erythematosus (SLE). They are also found in patients with other

autoimmune diseases, as well as in some with no apparent underlying disease. Elevated levels of ACA have been reported to be significantly associated with the presence of both venous and arterial thrombosis, thrombocytopenia, and recurrent foetal loss, as well as neurological conditions.

Autoantibodies to Cytochrome C contribute to Cytochrome C Oxidase Deficiency, so far thought to be an inherited metabolic disorder. Deficiency of Cytochrone C Oxidase may be limited to the tissues of the skeletal muscles or may affect several tissues, such as the heart, kidney, liver, brain, and/or connective tissue; in other cases it may be systemic. The disorder may be characterised by a generalised weakness of skeletal muscles, abnormalities of the heart and kidneys, and/or abnormally high levels of lactic acid in the blood. Other forms of Cytochrome C Oxidase deficiency are characterised by progressive degeneration of the brain and dysfunction of other organs of the body, including the heart, kidneys, muscles and liver. Symptoms may include loss of previously acquired motor skills, loss of appetite, vomiting, irritability, and/or seizures.

The Purdue study also found that vaccinated dogs were developing autoantibodies to collagen. About one quarter of all the protein in the body is collagen. It is a major structural protein, forming molecular cables that strengthen the tendons and vast, resilient sheets that support the skin and internal organs. Bones and teeth are made by adding mineral crystals to collagen.

See also the following peer-review journal report: **"Acquired autoimmunity after viral vaccination is caused by molecular mimicry and antigen complimentarity in the presence of an immunologic adjuvant and specific HLA patterns."**

> "Acquired autoimmunity syndromes occur after viral vaccinations. Molecular mimicry is involved in these phenomena as is the necessity for the presence of two chemically complimentary antigens and an immunologic adjuvant. The HLA pattern of the host is also an important factor. The example used to explain these phenomena is demyelinating disease that follows hepatitis B vaccination. The somatic antigen of the hepatitis B virus in the vaccine has chemical complimentarity with the Epstein-Barr virus antigen in the vaccine recipient. The Epstein-Barr virus shows molecular mimicry with human myelin. The immunologic adjuvant is either present in the vaccine or muramyl peptides in the individual who is vaccinated."
> **Waisbren BA Sr, *Med Hypotheses; 70(2):346-8.* -- 7/13/2007**

Vaccine contaminants

As has been briefly shown earlier, legislators and manufacturers are only able to **seek** to ensure that vaccines are free from contaminants. They are unlikely to be able to guarantee this.

Bet Hargreaves is a long-time Cavalier King Charles Spaniel breeder who has noted a correlation between vaccination and the onset of heart disease in her breed. She wrote to Dr Larry Glickman who, with his colleagues, conducted the Purdue study. In his reply he stated:

> "Our ongoing studies of dogs shows that following routine vaccination, there is a significant rise in the level of antibodies dogs produce against their own tissues. Some of these antibodies have been shown to target the thyroid gland, connective tissue such as that found in the valves of the heart, red blood cells, DNA, etc. I do believe that the heart conditions in Cavalier King Charles Spaniels could be the end result of repeated immunisations by vaccines containing tissue culture contaminants that cause a progressive immune response directed at connective tissue in the heart valves. The clinical manifestations would be more pronounced in dogs that have a genetic predisposition [although] the findings should be generally applicable to all dogs regardless of their breed."

Dr Glickman, it should be noted, is a strong pro-vaccinator who now works for the vaccine manufacturer Fort Dodge. The study dogs were re-homed and no follow up studies were conducted.

In addition to worrying about autoantibodies as a result of the injection of bovine tissue, other species are also used in vaccine manufacture. Monkeys, dogs, cats, hamsters, avian embryos, and so on, are used routinely. Bovine serum, used as a carrier in vaccines, was a concern during the BSE outbreak due to potential cross-species infection; foreign serum and animal protein also threaten inflammation and autoimmunity.

Adjuvants such as mercury and aluminium salts are also added to vaccines to increase the immune response. Mercury and aluminium are neurotoxins. In her book, 'Mark of the Beast' (12) veterinarian Dr Patricia Jordan discusses the link between the effects of aluminium on the P-53 oncogene and cancer. She says: "The adjuvant aluminum in vaccines is one culprit in mutating the genome and specifically the P53 oncogene, thereby ruining the individual's ability to stop tumor genesis." (13) (IARC International Agency for Research on Cancer; Summaries and Evaluations Surgical Implants and Other Foreign Bodies 1999 Feb 23; 74:24305-310.)

See:

Cross-Species Contamination of Commercial Serum Proteins, *The Journal of Immunology*, 1979, 122, 2135:

> One of the indications that *vaccinations may in fact be changing the genetic structure of humans* became evident in September of 1971, when scientists at the University of Geneva made the discovery that biological substances entering directly into the bloodstream could become part of human genetic structure. Dr. Maurice Stroun and Dr. Philip Anker in the *Department of Plant Physiology at the University of Geneva*, began to accumulate evidence that the transfer of genetic information is not confined to bacteria, but can also occur between bacteria and higher plants and animals. According to an article in *World Medicine* on September 22, 1971, "Geneva scientists are convinced that normal animal and plant cells shed DNA, and that this DNA is taken up by other cells in the organism.
>
> *"Bacterial DNA had been absorbed by the animal cells*. This phenomenon has been dubbed *transcession*. "

Another study, http://wvc.omnibooksonline.com/ data/papers/2010_V127.pdf concerns itself with the effects of contaminated feline vaccines.

> **Vaccine Induced Antibodies Against Feline Tissues**
> Michael R. Lappin, DVM, PhD, DACVIM
> The Kenneth W. Smith Professor in Small Animal Clinical Veterinary Medicine, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, CO, USA
>
> "We recently reported recombinant antigens of feline herpesvirus 1, calicivirus, and panleukopenia virus for use in serological assays (Lappin *et al*, 2002). In the same work, we showed that serology could be used to accurately determine need for FVRCP vaccination in cats if validated assays are utilized. While titrating the recombinant antigen based ELISAs by comparing to ELISAs performed using whole viruses, we discovered that **vaccinated cats make antibodies against a commonly used cell culture line**.
>
> The Crandall-Rees feline kidney (CRFK) cell line has been used to propagate feline viruses for years. While isolated from a kidney, the cell line has characteristics of a fibroblast. During virus purification for vaccine production (FVRCP) or immunoassay development, **it is impossible to remove all CRFK proteins or other cell constituents**. Thus, CRFK proteins contaminate the viral preparations and commercially available FVRCP vaccines grown on the cell line contain CRFK proteins. As a consequence, during the course of routine immunization, cats are exposed to CRFK proteins and may mount an immune response against those proteins. Since the CRFK cell line is derived from a feline cell line, administration of FVRCP vaccines induces antibodies that also bind to feline tissues."

> The team concluded: "At this time, we have not directly linked FVRCP vaccination to auto-immune diseases in cats. To further assess for disease associations with administration of CRFK containing FVRCP vaccines, we are currently performing a number of studies to assess for associations. **A general recommendation at this time would be to not use parenteral FVRCP vaccine at an interval shorter than every third year. In addition, FVRCP antigens should not be split and given yearly as that may result in increased exposure to the cell culture antigens."**

It seems that the world discovers vaccine effects as it goes along.

Cancer Revisited

Having seen an article in which I quote the Purdue study, Andrew Maniotis, PhD, Visiting Associate Professor of Bioengineering: Program of tumour mechanics and tissue regeneration, University of Illinois at Chicago, contacted me. He wrote: "I don't think it is coincidental that two of the molecules that the vets find (especially the tissue-controlling two molecules laminin and fibronectin) that are deregulated in vaccine-induced, cancer-harbouring animals, are the same ones we have found reverse, kill, or promote tumours.

"It is logical that these two tissue constructing molecules in the correct or incorrect amounts induce tumour dormancy or killing as we have found, and at different amounts (as when a vaccine disturbs a tissue and fibronectin is produced in abundance while laminin is suppressed) they can, when not in proper amounts, induce tumour growth and metastasis."

Gary Smith, another cancer researcher, explains how the inflammatory process can be intimately involved in cancer production and also how it is an essential process in malignancy. (14) (Smith, G.R. and S. Missailidis, Learning from cancer: The adaptive growth, wound and immune responses. *Gene Therapy and Molecular Biology*, 2009. 13(A): p. 158-185.)

Not only is inflammation synonymous with the vaccine process, we expect to see any of the four hypersensitivity reactions, albeit usually mildly, post-vaccination.

Gary Smith explains why wound or injury associated inflammation is immune suppressant, prevents the body from developing antibodies to foreign substances, and therefore serves as a hiding place for invaders. This type of inflammation occurs when cells, in response to stress, produce AT1 receptors (Angiotensin II type 1 receptors). When AT1 is activated it triggers a process intended for accelerated wound response and this manifests in rapid tissue remodelling and fibrosis.

While AT1 has a balancing receptor (AT2) that is supposed to switch inflammation off, he says that in most diseases this does not happen, often as a result of infections stimulating the process in order to escape adaptive immune

responses. The net effect of this in disease conditions is lingering pain, inflammation, fibrosis, dysfunction and suppression of the immune system that leaves the host open to additional co-infections.

In his recent paper, Gary also hypothesises how such a blind spot in our defences would have evolved. He explains that, in an injury or wound situation, the adaptive immune system is suppressed in order to avoid genuine autoimmunity developing whilst damaged tissue is cleared.

“Cancer has been described as the wound that never heals,” he says. “All successful cancers are surrounded by inflammation. Commonly, this is thought to be the body’s reaction to try to fight the cancer, but this is not the case. Infections such as the common cold, the flu, and herpes also cause inflammation, as do vaccines. This type of inflammation is not the body trying to fight the infection. It is the pathogen deliberately causing inflammation in order to hide from the immune system.”

The hypersensitivity or inflammatory reactions commonly associated with vaccination can, therefore, be the beginning of cancer and many other conditions – and not just at injection site.

Genetic damage?

Perhaps most worryingly, the Purdue study found that the vaccinated dogs were developing autoantibodies to their own DNA, which indicates that we are injecting inheritable damage into animals. Will the animal charities or the Kennel Club examine this concern if they are in receipt of funding from the veterinary pharmaceutical companies?

Systemic immune dysregulation

According to Cambridge Life Sciences, antibodies directed against native DNA were first detected in the serum of patients with SLE in the 1950s. The presence of anti-DNA autoantibodies is one of the four highly specific serological markers included in the 1982 American College of Rheumatology criteria for the classification of SLE. The more of these antibodies an individual has, the higher the disease activity. Long term risks include renal and central nervous system involvement.

See also:

> Neurocognitive deficits and neuroimaging abnormalities are prevalent in children with lupus: clinical and research experiences at a US pediatric institution. *Lupus* 19: 268-279
>
> Differential Responses to Smith D Autoantigen by Mice with HLA-DR and HLA-DQ Transgenes: Dominant Responses by HLA-DR3 Transgenic Mice with

Diversification of Autoantibodies to Small Nuclear Ribonucleoprotein, Double-Stranded DNA, and Nuclear Antigens. *J. Immunol.* 184: 1085-1091

Regulators of B-cell activity in SLE: a better target for treatment than B-cell depletion?. *Lupus* 18: 575-580

Fulminant onset of cerebral immunocomplex vasculitis as first manifestation of neuropsychiatric systemic lupus erythematosus (NPSLE). *Lupus* 18: 361-363

Induction of inflammatory and immune responses by HMGB1-nucleosome complexes: implications for the pathogenesis of SLE. *JEM* 205: 3007-3018

{alpha}-Actinin Immunization Elicits Anti-Chromatin Autoimmunity in Nonautoimmune Mice. *J. Immunol.* 179: 1313-1321

Accelerated Macrophage Apoptosis Induces Autoantibody Formation and Organ Damage in Systemic Lupus Erythematosus. *J. Immunol.* 176: 2095-2104

Models of Systemic Lupus Erythematosus: Development of Autoimmunity Following Peptide Immunizations of Noninbred Pedigreed Rabbits. *J. Immunol.* 176: 660-667

Key autoantigens in SLE. *Rheumatology (Oxford)* 44: 975-982

Anti-C1q antibodies in nephritis: correlation between titres and renal disease activity and positive predictive value in systemic lupus erythematosus. *Ann Rheum Dis* 64: 444-448

Peptides from antibodies to DNA elicit cytokine release from peripheral blood mononuclear cells of patients with systemic lupus erythematosus: relation of cytokine pattern to disease duration. *Lupus* 13: 490-500

Deocharan, B, Qing, X, Beger, E, Putterman, C (2002). Antigenic triggers and molecular targets for anti-double-stranded DNA antibodies. *Lupus* 11: 865-871

Lowering anti-dsDNA antibodies--what's new?. *Lupus* 11: 885-894

Molecular mimicry: anti-DNA antibodies may arise inadvertently as a response to antibodies generated to microorganisms. *Int Immunol* 13: 1099-1107 [

Accelerated development of IgG autoantibodies and autoimmune disease in the absence of secreted IgM. *Proc. Natl. Acad. Sci. USA* 97: 1184-1189

Lupus Nephritis. *J. Am. Soc. Nephrol.* 10: 413-424 “*Infective agents*, including historically tuberculosis and more recently retroviruses, have been considered as candidates for the provocation of the lupus syndrome; however, there is no convincing evidence of their participation in human disease.”

It makes one wonder how much more evidence is needed before the scientific community recognises the immune system damaging properties of vaccines.

Systemic Lupus Erythematosus

SLE is an autoimmune disease characterised by inflammation and destruction of a variety of tissues. Clinical presentation is varied, but a common feature is the presence of a number of autoantibodies. Damage to tissues is mediated by the antibody, either by the activation of complement or by the formation of antibody-antigen complexes, involving such antigens as nucleic acid or tissue protein.

Canine autoimmune haemolytic anaemia, which also occurs in isolation, can form part of the SLE syndrome. The other common manifestations of SLE are platelet deficiency and inflammation in blood vessels, joints, skin, peripheral nervous system, meninges and the thyroid.

The Journal of Veterinary Internal Medicine, Vol 10, No 5 (September October) 1996, published a paper entitled 'Vaccine Associated Immune Mediated Haemolytic Anaemia (IMHA) in the Dog'. (15) The paper states, "This study provides the first clinical evidence for a temporal relationship of vaccine-associated IMHA in the dog." However, the Merck Manual had made this association earlier.

The study remarked that there was a marked difference in frequency of IMHA between the first month after vaccination and subsequent months which was not seen in the control group. The authors concluded that, because not all cases are reported (none of the cases in their study had been reported), the prevalence of vaccine-associated IMHA is likely to be under-estimated.

The seventh edition of the Merck Veterinary Manual (1991) states: "Bone marrow suppression with transient (21 day) or chronic/latent erythroid dysplasia, in the presence or absence of thrombocytopenia and neutropenia, Combs' positive haemolytic anaemia, and immune-mediated thrombocytopenia have been associated with (i.e., may prove to be caused by) both retroviral and parvoviral infection in man and other species. **Also, modified live parvovirus vaccines in dogs, and killed feline leukaemia virus vaccine are suspects as causes (in genetically susceptible animals) of such haematological diseases."**

It is worth re-quoting Dr Jean W Dodds, writing in US *Dog World*, March, 1995, (16):

> Immune–suppressant viruses of the retrovirus and parvovirus classes have recently been implicated as causes of bone marrow failure, immune-mediated blood diseases, haematologic malignancies (lymphoma and leukaemia), dysregulation of humoral and cell-mediated immunity, organ failure (liver, kidney) and autoimmune endocrine disorders – especially of the thyroid gland (thyroiditis), adrenal gland (Addison's disease) and pancreas (diabetes). Viral disease and recent vaccination with single or combination modified live virus vaccines, especially those containing distemper, adenovirus 1 or 2 and

> parvovirus, are increasingly recognised contributors to immune-mediated blood diseases, bone marrow failure and organ dysfunction.

Dr Dodds also stated:

> The T-cell leukaemias of human and animals are examples of those associated with retroviral infections. The same class of viruses has been associated with the production of autoimmunity and immunodeficiency diseases. The recent isolation of a retrovirus from a German Shepherd with B-cell leukaemia exemplifies the role of these agents in producing leukaemia and lymphomas in the dog.

Vaccine shedding

We believe that we should also concern ourselves with vaccine shedding. In the DVM round table discussion mentioned earlier, Dr Rude asked whether the shedding of modified live virus vaccine viruses from vaccinated animals have the potential to cause disease in non-vaccinated contact animals of the same species and/or different species (which, of course, would include humans).

Dr Siegl replied that, "It has been shown that shedding of virus… can mean selection of new variant viruses which spread and cause disease. I would say the basic principle, as soon as a live virus is being applied to an individual of a certain species, is that out of the mass of various mutants … you are going to have an opportunity to select for one viral mutant which is able to replicate even in the presence of some sort of immunity. That new selected virus can spread within the same species or in a different species."

To translate for the layperson: "yes – when you vaccinate your dog with modified live virus vaccines, he can become a source of infection within his own species or within other species".

Dr Tizard commented: "I can think of one veterinary example, and that's laryngotracheitis in poultry. Vaccines used in the Northeast appear to be pretty good vaccines and are essentially avirulent. If vaccinated carrier birds are moved, say to the Southwest, these vaccinated birds are a source of infection for the naïve flocks and cause clinical laryngotracheitis."

The 1988 Concise Oxford Veterinary Dictionary postulates that parvovirus "originated from an attenuated feline enteritis vaccine strain". (17) This is, of course, only a suspicion – but how else did a deadly new canine virus spread across continents at the same time?

Vaccine-lab errors?

The VMD stated in its position document:

The emergence of parvovirus in dogs has been recently reviewed (Hoelzer & Parrish, 2010 *et al*) which confirms the origin of CPV-2 remains unproven despite various theories having been put forward to explain the emergence of the virus.

However, the paper referred to above was looking for a natural source for this deadly epidemic. It did not consider the potential laboratory-based emergence of this killer disease. Neither would the vaccine lab that developed the distemper vaccine on cats' kidneys that were infected with feline enteritis (which is closely related to parvovirus) be likely to own up to their lucrative mistake.

Although the science shows that my six-year-old Golden Retriever, Prudence, could have developed leukaemia as a result of an annual shot that she didn't need, I personally cannot rule out a potential association between leukaemia and our neighbour's cats who received vaccines against feline leukaemia.

Neither can I rule out the possibility that symptoms of viral disease, such as arthritis from parvovirus and the vaccine, might arise from the vaccine process, from shed vaccine, as well as field infection. (18) (Detection of Parvovirus B19 Capsid Proteins in Lymphocytic Cells in Synovial Tissue of Autoimmune Chronic Arthritis, *Mod Pathol* (2003), 16(8):811̃817)

More on inflammation

A review article in *In Practice*, Vol 20 No 2, Feb 1998, by Michael Day, senior lecturer in Veterinary Pathology at the University of Bristol (19) states that environmental influences are crucial to the expression of immune mediated disease and that the most important of these is likely to be exposure to microbial antigens following natural infection or **vaccination**. Mr Day divides immune mediated disease into four main groups – hypersensitivity diseases, autoimmune diseases, immune system neoplasia [tumour formation] and immunodeficiency diseases.

In a letter to *Veterinary Times* during July 1999, veterinarian Lyn Thomson responded, "This would indicate that veterinarians must consider and report the whole range of immune mediated diseases post vaccination, including flea allergy, atopic dermatitis, dietary hypersensitivity, contact hypersensitivity, asthma, autoimmune diseases, lymphoma, lymphoid leukaemia, multiple myeloma, plasmcytoma, hisiiocytoma, thymoma, and immunodeficiency disease."

A paper appearing in the *British Veterinary Journal* (May 1995, Bell, Carter, May and Bennett) states that dogs with rheumatoid arthritis showed higher anti-heat shock protein antibody levels in their sera and synovial fluids compared to control dogs. There was a significant correlation between anti HSP65 and antibodies to canine distemper virus, and the paper discussed the relevance of the presence of canine distemper virus within the joints. Since vaccines inject modified live

distemper virus into the dog, this research should be of concern with regard to vaccine-induced arthritis. Shed attenuated live vaccine might also be considered in this regard. (20)

It is interesting that although distemper is now a very rare disease in dogs in the UK, veterinarians continue to administer annual distemper vaccines – even when, according to independent DOI studies, immunity persists for years or life. Where is the science in this? Are veterinarians unwittingly injecting arthritis into the UK canine population through repeated unnecessary distemper vaccines?

Rheumatoid arthritis is, of course an autoimmune condition in which there is inflammation of joints and progressive erosion of cartilage and bone, which also reflects the autoantibodies to collagen found in the Purdue study.

In 2000, research showed that polyarthritis and other diseases like amyloidosis in dogs were linked to combined MLV vaccines (*Am Coll Vet Intern Med*, 2000; 14: 381). (21) Dr Ronald Schultz is quoted in Vet Med Today (*JAVMA* Vol 207, No 4, August 15, 1995): "Immune-mediated disease has developed in human beings following vaccination, as was seen with cases of Guillain-Barre syndrome following swine flu vaccinations, and rheumatoid arthritis following influenza vaccination". (22)

In the 1996 Canine Health Concern vaccine survey, we found that a high percentage of dogs with arthritis in the survey were diagnosed with the condition in a cluster nine months after a vaccine event.

A veterinary internet site, http://www.vetinfo.com/dencyclopedia/dehod.htm, states:

> **Hypertrophic osteodystrophy** causes lameness and extreme pain in young growing dogs, usually of a large breed. Great Danes, German Shepherds, Dobermans, Retrievers and Weimaraners are examples of breeds that may be affected by this condition. It appears to occur in Weimaraners as a vaccine reaction and this may also affect Mastiffs and great Danes. In this case, it usually occurs a few days after vaccination and may appear to be worse than the "average" case on radiographs.
>
> HOD usually shows up as an acute lameness, often seeming to affect all four legs simultaneously. Affected dogs may stand in a "hunched up" stance or refuse to stand up at all. They may have a fever but this is not consistently present. They usually have painful swellings around the lower joints on the legs. Some puppies will die from this disease, some suffer permanent disability but many recover later. The disease is so painful that many owners elect to euthanize the puppy rather than watch it suffer, despite the reasonably good chance for recovery, long term. Affected dogs may be so ill that they refuse to eat.
>
> X-rays confirm this diagnosis in most cases. There are very typical X-ray changes, although it can look a little like bone infection from aseptic condition. There is some evidence at this point that viral or bacterial infections may underlie

> some cases of HOD as canine distemper virus has been found in the affected areas in some dogs. There can be high white blood cell counts and the alkaline phosphatase level in the blood stream is often elevated.

Dermatitis, another inflammatory disease, has also been linked to vaccination. A study conducted by Frick and Brooks in 1983 showed that dogs predisposed to develop atopic dermatitis didn't develop this hereditary condition when exposed to an allergen and later vaccinated. But a second group who were vaccinated before being exposed to the allergen did develop the condition, indicating that vaccines can play a role in triggering this inflammatory disease. The trial group also developed conjunctivitis.

Merck also tells us that serum (which is used in vaccines) can cause Type III hypersensitivity reactions, including an inflammatory skin condition involving painful local lesions leading to tissue necrosis, as well as widespread vascular injury.

Although rare, I have come across three cases of dogs whose skin began to split post-vaccination. In one case involving a Golden Retriever called Spangler, pseudomona agruginosa was found in tissue samples. Some of Spangler's dead and dying skin was sent by his vet to an independent laboratory, which could neither confirm nor deny that his death was a result of bacteria entering his body at the time of vaccination. Readers would do well to remember Spangler's fate when viewing the human-related scientific studies listed later in this document.

Neurological damage

Neurological damage is one of the most prevalent and least desired adverse effects of the vaccine process. By over-vaccinating canines, we are introducing a potentially serious danger into society: brain damaged dogs.

As Coulter convincingly demonstrated in his book, *"Vaccination, Social Violence and Criminality"* the unwanted consequences of human vaccination include sudden unprovoked violence in children. No wonder the British government has seen the need to introduce the Dangerous Dogs Act.

We need here to remember the vaccine-induced antibodies against Cardiolipin that were found in the Purdue study. Elevated levels of anti-cardiolipin autoantibodies (ACA) have been reported to be significantly associated with . . . neurological conditions.

The Merck Manual describes encephalitis as "an acute inflammatory disease of the brain due to direct viral invasion or to hypersensitivity initiated by a virus or other foreign protein … Secondary encephalitis, usually a complication of viral infection, is considered to have an immunologic mechanism. Examples are the

encephalitides following measles, chickenpox, rubella, smallpox vaccination, vaccinia, and many other less well defined viral infections."

Encephalitis has been shown to appear in dogs after vaccination. (23) (Grene, CE, ed, Appel MJ, Canine Distemper in *Infectious Diseases of the Dog and Cat,* 2nd edition, Philadelphia: WB Saunders, 1998: 9-22).

Writing in the *Veterinary Record* during 1992 (130, 27-30), AIP McCandlish et al state: "Post-vaccinal encephalitis is a recognised complication of the administration of certain strains of live attenuated canine distemper vaccine (Hartley 1974, Bestetti and others 1978, Cornwell and others 1988)". (24)

According to *Braund's Clinical Neurology in Small Animals: Localisation, Diagnosis and Treatment*:

> "post vaccinal canine distemper encephalitis occurs in young animals, especially those less than six months of age. It has been recognised as a disease entity for a number of years, and is believed to be association with vaccination using live virus. The pathogenesis of this disease is unclear, but may result from insufficient attenuation of the vaccine virus which causes subsequent infections of the CNS; the triggering of a latent distemper infection by vaccination; other vaccine components; or an enhanced susceptibility of the animal (e.g., animals that are immunosuppressed)." (25)

Merck states: "Symptoms of encephalitis may be associated with cerebral dysfunction (alteration in consciousness, personality change, seizures, paresis) and cranial nerve abnormalities."

It should be noted that encephalitis is a spectrum disease, ranging from mild and undetectable, through to severe manifestations, and even death.

Paresis, is of course another potential sequel to vaccine-induced encephalitis; Merck describes paresis as: "Muscular weakness of neural origin. It is usually regarded as a state of partial or incomplete paralysis, resulting in a deficit of voluntary movement. Paresis may result from lesions at any level of the descending motor innervation pathway from the brain."

In addition to my own four-year-old Golden Retriever, Oliver, presenting with paresis of both hind limbs before dying suddenly, I have been presented with many other anecdotal reports of dogs suffering paresis shortly after vaccination where the vets suspected no link to their vaccines, and no adverse event reports were filed.

Epilepsy is also listed by Merck as a symptom of encephalitis, and we know that encephalitis can be vaccine-induced. Merck states: "non-infectious causes of encephalitides include … vaccine reactions: many". It adds that epilepsy can be

caused by “CNS infections (meningitis, Aids, encephalitis) and also by a foreign serum or drug allergy, or by convulsive or toxic agents”.

See also Ballerini, Rico B et al., Neurological Complications of Vaccination With Special Reference to Epileptic Syndrome *Riview Neurol*, Jul-Aug 1973; 43: 254-258.

See also: "Encephalitis following vaccination against distemper and infectious hepatitis in the dog" "A 4-months-old, male, healthy dog developed CNS-symptoms 10 days after the second vaccination with live, attenuated distemper and canine hepatitis virus."
G. Bestetti1, et al, *Acta Neuropathologica Volume 43, Numbers 1-2 / 69-75 -- 1/1/1978*

According to the Society for Companion Animal Studies, “epilepsy is the commonest neurological disorder seen in dogs and constitutes a major health problem. (26) (Brewer, 199; Berendt 2002). “It is probable that between 30,000 and 366,000 of the 6.1 million dogs in the UK suffer from epilepsy.”

Many dog owners have noted personality changes in their dogs shortly after vaccination, including nervous, worrying disposition; short attention span; and aggression. The Canine Health Concern survey found that high percentages of these conditions, where they existed in survey dogs, were reported to have started within three months of vaccination. The study is detailed in *What Vets Don’t Tell You About Vaccines*, Catherine O’Driscoll. (27)

Scientists other than Dr Andrew Wakefield have discovered a vaccine-autism (neurological) link. For example, the Department of Paediatrics, Tokyo Medical University, Japan, found the measles virus in patients with inflammatory bowel disease and autism. (28) (*Dig Dis Sci*, 2000, Apri; 45(4) 723-9) . The sequences obtained from the patients with ulcerative colitis and children with autism were consistent with vaccine strains. It should be remembered that the measles virus and canine distemper are very closely related.

In *Toxicol Environ Chem* 2008 90(5):997-1008, researchers also found a correlation between the Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years. (29)

The truth-seeker will be able to locate many further studies linking vaccines to brain damage; many of them are included later in this document.

The myelin sheath may also be pertinent in relation to vaccine damage. Merck states: “The myelin sheaths of many nerve fibres promote transmission of the neural impulse along the axon. Many congenital metabolic disorders affect the developing myelin sheath. Unless the innate biochemical defect can be

corrected or compensated for, permanent, often widespread, neurological deficits results."

But vaccines can also play their part. Merck adds: "In acute disseminated encephalomyelitis (post infectious encephalitis), demyelination can occur spontaneously, but usually follows a viral infection or inoculation (or very rarely a bacterial vaccine), suggesting an immunologic cause."

As mentioned previously, vaccines have been shown to cause dogs to develop autoantibodies to their own albumin (Purdue study). Albumin is manufactured by the liver, enabling fluid to remain in the bloodstream rather than leak into tissues. If albumin gets low, fluid builds up and inflammation can occur in the body.

Fatty acids are carried with the aid of albumin to cells in the body. They are the building blocks for lipids, which form all of the membranes around and inside cells. Fatty acids are essential for life, and albumin is essential for their distribution. If vaccinated dogs are attacking their own albumin, then neurological function could be impaired. This, in turn, has a bearing on the UK's Dangerous Dogs Act, the danger posed by vaccinated dogs to humans, and the perceived need for such an Act.

> **From Purdue University:** Each year, millions of dogs are abandoned and euthanised. Among the various reasons for euthanasia, behavioural problems account for 50% to 70% of all terminations. Aside from uncontrollable factors that contribute to this problem such as genetics, disease, and ageing, nutritional imbalance can also be a factor. However, since nutrition is a controllable factor, it is among the easiest to correct.
>
> Behaviour is regulated in the central nervous system through the actions of neurotransmitters and hormones. Dietary factors may directly contribute to the availability of these factors, or indirectly influence the environment where the actions of these factors take place.
>
> It is well known that polyunsaturated fatty acids, especially omega-3 and omega-6, play important roles as structural constituents in the brain. Recent studies also established that omega-3 fatty acids are necessary for proper brain and eye development. There is evidence that a dietary supply of omega-3 and omega-6 could modify aspects of dopamine and serotonin in the body, and subsequently affect cognitive performance and behaviour.
>
> It is also shown in humans, as well as in rats, that alterations in omega-3 fatty acids and an elevated ratio of omega-6/omega-3 fatty acids are linked to behavioural alterations, including aggression.
>
> Reports also showed that, relative to normal dogs, aggressive dogs showed lower circulating DHA (an omega 3 fatty acid) concentrations and a higher ratio of omega-6/omega-3 fatty acids in the measurement of baseline fasting plasma essential fatty acid composition.

> Considering the fact that the most abundant fatty acid in the brain is DHA, it is apparent that deficiency in this essential nutrient could have a profound effect on the behaviour of the dog.
>
> In conclusion, dietary DHA, as well as its precursor omega-3 fatty acids, could be a potential resource in fending off canine behavioural problems. These are found in fish oils.

If dogs develop autoantibodies to albumin as a direct result of routine vaccination, their neurological function is but one likely casualty.

Cumulative vaccine damage

> "There is a real concern that vaccines may predispose certain genetically susceptible individuals to immune-mediated disease," says Dr Schultz. "The more antigens we administer, the higher the potential for hypersensitivity. Type I is IgE mediated; type 2, cytotoxic antibody mediated; type 3, immune-complex mediated; and type 4 cellular mediated. All of these hypersensitivities are natural parts of the immune response, but they cause a certain amount of tissue damage. That damage may occur in the kidney, liver, or as was the case with canine adenovirus 1, in the eye. In many cases it is impossible to show a direct connection between the damage and a vaccine, since it is the accumulation of many antigens over many years that results in clinically evident disease." (30)

Many adverse reactions to vaccines occur which vary in severity amongst individuals due to genetic factors (31) Factors thought to be responsible for activating genes include heavy metals, chemicals, viruses, bacteria, nutrition and emotional states and stress (31). Many of these triggers are found in vaccines. It is now known that an individual can be pre-disposed to a disease by having the gene for that disease - but expression of the gene can depend upon an environmental factor (32). That environmental factor is, too often, an unnecessary vaccine.

Further, vaccine reactions can occur immediately after the injection and they can occur later. Animal studies show delayed reactions to vaccine ingredients. A reaction may occur days, weeks, months or years after an animal or human is exposed to vaccines. (33)

The World Small Animal Veterinary Association Vaccination Guidelines Group states: ***"We should aim to vaccinate every animal, and to vaccinate each individual less frequently."*** (34)

David Hustead, who at the time of writing his paper "What you can and cannot learn from reading a vaccine label" was International Technical Director of Fort Dodge Animal Health, admits that ***the biologic necessity to revaccinate annually has not been demonstrated***. (35)

Hustead also notes that *"the quality and quantity of safety information on an animal vaccine label is much less than that found on the labels of common human vaccines".* According to Hustead ***"it is not unusual for an animal vaccine label to essentially ignore the safety concerns of vaccine administration with the exception of anaphylaxis"***. Animal vaccine labels contain only ***"a few short safety statements, that in all probability do not accurately reflect the clinical safety of the product as observed by all users"***.(36)

In his paper "Vaccine side effects: Fact and fiction", Michael Day notes that *"vaccination-induced immunosuppression may on occasion be sufficient to permit the development of severe disease in animals that are carrying subclinical opportunist pathogens"*. (37)

In a paper published in January 2010, Day also acknowledges the cumulative effects and consequences of repeated vaccination are unknown saying that "**few *investigations have studied the phenomenon of 'inflammageing' (the effect of cumulative antigenic exposure and onset of late life inflammatory disease)"*** in dogs and cats.(38)

Decisive action needed

It is imperative that we take on board Dr Schultz's statements made as a result of his duration of immunity studies, namely that, **"Once an animal is immune to viral disease, he is immune for years or life".** Dr Schultz was motivated to conduct his studies when he reflected that children didn't need vaccinating every year, so why do dogs? It is also worth noting that no science has ever been put forward to justify annual vaccination, or three-yearly vaccination for that matter.

If the VMD refuses to take the lead in the over-vaccination issue, then the British government itself will be responsible for a loss of faith in vaccination per se – and then we quite possibly <u>will</u> see widespread disease outbreaks.

We need to be able to trust our government's guidance.

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VACCINE RISKS VS VACCINE BENEFITS

In its position document, the VMD stated:

> **Advising on the correct vaccination course to follow is not an easy task as a routine programme of vaccination may require adaption to the local epidemiology of the various diseases to provide the best health security. It is right therefore, that the decision is taken by the animal owner following discussion and advice from their veterinary surgeon.**

Canine Health Concern wrote to the VMD to ask them to withdraw one-year vaccines for 'core' canine diseases. To clarify the confusion that may arise as a result of the VMD's statement above, it should be noted that:

> **All studies based on persistence of antibody as well as challenge show that immunity to CDV, CPV-2 and CAV-1 [distemper, parvovirus and adenovirus] persists for a lifetime after vaccination, similar to the persistence of immunity after natural infection (Schultz, 2006).**

As the previous pages of this document have shown, the vaccination process is in no way similar to pricking your thumb with a needle, where bleeding is an expected and predictable outcome. Rather, vaccine damage involves a wide array of potential effects, and these effects do not always occur immediately. Diseases such as SLE (and its myriad symptoms), arthritis, organ failure, cancer and leukaemia, to name but a few, may develop over time. Autoimmune disease may be present for a long time before overt symptoms present themselves. We must also consider the scientific evidence that points towards inheritable vaccine damage.

There is, unfortunately, always a risk benefit analysis to be conducted when any vaccine is used, since none appears to be free from potential adverse reactions. We demonstrate this fact within this response, simply to illustrate that we should vaccinate no more frequently than is absolutely necessary.

Governments around the world have formed vaccine damage compensation schemes for humans who have been damaged by vaccines, which illustrates that adverse events to vaccines are both known, expected, and compensated for. It is thought that the compensation schemes are in place to limit the damages paid. Nevertheless, parents often have a hard time 'proving' that a vaccine was the cause of their child's poor health or death.

No vaccine damage compensation scheme exists for pets who are damaged by vaccines.

Informed consent

As the law currently stands, veterinarians are not asked to obtain informed consent from pet owners in the UK. Indeed, datasheets accompanying vaccines are generally retained and disposed-of by veterinarians. These datasheets are also written in a language that would be difficult for the average pet owner to understand. Pet owners would not, for example, generally be expected to understand the implications of the words, “immunocompetence may be compromised by a variety of factors”. Neither are pet owners able to see the revaccination data provided with each vaccine product if they are not privy to the datasheets.

Further, pet owners could not be expected to be aware of the duration of immunity studies conducted by independent scientists which illustrate the principle that, “once immune to viral disease, dogs and cats are immune for years or life”.

Nor are pet owners generally aware of scientific research which shows the myriad potential adverse reactions to their pets’ vaccinations.

One cannot make an informed choice if one is not informed.

Pet owners, for the most part, place their trust in the veterinary profession. If a veterinarian tells a pet owner that their dog or cat must be vaccinated against core viral diseases every year, few pet owners have the expertise or knowledge with which to question this advice. They are even less likely to do so if they have seen TV and press advertisements which suggest a pet has “lapsed” if it hasn’t had a booster within the last eighteen months.

If a pet owner wishes to place their dog in a kennel, or their cat in a cattery while they take a holiday, the kennel or cattery will most likely demand evidence of a recent booster. Kennel owners are unlikely to discriminate between core and non-core diseases.

In turn, kennels are likely to ask for evidence of annual boosters because the advice given to local councils is that such evidence is necessary. Since local councils both grant and withdraw kennel licences, kennel owners risk their livelihoods if they wish to adhere to the known science relating to lifelong DOI.

Pet owners do not have automatic access to the information that would enable them to make informed choices. Rather, they are told by the media, by their vets, by pet charities such as the Dogs Trust and the RSPCA, and by boarding establishments, that annual vaccination is required.

Therefore, to minimise the potential for adverse events associated with unnecessary vaccines, the government must make the science known – to

veterinarians, boarding establishments, to legislators, and to the pet owning public.

No pet owner would wish to lose their pet to an infectious disease; nor would they wish their pet to die from the very vaccine that was administered in order to prevent infectious disease. And they would not wish to see their pet suffer from the adverse effects of a vaccine.

Therefore pet vaccination must be guided by the Precautionary Principle – which summarises as the need to err on the side of caution or, in veterinary and medical terms, to "first do no harm". The emphasis must therefore be upon vaccinating no more frequently than is shown to be necessary.

Precautionary Principle: The burden of proof of harmlessness of any pharmaceutical product is on the proponent NOT the general public.

A WIDER PICTURE - THE HUMAN VACCINE SAFETY RECORD

We seek to demonstrate with the inclusion of this information that vaccination is never without risk. Pets are generally thought to be less important than humans. The legislation for human medicines and food products is arguably more rigorous than it is for animals. Nevertheless, human vaccine tragedies are reported frequently.

Individuals may react badly to their vaccines because they are immunocompromised. They may be stressed. Their diets may be inadequate. They may have inherited immunodeficiency diseases. The vaccine may be contaminated, or incompletely attenuated. They may just be one of the expected 'small number' of unfortunate people or animals who become an "acceptable" casualty.

The following information would, we hope, illustrate why no vaccine should be given unless it is shown to be absolutely necessary.

SMALLPOX – THE 'GOLD STANDARD'?

Much of the VMD's position document relates to the safety and efficacy of veterinary vaccines. To illustrate this point, the VMD stated in the introduction to its position document:

> **The gold standard is provided by the example of small pox in humans. The last case in man was recorded in 1977 and in 1980 the WHO officially announced smallpox had been eradicated from the world.**

We respond to the VMD's statement with regard to smallpox below - in order to illustrate the risks associated with any vaccine, even the vaccine lauded as the gold standard. Knowing that even the gold standard is not without its risks, it is clear that we should adhere to the precautionary principle when administering vaccines; we should not administer veterinary vaccines on an annual basis when they have been shown to be unnecessary.

The truth seeker will also see many correlations between the adverse effects of the smallpox vaccine, other human vaccines (detailed later), and the adverse effects experienced by the pet population as a result of vaccination.

The VMD states in its position document:

> **The current low incidence of dog and cat infectious diseases provides an incentive for some animal owners to argue vaccination is no longer necessary. This is generally regarded as being impractical and so the debate has focused upon the frequency of vaccination required to provide**

protection throughout the animal's lifetime and the potential for routine vaccination to do harm to the individual animal.

It is entirely pertinent for the VMD to make the above statement immediately after hailing the smallpox vaccine as the 'gold standard', for the smallpox vaccine was surrounded by controversy before it was eventually withdrawn from routine use. The vaccine was seen to be more dangerous than the disease threat.

Many dog owners in the UK are waking up to the fact that the unthinking and unscientific routine annual vaccination of dogs – comprising a cocktail combination for both core and non-core diseases – is indeed posing more of a health threat than the diseases we are seeking to prevent. Unfortunately, those who are waking up are generally the pet owners whose pets have become ill or died as a result of unnecessary vaccines. Too late.

In a similar vein, one of the UK's most eminent vaccine scientists, the late Professor George Dick, repeatedly called upon the government to withdraw the smallpox vaccine since it was killing more people than it was helping. Only after the vaccine was eventually withdrawn did smallpox die out. The following is taken from Professor Dick's obituary in the *Guardian* newspaper:

> PROFESSOR GEORGE DICK, the immunologist who died aged 82, waged a long war against the vaccination of children for smallpox, which he blamed for killing more victims than the disease.
>
> By the 1950s smallpox was so rare in Britain that mass vaccination, even with its small risk of mortality, was killing more children than would have died without it. In 1962 Dick spoke out at the British Medical Association annual meeting against the smallpox vaccination programme enjoined by the Minister of Health, Mr Enoch Powell. "He is asking for a sacrifice of at least 20 babies a year," Dick said.
>
> Dick's conclusion was that, for smallpox, "we should now give up routine infant vaccination and depend on epidemiological control". To cheers from his fellow doctors, Dick advised Mr Powell to spend "more effort on devising a plan to reduce the risk of importation of smallpox into Britain."
>
> But it was not until 1971 that Sir Keith Joseph, as Secretary of State for Social Services, announced in a letter to all GPs that the government-backed programme encouraging vaccination for children was to be dropped. Dick had made known his opposition to childhood smallpox immunisation to the committee that advised Joseph to drop the programme.
>
> Since then the disease has become extinct, not only in Britain but also, according to the World Health Organisation, throughout the world.

It must be noted that Professor Dick was one of the UK's most eminent and highly decorated pro-vaccine scientists. Our reason for including this information is that whilst vaccines can be praised for reducing infectious diseases, their use

must also be balanced in relation to disease prevalence, as well as the safety and efficacy of each vaccine.

Importantly, vaccines should never be given as a matter of routine if immunity already exists. There is no benefit, but plenty of risk.

The following references relate to the smallpox vaccine. It is worth reading them rather than glossing over them. They will give you a clear picture of the vaccine-induced, iatrogenic (doctor-induced), conditions besetting both man and animal. You will also notice that whilst adverse effects are repeatedly reported in peer review journals, nothing much changes. History continues to repeat itself :

> A letter appeared in *The Lancet on July 7th, 1860*, signed a "Military Surgeon:" It discussed the high number of amputations of the arm, and deaths, amongst soldiers following vaccination.
>
> In 1867, non-payment of fines for refusing smallpox vaccination in the UK resulted in harsher penalties. Thousands left Britain rather than submit their children to the practice.
>
> In 1868 the Anti-Compulsory Vaccination League was formed in Britain.
>
> Smallpox vaccination in America led to an alarming spread in leprosy, according to successive reports to the Board of Health in 1868. This pattern was repeated following smallpox vaccination programmes in 1873 and 1881.
>
> In 1868, Joseph Jones MD, Professor of Physiology and Pathology, University of Nashville, wrote that federal prisoners at Camp Sumpter, Georgia, were vaccinated and large gangrenous ulcers appeared at the vaccination point. This caused extensive destruction of tissues, exposing arteries, nerves and bones, and necessitating amputation in more than one instance. One-third of prisoners perished in less than seven months.
>
> In 1870, despite the smallpox vaccine programme, an outbreak of smallpox occurred all over Europe.
>
> During 1871, the Vaccinator-General of Trinidad gave evidence before the Select Parliamentary Committee that those who were not vaccinated experienced a rare incidence of leprosy, whereas soldiers who were subjected to mandatory military vaccines experienced high levels of leprosy.
>
> In 1879 Mr. PA Taylor wrote in *The Lancet* that he had seen scores of people who honestly believed that their children had died from vaccination. They took perfectly healthy children to be vaccinated, and in a few days a sore appeared on the arm, which spread all over the body, and finally the children died in agony.
>
> Mr. JT Hibbert, MP, Parliamentary Secretary to the Local Government Department, wrote: "The Return shows an increase of deaths from syphilis of infants under one year which, in my opinion, is one of the most unsatisfactory features in connection with vaccination, and one which leads me to support the

proposed modification of the Vaccination Law now before the House of Commons." *Lancet, July 17th*.

Between 1886 and 1892 in Australia, when children died as a result of smallpox vaccinations, the government abolished compulsory vaccination, and smallpox then declined to vanishing point. Australia had only three cases of smallpox in 15 years as compared with Japan's record of 165,774 cases and 28,979 deaths in only seven years under compulsory vaccination and re-vaccination.

In the *Occidental Medical Times, April, 1892*, Dr Sidney Bourne Swift wrote*:* "It must not be forgotten that leprosy was first discernible at the points of inoculation. Nor can it be considered remarkable, knowing how the disease had been propagated by the vaccination lancet. In one instance an entire school in Hawaii was swept away, with the exception of a single survivor, by this means."

Hawaiian Legislature, June 25, 1892. David Dayton, President, Board of Health wrote: "An effort is being made in the Legislature to repeal or amend the law relating to vaccination; the object being to leave vaccination optional with parents and individuals. The chief objection raised against the present compulsory system appears to be the belief that leprosy, and other diseases, have been propagated by means of vaccination."

Final report of the Royal Commission on vaccination, 1896: The commission could not ignore the evidence against vaccination so they recommended that mandatory vaccination should be stopped.

"Disorders in the Murine Chromosome Apparatus Induced By Immunization with a Complex of Anti-viral Vaccines" "Immunization of mice with a number of live virus vaccines (poliovaccine, smallpox vaccine, measles vaccine) given consecutively at 14-day intervals resulted in increased frequency of chromosomal aberrations in bone marrow cells of the animals after the completion of the entire vaccination course (14 and 30 days after the last vaccination). Measles vaccine and, particularly, smallpox vaccine exert a significant harmful effect on the karyotype of the bone marrow cells. "
Cherkeziia, SE, et al, *Vopr Virusol, 1979 Sept Oct, (5):547-550* -- 1/1/1900

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"A variety of neurologic complications of smallpox vaccination have been reported, including encephalitis, transverse myelitis, meningitis, and polyneuritis"
Lanska, D, *Meldink.com: neurology* -- 1/1/1900

The question of encephalitis following vaccination was investigated by the League of Nations, and on August 27, 1928, the League published a report on the situation. The report stated: "The post-vaccinal encephalitis with which we are dealing has become a problem of itself . . . a new, or at least previously unsuspected or unrecognized risk attaches to vaccination. . . "

The Journal of the American Medical Association on April 2, 1937: "A multiplicity of untoward sequelae have been observed in patients treated with immune serum…The common symptomatology includes fever, urticaria, erythema, oedema, lymphadenoma, artharaliga, smothering sensations, headache, nausea

and vomiting. Occasionally there are more serious and lasting manifestations such as peripheral neuritis, epididymitis and orchitis."

The April, 1941, issue of the *Naval Medical Bulletin* reports on the results of tests on 20,000 recruits at the Naval Training Station at San Diego, California. It states: "All were found free of syphilis, and were then confined. These men were vaccinated against smallpox. Those who did not show 'successful' vaccination were re-vaccinated. The experiment showed that more of these developed syphilis from the smallpox vaccination than the percentage who developed syphilis from all causes in the civilian population in the United States."

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"A case of disseminated vaccinia is presented. It is suggested that patients with sunburn may be susceptible to the complications of smallpox vaccination."
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"Summary An increased frequency of chromosomal changes and sister chromatid exchanges was detected in 10 women 7 days after smallpox vaccination"
Knuutila, S et al, *Hum Genet, 41(1):89-96* -- 2/23/1978

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"Including this case, only five have been reported. This is the first report of a leiomyosarcoma arising in a smallpox vaccination scar."
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"The Smallpox Vaccine and Postvaccinal Encephalitis"
"Before we become complacent with the idea that we will respond to a bioterrorism attack with a mass immunization program for smallpox, it is important to be reminded of the risk and clinical manifestations of postvaccinal encephalitis… The first case of postvaccinal encephalitis as a complication of the Jennerian cowpox inoculation was observed in 1905. A century later, there is no effective therapy."
Karen L. Roos, et al, *Semin Neurol 22: 095-098* -- 1/1/2002

Smallpox vaccination: Risk considerations for patients with atopic dermatitis"
"Individuals with active or quiescent atopic dermatitis are at increased risk for vaccinia (small pox) complications."
Renata J. M. Engler MD, et al, *Journal of Allergy and Clinical Immunology Volume 110, Issue 3 , Pages 357-365* -- 9/1/2002

"Encephalitis Complicating Smallpox Vaccination"
"Postvaccinal encephalitis is a complication of this vaccine. The clinical presentation, course, neuroimaging findings, and spinal fluid abnormalities are similar to a disorder that physicians are familiar with, acute disseminated

encephalomyelitis."
Augusto Miravalle, et al, *Arch Neurol.;60:925-928* -- 1/1/2003

"A Risk of serious complications and death from smallpox vaccination:"
"Results: The life-threatening complications of post-vaccinial encephalitis and vaccinia necrosum were at least 3 and 1 per million primary vaccinations, respectively. Twenty-nine percent of vaccinees with post-vaccinial encephalitis died and 15% with vaccinia necrosum died."
Tomás J Aragón, *BMC Public Health, (3) 26* -- 1/1/2003

"US Military Smallpox Vaccination Program Experience"
"Results: … One case of encephalitis and 37 cases of acute myopericarditis developed after vaccination."
John D. Grabenstein, RPh, PhD; et al, *JAMA. 289:3278-3282* -- 1/1/2003

"Myopericarditis Following Smallpox Vaccination Among Vaccinia-Naive US Military Personnel"
"Conclusion: Among US military personnel vaccinated against smallpox, myopericarditis occurred at a rate of 1 per 12 819 primary vaccinees. Myopericarditis should be considered an expected adverse event associated with smallpox vaccination."
Jeffrey S. Halsell, et al, *JAMA. 289:3283-3289* -- 1/1/2003

"Myocarditis after Smallpox Vaccination: A Case Report"
"A 20-year-old airman (US Air Force) developed myocarditis 8 days after smallpox vaccination. He was treated with nonsteroidal anti-inflammatory agents, and his symptoms promptly resolved. However, post-vaccinial myocarditis can lead to serious complications and even death."
G. Saurina, et al, *Clinical Infectious Diseases, volume 37 (2003), pages 145–146* -- 1/1/2003

The Ocular Complications of Smallpox and Smallpox Immunization"
"Conclusions: Folliculitis is a common and benign eruption observed in vaccinia-naive adult volunteers following smallpox vaccination."
Thomas R. Talbot, MD, MPH, et al, *JAMA ;289:3290-3294* -- 1/1/2003

"Smallpox Vaccination and Adverse Reactions . Guidance for Clinicians"
"Adverse reactions that might require further evaluation or therapy include inadvertent inoculation, generalized vaccinia (GV), eczema vaccinatum (EV), progressive vaccinia (PV), post-vaccinial central nervous system disease, and fetal vaccinia."
Joanne Cono, M.D.1, et al, *CDC, MMWR; 52(RR04);1-28* -- 2/21/2003

Cardiac adverse events following smallpox vaccination in the US. (Market Research Studies).
Biomedical Market Newsletter March 31, 2003

During Jan. 24-March 21, 2003, smallpox vaccine was administered to 25,645 civilian healthcare and public health workers in 53 jurisdictions, as part of an effort to prepare the US in the event of a terrorist attack using smallpox. Seven

cases of cardiac adverse events have been reported among civilian vaccinees since the beginning of the smallpox vaccination program.

In addition, 10 cases of myopericarditis have been reported among military vaccinees. This report summarizes data on the seven cases reported among civilians and provides background information on recent military vaccinees.

Although a causal association between vaccination and adverse cardiac events in the civilian population is unproven, as a precautionary measure, CDC recommends that persons with physician-diagnosed cardiac disease with or without symptoms (e.g., previous myocardial infarction, angina, congestive heart failure, or cardiomyopathy) be excluded from vaccination during this smallpox preparedness program.

The CDC, FDA and state health departments are conducting surveillance for vaccine-associated adverse events among civilian vaccinees. The Department of Defense (DoD) is conducting surveillance for vaccine-associated adverse events among military vaccinees.
http://www.highbeam.com/doc/1G1-100141025.html

"On March 25, an Army National Guardsman aged 55 years with a history of smoking and treatment for hyperlipidemia was found unresponsive in a vehicle 5 days after receiving smallpox vaccine and two other inactivated vaccines. He was resuscitated but died the next day."
Staff, *CDC, Morbidity & Mortality Weekly Report* -- 4/17/2003

"A man aged 29 years had ILI symptoms during the same week of primary smallpox vaccination. At the time of smallpox vaccination on March 8, he also received five other inactivated vaccines; 19 days after vaccination, he sought treatment at an ED for dyspnea while lying flat. On March 28, he was hospitalized and had myopericarditis diagnosed based on ECG findings and elevated troponin I and CK-MB."
Staff, *CDC, Morbidity & Mortality Weekly Report* -- 4/17/2003

"Adverse Events Following Smallpox Vaccination - United States, 2003"
"The 14 patients with myocarditis and/or pericarditis ranged in age from 21 to 33 years. Severity ranged from mild (no ECG or echocardiogram changes) to severe (congestive heart failure), with onset 7 to 19 days after vaccination."
Staff, *CDC, Morbidity & Mortality Weekly Report* -- 4/17/2003

"Dermatofibrosarcoma protuberans occurring in a smallpox vaccination scar"
"Dermatofibrosarcoma protuberans (DFSP) is a locally aggressive, rarely metastatic, spindle cell tumor. Trauma has been associated with its development. Since the 1940s, malignant tumors have been described to occur in sites of smallpox vaccination scars."
Justin J. Green MD, et al, *Journal of the American Academy of Dermatology Volume 48, Issue 5, Part 2 , Pages S54-S55* -- 5/1/2003

"Adverse events occurring after smallpox vaccination"
"Nearly one-half of the United States population is vaccinia-naïve and may be at risk for development of serious adverse events… In the 1960s, death occurred

approximately once in every million primary vaccinations, with fatalities resulting from progressive vaccinia, postvaccinial encephalitis, and eczema vaccinatum…. In today's population, death rates might be higher because of the increased prevalence of immune deficiency and atopic dermatitis."
J. Michael Lane MD, MPH, et al, *Seminars in Pediatric Infectious Diseases ,Volume 14, Issue 3, Pages 189-195* -- 7/1/2003

Myopericarditis, which involves the inflammation of the heart muscle or sac surrounding the heart, should be an expected but apparently uncommon adverse event associated with smallpox vaccination, researchers say.

In the June 25, 2003, issue of the *Journal of the American Medical Association (JAMA),* Jeffrey S. Halsell, DO, James R. Riddle, DVM, MPH, and members of the U.S. Department of Defense Smallpox Vaccination Clinical Evaluation Team reported on the first 18 cases of probable myopericarditis following smallpox vaccination among otherwise healthy, young adult members of the U.S. military who were vaccinated between …
http://www.highbeam.com/doc/1G1-105192203.html

"Myocarditis: the unexpected return of smallpox vaccine adverse events"
"The evidence that myocarditis is caused by the N smallpox vaccination is compelling because the classic tenets of causality have been fulfilled. "
Staff, *Lancet, Vol 362* -- 10/25/2003

"Cardiac Dysrhythmia following Smallpox Vaccination"
Timothy J. Whitman, et al, *Clinical Infectious Diseases, volume 37 (2003), pages 1579–1580* -- 11/7/2003

"Urticaria, Exanthems, and Other Benign Dermatologic Reactions to Smallpox Vaccination in Adults"
"Rashes appeared 6-19 days after vaccination and had 5 different clinical presentations. Five volunteers had urticarial rashes that resolved within 4-15 days, 1 had an exanthem that lasted 20 days, and 1 each presented with folliculitis, contact dermatitis, and erythematous papules found only on the hands and fingers. Volunteers reported pruritus, tingling, and occasional headaches."
Richard N. Greenberg,, *Clinical Infectious Diseases, volume 38 pages 958–965* -- 1/1/2004

"Smallpox vaccination and myopericarditis: a clinical review"
"If a widespread vaccination program is undertaken in the future, many more cases of post-vaccinial myopericarditis could be seen. Practicing physicians should be aware that smallpox vaccine-associated myopericarditis is a real entity."
Dimitri C. Cassimatis, MD, et al, *J Am Coll Cardiol, 43:1503-1510* -- 1/1/2004

Myopericarditis following Smallpox Vaccination"
"Fifty-eight males and one female aged 21–43 years with confirmed or probable acute myopericarditis were detected following vaccination of 492,730 US Armed Forces personnel from December 15, 2002, through September 30, 2003."
Mark K. Arness, et al, *American Journal of Epidemiology 160(7):642-651* -- 1/1/2004

"Incidence and follow-up of inflammatory cardiac complications after smallpox vaccination"
"CONCLUSIONS: Post-vaccinial myopericarditis should be considered in patients with chest pain within 30 days after smallpox vaccination. Incidence and follow-up of inflammatory cardiac complications after smallpox vaccination. "
Robert E. Eckart, DO, et al, *J Am Coll Cardiol, 44:201-205* -- 1/1/2004

Smallpox: Clinical Features, Prevention, and Management"
"The vaccine may cause moderate to severe adverse events such as eczema vaccinatum, progressive vaccinia, and generalized vaccinia. CONCLUSIONS: The balance between the risks and benefits of mass vaccination in prevention of an epidemic is not clear. "
Roy Guharoy, PharmD FCP FCCP FASHP, *The Annals of Pharmacotherapy: Vol. 38, No. 3, pp. 440-447* -- 1/30/2004

Cambridge, UK and Cambridge, Massachusetts - April 13 2004 - Acambis plc (LSE: ACM, NASDAQ: ACAM) announces that it has suspended the recruitment of additional volunteers into its Phase 3 clinical trials involving its investigational smallpox vaccine ACAM2000 and DryvaxA', the comparator smallpox vaccine being used in the trials. This precautionary measure was taken after three suspected myopericarditis cases were discovered in both ACAM2000 and DryvaxA'-vaccinated subjects. Myopericarditis is a condition where there is an inflammation of the heart and surrounding tissues.

Acambis' independent Data and Safety Monitoring Board (DSMB) recommended that enrolment into the studies be suspended pending further review and until additional data can be obtained. As a precaution, Acambis has also suspended another, smaller study vaccinating individuals with ACAM2000 and DryvaxA'.
http://www.highbeam.com/doc/1G1-115255261.html

Dermatology Nursing August 1, 2004
Although the last natural reported cases of smallpox occurred in the late 1970s, concerns that it could be revived as a biological weapon led to the initiation of the federal smallpox preparedness program carried out in 2003. The February 2004 issue of *Dermatology Times* described the two components of the plan, which are vaccination of military personnel, and limited vaccination of medical workers, public health workers, nurses, and other "key responders" who will evaluate smallpox cases, and initiate control measures, if necessary.
Health care and public-health workers reported few of the negative effects historically associated with smallpox, but unexpected cardiac …

Warning Links Dryvax, Heart Inflammation

AP Online November 12, 2004
Wyeth Pharmaceuticals Inc. will add black box warnings linking its smallpox vaccine to heart inflammation, the government announced Friday.

Healthy adults given Dryvax vaccine suffered acute myopericarditis - inflammation of the heart and its surrounding sac - says the warning approved by the Food and Drug Administration.

Wyeth spokesman Doug Petkus said the company no longer manufactures or markets the smallpox vaccine. The vaccine had remained in storage since the 1980s. After Sept. 11 domestic terrorist attacks, the government asked Wyeth to test the smallpox vaccine to ensure it … **http://www.highbeam.com/doc/1P1-102407460.html**

"Neurologic Adverse Events Associated With Smallpox Vaccination in the United States, 2002-2004"
"Serious neurologic adverse events, such as postvaccinal encephalitis, Bells palsy, and Guillain-Barré syndrome, occurred in accordance with expected ranges."
James J. Sejvar, MD, *JAMA :94:2744-2750* -- 1/1/2005

Smallpox Vaccine and Adverse Reproductive Health Outcomes in Military Service Members"
"As a live virus product, smallpox vaccine has resulted in fetal vaccinia when administered to pregnant women. This perinatal infection most often results in pregnancy loss or neonatal death; .. At least as concerning as pregnancy loss, and increased risk of birth defects can be extraordinarily alarming to prospective parents. Smallpox vaccination given during pregnancy has been associated with birth defects, specifically club foot malformations..."
Ryan, Margaret A, *NAVAL HEALTH RESEARCH CENTER SAN DIEGO CA* -- 1/1/2005

“Smallpox Vaccine and Adverse Reproductive Health Outcomes in Military Service Members"
"Currently, with the exception of the passive Vaccine Adverse Event Reporting System (VAERS) for short-term outcomes, there is no structured system to evaluate reproductive health effects of vaccinations."
Ryan, Margaret A, *NAVAL HEALTH RESEARCH CENTER SAN DIEGO CA* -- 1/1/2005

"Adverse Events Associated With Smallpox Vaccination in the United States, January-October 2003"
"Results… A total of 590 adverse events (72%) were reported within 14 days of vaccination… One hundred adverse events (12%) were designated as serious, resulting in 85 hospitalizations, 2 permanent disabilities, 10 life-threatening illnesses, and 3 deaths."
Christine G. Casey, et al, *JAMA. 294:2734-2743* -- 10/1/2005

"Frequency of Adverse Events after Vaccination with Different Vaccinia Strains."
"CONCLUSIONS: Previous analyses of smallpox vaccination policies, which rely on the commonly assumed value of one death per million vaccinations, may give serious underestimates of the number of deaths resulting from vaccination."
Kretzschmar M, et al, *PloS Med; 3(8)* -- 8/22/2006

"Adverse Reactions: Adverse reactions caused by smallpox vaccination range from mild and self-limited to severe and life-threatening. Certain smallpox vaccine reactions are similar to those caused by other vaccines (e.g., high fever, anaphylaxis, and erythema multiforme [EM]). Other adverse reactions specific to

smallpox vaccination include inadvertent inoculation, ocular vaccinia, generalized vaccinia (GV), eczema vaccinatum (EV), progressive vaccinia (PV), postvaccinial encephalopathy (PVE) and encephalomyelitis (PVEM), and fetal vaccinia. Vaccinia-specific complications can occur among vaccinees or their contacts who have been inadvertently inoculated with vaccinia."

"Other Vaccine-Specific Adverse Events: Less frequently reported adverse events temporally associated with after smallpox vaccination include myocarditis, pericarditis, precipitation of erythema nodosum leprosum or neuritis among leprosy patients, and osteomyelitis (sometimes confirmed by recovery of vaccinia virus). Reported skin changes at the vaccination scar have included malignant tumors (e.g., melanoma, discoid lupus, and localized myxedema as a symptom of Graves disease). Reported neurologic complications after smallpox vaccination include transverse myelitis, seizures, paralysis, polyneuritis, and brachial neuritis. "
***National Guidelines Clearinghouse* -- 3/21/2007**

Article: FDA Panelists Cast Favorable Votes For Smallpox Vaccine.

BIOWORLD May 18, 2007
GAITHERSBURG, Md. - The FDA's Vaccines and Related Biological Products Advisory Committee voted 11-0 that Acambis plcs's smallpox vaccine ACAM2000 is safe and effective for use in high-risk situations.
That's in line with the company's biologics license application to use the live vaccinia virus product in those types of settings, including use by the military, first-responders or health care workers. It's not designed for sale to the general public, although the Department of Health and Human Services (HHS) considers smallpox a potentially major bioterror threat.
"As long as variola virus exists anywhere, there will be the need to have a smallpox vaccine," said John Neff of the Seattle Children's Hospital and …
http://www.highbeam.com/doc/1G1-163496109.html

"FDA approves Acambis smallpox vaccine"
"The FDA said there are serious safety concerns associated with smallpox vaccines. In clinical studies, about 1 in 175 healthy adults who received the vaccine for the first time developed inflammation and swelling of the heart, or myopericarditis, and/or surrounding tissues, which can be fatal in severe cases."
Corbett J, *MarketWatch* -- 9/1/2007

Smallpox vaccination and ischemic coronary events in healthy adults."
"Although smallpox vaccine-associated myopericarditis has been reported, the risk of cardiac ischemic events remains uncertain. "
Eckart RE, et al, *Vaccine.;25(50):8359-64. Epub 2007 Oct 17.* -- 12/5/2007

"Occurrence of a basal cell carcinoma and dermatofibroma in a smallpox vaccination scar."
Curry JL, et al, *Dermatol Surg.;34(1):132-3; discussion 133-4.* -- 1/1/2008

"Persistence of vaccinia at the site of smallpox vaccination."
"Persistence of vaccinia at vaccination sites may help determine the risk associated with secondary transmission. Culture, PCR, and antigen detection

were performed on serial vaccination site swab specimens. On day 21 after vaccination, 37% of volunteers were culture positive, most of whom had received vaccine for the first time."
Cummings JF, et al, *Clin Infect Dis.;46(1):101-2.* -- 1/1/2008

"Occurrence of a basal cell carcinoma and dermatofibroma in a smallpox vaccination scar."
Curry JL, et al, *Dermatol Surg.;34(1):132-3; discussion 133-4.* -- 1/1/2008

“Mystery Of Potentially Fatal Reaction To Smallpox Vaccine Solved"
"Researchers from the La Jolla Institute for Allergy & Immunology have pinpointed the cellular defect that increases the likelihood, among eczema sufferers, of developing eczema vaccinatum, a severe and potentially fatal reaction to the smallpox vaccine. The research, conducted in mouse models, was funded under a special research network created by the National Institutes of Health in 2004. "
***ScienceDaily* -- 5/25/2009**

Investigators at Emory University release new data on immunization.
Bioterrorism Week July 27, 2009
According to recent research from the United States, "In 2002, the US Federal government initiated a campaign to vaccinate military personnel and members of the civilian population against smallpox to counter a possible bioterrorism attack. More than 1,200,000 military personnel and approximately 40,000 civilians have been vaccinated since that time."

"The incidence of myopericarditis in these vaccinees has clearly exceeded calculated background rates and has prompted discussion about cardiac inflammation and other potential vaccine-associated cardiac complications such as dilated cardiomyopathy (DCM) and myocardial ischemia.
http://www.highbeam.com/doc/1G1-204242489.html

As you will have seen from the above references, the smallpox vaccine has been associated, in peer review journals, with fatal myocarditis, diabetes insipidus, purulent meningitides, encephalopathy, neuromyelitis optica: severe demyelination, cytogenetic characteristics, plexus paresis, skin changes, leiomyosarcoma, Folliculitis, dermatofibrosarcoma protuberans, malignant tumours, postvaccinal encephalitis, Bells palsy, Guillain-Barré syndrome, pregnancy loss, neonatal death, birth deformities, nodosum leprosum or neuritis among leprosy patients, and osteomyelitis (sometimes confirmed by recovery of vaccinia virus). Reported skin changes at the vaccination scar have included malignant tumours (e.g., melanoma, discoid lupus, and localized myxedema as a symptom of Graves disease). Reported neurologic complications after smallpox vaccination include transverse myelitis, seizures, paralysis, polyneuritis, and brachial neuritis. Death is an oft-reported sequel in these reports.

QUESTION TO THE VMD:

What we don't understand, and perhaps the VMD is able to explain, is why adverse events associated with the smallpox vaccine have been recorded up to 2009, when the global eradication of smallpox was certified, based on intense verification activities, by a commission of eminent scientists on 9 December 1979 and subsequently endorsed by the World Health Assembly on 8 May 1980?

Bioterrorism was said by our governments to be imminent but it never happened. Meanwhile, citizens lined up to receive a vaccine that has been shown to cause myopericarditis in about 1 in 175 people who received the vaccine – not to mention the other potential adverse effects. Were they warned, or is the general public just supposed to do as the man in the white coat tells them?

We were also interested to learn that smallpox is considered to be the only human infectious disease to have been eradicated and that whilst the vaccine programme is lauded as the hero of this eradication, "ring vaccination" was enforced. Infected individuals were quarantined and contained, stopping the transmission of the disease. This is, of course, how the bubonic plague was eradicated before vaccines were invented, and how the failed rabies vaccination experiment was rescued in the Serengeti.

One study, **Neurologic Adverse Events Associated With Smallpox Vaccination in the United States, 2002-2004,** *JAMA.* 2005;294:2744-2750, stated:

> **Results** Between December 16, 2002, and March 11, 2004, 214 neurologic adverse events temporally associated with smallpox vaccination were reported; 111 reports involved Department of Health and Human Services and 103 involved Department of Defense vaccinees. Fifty-four percent of these events occurred within 1 week of vaccination, and 53% were among primary vaccinees. The most common neurologic adverse event was headache (95 cases), followed by non-serious limb paresthesias (n = 17) or pain (n = 13) and dizziness or vertigo (n = 13). Serious neurologic adverse events included 13 cases of suspected meningitis, 3 cases of suspected encephalitis or myelitis, 11 cases of Bell palsy, 8 seizures (including 1 death), and 3 cases of Guillain-Barré syndrome. Among these 39 events, 27 (69%) occurred in primary vaccinees and all but 2 occurred within 12 days of vaccination.
>
> **Conclusions** During the 2002-2004 smallpox vaccination campaign, reported neurologic events were generally mild and self-limited, and no neurologic syndrome was identified at a rate above baseline estimates. Serious neurologic adverse events, such as postvaccinal encephalitis, Bells palsy, and Guillain-Barré syndrome, occurred in accordance with expected ranges.

Language such as that used in the above report – “within expected ranges” - raises a number of moral questions, which relate directly to the unnecessary and potentially harmful vaccines given to our pets.

- Were vaccine subjects warned of the potential adverse effects?
- Were the vaccine subjects given a choice as to whether they received this vaccine?
- Adverse reactions are expected?
- Who decides what is acceptable on behalf of vaccinees?
- Does the VMD use similar language in relation to deaths and illnesses relating to unnecessary pet vaccines? Are our pets just statistics?

OTHER VACCINES FOR HUMANS – THE SAFETY RECORD

We seek with the following small selection of scientific references to convey some of the established and known scientific data with regard to vaccine adverse events in the human field (since your position document made use of human vaccine data in order to justify the vaccine schedules applied to dogs, cats and other animals in the UK).

Seeing the studies below, it is clear that all vaccines carry the risk of serious adverse effects. We urge caution in the re-administration of any vaccine, and particularly those administered to companion animals when the principle of lifelong DOI has been established in both dogs and cats.

We point out that all of these vaccine adverse events were recorded and identified after the vaccine products had undergone "rigorous quality and safety tests" according to their own licensing procedures.

These studies illustrate the experimental nature of the vaccine process, and the fact that governments, scientists, and vaccine manufacturers - and not citizens – assume authority for the risks associated with vaccination, but rarely the responsibility. We pet owners are the ones who sit with our friends as they die. We are the ones who pay the vet bills, usually ignorant of the fact that vaccines made our pets ill. We deserve to be given honest information about duration of immunity, and our pets do not deserve to be put at risk by unnecessary vaccines.

The fact that legislators and vaccine manufacturers escape from responsibility is evidenced by the known under-reporting of vaccine adverse events, which the VMD concedes in its position document. In the case of companion animals, there are no vaccine damage compensation schemes. Pet owners whose dogs are damaged by vaccines are reliant upon discretionary financial handouts from vaccine manufacturers which frequently require them to sign gagging orders, or they are forced to resort to law.

As the law stands in the UK, a pet is worth no more than a piece of furniture, and pet owners would be required to take on the financial might of international pharmaceutical companies in order to have it recorded that their family friends were damaged by a vaccine. Further, the science is such that unless someone has taken the trouble to prepare a peer-reviewed study on what is otherwise termed an 'anecdote', the pet's death is in vain.

The vaccine process is inherently associated with risk.

No vaccine is entirely safe

The following adverse event reports and journal articles illustrate the myriad known sequelae to vaccines. They also relate to many different vaccine products. Despite rigorous testing before products are released, vaccines retain their risks once out in the field. Once again, consider the repetitive nature of these reports**:**

"Very rarely, yellow fever vaccine-associated neurotrpic disease (YEL-AND) has been reported following vaccination, with sequelae or with fatal outcomes in some cases. Clinical features have appeared within one month of vaccination and include high fever with headache that may progress to include one or more of the following: confusion, encephalitis/encephalopathy, meningitis, focal neurological deficits, or Guillain Barre syndrome."
Package insert, *Sanofi Pasteur, Manufacturer* -- 1/1/1900

"Coincidence of virus encephalitis and measles-mumps vaccination"
"A 15-month-old girl developed meningoencephalitis 7 days after measles/mumps vaccination, and died 3 days later. "
Jorch, G. et al, *Monatsschr Kinderheilkd 1984; 132(5):299-300* -- 1/1/1900

"Relapsing Neuropathy due to tetanus toxoid."
"Summary: A unique case history is presented of a 42-year-old patient who has suffered three episodes of a demyelinating neuropathy, each of which followed an injection of tetanus toxoid."
Pollard, JD; Selby, G, *Journal of the Neurological Sciences, 1978, 37: 113-125* -- 1/1/1900

"But Doctor, About That Shot...The Risks of Immunizations and How to Avoid Them"
"Complications occurring following tetanus vaccinations include: high fever, pain, recurrent abscess formation, inner ear nerve damage, demyelinating neuropathy (degenerative condition of the nervous system), each of which followed an injections of tetanus toxoid." **Robert S. Mendelsohn, M.D., *Journal of Neurological Sciences, 1978* -- 1/1/1900**

"Optic neuritis and myelitis following rubella vaccination"
Kline L, Margulies SL, *Arch Neurol 1982;39:443-4* -- 1/1/1900

"A case of fatal tuberculous meningoencephalitis after typhoid-paratyphoid vaccination."
Camba R, *Rass Med Sarda;55(5-6):186-96.* -- 5/1/1953

"Etiology of acute encephalomyelitis after rabies vaccination."
Piskareva NA, *Vopr Virusol; 1(6):47-50.* -- 11/1/1956

"Experimental studies on paralysis after antirabies vaccination. I. Histological studies on acute demyelinating encephalomyelitis in guinea pigs."
Shiina T, et al, *Jpn J Microbiol; 2(2):187-96.* -- 4/1/1958

"Clinical picture of postvaccinal encephalitis after rabies vaccination and sequelae."
Uchimaura Y, et al, *Nervenarzt; 29(7): 303-7.* -- 7/1/1958

"Encephalitis after yellow fever vaccination"
"…is concluded that there is a cause and effect relationship between the administration of yellow fever vaccine and the occurrence of subsequent encephalitis in this infant."
Morris Feitel M.D, *Pediatrics Vol. 25 No. 6, pp. 956-958* -- 6/1/1960

"Death of an infant in hyperthermia after vaccination"
"Death following hyperpyrexia and coma of rapid onset nine days after vaccination of an infant is reported. Death appeared to be due to overwhelming vaccinial infection without encephalitis."
Apostolov, K., et al, *J Clin Pathol. 14(2): 196–197* -- 3/1/1961

"On a Case of Benign Acute Cerebellar Ataxia in Childhood."
Provvidenza, G et al, Arch Ital Sci Med Trop, 43:189-194 -- 4/1/1962

"Transient cerebellar ataxia following the administration of attenuated oral antipoliomelitis vaccine (Sabin types II and III)."
Colarizi A, et al, Riv Ist Sieroter Ital.; 38:1-12. -- 1/1/1963

"2 cases of hypoglycemic coma in the immediate sequelae of vaccination."
Sirand L, *Pediatrie. 1963; 18:581-2.* -- 1/1/1963

"Myelitis as a complication following rabies vaccination."
Gospavic J, et al, Srp Arh Celok Lek; 91:141-8. -- 2/1/1963

"Coma revealing an acute leukosis in a child, 15 days after an oral antipoliomyelitis vaccination. Anatomoclinical study and reflections on cerebral lesions in acute leukoses"
Castan P and Dehing, J, *Acta Neurol Bekq, ,65:349-367* -- 5/1/1965

"Multiple sclerosis and vaccination."
Miller H, et al, *Br Med J.; 2(5546): 210-3.* -- 4/1/1967

"The management of meningoencephalitis following rabies vaccination"
Klemm D, et al, *Med Klin;63(34):1354.* -- 8/1/1968

"Morphological changes in the central nervous system in post-vaccinal encephalomyelitis developing after chickenpox vaccination in children"
Ravkina LI, et al, *Zh Nevropatol Psikhiatr Im S S Korsakova. 1970; 70(10): 1465-71.* -- 1/1/1970

36. "Incomplete transverse myelitis following rabies duck embryo vaccination."
Harrington RB, et al, JAMA; 216(13):2137-8. -- 6/1/1971

"Encephalitis after rabies vaccination"
Kreiner R, Seege D, *Psychiatr Neurol Med Psychol (Leipz); 23(9): 532-6.* -- 9/1/1971

"Meningomyelitis after rabies vaccination. Apropos of 3 cases"
Giordano C, et al, Med Trop (Mars); 32(4):483-92. -- 7/1/1972

"Further Studies of a Simian Virus 40-Like Virus Isolated from Human Brain"
"A virus similar to simian virus 40 was reisolated from brain homogenates of a patient with progressive multifocal leukoencephalopathy onto cultures of human fetal brain cells."
L. P. Weiner, *J Virol.;10(1): 147-149* -- 7/1/1972

"Relapsing encephalomyelitis following the use of influenza vaccine"
Yahr MD and Lobo-Antunes, J, *Arch Neurol. 27(2):182-3.* -- 8/1/1972
"Hyperacute Allergic Encephalomyelitis: A localised form produced by passive transfer and pertussis vaccine."
"Blockade of histamine H1 receptors may reduce mortality in pertussis immunisation-induced encephalopathy in mice."
Levine,S et al, *American Journal of Pathology; 73:247-260* -- 1/1/1973

"Panencephalitis Following Measles Vaccination."
Cho, CT, et al, *JAMA, 224:1299* -- 5/28/1973

"Encephalitis after administration of live measles vaccine"
"In a previously well child with no evidence of pre-existing immunologic defect a fatal encephalitis developed 10 days after administration of measles vaccine."
F. Jagdis, et al, *Canadian Medical Association Journal, Vol 112, Issue 8 972-975* -- 1/1/1975

"Letter: Vaccinations in chronic myelosis?"
Mohr W, Dtsch Med Wochenschr 12; 101(11):430. -- 3/1/1976

"Transverse myelitis after diphtheria, tetanus, and polio immunisation. "
Whittle E, et al, Br Med J.; 1(6074): 1450. -- 6/1/1977

"Relapsing neuropathy due to tetanus toxoid. Report of a case."
"A unique case history is presented, of a 42-year-old patient who has suffered three episodes of a demyelinating neuropathy, each of which followed an injection of tetanus toxoid. "
Pollard JD, et al, J Neurol Sci.; 37(1-2): 113-25. -- 6/1/1978

"Meningoencephalitic syndrome following influenza vaccination"
"Immunological reactions to non-virus substances of vaccines may be of considerable significance in the pathogenesis of neurological complications after anti-influenza vaccination. A 60 year old female patient with a known allergic diathesis developed a meningoencephalitic syndrome a few hours after vaccination. "
W. L. Gross, et al, *Journal of Neurology Volume 217, Number 3 / 219-222* -- 9/1/1978

"Acute Meningoencephalitis Immediately after an Influenza Vaccination."
Froissart, M. et al, *Lille Med, 23(8):548-551* -- 10/1/1978

"Neurological complications following measles virus vaccination. Evaluation of the cases seen between 1971--1977"
"Within 11 days following vaccination with live virus vaccine in Hamburg 18 cases of neurological complications have been observed between 1971--1977, including 2 cases of abortive encephalitis."
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"Chinese police haul off "bad vaccine" protesters"
"Chinese police hauled off a small group of people on Thursday who… say that their children were vaccinated against Japanese encephalitis B in 2003 in the southern province of Guangdong, and that the vaccine has paralysed their sons and daughters. We were taken away by the police a little while ago, Liang Yongli, father of one of the children, told Reuters by mobile telephone. I don't know where we are but there seem to be lots of people like us here. "
Staff, *Reuters* -- 8/17/2006

"Poliomyelitis: A Case Report of Flaccid Monoparesis after Oral Polio Vaccine"
"This report describes a case of acute flaccid paralysis after administration of oral polio vaccine (OPV). A 4 month-old male patient with the decreased movement of left lower extremity for 1 month was transferred to the Department of Pediatrics. He received OPV with DTaP at 2 months of age. Flaccid paralysis was detected 4 weeks after OPV immunization."
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"Neurologic disease associated with 17D-204 yellow fever vaccination: a report of 15 cases."
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"Nigeria fights rare vaccine-derived polio outbreak"
"Nigeria is fighting a rare outbreak of vaccine-derived polio after 69 children caught the paralysing disease from others who had already been immunised, the World Health Organisation said on Monday."
MacInnis L, *Reuters* -- 10/8/2007

"Safety of Varicella Vaccine after Licensure in the United States: Experience from Reports to the Vaccine Adverse Event Reporting System, 1995–2005"
"There were 25,306 adverse events reported (52.7/100,000 doses distributed); 5.0% were classified as serious (2.6/100,000 doses distributed). Adverse events associated with evidence of vaccine strain VZV included meningitis in patients with concurrent herpes zoster."
Chaves, SS, et al., *The Journal of Infectious Diseases 197:S170–S177* -- 1/1/2008

"Vaccine Court: Hepatitis B Shot Caused MS"
"But another omnibus proceeding involving Hepatitis B vaccine and autoimmune disorders in adults, including MS, has already been quietly ruling in favor of several petitioners. The most recent case was announced about a week ago. In it, the Court ruled that the victim, an adult female, had contracted a form of demyelinating disease and MS, and eventually died, after receiving the Hepatitis B vaccine series."
Kirby, D, *Age of Autism* -- 2/3/2009

> **(NaturalNews)** May 2010
> http://www.naturalnews.com/028773_vaccines_convulsions.html
>
> Studies financed by pharmaceutical corporations and government agencies - which are now largely under the control of big pharma - keep stating that there is no link between autism and vaccinations or thimerosal.
>
> As a previous News Target article, http://www.NaturalNews.com/022237.html) *Dissecting A Thimerosal Study* demonstrates, these studies are often tainted by their funding. Nonetheless, parents find themselves under tremendous pressure, both overt and subtle, to have their children vaccinated, in spite of little or no documentation showing efficacy, let alone safety. Worse, information produced by the American Medical Association clearly demonstrates that vaccinations have done nothing to increase longevity, and may have caused increases in deaths from disease.

Vaccination's Smoking Gun

More dramatic, though, is a virtual smoking gun - a study showing a clear connection between neurological disorders and vaccinations. The results are dramatic, showing that more than twice the number of vaccinated children had autism than those who had not been vaccinated. Worse, the rates of vaccinated children with other neurological problems are even higher.

Done in June 2007, the study was financed by Generation Rescue, a group of families with autistic children who have been working to find out why this has happened to their youngsters and how to help them. The study itself is a survey of 11,817 California and Oregon households, with a total of 17,674 children, 991 of whom had never been vaccinated. It was produced by SurveyUSA, an independent company.

The SurveyUSA Study

There seems little likelihood of bias in favor of results showing a link between vaccinations and autism, as SurveyUSA includes several pharmaceutical firms among its clientele, including Abbott Laboratories, Alcon Laboratories, AstraZeneca Pharmaceuticals, Bayer Corporation, GlaxoSmithKline, Merck Laboratories, Monsanto Company, Nexium, Pfizer, and Schering Plough — all documented in the SurveyUSA list of clients http://www.surveyusa.com/index.php/...). If SurveyUSA has a bias, it must be in favor of the pharmaceutical corporations. Yet, this study shows a result that does not benefit any of these businesses.

The Study's Methodology

Nine counties in California and Oregon were selected for the study.

Target households were those with children ages 4 through 17. Data were gathered for 9,175 boys and 8,499 girls. Information elicited whether each child had been vaccinated and, vaccinated or not, whether the child had one or more of the following disorders:

* Attention deficit disorder
* Attention deficit hyperactivity disorder
* Asperger's syndrome
* Pervasive developmental disorder - not otherwise specified
* Autism
* Asthma
* Juvenile diabetes

Data were analyzed according to sex and county, and broken down by age ranges 4 through 10 and 11 through 17. Percentages of children with these disorders were noted according to whether they'd been vaccinated or not, and the correlation between the two numbers, called the Risk Ratio (RR), was calculated.

The RR is a simple calculation that compares the percentage of vaccinated to unvaccinated children with each disorder. Thus, if 4.5% of vaccinated children have Asperger's and 2.7% of non-vaccinated children have the same disease, the RR is 4.5% divided by 2.7%, giving an RR value of 1.67. (4.5/2.7 = 1.67) Thus, an RR over 1.0 indicates that vaccinations are related to a higher disease incidence, and an RR under 1.0 indicate that vaccinations are related to a lower disease incidence.

All results of the study were tabulated and have been made available to the public to assure complete transparency (www.generationrescue.org/pdf) In other words, no attempt has been made to hide or otherwise manipulate the data.

The survey was automated, thus eliminating any chance that an individual might mislead a respondent. Responses were given via telephone touchpads. This is also the manner that the Centers for Disease Control says is most accurate. The survey questions used in Sonoma County can be found here (http://www.generationrescue.org/pdf...). In my reading of the survey, there is no language that could indicate a desired response either for or against vaccinations.

Survey Results

The results are stunning. The data shows dramatic increases in neurological diseases and asthma in vaccinated children. Generation Rescue is cautious in its interpretations. They have taken a humble position, saying that, "We are a small non-profit organization. For less than $200,000, we were able to complete a study that the CDC, with an $8 billion a year budget, has been unable or unwilling to do. We think the results of our survey lend credibility to the urgent need to do a larger scale study to compare vaccinated and unvaccinated children for neuro-developmental outcomes."

On the other hand, a survey, taken randomly from 17,674 children and focused on nine counties in various areas separated by hundreds of miles, is a significant number by itself. Unless the CDC should do an equivalent study, done with the same rigor, over a larger population, then this one must stand as nothing less than a smoking gun for the link between childhood vaccinations and neurological disorders, plus asthma. The only disease in the survey that did not show an increase associated with vaccination was juvenile diabetes.

Results Summary

Vaccinated boys:

* Neurological disorder, RR = 2.55 (155% more likely to have neurological disorder than unvaccinated boys)

* ADHD, RR = 3.24 (224% more likely to have ADHD than unvaccinated boys)

* Autism, RR = 1.61 (61% more likely to have autism than unvaccinated boys)

Vaccinated boys ages 11-17:

* Neurological disorder, RR = 2.58 (158% more likely to have neurological disorder than unvaccinated boys)

* ADHD, RR = 4.17 (317% more likely to have ADHD than unvaccinated boys)

* Autism, RR = 2.12 (112% more likely to have autism than unvaccinated boys)

The study notes that older children are more likely to have been diagnosed with a neurological disorder, because such diagnoses are often missed in younger children. Therefore, this is likely the more accurate figure.

All vaccinated boys and girls were 120% more likely to have asthma than unvaccinated children (RR = 2.20).

Vaccinated girls showed no significant difference from unvaccinated girls in neurological disorders. Whether this is due to the relatively small number of girls with these same disorders or because of the relatively small number of girls with such disorders in the study is unknown.

Conclusion: Stop Vaccinating Our Children!

What more do you need to know? This study shows a clear link between neurological disorders and vaccinations. It indicates that autism rates may be more than double in vaccinated boys than in those who were not vaccinated.

The question needs to be asked: Why doesn't the CDC or the FDA or the AMA do a large-scale equivalent study to determine whether the pharmaceutically-funded studies are valid? The methodology is simple, and it adheres to the techniques that the CDC has approved. Rather than continuing to spend huge amounts of money on clearly flawed studies to placate the pharmaceutical corporations and give a false sense of security to parents, it's time for these organizations to put their money where their mouth is. It's well past time for them to use Generation Rescue's methods on a national scale. This is the sort of study that can definitively show whether there's a link between neurological disorders and vaccinations.

Until these agencies produce such a study, it's time for them to stop forcing vaccinations on our children. Let them try to prove, using transparent studies in which all children of all families contacted are included, without exception, unlike the recent one documented in

Dissecting A Thimerosal Study (http://www.NaturalNews.com/022237.html), in which the vast majority of children were eliminated for specious reasons. Until they're willing to do this, they must stop destroying the lives of our young for their profits.

News Reports come in about vaccine failings and adverse effects with almost boring repetition. They begin in the early days of vaccination, and continue to this day.

http://www.watoday.com.au/wa-news/flu-vaccination-ban-goes-national-after-fever-convulsions-in-children-20100423-tglp.html:

Flu vaccination ban goes national after fever, convulsions in children
Australia, April 23, 2010

Doctors are being advised to stop giving the flu vaccine to children. Seasonal flu vaccinations across Australia for children under five have been suspended after 23 children in Western Australia were admitted to hospital with convulsions following their injections. One child, aged 1, remains in a coma in a Perth hospital.

Commonwealth chief health officer Professor Jim Bishop yesterday announced the suspension while authorities urgently review data from around the country. WA's chief public health officer Tarun Weeramanthri has defended the response time in closing down the state's juvenile flu vaccine program amid revelations that children were presenting with convulsions.

More than 60 children around the state may have had adverse reactions to the vaccine, including fevers, vomiting and febrile convulsions - a type of fit brought on by a high fever. One child remains in a critical condition in hospital after being given the vaccine. Dr Weeramanthri said he had few details on the child's condition but they were "seriously ill".

He said a national process set by the Therapeutic Goods Administration had been observed in responding to the reactions. Under the process the best clinical information was collected from as many doctors as possible and an assessment made on the "totality of that".

"We take all reports very seriously and we believe we've acted in a very timely fashion," Dr Weeramanthri said.

"We've been monitoring the situation, we've been talking to clinicians and we've acted as soon as we can."

He said that since this year's vaccine program started a month ago, 23 children under the age of 10 had presented to Princess Margaret Hospital with convulsions related to vaccinations they had received less than 12 hours before.

Another 40 convulsion cases had been detected in the past month in children at other metropolitan hospitals and in Bunbury. Doctors are now working to determine how many of those children received the flu vaccine.
Aside from the convulsions, affected children were suffering fever and vomiting within 12 hours of their flu shots.

A teleconference today with state, territory and TGA officials confirmed the picture in other states would not be available for "a few days".

Dr Weeramanthri said the TGA was assessing the geographical spread of symptoms across Australia, and directly testing batches of vaccine for any impurity.

Rogue batch may be to blame

Health authorities are also working to determine if the entire Fluvax drug, or just batches, have caused the symptoms, and whether an alternative vaccine should be used.

University of Western Australia school of Paediatrics and Child Health Associate Professor Peter Richmond said that only Fluvax - produced by Australia's biggest biopharmaceutical company CSL - was being used to vaccinate children in WA.

Dr Richmond said researchers were trying to determine whether it was the entire vaccine, or just batches, that had caused the problems which today prompted Australia's chief medical officer to tell doctors to stop giving the vaccine to children.

He said the side effects had been largely limited to children under the age of five and he would not recommend that anybody in other groups - including elderly people - cancel their flu shots.

"This is not a long-term safety issue with vaccines," Dr Richmond told WAtoday.com.au. He recommended parents of young children who had received only the first of the required two vaccination doses hold off on the second dose for now. This was despite the fact children who had no side effects from their first dose were unlikely to receive complications from their second.

Dr Richmond said the first dose provided partial protection against the flu anyway.

He said researchers were examining whether an alternative drug to Fluvax could be used for the second dose - generally scheduled for four weeks after the first.

Researchers were also trying to determine if the problem with Fluvax was temporary only - and whether the drug could still be used in coming weeks for the second dose.

He stressed that the vast majority of children receiving Fluvax had suffered no complications.

National warning to GPs

Commonwealth chief medical officer Jim Bishop issued a national warning to GPs not to use the vaccine followed a decision last night by the WA government to suspend the free vaccination program for children under five over concerns it was causing high fevers and convulsions.

"We suggest doctors and health professionals vaccinating children don't use the seasonal flu vaccine for the moment, until we can get the Therapeutic Goods Administration (TGA) to investigate this in more detail," Professor Bishop told ABC TV.

He said the concerns stemmed from a significant rise in the number of children developing a fever after receiving the vaccine.

"We need more information about what's happened in WA, but also what we can now find out from all the other states from their experience," Professor Bishop said.

"If this has been brought up as a possible side-effect of this drug, then we ought to at least suspend its use until we know more."
In light of the seasonal flu shot suspension, Professor Bishop suggested children get vaccinated against swine flu instead, because that could be a health risk this winter too.

He said there did not appear to be any side effects from the swine flu vaccine Panvax.

"It is safe to have the swine flu vaccine," Professor Bishop said. "The TGA's assessment of clinical trials and the advice of its expert committees is that Panvax is a safe, effective vaccine for prevention of the H1N1 influenza.

"It is expected that the dominant flu this winter season will be swine flu and the specific Panvax vaccine is available free for all Australians."

'I was petrified'

Perth mother of two Bea Flint said her 11-month-old boy Avery had a seizure after receiving the first dose of the two-dose flu vaccination on Saturday.
Mrs Flint said that after the 9am vaccination she noticed Avery had a minor temperature about 2pm. She treated him with Panadol and by Avery's 7pm bedtime he seemed "OK".

However, at 7.45pm, Avery started whimpering and moaning. When Mrs Flint got to his cot the baby had vomited and was lying on his side having a seizure. "In the car driving to the hospital he was just whimpering," she said.
"He couldn't cry - his head was hanging down in the car seat and he couldn't move. I was petrified - it was one of the worst experiences of my life."

By the time Avery arrived at St John of God Hospital in Murdoch, he was burning up with a fever of 39.5 degrees. The doctor who treated Avery told Mrs Flint her baby was the fifth child with similar symptoms admitted to the hospital that day.

WA vaccine program suspended

Health Minister Kim Hames last night advised of the state-wide suspension as a precautionary measure. He said the suspension came after a significant rise in the number of children who had developed a high temperature after receiving the vaccine. He said some children had gone into febrile convulsions, a fit caused by a high fever, following the vaccinations.

Dr Hames said it was unclear if the fevers were related to the influenza vaccination but the precautionary measure was the most responsible course of action. Fevers in most instances are treatable.

"People should give Paracetamol according to the instructions and tepid sponging to keep the temperature down." Dr Hames said.
"On rare occasions children can have a convulsion as the result of the high temperature and sometimes that can be prolonged, which can be a risk to the child."

He said parents should not take children under the age of five to be vaccinated against influenza until further notice.

17th May 2010, from the Indian Express:

Villagers of Shaikhpara at Gajol in Malda district staged protests today following the death of two infants who received DPT and BCG vaccines at the Sheikpara Sub-Health Centre two days ago.

Nazeer Ansari (3) and Rohan Reza (6) were vaccinated along with eight other children, who all fell ill after that.

On Thursday, five of them were admitted with high fever at Gajol Rural Hospital and the rest were released after preliminary treatment. Of them, Nazeer and Rohan were referred to Malda District Hospital and they died while being brought there.

Wahedullah Shah and Abdul Karim, fathers of Nazeeb and Rohan, said the health worker who usually administers the vaccines at the health centre, was absent that day and one Rehana Khatun was in duty in her place. They said the latter might have mishandled the dosage.

As people demonstrated in front of the hospital, the situation was brought under control by police intervention.

http://www.telegraph.co.uk/health/healthnews/7736958/Babies-should-be-given-MMR-jab-earlier-to-cover-immunity-gap-for-measles.html:

Babies should be given the MMR jab earlier to protect them against measles because of a "gap" in their immunity, new research suggests.

By Richard Alleyne, Science Correspondent
19 May 2010

Researchers have found that natural protection against the disease passed down from their mothers only lasts between one and four months, leaving a window of vulnerability until they are vaccinated at a year old. Now they are recommending that doctors should consider giving the measles, mumps and rubella vaccine earlier especially if it is known there is an outbreak of the potentially fatal disease.

Dr Elke Leuridan, of the University of Antwerp, Belgium, and colleagues said their findings underline the importance of measles vaccination around a child's first birthday and support ongoing research into earlier vaccination.

"This study describes a very early susceptibility to measles in both infants of vaccinated women and women with naturally acquired immunity," they said. “If future studies show measles vaccines can be offered with success at an age of less than nine months, policy-makers could consider moving forward the routine measles vaccination programme."

The study, published in the British Medical Journal, involved 207 healthy women and their babies recruited from five hospitals in Antwerp.

Medical records were analysed and the women divided into two groups – those who were vaccinated against measles as children, and those who had acquired immunity from catching measles.

Levels of measles antibodies were measured from blood samples taken during week 36 of pregnancy, at birth (from umbilical cord blood), and in all babies when they were one, three and 12 months old. The babies were also randomly tested at either six or nine months.

Results showed that vaccinated women had far fewer antibodies than women who were naturally immune.

The babies of vaccinated women also had significantly lower antibody levels than those of naturally immune women.

In the group of babies, maternal antibodies typically lasted for 2.61 months on average. The figure was 3.78 months for infants of naturally immune women and 0.97 months for babies of vaccinated women.
At six months old, more than 99 per cent of babies of vaccinated women and 95% of babies of naturally immune women had lost the protection from their mother's antibodies.

> Aged nine and 12 months, no babies had any levels of protection. The MMR jab is given in two doses to ensure immunity. The most recent figures show 92.1 per cent of youngsters have had their first dose of MMR but only 83.2 per cent have had their second.
>
> Uptake is therefore below the 95 per cent level recommended by the World Health Organisation to prevent outbreaks of disease.
>
> In 1996, two years before MMR was linked to autism in controversial medical research, there were just 112 cases of measles in England and Wales.
>
> By 2008 this figure had jumped to 1,370, and to 1,144 cases in 2009. In the latest study, breastfeeding, birth weight, educational level of mothers and whether the babies were in day care or had been delivered by Caesarean had no significant impact on the results.
>
> The researchers found no significant impact of breastfeeding, birth weight, educational level, caesarean section or day care attendance on the duration of maternal antibodies.
>
> They suggested that at the moment early vaccination should be considered during an outbreak or after contact with siblings with measles, and for infants travelling or migrating to endemic areas.
>
> "Most importantly, we confirm the extreme importance of timely administration of the first dose of measles vaccine," they added.

It is interesting that, rather than concluding that the measles vaccine is lowering immunity against measles in successive generations, researchers suggest that babies are vaccinated earlier! This is despite scientific studies which show that the MMR jab is associated with neurological impairment.

In the field of human medicine, the recent swine flu debacle illustrates public concern, voiced by the press around the world:

> Like the Avian Flu before it, the ‘swine flu epidemic’ proved to be nothing like they predicted. Far from being an epidemic, it wasn’t any different to regular seasonal flu.
>
> Meanwhile, governments around the world have handed billions over to the pharmaceutical industry in a sort of reverse tax bonus for vaccine manufacturers.
>
> Substantial numbers of people and groups around the world refused the swine flu shot.
>
> BBC News reported during December that plans to vaccinate children under the age of five against swine flu were in disarray after doctors refused to sign up to the deal because it would leave them out of pocket. Record numbers of doctors and nurses refused the shot for themselves.

According to Kyodo News, the Japanese health ministry planned to launch an investigation into whether or not the H1N1 vaccination can increase the death risk for people with serious chronic diseases. This followed an increased number of reported deaths and serious side-effects amongst people who received their shots.

The ministry said post-vaccination deaths totalled 104, around 80% of whom were people aged 70 or older; nearly 1,900 cases of side-effects were also reported.

In America, Jordan McFarland, a 14-year-old boy from Virginia, was reported to be weak and struggling to walk after coming down with Guillain-Barre syndrome (GBS) within hours of receiving the H1N1 vaccine for swine flu. Jordan left hospital in a wheelchair nearly a week after developing severe headaches, muscle spasms and weakness in his legs following a swine flu shot.

Likewise, a young woman in France was also diagnosed with GBS after a swine flu shot. The woman, identified only as a health worker, was diagnosed with GBS six days after she received the swine flu shot.

Swedish and Chinese health officials also reported a number of serious side effects, including deaths of people who received the H1N1 vaccine.

In China, the Ministry of Health announced that the two people, including one teacher from Hunan province, died hours after receiving their inoculations. Chinese health officials have withdrawn all vaccines from the same batch used to inoculate the teacher.

Fifty-four percent of Chinese residents reported in a *China Daily* survey that they would not get the H1N1 vaccine because of concerns about the shot's safety. Among those inoculated so far in China, more than 1,200 have complained of side effects ranging from sore arms, rashes, and headaches, to anaphylactic shock and sudden drops in blood pressure.

In Atlanta, USA, according to Associated Press, hundreds of thousands of swine flu shots for children were recalled because the vaccines had ‘lost strength’.

The Shots, made by Sanofi-Pasteur, were for children between the ages of six months and three years. Despite the recall, parents were told not to worry, and not to bother doing anything if their children had received the defective shot. “The vaccine is safe and effective,” said Dr Anne Schuchat of the Center for Disease Control.

In February, another manufacturer, Novartis, recalled five lots of seasonal flu vaccine under similar circumstances.

In the UK, according to the Telegraph, the government was preparing to offload millions of unwanted swine flu vaccines as officials predicted there would be no third wave of the ‘pandemic’ this winter. They were also considering whether to

stand down the National Pandemic Flu Service. Fewer than 5,000 people in Britain were thought to have contracted swine flu by the 9th January.

Ministers had signed contracts worth £100 million to deliver 90 million vaccines to Britain.

The government was considering exercising a break clause in its contract with Baxter, which supplies vaccines used by the NHS. There is no such clause in the GlaxoSmithKlein contract but ministers were in discussions with the company about future supplies.

Professor David Salisbury, the Department of Health's director of immunisation, admitted that this still left the problem of vaccines which had already been delivered, but added that the government would keep a stock in case the virus returned. The amount of taxpayer money wasted was considered to be a matter of 'commercial confidentiality'.

A number of other countries, including France, have also announced plans to sell off their surplus vaccines.

Meanwhile the vaccine manufacturers did quite well out of inaccurate pandemic predictions for the fourth quarter of 2009. GlaxoSmithKline made $1.7 billion, Novartis got $700 million, and Sanofi-Aventis pocketed $500 million.

According to Pharma News, the Parliamentary Assembly of the Council of Europe (PACE) planned to hold an emergency debate and inquiry into the "influence" exerted by drug makers on the World Health Organisation's (WHO) global H1N1 flu campaign.

The text of the PACE resolution approved by the Assembly stated: "In order to promote their patented drugs and vaccines against flu, pharmaceutical companies influenced scientists and official agencies responsible for public health standards to alarm governments worldwide and make them squander tight health resources for inefficient vaccine strategies, and needlessly expose millions of healthy people to the risk of an unknown amount of side-effects of insufficiently tested vaccines."

The WHO's "false pandemic" flu campaign is "one of the greatest medicine scandals of the century," according to Dr Wolfgang Wodarg, chairman the PACE Health Committee, who introduced the parliamentary motion. "The definition of an alarming pandemic must not be under the influence of drug-sellers," he said.

Conducting its own analysis, Harvard University concluded that the swine flu 'pandemic' was oversold. The paper suggested that swine flu was unlikely to create a severe epidemic. In light of this, according to the report, officials had taken many steps that may have been unnecessary, including mass vaccinations.

VACCINES ARE BIG BUSINESS

The general public, were it privy to the information below, and given the chance to compare this information with the seemingly endless stream of adverse reaction reports, would be forgiven for concluding that vaccine policy is more about profit than it is about public health.

> From *FierceBiotech*, the Biotech industry's daily monitor, July 2009:
>
> **"In times of crisis, Big Pharma turns to vaccines"**
>
> "Long being regarded as an unattractive market, vaccines have re-emerged as successful growth driver for Big Pharma. The launch and rapid uptake of novel, high-price products such as Wyeth's Prevnar or Merck & Co's Gardasil, along with the emergence of novel vaccine technologies and favourable legislation have brought vaccines back into the main focus of pharmaceutical and biotech companies."
>
> According to the *Wall Street Journal*:
>
> **Shares of the world's largest flu vaccine makers rallied Friday afternoon, the day after the World Health Organization declared its first official flu pandemic, for the H1N1 virus, since 1968.**
>
> Large-scale vaccine makers were in sharpest focus, with shares of GlaxoSmithKline PLC, AstraZeneca PLC, Novartis AG and Baxter International all advancing at least 4%. Sanofi-Aventis, another leading manufacturer, saw its shares rise 3%.
>
> Novartis also said on Friday that a test run of its new cell-based vaccine production technology was able to produce a H1N1 vaccine within weeks. Current technologies, which use eggs to culture vaccine, can take up to six months.
>
> Novartis already has one cell-based production plant on-line, in Marburg, Germany. A second plant is under construction in Holly Springs, N.C.
>
> Novartis received culturing batches of the H1N1 virus from the Centers for Disease Control on May 27 and hopes to have initial vaccine batches ready for clinical testing in July.
>
> Savient Pharmaceuticals was the big winner amongst the mid-sized caps, with shares rocketing over 50% to $8.97.

A *Marketwire* report adds to the picture:

“New Report Forecasts More Than Doubling of Vaccine Sales by 2013”
NEW YORK, Jun 11, 2009:

2008 was another stellar year for the world vaccine market. Sales grew 21.5% since 2007 to reach $19.2 billion. Few areas of pharmaceuticals have seen the fast-moving developments in the marketplace that the vaccine market has.

A new report forecasts the market to more than double by 2013 due to a strong pipeline of new products and rising usage of current products around the world.

"New products and better-than-expected profits, as well as merger activity, have transformed the vaccine marketplace," says Bruce Carlson, publisher of Kalorama Information.

Growth is also being fuelled by vaccines that have recently been introduced or are in the approval process that address meningitis, swine flu, malaria, and Japanese encephalitis, as well as a growing number of combination vaccines which are enjoying one of the highest growth rates of any vaccine segment.

Baxter filed a swine flu vaccine process patent a year ahead of the ‘Pandemic’.

Luckily, Novavax hasn’t been left out of the party because:

Novavax shares soar on NIH swine flu agreement

Novavax saw its stock soar 75 percent to a high of $3.26 after the company announced it will be working with the National Institutes of Health to evaluate its first batch of H1N1 vaccine. The National Institute of Allergy and Infectious Disease’s Division of Microbiology and Infectious Diseases unit has agreed to work with Novavax to evaluate the VLP vaccine.

These news reports of course relate to vaccines for humans. The veterinary vaccine business is perhaps small beer in comparison, but it is still a multi-billion industry. It is sufficiently profitable for manufacturers to wish to hold onto their market which, unlike human vaccines, promises profits from **annual** shots.

Added to vaccine profits, one must also consider the business generated for the pharmaceutical industry in providing drugs to treat the illnesses that have been caused by vaccines.

VACCINE ADVERSE EVENT REPORTING – A WOEFUL PICTURE OF FAILURE

In its Position Paper on Authorised Vaccine Schedule for Dogs, the VMD stated, with respect to adverse event reporting:

> **Over 82 million doses of the vaccines currently available on the UK market have been sold for use in dogs since 1985 and there have been less than 7,000 reports of adverse events as a result. It is acknowledged that any pharmacovigilance system is primarily reactive and under-reporting is an inevitable feature.**
>
> **However, under-reporting will apply equally to all products and given that changes in the incidence rates of adverse events are the useful indicators of issues which need to be investigated, it is the clinical detail in the reports and the trends and patterns of adverse events that are far more important tools in the science of pharmacovigilance. Therefore under-reporting is not a significant issue. Nevertheless, this does not mean increased levels of reporting should not be encouraged.**
>
> **The fact that both immediate and longer term adverse events may occur make the benefits of vaccination for a healthy animal more difficult to assess especially as the prevalence of a disease against which a vaccine will protect may not be measurable with any degree of certainty. In such cases a decision regarding vaccination of a healthy dog is largely a matter of judgement on the part of the owner following advice from their veterinary surgeon. It is acknowledged that more information is needed on the prevalence of canine diseases in the UK to enable veterinary surgeons and their clients to make more meaningful benefit/risk assessments on whether to vaccinate an individual animal.**
>
> **Of the 2,392 Suspect Adverse Reaction (SAR) reports received by the VMD, 25 have been associated with immune mediated complications.**
>
> **The purpose of pharmacovigilance is to protect animal health and to ensure the balance of benefits and risk remains favourable. Adverse reactions to canine vaccines are rare with less than 18.5 reports per 100,000 doses. Whilst acknowledging a level of under reporting that is unquantifiable, the benefits of vaccination are considered significantly greater than the risks of infection of the ever present canine infectious diseases in the UK.**

It is a significant concern that the VMD acknowledges that adverse events are under reported, calls this 'insignificant', and brushes under-reporting off in an attempt to claim that infection poses a greater risk than vaccination. How can the VMD possibly quantify risk versus benefit when the rate of adverse events is unknown, and the rate of disease prevalence in UK dogs is unknown?

The logic of the above statement also appears to deliberately overlook the fact that duration of immunity studies have established the principle that immunity to

core viral disease is long-lived, and that we do not need to vaccinate our dogs every year.

Vaccines are known, scientifically, to cause immune system disruption, the production of autoantibodies which come with significant health implications, heart disease, neurological damage, arthritis, epilepsy, behavioural changes, cancer, leukaemia, and myriad other diseases.

These diseases can begin immediately post-vaccination; they can show overt symptoms within weeks or months of vaccination. They can even become apparent a year or more post-vaccination. Evidence also points towards vaccine damage being visited upon subsequent generations. But we are really vaccinating in the dark: although the science is available to show cause and effect in principle, it cannot always definitively prove that 'this dog's cancer' was vaccine-induced.

Further, there are no scientific tests that are able to confirm that every vaccine-induced illness is, indeed, vaccine-induced.

Therefore the adverse event reporting system is a red herring.

Put another way, its aim is potentially not to quantify vaccine damage but to hide it. The SARSS scheme doesn't stand a chance of delivering a true picture of the effects of vaccination.

The VMD stated in its position paper:

> **… pharmacovigilance which has been defined by the World Health Organisation as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any medicine-related problem…**

By the VMD's own admission, adverse events to vaccination are under-reported. Therefore, the pharmacovigilance as practiced by the VMD cannot be described as a science. (Science: the study of the physical and natural world and phenomena, especially by using systematic observation and experiment.)

If it is openly acknowledged that the data is unavailable, then it is guesswork and estimation – not science. If adverse events are under-reported, and the VMD can only guess at the level of that under-reporting, then it is not science.

These are the problems with the VMD's SARS System:

1. the word 'suspected'.

2. the fact that no-one is compelled to submit an adverse event report, except vaccine manufacturers who – as we shall see – appear to automatically deny events that are drawn to their attention.

3. the fact that scientific studies sit on dusty shelves, unloved and disregarded. The studies have been done, but few people know about them. Only the studies paid for by the veterinary vaccine industry, which carry findings that generate profits for the veterinary vaccine industry, are touted at industry-sponsored events, and in veterinary surgeries by visiting sales reps.

4. inadequate training, with regard to vaccine adverse events, of the veterinary profession

5. the fact that the average veterinarian would not think to link arthritis, epilepsy, behavioural changes, cancer, leukaemia, dermatitis, allergies, heart failure, kidney failure, liver failure, pancreatitis, thyroid disease, Graves disease, Addisons, bone marrow failure, or other vaccine-associated diseases with a vaccine event unless the reaction occurred within a very short timeframe post-vaccination.

The Veterinary Medicines Directorate stated in its position statement that:

> **Of the 2,392 Suspect Adverse Reaction (SAR) reports received by the VMD, 25 have been associated with immune mediated complications.**

Doesn't this just illustrate the problem? If you don't know why, go back and read the science presented earlier in this document.

The science is clear: vaccines cause widespread "immune mediated complications". The VMD's figure is shockingly low because veterinarians in college are not trained to know what an immune mediated vaccine complication looks like. Further, the symptoms associated with immune mediated complications do not necessarily develop immediately after a vaccine event. They frequently develop over time.

The methods the VMD employs to accept an adverse reaction could also be viewed as insulting to anyone who grieves the loss of their vaccine damaged dog. According to the VMD's website:

> **Single reports will not usually result in action by the VMD. However, should a pattern of adverse events for a specific product emerge, regulatory actions to improve the safety of that product will be initiated depending on the seriousness of the adverse events and the conditions under which they occurred.**

Depending on the seriousness? This is hardly a consumer-friendly policy.

In order for adverse reactions to pet vaccinations to be properly recorded and acknowledged, several things need to happen:

1. Veterinarians must be aware of the full range of potential unwanted sequelae to vaccines, which currently they are not.

2. Veterinarians must file an adverse event report, which is currently not mandatory, and which currently rarely happens.

3. The system needs to be computerised so that trends can be automatically collated and assessed in relation to each vaccine event. We need to look at trends of vaccine reactions, and not trends relating to specific vaccine products.

4. We also need data from the dog owners who no longer vaccinate their dogs, so that comparisons can be made. There are many such people within the Canine Health Concern membership. Further, according to Intervet sales material, there is a 'shocking' percentage of dog owners who do not vaccinate their dogs.

5. This system should be overseen by individuals who have no ties to the veterinary pharmaceutical industry, and within an organisation that has no ties to the veterinary pharmaceutical industry (i.e., not the VMD as it is currently organised).

6. Published scientific papers must be available to guide veterinarians so that they are able to assess whether an illness arising post-vaccination is already a known vaccine reaction or, indeed, vaccine-associated.

7. The VMD must adopt, and be seen to adopt, a distancing from the veterinary pharmaceutical industry.

8. The VMD must stop relying upon industry data in relation to disease prevalence and adverse events.

9. The POOCH survey, for example, is described by the VMD as 'independent' when it clearly was not. It was paid for by the veterinary vaccine industry. The Animal Health Trust, which was paid to conduct the survey, receives considerable funding from the veterinary vaccine industry and even describes itself in its report and accounts as a 'vaccine developer'.

10. The VMD must stop minimising adverse events, using phrases such as:

    under-reporting is an inevitable feature

    under-reporting is not a significant issue

    adverse reactions to canine vaccines are rare

    the benefits of vaccination are considered significantly greater than the risks of infection

11. The VMD must get out of bed with the veterinary vaccine industry.

ADVERSE EVENTS ARE EXPECTED

News in recently illustrates that veterinary vaccines are expected to generate a level of adverse events, although such news hits us with alarming regularity:

> **Intervet Schering-Plough has announced an urgent recall of PreveNile® West Nile Virus vaccine**
> Posted by Barbara F. on May 4, 2010 at 9:08pm in HORSEjournals.com
> May 4, 2010
>
> Intervet Schering-Plough has announced an urgent recall of all serial numbers of PreveNile® West Nile Virus vaccine for horses due to an **increased number of adverse event reports** associated with the use of these vaccines. According to a letter distributed by the manufacturer, the USDA has been alerted of this recall.
>
> The recalled serial numbers include one-dose and five-dose vials of the vaccine.
>
> Veterinarians with any of these serial numbers in stock should contact their distributor to arrange for the product's return.
>
> In an April 28 letter to veterinarians, the company states: “This recall is being conducted because Intervet has identified increased incidence of adverse events related to currently marketed serials.”
>
> For PreveNile One-Dose, those series include:
>
> 91669001
> 91669002
> 91669005
> 91669006
> 91669007
> 91669012
> 91669013
> 91669014
> 91669015
> 91669016
> 91660001
> 91660002
>
> Serials for PreveNile Five-Dose include:
>
> 91669003
> 91669004
> 91669008
> 91669009
> 91669010
> 91669011
> 91660003
> 91660004

> Intervet's statement does not indicate numbers or types of adverse event reports tied to PreveNile or the incidents' severity.

Please carefully note the wording: "an increased number of adverse event reports" … "Intervet has identified increased incidence of adverse events". The recall acknowledges, by its wording, that adverse events are expected to a certain limit, and that the recall is due to an increase in numbers.

For this reason alone, irrespective of how many adverse events really happen, we should vaccinate our animals no more frequently than is necessary.

The following wording appeared alongside another recall:

> Rhone Merieux and Mallinckrodt Inc (Mallinckrodt's vaccines are made by Rhone Merieux), initiated a recall and discontinuation of use of all their vaccines containing distemper products. "The vaccines have been associated with a higher than normally expected rate of post vaccinal central nervous system reactions, occurring 1-2 weeks after vaccination. Problems first began to be reported in January 1995, and extended to RM Canine 4, RM Canine 5, RM Canine 6, RM Canine 4+ Corona-MLV, RM Canine 6+Corona-MLV, Quantum 4, Quantum 6, Tissuvax 5, and Tissuvax 6." (JAVMA 12.1.95)

Note the phrase, 'higher than normally expected', meaning some measure of post vaccinal central nervous system reactions were expected. Does anyone offer pet owners the courtesy of telling them, before the event, that their dog, cat, horse, rabbit or ferret may be amongst the expected casualties – for a vaccine that was not needed?

Vaccine failures are experienced in the field. The licensing system cannot and does not prevent this.

In an article in Charlotte Observer, June 10, 2006 - http://www.charlotte.com/mld/charlotte/business/14786163.htm, Fort Dodge recalled 330,000 doses of rabies vaccine. Vets on the case said that all the other animals in the household of the dog that contracted the rabies were euthanized and tested for rabies including two horses. None of the animals had rabies - just the vaccinated dog:

Vaccine Maker Recalls Rabies Doses

Veterinarians to notify pet owners about shots
by Stella M. Hopkins

> A leading rabies vaccine manufacturer has voluntarily recalled about 330,000 doses sold nationwide after a vaccinated dog contracted the deadly disease.

"They don't know why ... the animal contracted rabies," said Kelly Goss, a spokeswoman for Fort Dodge Animal Health, based in Overland Park, Kan., and a division of health care giant Wyeth. "In the best interest of pet owners and animals, we made a decision to voluntarily recall that product."

The company mailed notices to veterinarians on May 25, and will reimburse them for revaccination, Goss said. Doctors are notifying pet owners to bring in animals for free shots.

Fort Dodge began selling the recalled batch in January 2005. Goss didn't know how many vets bought the problem lot. Fort Dodge tested batches of vaccine with serial numbers issued around that of the affected lot and found no problems, she said.

Animals at greatest risk are outdoor pets and those such as puppies and kittens, who received the recalled medication as their first and only vaccination, said Dr. Steve Marks of the N.C. State University College of Veterinary Medicine in Raleigh.

"If that initial vaccination did not work, then they're ... at risk for rabies," he said.

Notified pet owners should act quickly to have their animal revaccinated, Marks said, but he cautioned against panic.

"Just call your veterinarian if you're in doubt," he said.

What This Means to Pet Owners
Fort Dodge Animal Health recalled rabies vaccine Rabvac 3 TF, serial number 873113A. Your vet should notify you if your pet was vaccinated with the problem batch. You can also check the rabies certificate that you should have received, which lists the manufacturer and serial number.

VMD ASSERTS VACCINE SAFETY

Much of the Veterinary Medicines Directorate's Position Paper on Authorised Vaccination Schedules for Dogs concerned itself with the safety of veterinary vaccines. It described the licensing procedure, independent assessments, and quality controls. For example:

> **Before a veterinary vaccine can be placed on the UK market it undergoes a rigorous independent scientific assessment to ensure the product meets the required standards. In the UK the standards are set by the European legislation. Independent assessment seeks to ensure three major factors are in place before any vaccine is made available for use:**
>
> 1. **vaccines are manufactured to a consistent and acceptable quality using high grade materials and are uncontaminated with potentially harmful infectious agents or other toxic substances;**
>
> 2. **vaccines are safe to be administered to young and older animals where relevant, and pose no risk to the owner, their families or other animals and persons coming in contact with vaccinated animals. Where necessary, specific warnings are added to the product literature to minimise any risk of an adverse reaction following administration of the product;**
>
> 3. **high quality scientific data is available to support the primary and any revaccination (booster) schedule and this has been assessed to ensure the vaccine can be expected to provide the required onset and duration of immunity claimed by the manufacturer to protect animals against disease."**

VMD Complacency

Referring to point 1 above:

> **vaccines are manufactured to a consistent and acceptable quality using high grade materials and are uncontaminated with potentially harmful infectious agents or other toxic substances**

Although we have already addressed the VMD's point 1 above, there is much more to say on this subject. These safeguards do not appear to address the following issues:

- Vaccine contamination is a real and present danger. Vaccines remain free of contaminants only in so far as they are screened for specific contaminants, and only in so far as screening technology is able to detect contaminants.

- As a very recent paper has illustrated (***Isolation of an Infectious Endogenous Retrovirus in a Proportion of Live Attenuated Vaccines for Pets,*** *Journal of Virology, April 2010, p. 3690-3694, Vol. 84, No. 7.)*, there is retrovirus contamination in veterinary vaccines in both the UK and Japan. The authors state, "although the risks posed by RD-114 are seemingly small, it would be appropriate to produce live attenuated vaccines in cells that do not express this endogenous retrovirus".

Although the authors of this study feel that the risk is seemingly small, it is not possible to rule out untoward consequences in relation to retrovirus contamination in vaccines.

In view of the fact that veterinary vaccines in the UK have recently been shown, by independent review, to be contaminated with a retrovirus, the VMD cannot make the claim that the licensing procedure, and the quality and safety measures, are beyond reproach. Neither can the VMD legitimately claim that errors and failings do not occur.

This fact in isolation illustrates the need to revaccinate as infrequently as possible, thereby minimising the vaccine risk.

A similar paper was prepared by Intervet employees Hesselink and Makoschey: **"Bovine virus diarrhoea virus in bovine serum used for vaccine manufacturing"** http://cat.inist.fr/?aModele=afficheN&cpsidt=18206865.

Apart from highlighting vaccine contamination, this report also highlights the strangely cavalier mindset of the vaccine industry.

The authors stated:

> "These results demonstrate that the BVDV [bovine virus diarrhoea virus] in the respective batch of serum, despite the high levels, was indeed non-infectious and did not result in sero-conversion. The supply of batches completely free of BVDV is insufficient to satisfy the demands of vaccine manufacturers. As has been shown, adequate tests to detect BVDV and to discriminate between infectious and non-infectious BVDV have been developed and are now available. However, given the adequacy of the gamma-irradiation treatment, we would like to question the justification of the strong emphasis put upon testing bovine serum batches for BVDV in both EMEA guidelines."

Perhaps vaccine company scientists are more educated and expert in their fields than regulators, and are therefore justified in minimising the need for tests to rule out cross-species viral contamination, or the seriousness of various contaminants found in vaccines. Alternatively, perhaps vaccine contamination is an issue that is still open to debate?

Such research raises the question whether vaccine technology is more experimental than the general public is aware, and whether vaccine disasters are routinely dealt with after they occur, rather than benefiting from effective screening techniques beforehand. The following paper raises many of the issues surrounding vaccine contamination.

What Is Coming Through That Needle?
The Problem of Pathogenic Vaccine Contamination
Benjamin McRearden

The purpose of this report is to examine the existing scientific evidence of pathogenic contaminants in vaccines. This summary, while making no claim of being a complete review of the subject, will point out sufficient examples and illustrations of contamination with bacteria, viruses, and their components, so as to enable the reader to make a more informed decision regarding accepting a vaccination (or forcing others to receive one). It is presented in a format intended for the public, their physicians, and their agency or governmental representatives, and may be freely copied in its entirety.

If you as an individual are too busy to read this brief summary in one sitting, please be aware there is ample evidence in the scientific literature that serious viruses, bacteria; or components and toxins therefrom; as well as foreign animal or cancer-related proteins and DNA are finding their way into the commercial vaccines intended for humans, pets, and agricultural animals. If you are interested in the short and long-term health of yourself and those you care about, or serve as a public servant or medic al advisor, you do owe it to yourself to be informed.

In the production of viral vaccines on a commercial scale, the virus of concern must be reproduced in large quantities. Viruses cannot survive or reproduce without being introduced into cells that nourish them, which enables the viral reproductive activity. In that sense all viruses can be considered parasitic on other cells. Living cell types commonly used to reproduce viruses in the lab include monkey kidney cells, chicken embryos, as well as other animal and human cells. These cells must also be nourished with food, and are most often fed with a nutrient mix containing in large part, bovine (cow) calf serum (usually, serum extracted from fetal calf blood). This product can carry many types of bovine blood-borne viruses, and is one of the primary sources of vaccine contaminants.

A journal article states, “a potential risk associated with the production and use of biological products is viral contamination. This contamination may be present in the source material, e.g. human blood, human or animal tissues, cell banks, or introduced in the manufacturing process through the use of animal sera...”(1)

Bovine viruses

The viruses and other agents that can contaminate bovine calf serum are numerous. One of the most prominent is a pestivirus called bovine viral diarrhea virus (2). More specifically, we see in several scientific journal sources these

types of statements: “contamination of a vaccine as a consequence of infection of fetal calf serum”(3); “many batches of commercially available serum are contaminated with viruses such as BVD” [bovine viral diarrhea] (4); “virus was isolated from 332 of 1,608 (20.6%) lots of raw fetal calf serum obtained specifically for the Center and 93 of 190 (49%) lots of commercially available fetal calf serum (5); “agents most frequently detected in CCL's [continuous cell lines] have been bovine viral diarrhea virus and mycoplasma.

Our laboratory has consistently found that the source of bovine viral diarrhea contamination of CCLs has been the use of contaminated fetal bovine cell culture enrichment serum”(6); and finally, “In conclusion, **most commercially available bovine sera are contaminated with BVDV** and, although there is no evidence that the virus is infectious, bovine sera should be screened for this virus…for the development or production of vaccine.”(7)

Can this virus cause infection or disease in humans? New evidence shows this is possible, as researchers have found a new strain that was isolated from human cells, and it is very closely related to the bovine strains (8). One study finds that an alarming 75% of all laboratory cell lines examined were contaminated with pestivirus strains; of these, **all** of the bovine cell lines were contaminated with one of three possible BVDV strains; cell lines from other animal sources including primates, sometimes contained one of these BVDV strains (9).

There is now heightened concern that this virus and others can cross species lines, creating new strains as they adapt to their new hosts, and this would include passage of the virus to and from humans. Whether the human strain of BVDV causes overt illness is uncertain, because physicians may be uninformed and not even be looking for this virus. It may be useful however, to compare the infection patterns in cattle. They can be persistently infected at a low level for their entire life with a non-pathogenic strain of the virus. Under these conditions, they consistently create and shed virus into the surrounding environment, which then infects other animals. The virus can nonetheless become lethal to the animal if it mutates, with the new form also causing “visible cell damage and death” in cultured conditions (10).

The animal succumbs to gradual or acute deterioration of the gastrointestinal mucous lining, which produces diarrhea and its eventual demise. However, mutated virus is not *always* necessary to provoke debilitating illness and death, and ordinary virus can be isolated from the cow’s pancreas, adrenal glands, and pituitary glands (11); the virus has also been documented as causing serious pulmonary illness (12). A study describes an outbreak of disease among goats due to a vaccine contaminated with a bovine pestivirus; oddly, these animals experienced reproductive failure and lesions to the central nervous system (13). So, can these disease symptoms in varied organs and tissues also occur in humans when they carry this virus short or long term?

A cursory examination of the literature indicates this may be occurring. One revealing study tells us “faeces from children under 2 years old who had gastroenteritis that could not be attributed to recognised enteric pathogens were examined…for Pestivirus antigens. Such antigens were detected in 30 of 128 episodes of gastroenteritis…The diarrhoeal disease in children excreting

Pestivirus antigens resembled that in other children except that it was more commonly associated with signs and symptoms of respiratory inflammation."(14)

There are also concerns regarding a pattern of pestivirus infection in infants born with microcephaly, a condition wherein the head or cranial capacity is unusually small (15, 16).

QUESTION TO THE VMD:

Have pestivirus-contaminated vaccines been ruled out in cases of Syringomyelia in dogs, particularly King Charles Cavalier Spaniels? With Steve Dean sitting as a Trustee of the Kennel Club, and with the Kennel Club's ties with the Animal Health Trust and others within the veterinary pharmaceutical industry, will this question go any further within the Kennel Club?

Syringomyelia (SM) is an extremely serious condition in which fluid-filled cavities develop within the spinal cord near the brain. It is also known as "neck scratcher's disease", because one of its common signs is scratching in the air near the neck.

The back half of the Cavalier King Charles spaniel's skull typically may be too small to accommodate all of the brain's cerebellum, which may also be too large, and so it squeezes through the foramen magnum – the hole at the back of the skull – partially blocking the flow of cerebrospinal fluid (CSF) down the spinal cord. The variable pressure created by the abnormal flow of CSF is believed to create the SM cavities – called syrinx – in the spinal cord.

The paper continues:

Scientists from the USDA National Veterinary Services Laboratory describe the situation quite clearly, and give an indication of the seriousness of the problem: "The high frequency of virus and antibody detection in individual animal or small pool samples suggests that any large pool of unscreened sera will be contaminated. Infection of cell cultures with BVDV can lead to interference with the growth of other viruses. **Vaccine produced on contaminated cells may in turn be contaminated, leading to seroconversion or disease in the vaccine.** The safety, purity, and efficacy of viral vaccines require BVDV testing of ingredients, cell substrates and final product."(17)

And here is a similar statement from a New York Blood Center: "Bovine viral diarrhea virus, whose small virion size does not allow 100% assurance of its removal by filtration, **may potentially contaminate every lot of commercially produced fetal bovine serum**."(18)

In reality though, how much of this particular viral contaminant has trickled into humans? Well, in spite of manufacturers and regulatory agencies claiming efficacy of their testing procedures, one 2001 study found 13% of human MMR, polio, or Streptococcus pneumoniae vaccines tested positive for pestivirus RNA (19). And another researcher observes, "serum antibodies against BVDV have been detected in approximately 30% of human population who had no contact

with potentially infected animals."(16) Also, "pestiviruses adapted to human cell cultures may be harmful because serious BVDV infections in humans have been frequently suggested…The BVDV persistently infected in cell cultures used for vaccine productions have been shown to be a source of contamination in live virus vaccines. It is, therefore, prerequisite to examine pestivirus contamination in cell cultures to avoid secondary infections in humans as well as in animals."(20)

Continuous immortal cell lines

This same scientist brings up another important issue. Because many medical-use biological products (including vaccines) are now being cultured or produced on what is called "continuous" cell lines (i.e., these are cell cultures consisting of "immortal" or cancerous types of cells because they have no limits on how many times they can divide), there is concern that viral contamination of these cell lines with a pathogen like bovine viral diarrhea virus, could spread cancer-promoting material into the human recipient.

How could this happen? Briefly, it works like this. The virus (which in this case has a single strand of RNA for its genome) is capable of incorporating RNA from the cells in which it has been cultured, into its own genome. If any contaminant RNA virus is present in a culture that contains immortal cancerous cells, this virus can easily mutate to include unwanted oncogenic material, which can then get passed into the biological product intended for human medical use (16).

Were you aware that biological products, including some common vaccines (for instance, polio and rabies), are being produced on "continuous" immortal cell lines? Manufacturers, scientists, and agencies will often assure us that these cells themselves are not "tumorigenic", i.e., they do not cause tumors per se. A closer look however, shows this is not always the case. While lab culturing may indicate that these types of cells are not immediately changing to overt tumor cells, it is now well known in the scientific community that after these cells have been repeatedly cultured a certain number of times, something causes them to convert to a cancerous state (21).

This journal article summary addresses the issue in regards to Vero cells, which is a continuous cell line coming from the African green monkey, and is commonly used in vaccine production. It states, "One of the current criteria for evaluating the acceptability of cell lines for use in vaccine production is lack of tumorigenicity. Vero cells represent an example of a class of cells known as continuous cell lines. They were derived from African green monkey kidney, and their growth properties and culture characteristics have many advantages over other cell substrates for use in vaccine production. We have tested Vero cells for tumorigenicity in nude mice and in a human muscle organ culture system, and found a significant increase in their tumorigenic potential with increasing passage numbers. Cells at passage 232 and higher produced nodules in all nude mice inoculated."(22) [The term "passage" in this context means the number of times a cell line has been cultured].

There is another very important issue reported in studies that is evidently being largely ignored as regards long-term vaccine effects and safety. There is obvious evidence that in the lab, continuous immortal cell lines react differently between

one type of animal species and another (21, 23). As an example, tissue from one species will allow the immortal cell to induce a cancerous change more quickly, in comparison to tissue from a different species. These results then beg the following questions.

How extensively have these continuous cell lines been tested on human tissues, and would the results vary from one *type* of tissue to another? And what happens over the long term…if an immortal cell from a vaccine culture makes its way into the final vaccine product, does it keep dividing in the human body? Another scenario might suggest the tumor-promoting portion of its DNA inserting into a viral genome, which then gets injected into the body…what happens at that point?

Furthermore, given the evidence that closely-related animal species (as an example, various species of monkeys) react differently to immortal cells, do we also need to consider that any one vaccine intended for all humans might ultimately react differently among the various races, ethnic groups, and sexes? And what are the effects of the vaccine contaminants on persons with immune depression, on the elderly, or on infants?

A letter from the FDA to vaccine manufacturers dated as recently as March 2001 shows that this issue regarding immortal cell lines is still of concern. It states, “In general, CBER [Center for Biologics Evaluation and Research] currently views Vero cells as an acceptable substrate for viral vaccines, but has residual concerns…CBER recommends that all products derived from Vero cells be free of residual intact Vero cells. If your manufacturing process does not include a validated filtration step or other validated procedure to clear residual intact Vero cells from the product, please incorporate such a procedure into your manufacturing process.”(24)

It is now 16 years after the WHO gave a go-ahead (in 1986) to use continuous cell lines for vaccine production (25), and yet there are **very basic** safety questions not resolved by the manufacturers, agencies, and scientific community, much less the finer details (26, 27).

One 1991 study reports: “Cell substrate DNA was shown to be an abundant contaminant in the clarified preparations of the Sabin type 1, 2 and 3 poliovaccines produced on a continuous cell line”(28). Another indicates that immortal cell lines showed 100-times greater number of DNA recombination events compared to normal cells (29). As one researcher states, “Using neoplastic cell lines as substrates for vaccine development could inadvertently result in viral-viral or viral-cellular interactions whose biological consequences are unclear…viral-viral and viral-cellular interactions **can result in the generation of new retroviruses** with pathological consequences.”(30).

We note the term “neoplastic” means the quality of having an abnormal growth characteristic. There is an even stronger statement dating back to 1990. A scientist in the field writes, “The present concern is for safety of vaccines made using transformed or neoplastic mammalian cells that may contain endogenous contaminating viruses or integrated gene sequences from oncogenic viruses.

There is also concern for use of plasmid vectors employing promoter elements from oncogenic viruses. The principal concern for safety lies with retention of residual DNA in the vaccine, **especially since induction of cancer is a single - cell phenomenon, and a single functional unit of foreign DNA integrated into the host cell genome might serve to induce cell transformation** as a single event or part of a series of multifactorial events. Current proposed standards for vaccines would permit contamination with up to 100 pg [picograms] of heterologous DNA per dose. This is equivalent to about 10(8) 'functional lengths' of DNA. Total safety would seem to require complete absence of DNA from the product."(31)

Please note that 10(8) means 10 to the power of 8, or **100,000,000 "functional lengths" of DNA are allowed per dose of vaccine** . Is there something wrong with this picture? How long will the general public be subjected to these vaccine products that according to this information, are nowhere near safe?

It has taken, for instance, approximately forty years for the scientific community to finally acknowledge that we have a serious problem as a result of the contamination of polio vaccines with simian virus 40 (SV40) in the late 1950s-early 1960s. There has been previous evidence of some human brain and other tumors containing this virus (32, 33), but the medical community has been slow to acknowledge a definitive link between SV40 and cancer in humans. However, two independent research teams have recently found this virus present in 43% of cases of non-Hodgkins lymphoma (34, 35). Another study found it present in 36% of brain tumors, 16% of healthy blood cell samples, and 22% of healthy semen samples (36). And strangely, SV40 has now been found to infect children (37).

Considering that children of this era, are not supposed to be receiving the virus via the vaccine contamination route, this would therefore imply that SV40 is being transmitted from one human to another, in ways not previously known.

Other simian viruses may also be contaminating the (Vero) monkey cell lines used for vaccine production. One example from the literature cites the contamination presence of SV20, which is a oncogenic simian adenovirus (38).

Simply put, are we in a state of denial that vaccines are ultimately transmitting viruses, DNA, and proteins into humans from foreign animal sources (and possibly unhealthy human sources), and that this may be strongly contributing to the incredible upsurge in cancers and serious chronic diseases? Are these foreign animal genes altering *your* DNA? Furthermore, given that viral presence can sometimes take years to manifest actual disease symptoms, and then considering the tendencies of health-related agencies and corporations towards **short**-term solutions and profits, will we ever truly know the **long**-term consequences until it is too late?

Other bovine viruses

Another contaminating virus found in the calf serum used for vaccine production is bovine polyomavirus (polyomaviruses are strongly associated with cancer); one pertinent article is titled "Bovine polyomavirus, a frequent contaminant of calf

serum"(39). Other contaminants include a virus from the parvovirus family (40); another study cites "virus-like particles" and "mycoplasma-like agents" in 68% and 20% of the samples, respectively (41); and yet another mentions the presence of infectious bovine rhinotracheitis virus (aka bovine herpesvirus 1), and parainfluenza-3 virus in addition to the common BVDV (42).

An interesting report from 1975 not only affirms the presence of these viruses in calf serum, and mentions the additional presence of bovine enterovirus-4, but also tells us that 25% of serum lots that were pre-tested by the suppliers and "considered to be free of known viral contaminants" were actually contaminated with bovine viruses (43). It should be obvious that any bovine blood-borne virus (including serious retroviruses such as bovine leukaemia virus, bovine visna virus, and bovine immunodeficiency virus) could ultimately end up in human or animal vaccines via the use of calf serum in the manufacturing process.

Contamination of calf serum with certain bovine herpesviruses, and the possible implication for human health, deserves a bit of scrutiny. It is known that bovine herpesvirus-1 replicates easily in a human embryo cell line called WI-38 (44). It is also known that bovine herpesvirus-4 is quite "persistent" in calf serum, and has a wide host range, including human cells (45). In fact, this particular virus strongly replicates in two human embryonic cell lines, WI-38 and MRC-5, enough so to prompt one author to give these details and a warning: "PCR [polymerase chain reaction] detected a 10,000-times-higher level of BHV-4 [bovine herpesvirus-4] DNA… the supernatant indicated a 100-fold increase of infectious particles. Since this is the first bovine (human herpesvirus 8 and Epstein-Barr virus rela ted) herpesvirus which replicates on human cells in vitro, the danger of possible human BHV-4 infection should not be ignored." (46)

The clincher to this possible contamination, is that these same human cell lines WI-38 and MRC-5 are two of the **most common human cell lines used to manufacture viral vaccines**, (for example - rubella, chickenpox, smallpox) and these cell lines are of course, commonly nurtured with calf serum.

Contaminants from chicken sources

Some viral vaccines are produced by growing the virus in chicken eggs. Common human vaccines manufactured by this method include influenza, mumps, measles, yellow fever, and others.

Like the vaccines that include bovine-source materials, those derived from chicken embryo culture are plagued with some very serious viral contamination problems.

Avian leukosis virus (aka avian leukemia virus or ALV) is a retroviral pathogen that infects large segments of the modern poultry industry, is present in commercial chickens and eggs, and thus exposes humans on a consistent basis (47).

An interesting virus in the sense that it can be considered a "parent", it easily transforms into a dizzying array of related viruses by hijacking one of numerous cancer-related gene segments from its host, and inserting it into its own genome.

Furthermore, it has the additional capability of inserting itself into the host (including human) genome, hiding out so to speak, and causing cancerous cell transformation from that location. There is now much scientific literature available that describes the various active mechanisms of this and other cancer-associated viruses (48).

Viruses that originate from the "parent" avian leukosis virus, include the potent Rous sarcoma virus, Rous-associated viruses, avian myeloblastosis virus, avian myelocytoma virus, avian erythroblastosis virus, Fujinami sarcoma virus, etc. One group of researchers studying the mechanism of ALV writes, "Serial passaging of a retrovirus that does not carry an oncogene on such cultures **leads with a high frequency to the emergence of new viruses** that have transduced oncogenes…"(49). In other words, given the right growth conditions, ALV can easily transform into other closely related viruses that are known to be cancer-related.

Just how common is this avian leukosis virus in viral vaccines? The first evidence of contamination came to light in the 1960s when yellow fever vaccine was found to contain it (50). Since that time, it is common knowledge in the industry that this virus (or components thereof) still linger in human and animal vaccines (51). Indeed, the respected Fields Virology text (year 2001 edition) states, "At the present time, vaccines produced by some of the world's 12 manufacturing institutes are contaminated with avian leukosis virus"(52).

One point that researchers in this field *do* agree upon, are the presence of ALV, avian endogenous virus, avian reticuloendotheliosis virus (another poultry retrovirus), and also an enzyme called reverse transcriptase (a component of retroviruses) in final vaccine products intended for human use, especially the mumps, measles, yellow fever, and influenza vaccines (53, 54, 55). What they do *not* agree upon are the effects on humans in terms of transmission, infection, and possible subsequent disease. A recent study coming out of the U.S. CDC (Centers for Disease Control), which analyzed frozen blood serum samples from children that had received MMR vaccinations, reports no avian viral presence in these samples (56).

And yet, we see reports from other researchers that make us question the results of that study. As is often the case with viruses, some strains will show particular affinities for certain types of tissues or growth conditions, and ALV is no exception (57). One researcher makes the effort to explain, "Because of the difficulty in infecting mammalian cells in vitro with these viruses, it is generally held that they do not infect humans…Our results show that exposed poultry workers **and subjects with no occupational exposure to these viruses** have antibodies in their sera specifically directed against ALSV [Avian leucosis/sarcoma viruses]… Further investigation into whether these findings mean that virus has been integrated into the human genome is needed, to assess the public health implications of these results."(58).

He also explains in another article, that given the known behavior of these viruses in mammalian cellular culture, a blood serum test will not always provide the correct evidence of viral presence in the human body (47). In other words, does the virus (or viral antibodies) need to be actively present in the blood

stream at the time of the blood draw? What if the viral particles have retreated into other tissues? Thus the CDC study mentioned above may not have presented an accurate assessment of viral presence, or long-term effects from the numerous ALV associated “offspring” viruses.

Considering that ALV can for example, easily capture the human “erbB” oncogene (59), and that erbB as well as the oncogene called myc are strongly associated with common forms of human breast cancer, it seems that the issue of ALV vaccine contamination would deserve a high level of attention! (By the way, the general reader should not feel intimidated by the abbreviations associated with oncogenes…erb refers to “erythroblastosis”, and myc refers to myelocytomatosis, which are the names of two ALV-associated offspring viruses).

A well-known microbiology text reinforces these concepts by teaching, “Proto-oncogenes become incorporated into retroviral genomes with surprising ease.” (60)

Toxin contamination

The unintentional presence of bacterial-source toxins (called “endotoxins” or “exotoxins”) in human and veterinary vaccines has been recognized for many years. Such toxins are originally present in source materials, or are produced as a result of bacterial infection during the manufacturing process (61, 62). The various methods used in attempts to eliminate viruses and bacteria from vaccines are simply not effective in the removal of these problematic toxic proteins (63).

Several observers have expressed concern that the presence of endotoxin may be a source of severe adverse reactions seen in some individuals after receiving a vaccine (61, 64). Some vaccines, such as those for diphtheria and tetanus, are specifically created to induce a protective mechanism in the body against the bacterial toxin; however, vaccines prepared from bacteria can contain appreciable and potentially dangerous lingering amounts of toxin, despite the steps used during manufacture to decrease the toxic potency, as described in this comment: “Vaccines composed of gram-negative bacteria contain endotoxin in considerable amounts. This may result in adverse effects after vaccination of sensitive animals.” (65). It has also been reported that bacterial toxin contamination residing in calf serum, can cause breaks in the DNA of human cells (66).

Bacterial contamination - nanobacteria

Nanobacteria is a recently discovered pathogen that infects humans. Now considered to be the smallest existing bacterial form known to science, it escapes through common filtering processes, and can easily invade other cells and cause cell death. Nanobacteria also are classed as “pleomorphic”, that is, they have the ability the change physical form. A human variety of this pathogen has been found to cause or be associated with a host of disease conditions, only a few of which include atherosclerosis, coronary artery / heart disease, kidney

stones and kidney disease, arthritis, MS, Alzheimers, some cancers, and other conditions (67).

Since this species of bacteria is specific to mammals, and must be lab-cultured in mammalian blood or serum, it is not surprising that this variety of nanobacterium has been isolated as a contaminant from bovine calf serum, other mammaliam bio-products, and vaccines. One study reports that 100% of serum of cattle in a US herd showed antigens to nanobacteria, and cites another report from Europe that, “more than 80% of commercial bovine serum lots contain Nanobacterium” (68).

Obviously, any vaccines that must incorporate mammalian products during production (which would include cow, monkey, or human cells, blood or serum), will be prone to nanobacterial contamination. This was indeed verified when a group of researchers found that 2 out of 3 lots of inactivated polio vaccine, and 3 out of 6 lots of veterinary vaccines were contaminated with nanobacteria. They also point out that the bacteria could be coming from calf serum *and* contaminated culture cell lines (69).

Any reasoning person with a basic knowledge of vaccine production can deduce that nanobacteria have undoubtedly been infecting humans in a fairly widespread manner via vaccination procedures. One might also wonder whether it has contributed to the current prevalence of atherosclerosis and generalized heart disease.

Bacterial contamination – mycoplasmas and related forms

If there is any one type of bacterial contamination in vaccines that warrants particular attention, it would be mycoplasmas. These small organisms have a structure not characteristic of most forms of bacteria, i.e., they usually contain a thin outer membrane as compared to the more complex walls of common bacterial forms. They are described as being capable of slipping through filtration procedures, and can transfer to other media through the air or via routine handling in the lab (70).

One source states that “less than 10% of laboratories actually test for infection/ contamination regularly”…that mycoplasmas are “influencing almost every aspect of cell biology”…and that labs “which do not test for mycoplasma probably harbour contaminated cell lines and may even have their entire stocks contaminated, as mycoplasma spreads readily along cell lines via regents and media, the operator and the work surface” (71). They are resistant to certain types of antibiotics used to kill other bacteria (70, 72), and are subject to changing form under varying physiological or biochemical conditions (73).

The journal and industry literature is filled with references to the problems of mycoplasma contamination in cell cultures and vaccines. Various studies cite corrupted cell lines ranging in occurrence from 5% to 87% (71, 72, 74, 75, 76), and as we now know, once this pathogen is in the cell culture being used to make the vaccine, it is liable to end up in the final product (77, 78, 79,80).

One author states, “Mycoplasma contaminants can be considered important not only because of their role as pathogens but also because they may indicate that insufficient care has been taken during vaccine manufacture or quality control.” (81).

Species of mycoplasmas that have polluted the cell cultures include Mycoplasma hominis, M. fermentans (implicated in Gulf War illness), M. arginini, M. hyorhinis, M. orale, M. pirum, M. pneumoniae, and Acholeplasma laidlawii (75, 76, 82). Any reputable company that sells tissue or cell culture material, also must test for and sell kits to detect mycoplasmas (72, 75, 76, 83, 84).

Mycoplasmas and associated variant forms have long been associated with many disease processes, including cancer, chronic illnesses such as chronic fatigue syndrome, fibromyalgia, arthritis, Gulf War Illness, and many others (73, 85, 86). It would be impossible to cite all the pertinent references in this short report, on this vast arena of microbiology that is often ignored by much of the medical community, sometimes with tragic consequences. Mycoplasmas without question have the capability of altering cell membranes and their antigens, disrupting DNA, and altering cellular metabolism both in vitro and in vivo (70, 71, 72, 73, 86).

Cross-contamination of cell lines

As we recall that all viral vaccines can only be produced with the use of cells, the purity of the cell lines an important issue. The most famous example of many cell lines becoming contaminated from outside sources, occurred when the famous and extremely fastidious HeLa cancer cells started showing up in labs across the world in the 1960s. The phenomenon is well-documented (87, 88, 89, 90), and is even the subject of an entire book (91).

One study from 1976 cited a litany of contamination in **all** primary and continuous cell lines that were examined – many viruses were found, as well as HeLa cells (92). As the years progress, the reports continue to come in: one from 1984, for instance, tells of inter- and intra-species cell cross-contamination, that 35% of all cell lines were corrupted, and that most of these lines were (originally) cells of human origin (93).

Let’s fast-forward to 1999. A study in Germany finds that the problem is continuing, if not worsening. In a survey of human cell lines, the most common cross-contaminants came from “classic tumor cell lines”; that these polluted lines had been unknowingly used in “several hundred” projects which generated potentially false reports; and that they considered it a “grave and chronic problem demanding radical measures” (94).

The situation is such that several scientists were prompted to write a letter to the respected journal “Nature” in January 2000, calling for immediate action to institute procedures that would verify the purity of cells used for research and production of biological products, ensure freedom from mycoplasma, and include biohazard information (95). (Did I hear that correctly – cells can be considered a biohazard)? Has anything changed since then to remedy the situation? There is

another report from Jan. 2002, that two major cell lines used in research projects actually turned out to be HeLa cells (96).

I ask the reader to now recall information from earlier in this report, that there are proposals being considered to produce vaccines and other biological products using distinctly cancerous cell lines, including HeLa (25). Does this seem reasonable, especially since the current lines are already dangerously tainted with HeLa and possibly *other* cancerous cells? Please remember the 100,000,000 allowable pieces of cell-source DNA allowed per dose of vaccine (and this does not include the viral contaminants). Anyone care for a small, under-the-skin serving of human cancer-cell-component soup? With maybe a few monkey cell fragments for garnish, and viruses for flavor?

Additional points to consider

There are several issues the public and medical community may want to be aware of concerning safe administration of vaccines. The human and animal body has normal barriers that help to protect against infiltration by foreign agents, among them are the skin, the respiratory and intestinal mucous linings, and the blood-brain barrier. The puncture of skin by a needle breaches that barrier. A group of researchers states, “Virus contamination of bioproducts such as vaccines, blood products or biological material used in surgery and for transplantations also is more hazardous because the application of contaminating virus usually occurs by circumvention of the natural barrier systems of the body…virus contamination of bioproducts should be considered as a hazard no matter which method has been used for its detection.” (97).

Of even more concern, is the administration of vaccines nasally (through the nose), or accidental passage via that route (98). Fields Virology text (2001) says, “The olfactory tract has long been recognized as an alternative pathway to the CNS [central nervous system]…olfactory neurons…are unprotected by the blood brain barrier.” While that writer particularly addresses the flavivirus family [i.e., “intranasal inoculation of flaviviruses may result in lethal encephalitis” (99)], this pattern of potential danger may deserve further attention than it currently receives, especially if there ever is consideration to use a method of nasal inoculation for mass vaccination of the public or military, and there may be contaminating viruses or toxins in a vaccine that have an affinity for nerve cells and tissues.

Mass immunization programs often use jet injectors to save the time and inconvenience associated with needles and syringes. However, a study published in July 2001, found that the four injectors tested had the capability of transferring tiny amounts of fluid and blood (and thus, viruses such as hepatitis B and C, HIV, etc.) from one recipient to the next (100). Numerous other articles confirm the danger, and question the safety of these devices, including one study that reported an outbreak of hepatitis B associated with use of a jet injector (101, 102).

Some of the newest types of vaccines are called “subunit” and “naked DNA” vaccines. Without going into the intricacies of their production, they involve techniques used in genetic engineering. Subunit vaccines generally will insert a

viral or bacterial DNA section into the DNA from yeast, which is allowed to reproduce in large quantities. The protein intended for inclusion in the vaccine is then separated from the yeast cells. In the case of naked DNA vaccines, the viral or DNA gene is first reproduced, then spliced into a plasmid (which is essentially free DNA, widely used in recombinant technology), reproduced in bacteria or cells, and then separated from them for inclusion in the vaccine. Recombinant gene vaccines can also be produced via these methods – for instance, hepatitis B is now an exclusively recombinant vaccine (103, 104)

One of the major concerns with these methods is the unpredictability and interaction of the final vaccine product with the proteins or DNA of the host. A document from the FDA states: “Genetic toxicity: Integration of the plasmid DNA vaccine into the genome of the vaccinated subjects is an important theoretical risk to consider in preclinical studies. The concern is that an integrated vaccine may result in insertional mutagenesis through the activation of oncogenes or inactivation of tumor suppressor genes. In addition, an integrated plasmid DNA vaccine may result in chromosomal instability through the induction of chromosomal breaks or rearrangements.” (105).

Another group advises, “Research findings in gene therapy and vaccine development show that naked/free nucleic acids constructs are readily taken up by the cells of all species including human beings. These nucleic acid constructs can become integrated into the cell's genome and such integration may result in harmful biological effects, including cancers.” (106).

And to reiterate the danger of tumorigenic cell lines, a researcher says, “More recently, recombinant DNA technology has expanded beyond bacterial cells to mammalian cells, some of which may also be tumorigenic.” (107).

It seems obvious that there needs to be a new and open dialog regarding vaccines among the regulatory agencies, manufacturers, research and medical community, and the public. Many have been ridiculed for refusing vaccination for themselves or their children, but considering the occurrences of short-term adverse events and questionable efficacy (108), possible long-term health damage, and now also facing the potential of wide-ranging loss of civil liberties (109), is it so surprising that many are questioning what the actual benefits are surrounding most vaccination protocols? Are the cases of damaged children, non-functional adults, the huge increases in cancer rates, immune and chronic diseases to be simply and blindly accepted by the public as “tolerable losses”?

As a citizen with a right to good health, please be advised of the following issues. Vaccine quality in the U.S. relies for the most part, on manufacturers reporting to the FDA. Here is a relevant statement from the CDC: “Manufacturers are required to submit the results of their own tests for potency, safety, and purity for each vaccine lot to the FDA. They are also required to submit samples of each vaccine lot to FDA for testing. However, if the sponsor describes an alternative procedure which provides continued assurance of safety, purity and potency, CBER may determine that routine submission of lot release protocols (showing results of applicable tests) and samples is not necessary.” (110)

Yes, this is the scope of the quality-control protocol that oversees a market worth billions of dollars, yet allowing all these contaminants into the vaccines.

It may be helpful to have an idea of the scope of the operation to understand what we are dealing with here. We are advised that “Large-scale cell culture operations for biotechnology products use millions of litres of complex media and gases as well as huge quantities of organic and inorganic raw materials. These raw materials must always be assumed to contain contamination by adventitious agents” (111).

And because there is a potentially large number of animal and human viruses (or viral segments) that could be entering into the final vaccine products, it would take a equally large bank of molecular probes, as well as frequent, wide-spread testing, to screen for presence of these contaminating agents. This would obviously add time and expense for the manufacturers. What needs to be decided is this – is the effort and cost involved in cleaning up these admittedly filthy medical products, worth the resultant benefit to the public health?

And since certain animal products are necessary for the production of vaccines, it may also be necessary to clean house at several levels, including the agricultural sector. It is no secret for instance, that commercial chicken flocks raised for meat and eggs are often carrying infectious avian leucosis virus, mentioned earlier in this report (112, 113, 114)

For the record, the smallpox vaccine ordered by the U.S. government from Aventis is being produced on two types of continuous cell lines, the human embryonic MRC-5 and the green monkey Vero cells (115). We might also be advised of one researcher’s thoughts, that “normal embryo and foreskin cells presumably represent a state in development which is genetically unstable, rendering them considerably more susceptible to malignant transformation.” (116). Are remnants of these types of cells something we want injected into our bodies?

The decision you make in accepting or refusing a vaccination can be a very personal one, but whatever you decide, do try to be informed of the true benefits and risks. Nobody should be forced to submit to any medical procedure, *especially* one of questionable value.

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[Items with a PMID number will usually have abstracts available to read. Go to the PubMed website: http://www4.ncbi.nlm.nih.gov/entrez/query.fcgi and enter the accession number into the search box.]
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Please note that the use of bovine serum in canine vaccines has been seen to initiate production of a wide range of autoantibodies in dogs (Glickman, et al, Purdue University, which was referred to earlier).

A Finnish study also showed the presence of nanobacteria in bovine serum used in vaccines. (*Mol. Biol. Cell, Suppl., Vol. 7, (1996): 517a*, Fatal (fetal) bovine serum: discovery of Nanobacteria:

> ”A new potential threat for blood and blood products, cell culture, cell and tissue banking and biotechnology has been discovered: Nanobacterium sanguineum gen. et sp. nov.. These self-replicating ultrafilterable bacteria were isolated from over 80% of commercial sterile fetal and newborn bovine sera and are thus the most common contaminant present in cell cultures. Growth occurred in vitro under cell culture conditions (with or without mammalian cells) but not under anaerobic conditions. Their doubling time was 1-5 days. They were culturable also in protein and lipid-free medium beyond three years with monthly passages. Colony formation on solid media was poor. The agent multiplied in culture with serum in a logarithmic mode that could be prevented with aminoglycoside antibiotics, EDTA, cytosine arabinoside and gamma irradiation. They showed procaryotic structure with specific antigens detectable by monoclonal antibodies,

were generally mobile, coccoid with a diameter of 200 to 300 nm in serum, stained poorly with bacteriological stains, were very resistant to antibiotics and passed through 100 but not 50 nm filters. Their aminoterminal protein sequences were novel and reproducible.

"Considerable evidence suggested presence of nontraditional DNA. They incorporated radiolabelled uridine into DNA. 16S rRNA gene sequence results place them in alpha-2 subgroup of Proteobacteria which includes Brucella, also pathogens of mammalians with preference to the fetus. This new agent causes cytotoxicity and senescence in many cultured cell lines by apoptotic cell death and growth arrest. "As reported May 23rd, 2001at the 101st General Meeting of the American Society for Microbiology, Nanobacteria has been found to be a contaminant in previously assumed-to-be-sterile medical products, specifically **IPV Polio Vaccine**. Most human biologicals and vaccines are made in fetal bovine serum, a medium that is known to be contaminated with nanobacteria. In order to prevent this problem in the future, human biological products must be made in Nano-Free Culture medium (filtered first through 20 nanometer filters,Gamma-Irradiated with 150 megarads and then heated to 90 degrees Centigrade for at least an hour to kill any nanobacteria present)"

Similarly, the Salk polio vaccine is renowned for its contamination with SV40 (simian immunodeficiency virus 40) which is implicated in human cancer. Other scientists have linked the Salk polio vaccine with the emergence of HIV, as an offshoot of SIV (simian immunodeficiency virus) believed to be present in the Salk polio vaccine.

SUBACUTE SCLEROSING PANENCEPHALITIS AND SALK VACCINE
The Lancet, Volume 302, Issue 7832, Pages 763-765

"From 1956 to 1966 the incidence of subacute sclerosing panencephalitis (S.S.P.E.) in the northern half of the North Island of New Zealand was approximately one hundred times greater than might be expected. No case was seen before 1956, and none has been seen since 1969. The incidence of the disease was greatest in the late 1950s, then it waned and was associated with an increasing age at onset of symptoms. Mass vaccination of primary-school children with Salk vaccine was begun in 1956. The vaccine used is likely to have contained live SV40 virus. Killed measles virus is another possible contaminant. It is believed that the administration of Salk vaccine in New Zealand was related to the appearance of S.S.P.E. in the community. The idea that an unusual reaction to measles infection is the sole cause of S.S.P.E. is not consistent with the observations in New Zealand."

From http://www.virology.ws/2010/04/13/poliovirus-vaccine-sv40-and-human-cancer/ :

Deep sequencing – which identified a viral contaminant of the rotavirus vaccine Rotarix - could have revealed the presence of simian virus 40 (SV40) in the poliovirus vaccine, had the technique been available in the 1950s. Exposure of over 100 million Americans to SV40, and many more worldwide, could have been

avoided, as well as the debate about the role of this monkey virus in human cancer.

SV40 was discovered by Maurice Hilleman in 1960 as a contaminant of poliovirus vaccine. It was present in batches of both the Salk and Sabin poliovirus vaccines produced and distributed from 1954 to 1963. The source was the rhesus and cynomolgous monkey kidney cells used to produce the vaccine. Even more troubling was the observation that SV40 could cause tumors in hamsters. By 1963 screening procedures were instituted to ensure the absence of SV40 in poliovirus vaccines. Ironically, monkey cells were used for poliovirus vaccine production because it was feared that human cells might contain unknown human cancer viruses.

SV40 does not cause tumors in its natural host – monkeys – because it kills infected cells. However, in the wrong host- such as a hamster – the viral replication cycle is incomplete and virions are not produced. At a very low frequency, pieces of the viral DNA become integrated into the host chromosomal DNA. Problems arise if these viral DNA fragments encode the viral T (tumor) antigen. This protein is essential for lytic replication (which takes place in monkey cells) because it kick-starts cellular DNA synthesis. The cellular DNA synthetic machinery is then co-opted for replication of the viral DNA. When only T antigen is present, the cells divide without stopping – they are transformed, and on the way to becoming a tumor. SV40 does not need to cause tumors as part of its life cycle; they are an aberrant result of having T antigen push the cells to divide. SV40 T antigen can transform human cells, and therefore in theory the virus could cause human tumors.

The results of epidemiological studies initiated in the 1960s through the 1970s, in which thousands of poliovirus vaccine recipients were studied, indicated that this population did not have an increased risk of developing cancer. More recent reports that SV40 viral DNA is present in human tumors have led to a debate on the contribution of this virus to human cancer. Some of the arguments for and against presence of SV40 in human cancers are presented below.

Evidence that SV40 is present in human tumors

- SV40 DNA has been detected in several human tumors, including osteosarcoma, mesothelioma, and non-Hodgkin's lymphoma. Similar tumors are induced by the virus in hamsters.
- Poliovirus vaccine produced in 1954 contained a variant of SV40 that can be distinguished from common laboratory strains. This viral variant has been found in three non-Hodgkin's lymphoma patients

Evidence that SV40 is not present in human tumors

- SV40 DNA is not present in all samples of a cancer, and in some studies of mesotheliomas, it has not been detected in any.
- SV40 viral DNA has been detected in tumors of those who could not have received contaminated poliovirus vaccine.

- In a comparison of mesotheliomas and normal tissues, SV40 DNA has been detected as frequently in both.
- Analysis of the SV40 sequences in mesotheliomas showed that the viral DNA was derived from a laboratory strain which contains a gap that is not present in the wild type viral genome.

Even if SV40 DNA were definitively shown to be present in human tumors, this would not answer the question of whether the virus caused the cancer. The debate on the role of SV40 in human malignancy illustrates the difficulty in establishing cause and effect, and provides ample impetus for using genomic technologies to ensure that vaccines and other biological products are free of adventitious agents.

See also:

Garcea, R., & Imperiale, M. (2003). Simian Virus 40 Infection of Humans *Journal of Virology, 77* (9), 5039-5045 DOI: 10.1128/JVI.77.9.5039-5045.2003

López-Ríos F, Illei PB, Rusch V, & Ladanyi M (2004). Evidence against a role for SV40 infection in human mesotheliomas and high risk of false-positive PCR results owing to presence of SV40 sequences in common laboratory plasmids. *Lancet, 364* (9440), 1157-66 PMID: 15451223

PEDEN, K. (2008). Recovery of strains of the polyomavirus SV40 from rhesus monkey kidney cells dating from the 1950s to the early 1960s *Virology, 370* (1), 63-76 DOI: 10.1016/j.virol.2007.06.045

Occupational Medicine 2007 57(8):564-568; doi:10.1093/occmed/kqm079
Simian virus 40 and mesothelioma in Great Britain
http://occmed.oxfordjournals.org/cgi/content/full/57/8/564 :

Various investigators have conducted studies to address the possible association of SV40 with human malignancies and SV40 has been detected in various human tumours including pleural mesotheliomas. A panel of experts at an international consensus meeting held at the University of Chicago in April 2001 concluded that there is overwhelming evidence that SV40 is capable of infecting humans and that it may be involved in the pathogenesis of some human mesotheliomas, though the mechanisms were acknowledged as being largely not well understood. A recent review concluded that the evidence for a causal link between SV40 and the development of human tumours is most convincing for the mesothelioma tumour type. However, set against this evidence are the findings of a recent study which concluded that SV40 is at most only rarely present in human mesotheliomas and that its positive detection in many polymerase chain reaction-based studies may result from the wide use of assay designs susceptible to false-positive results. Most human epidemiological studies have not found a positive association between SV40 and increased mesothelioma risk though one study did suggest there may be an association. A further study suggested that SV40-exposed cohorts had not yet reached an age at which any increased risk might be detected. Reviews have generally concluded that there was inadequate

evidence to conclude whether or not the contaminated polio vaccine caused cancer.

However, there is evidence to suggest that SV40 infection can occur in humans by other means. Butel and Lednicky observed that a substantial proportion of individuals with no risk of exposure to SV40 through contaminated polio vaccines (~10%) had SV40-neutralizing antibody and suggested that this indicates an alternative source of human infection by SV40. Fisher *et al*. reported the ability of the SV40 to replicate, generate a subclinical infection and spread through oral and respiratory routes. Thus, SV40 may be more widespread in the general population than is defined by our assumption that potentially contaminated polio vaccines are the sole source of infection. This would have a diluting effect on the results, which would reduce the power of the study to detect an association between SV40 exposure and the subsequent contraction of mesothelioma, since there would be an increased proportion of persons in our defined unexposed cohort who have actually been infected with SV40.

See also:

http://www.uow.edu.au/~bmartin/dissent/documents/AIDS/Elswood94.html

Human exposure to SV40:.
Am J Epidemiol. *1976* Jan;*103*(1):*1-12*. *Human exposure to SV40*: *Shah K*, *Nathanson N*.

In short, we don't know whether a simian retrovirus which contaminated the Salk polio vaccine causes cancer or HIV infection in humans, although there is evidence that it 'might have done' – not only through the vaccine itself, but also through transmission from vaccinated individuals and by shedding.

Neither do we know the long-term effects of a pig virus contaminating a vaccine, reported this year.

http://www.reuters.com/article/idUSTRE64D58I20100514

FDA: Glaxo, Merck vaccines OK despite pig virus
Fri May 14, 2010

(Reuters) - Rotavirus vaccines made by GlaxoSmithKline Plc and Merck & Co Inc are safe to use despite being contaminated with a pig virus, U.S. health regulators ruled on Friday. The Food and Drug administration, in a statement, said it was safe for doctors to resume giving patients Glaxo's Rotarix and continue using Merck's Rotateq. The agency said there was no evidence the contamination caused any harm and the vaccines were important in preventing hospitalizations and death.

Rotavirus can cause fatal diarrhea. Both vaccines target the virus, but pieces of DNA from porcine circovirus (PCV) have been found in both companies' products.

> The FDA's decision follows a May 7 recommendation by its advisory panel, which ruled that the risk to humans from the pig virus was theoretical at best. It called for continued use of the vaccines, saying their benefits outweighed any potential risk.
>
> Some strains of the pig virus are believed to cause a wasting syndrome in young piglets, marked by diarrhea and an inability to gain weight, but they are not known to injure humans. Tests found DNA from the virus in master cells used to make the Glaxo's product.
>
> Glaxo officials have said the DNA may have come from a pig-derived enzyme called trypsin used early in development. The company has said there is no manufacturing or safety issue with its vaccine. Merck has also said its product is safe. Neither vaccine is a blockbuster product.
>
> Sales of Merck's vaccine totaled $522 million in 2009, including $468 million in the United States. Glaxo's rotavirus vaccine sales in 2009 were $440 million globally, including $118 million in the United States.
>
> Worldwide, rotavirus kills more than 500,000 infants each year, mostly in low- and middle-income countries. Deaths are rare in the United States, but severe illness that requires a hospital stay is possible.
>
> Glaxo's vaccine won U.S. approval in 2008.

See also Adventitious pestivirus RNA in live virus vaccines against bovine and swine diseases, *Vaccine***,** Volume 13, Number 1, January 1995 , pp. 100-103(4)

Another study - Evidence of Pestivirus RNA in Human Virus Vaccines, JOURNAL OF CLINICAL MICROBIOLOGY, June 1994, p. 1604-1605 http://jcm.asm.org/cgi/reprint/32/6/1604.pdf - states:

> The presence of pestiviruses in cell cultures and in fetal bovine serum has long been a recognized problem not only in laboratories but also among vaccine manufacturers (9). Therefore, it is quite possible for an adventitious pestivirus to be present in live virus vaccines prepared from pestivirus-contaminated master seed virus stocks and/or cell cultures. Procedures currently in use to detect the adventitious pestivirus in biological products are culture methods and immunological assays.
>
> Detection of pestivirus contamination in viral vaccines has been hampered because most (99%) of the pestivirus strains are noncytopathic in cell cultures. Immunological assays are sometimes incapable of direct detection of low-titre contamination of pestiviruses in vaccines. Therefore, the culture methods and immunological assays are not perfect for detection of pestivirus contamination in viral vaccines. To our knowledge, there is no publication available concerning pestivirus contamination in viral vaccines for human use.

This report represents the first evidence of contamination with pestivirus RNA or pestiviruses in live human virus vaccines from licensed manufacturers. We examined five commercial vaccines. Although it has not been established that BVDV infections cause specific symptoms in humans, infantile gastroenteritis associated with excretion of pestivirus antigens (19) and microcephaly in infants who were born to mothers seropositive for pestiviruses (10) have been reported. Serum antibodies against BVDV have been detected in humans who had no contact with potentially infected animals (3, 18).

Since noncytopathic biotypes of BVDV are capable of incorporating the host cellular RNA into their genomes (8, 11), pestivirus contamination would raise another issue with regard to the safety of live virus vaccines produced in continuous cell lines which are potentially oncogenic. Use of continuous cell lines as cell substrates for the production of human biologicals has been approved by the WHO Study Group (17).

There is no evidence presented in this paper to substantiate contamination of the human virus vaccines with infectious pestiviruses, **but iatrogenic infections have been reported for veterinary virus vaccines contaminated with infectious pestiviruses (5, 6, 15, 16).** It is important to avoid the risk of contamination of human viral vaccines.

In conclusion, we suggest that human viral vaccines be examined for the presence of adventitious pestiviruses by PCR, which will provide an additional assurance of safety because of its sensitivity. PCR will be particularly useful when it complements other tests (12) such as culture methods or immunological assays.

Virology, November 24, 2009 stated:

"The swine-origin influenza A (H1N1) virus that appeared in 2009 and was first found in human beings in Mexico, is a reassortant with at least three parents. Six of the genes are closest in sequence to those of H1N2 'triple-reassortant' influenza viruses isolated from pigs in North America around 1999-2000. Its other two genes are from different Eurasian 'avian-like' viruses of pigs; the NA gene is closest to H1N1 viruses isolated in Europe in 1991-1993, and the MP gene is closest to H3N2 viruses isolated in Asia in 1999-2000. The sequences of these genes do not directly reveal the immediate source of the virus as the closest were from isolates collected more than a decade before the human pandemic started. **The three parents of the virus may have been assembled in one place by natural means, such as by migrating birds, however the consistent link with pig viruses suggests that human activity was involved.**

"We discuss a published suggestion that unsampled pig herds, the intercontinental live pig trade, together with porous quarantine barriers, generated the reassortant. We contrast that suggestion with the possibility that laboratory errors involving the sharing of virus isolates and cultured cells, or perhaps vaccine production, may have been involved. Gene sequences from isolates that bridge the time and phylogenetic gap between the new virus and its parents will distinguish between these possibilities, and we suggest where they

should be sought. It is important that the source of the new virus be found if we wish to avoid future pandemics rather than just trying to minimize the consequences after they have emerged. Influenza virus is a very significant zoonotic pathogen.

"Public confidence in influenza research, and the agribusinesses that are based on influenza's many hosts, has been eroded by several recent events involving the virus. Measures that might restore confidence include establishing a unified international administrative framework coordinating surveillance, research and commercial work with this virus, and maintaining an registry of all influenza isolates."

Barbara Loe Fisher of the National Vaccine Information Center, USA, wrote the following referenced piece on April 7th, 2010:

On March 22, 2010, Food and Drug Administration (FDA) officials adhering to the precautionary principle advised American doctors to suspend use of Rotarix 1 vaccine until the agency finds out why DNA from a swine virus (porcine circovirus 1 or PCV1) was found in the live rotavirus vaccine. The FDA said there is "no evidence at this time" that the vaccine manufactured by GlaxoSmithKline and given to babies at 2,4 and 6 months of age to prevent diarrhea poses any safety risk. 2

Independent Lab Using New Technology Found Contamination

The discovery that viral DNA is contaminating Rotarix vaccine was made by a team of scientists at an independent research lab in San Fransisco, California, where they used new technology to detect fragments of viral genetic material in vaccines using genetic sequencing. 3

More testing confirmed that many copies of DNA from the pig virus were present in all Rotarix vaccine lots released since the vaccine was licensed in 2008 because the pig virus DNA also contaminated the working cell bank and the original viral "seed" stock, from which Rotarix vaccine was first produced. 4

Two Other Live Virus Vaccines Contaminated

The surprising discovery reportedly was made after the independent lab used new technology to evaluate the purity of eight live virus vaccines for polio, rubella, measles, yellow fever, human herpes 3 (varicella or chicken pox), rotavirus (Rotarix and RotaTeq) and MMR. In addition to pig viral DNA found in Rotarix vaccine, low levels of DNA fragments from avian (bird) leukosis virus (a retrovirus) was found in measles vaccine and DNA fragments of a virus similar to simian (monkey) retrovirus was found in RotaTeq vaccine. 5

FDA Looking For Answers

After the team double checked their findings, researchers notified GlaxoSmithKline (GSK) on February 9, 2010 and GSK notified the FDA on March 15, 2010, which prompted the FDA's action on March 22, 2010 to suspend use of

Rotarix. The FDA says it "*does not know how DNA from PCV1 came to be present in Rotarix"* or whether "*this means that intact virus is present. Additional studies are being conducted*." 6

Rotavirus Vaccines Use Monkey, Cow, Pig Materials for Production

Rotarix is a genetically engineered vaccine that GSK created by isolating human rotavirus strain infecting a child in Cincinnati and using African Green monkey kidney cells to produce the original viral seed stock from which all Rotarix vaccine has been made. 7 In the FDA licensing process, Rotarix had to meet certain FDA standards, that included demonstrating the vaccine was not contaminated with, for example TSE (Transmissable Spongiform Encephalopathy or "mad cow" disease, a brain wasting disease) 8 or with cow viruses because bovine (cow) serum was used to prepare the original viral seed stock. Porcine trypsin**,** an enzyme in the pancreatic juice of a pig, was also used to make the viral seed stock. 9

RotaTeq is a genetically engineered vaccine containing five human-cow reassortment strains of rotavirus that were created at the Children's Hospital of Pennsylvania (CHOP), where strains of rotavirus that give cows diarrhea were combined with strains of rotavirus that cause diarrhea in humans. The reassortment viruses were transported to Merck, where master seeds were produced using African Green Monkey kidney cell cultures. Fetal bovine (cow) serum and porcine trypsin was used to make the "seed" stock. 10 There are small amounts of bovine serum and cell culture media (monkey viral DNA) that remain in RotaTeq vaccine. 11 12

FDA Suggests Drug Companies Test for Vaccine "Purity"

In a February 2010 FDA document, *Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications,* the FDA lists "non-binding recommendations" for drug companies making vaccines using animal and human cell substrates. 13 Under the heading "Testing for Adventitious Agents," the FDA states "*assurance that products are free of adventitious agents is a critical component of meeting the [FDA regulations] requirement for purity*." Under the heading "Testing for Residual Cellular DNA," the FDA states, "*Residual DNA might be a risk to your final product because of oncogenic (cancer causing) and/or infectivity potential."*

QUESTION TO THE VMD:

Has the VMD asked veterinary vaccine manufacturers to improve their tests for vaccine purity in light of recent research coming from Glasgow and Japan?

Déjà Vu: Monkey Viruses Contaminated Polio Vaccines

Contamination of vaccines with animal viruses is not new. In the 20th century, polio vaccines given to tens of millions of people worldwide were contaminated with simian virus 40 (SV40), which was found to cause cancer in animals and is

associated with human brain, bone and lung cancers but the government denies SV40 is causing those cancers in humans. 14 15 16 17

There has been controversy about the link between experimental polio vaccines tested in Africa in the 1950's and 1960's that were contaminated with a monkey virus, simian immunodeficiency virus (SIV). Soon after the polio vaccine trials in Africa, the human immunodeficiency virus (HIV) emerged. 18 Many questions about the failure of researchers and technology to screen for monkey viruses in those vaccines remain to this day.

Using Cancer Cells to Produce Vaccines?

Vaccine manufacturers have long used cell material that comes from the bodies of mammals, including humans, monkeys, cows, pigs, dogs and rodents, as well as birds or insects to make vaccines now in use or to make experimental vaccines. There is an inherent risk of contamination with viruses and other microbes (or DNA from those microbes) that can escape detection during the vaccine development, testing, licensing, manufacturing and oversight process. 19 There has even been discussion among vaccine manufacturers and the FDA in the last decade about using neoplastic (cancer) cell substrates to make vaccines but the risk of contamination with cancer cell DNA is a big risk. 20

New Influenza Vaccines: Is Contamination Possible?

In searching for ways to make seasonal influenza vaccines in a faster, easier and less expensive way than relying on chicken eggs for production, drug companies have experimented with using dog kidney cells and human fetal retinal cells. However, these cell lines have been documented to cause tumors in animals, especially dog kidney cells (MDCK). 21

At a November 19, 2009 meeting of the FDA Vaccines & Related Biological Products Advisory Committee, a vaccine manufacturer asked for permission to use insect (caterpillar) cells to make pandemic influenza shots. But insect cells can be contaminated with insect viruses that are hard to detect. The FDA Committee, on that day, voted "no." 22

Unanswered Questions about Rotarix Contamination

There are lots of questions about how the manufacturer of Rotarix vaccine and the FDA both missed the pig virus DNA contaminating the original seed stock and all doses of Rotarix vaccine given to more than one million American children in the past few years. 23 Is there state-of-the-art technology that is being used by private laboratories but not by drug companies and the FDA?

Why did the independent team of scientists, who found the contamination, notify the vaccine manufacturer first rather than also immediately reporting their finding directly to the FDA?

What about the significance of finding bird viral DNA in measles vaccine and the monkey viral DNA in RotaTeq vaccine?

Wake Up Call for Industry & Government

The contamination of Rotarix vaccine is only the latest in a long history of vaccine contamination issues that require a re-examination of the way vaccines are made and tested. It is a wake-up call for industry and government.

The big question people are asking is: why do drug companies making vaccines continue to use cells from animals, birds and insects that can be contaminated with viruses and other adventitious agents that are hard to detect?

The FDA was right to suspend use of Rotarix vaccine until they know more. Hopefully, this serious vaccine production and testing issue will be addressed immediately by vaccine manufacturers. If not, the next pandemic or serious health problem affecting large populations may be one that comes out of a vaccine lab.

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3 **Racaniello V**. Deep sequencing reveals viral vaccine contaminants. www.virology.ws. March 29, 2010. http://www.virology.ws/2010/03/29/DEEP-SEQUENCING-REVEALS-VIRAL-VACCINE-CONTAMINANTS/?UTM_SOURCE=FEEDBURNER&UTM_MEDIUM=EMAIL&UTM_CAMPAIGN=FEED%253A+VIROLOGYBLOG+%2528VIROLOGY+BLOG%2529%0A

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6 FDA. See Reference #4 above.

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10 **European Medicines Control Agency**. Evaluation of Medicines for Human Use: RotaTeq Vaccine (*Active Substance (Manufacture)*. Pages 3-10. http://www.ema.europa.eu/humandocs/PDFs/EPAR/Rotateq/066906en6.pdf

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THE VACCINE PROCESS IS NEVER WITHOUT RISK

> ***"Vaccination should be need-based and all vaccines are deemed non-universal, unless specified otherwise based on scientific evidence. The mere availability of a safe and efficacious or even affordable vaccine cannot be a good enough justification for its widespread use. Vaccines are not consumer goods and should not be given or taken, unless their necessity is proven based on the scientific principles of public health,"*** Indian Council for Medical Research.

Whilst the VMD attests to the safety and quality of UK veterinary vaccines, it is also true to say that all medical products, including vaccines, have the potential to provoke adverse effects – both short and long-term – and after the product has been deemed to be acceptable by the licensing authorities. It is these unnecessary adverse effects, from vaccines that are not required, which we are seeking to minimise.

No science has ever been put forward to support the annual vaccination of dogs and cats against core viral diseases. This practice cannot be supported by the science, and claims that dogs need to be vaccinated annually against core viral diseases are either based upon ignorance, pseudoscience or, in the worst light, upon deception. It is this issue that we have asked the government through its licensing body, the Veterinary Medicines Directorate, to address.

QUESTIONS FOR THE VMD:

1. A number of UK veterinary vaccines were found to contain an infectious retrovirus in a proportion of live attenuated vaccines for pets, and the findings were published in April 2010. Did the researchers inform the VMD of this issue before, during or after publication?

2. If the VMD was aware of this study, why did it not make this known in its March position statement on authorised veterinary vaccines for dogs?

3. If the VMD was aware of this study, how did it feel able to assert that vaccines are rigorously tested for safety and quality, and that they are uncontaminated?

4. If the VMD was not aware of this study, why not?

5. Is there state-of-the-art technology that is being used by private laboratories but not by veterinary vaccine manufacturers and the VMD?

6. If so, how safe is the VMD's licensing procedure?

7. In view of the known process problems associated with vaccines, how can routine re-vaccination be justified when immunity against viral disease persists for years or life, and annual boosters are not even needed?

8. Are dog and cat owners to be made aware that there is a potential cancer-causing retrovirus in the vaccines they buy for their pets?

9. Why has the VMD refrained from responding to our request to withdraw one-year vaccines against core viral diseases from the market?

NON CORE VACCINES FOR DOGS

Leptospirosis

The web link cited by the VMD - http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733810062?p=1191942176648 – came back with 'page not found'. We ask the VMD to provide a link so that we can see what it is they refer to.

The VMD cites industry research with regard to the prevalence of leptospirosis in the UK (CICADA-Live survey, June 2009), which we believe to be data gathered in support of Intervet's National Vaccination Month marketing campaign, illustrated on its website with colour codes rather than any meaningful figures.

We must query this research since it was linked to a sales campaign, and also in view of the fact that leptospirosis is difficult to positively diagnose, for reasons which will be explained later.

In the CHC vaccine survey, 100% of owners who reported that their dogs were diagnosed with leptospirosis confirmed that they were diagnosed within three months of being vaccinated.

Does Intervet's sales data distinguish between vaccinated and non-vaccinated dogs contracting leptospirosis? Does it identify which of the strains of leptospirosis the dogs were infected with? Does it tell us whether vaccinated dogs were covered by the vaccine for the strains they met in the field? Does Intervet's National Vaccination Month vox pop concern itself with the effective treatment available for leptospirosis?

In emphasizing the symptoms of leptospirosis, why did the VMD not also emphasise or even mention the effective treatment that is available for leptospirosis?

Relying upon a live survey paid for by a sales organisation is dubious practice for a government department charged with the task of protecting the interests of the public and their pets. It is certainly not strong enough evidence to promote annual vaccination using a vaccine that is known to provoke serious adverse reactions, which is notoriously ineffective, and which has accordingly been deemed a non core vaccine by veterinary bodies around the world.

The VMD needs to be aware that some independent experts, including the pro-vaccinator Dr Ronald D Schultz, would not advocate the use of the leptospirosis vaccine in any circumstances due to the vaccine's lack of efficacy and the dangers associated with its use.

Amongst the reasons for caution being required with the leptospirosis vaccine is the fact that IgE antibodies are raised for at least four years after this vaccine has been administered. This means that the leptospirosis vaccine is capable of causing inflammation and allergy in the pet population, which lays the ground for cancer and other immune-mediated diseases.

The VMD position document states:

> **Given the risks of infection to both dogs and their owners and the albeit limited information on the prevalence of disease in the UK, which suggests veterinary practices are seeing clinical cases, leptospiral vaccines are in effect commonly used, often in combination with core annual vaccination programmes by most, if not all, veterinary practices for the benefit of the canine and human population in the UK.**

We are of course aware of common practice, and are interested to see that the VMD accepts core annual vaccination programmes by most, if not all, veterinary practices in the UK.

Does the government not think, however, that given the potential for adverse reactions associated with the leptospirosis vaccine, we should refrain from relying upon suggestion and assumption based upon casual industry vox pops, conducted in support of a vaccine manufacturer's sales campaign?

Where are the proper, reliable, figures in the UK to establish the prevalence, or not, of leptospirosis in dogs? Why - when the research relating to leptospirosis states that this disease is most common in tropical regions of the world, and is most commonly associated with contaminated water and farm workers – does the VMD believe that leptospirosis is a particular problem in the UK, requiring repeated vaccination for dogs?

With respect, we dog owners would appreciate proper independent scientific data on this, rather than industry sales figures, as a basis upon which to rest our 'informed' consent.

When using any medical or veterinary product, one must balance the risks with the benefits, and in order to do so, one needs reliable data. Without such data, a precautionary approach is required.

If the government insists upon using suspect industry data to justify repeat vaccination when the vaccine itself is deemed by world experts to be unnecessary and/or potentially harmful, the government puts the safety of the UK pet population at huge risk. The public will lose faith in the government's advice, and vaccination levels will drop accordingly.

The public requires evidence of need, safety and efficacy, and that evidence must be seen to be free from industry bias. In the absence of such data

quantifying need, the government should not be recommending the use of a vaccine that is protective against only two or three of dozens of serovars, and is capable of inducing severe adverse reactions.

The following article was written by an independent journalist and published in the UK's *Dogs Today* magazine in November 2006, following an approach from Intervet's PR company that claimed that the country was in the grip of a leptospirosis epidemic. It makes worrying reading for any citizen who wants to be able to trust the suppliers of veterinary drugs and biologics.

A shot in the dark

Opinion is divided on vaccinating and boosting – but Leptospirosis seems the most controversial of all debates. We delve into the pros and cons, so you can weigh up the risks yourself...

A few issues Ago (June 2006) *Dogs Today* carried a very sad story about Spangler, a Golden Retriever that seems to have died from a severe reaction to his annual vaccination. In the letters that followed, we received a request from Blue Zebra - a PR firm acting on behalf of Intervet, a major vaccine manufacturer - asking to put forward the other side of the argument, outlining the benefits of vaccination; something they felt was "a particularly relevant issue considering the recent Leptospirosis outbreaks across the UK."

Naturally we were alarmed by the frightening possibility of an epidemic but also puzzled, as our many contacts in the dog world, from vets to breeders to owners, had no knowledge of any such outbreaks. However, we welcomed the chance to find out more about Leptospirosis and its vaccine, especially in view of the fact that several canine vaccine experts in the United States were sceptical of its use - given that it does not cover all strains of the bacteria a dog might meet; it does not seem to confer immunity beyond a few months; there is ambiguous evidence over the real threat from the disease; and the vaccine itself has a reputation for being the one most commonly associated with serious side effects.

Dr Ronald Schultz, one of the world's leading authorities on veterinary vaccines, says, "I find there's still a fairly high percentage of dogs that do not respond to the Leptospirosis vaccine. In addition, of all the bacterin vaccines, Leptospirosis causes the most adverse reactions."

Given that its effectiveness has been questioned and the risks highlighted, was this really a vaccine worth having, we wondered? Intervet's PR company seemed keen to provide some answers. Unfortunately, when the response finally arrived, not all our questions were addressed. In particular, Intervet did not substantiate its claims regarding the Leptospirosis outbreaks, instead citing just one anecdotal account of an unvaccinated working Labrador that had died from the disease.

So we decided to launch our own investigation and take a deeper look at Leptospirosis - just how much of a threat is it and how effective is the vaccine?

The Leptospirosis vaccine is a particularly controversial one. Unlike viral vaccines (parvovirus, distemper and adenovirus), which have been shown to give immunity for several years and therefore may not need annual boosters, Leptospirosis is a bacterin-based vaccine that gives very poor lengths of immunity. In fact, clinical evidence suggests that bacterin derived vaccines may not even provide immunity for 12 months, which means that even annual boosters may not give enough protection.

Thus the fear of a decrease in vaccination levels leading to the re-emergence of disease is more relevant for bacterial diseases. This is a dilemma facing many dog owners as the time for their annual boosters rolls around. While they can safely leave their viral vaccines unboosted for longer intervals, they may not be able to do this for the bacterin-based vaccines. But should they be boosting for Leptospirosis?

Because it is a zoonotic disease - one that can be transferred to humans - the threat of Leptospirosis cannot be underestimated. However, this does not mean that vaccination is necessarily the answer. Not only is this the vaccine most commonly associated with serious adverse reactions, especially fatal canine anaphylaxis, but it also seems to give poor protection from the disease. If the vaccine were potentially dangerous and not very effective, why would you want to give it to your dog, unless there was a serious threat of exposure to the disease? Just how prevalent is the disease?

Leptospirosis is caused by a bacterium that infects the dog when he comes into contact with the urine of an infected host animal. This can be via the environment (such as contaminated water) or directly from animal to animal. After the bacteria enters the bloodstream, it replicates rapidly in several tissues, such as the kidney, liver and spleen, leading to lethargy, abdominal pain, jaundice, vomiting, bloody diarrhoea, and ultimately liver and kidney damage. The disease can be highly contagious and, in acute cases, rapidly fatal if left untreated. Even if a dog survives the illness, he will remain a carrier of the disease, shedding the bacteria in his urine.

In humans, Leptospirosis is known as Weil's disease and although relatively common in tropical climates, it is rare in Britain and is not included on the list of Notifiable Diseases at the Department for Environment, Food and Rural Affairs (Defra). In fact, Defra stated that the reason why they do not keep records of Leptospirosis is because it is so rare in humans. According to the Health Protection Agency (HPA), human cases recorded are commonly associated with occupations such as farming (cattle and pigs are strong carriers of Leptospirosis, as well as rodents) and recreational pursuits, such as canoeing, fishing and swimming in lakes and rivers. So although the disease poses a serious threat in being transferable to humans, in reality transmission from dogs to humans rarely happens.

Number crunching

There is debate over whether the disease is common in pet dogs. One of the reasons that Intervet gave for promoting the vaccine was the occurrence of

‘outbreaks’ across the UK. However, when pressed, Intervet admitted that this claim was not based on epidemiological research but on anecdotal reporting from vets in the field - there is no statistical evidence of outbreaks as such. (In fact, an ‘outbreak’ is simply defined as an elevation above the normal baseline, even if this is just an increase from 1dog in a million to 2 dogs in a million - arguably still a very small number and hardly an epidemic as such!

And interestingly, Catherine O’Driscoll of the Canine Health Concern has anecdotal evidence that shows the opposite, with many vets - particularly those in rural areas, arguably where dogs have the highest risk of exposure - stating that they had not seen a case of Leptospirosis in over a decade.)

Chris Bradley, Veterinary Adviser to Intervet UK, explained that their anecdotal reports are from government agencies, veterinary schools and veterinary laboratories, which obtain information from post-mortems and referrals. The only way Leptospirosis can be identified is by post-mortem or by blood tests; however, in most cases, due to financial constraints or emotional reluctance, owners refuse post-mortems on deceased pets or choose not to pursue extensive testing. This means that there is a general lack of reporting on the disease and only the occasional anecdotes drift back to Intervet regarding Leptospirosis cases.

But surely, I asked, there would be a record of these anecdotal reports, which when audited, would give some idea of the prevalence of the disease? Even something as simple as “there were 12 cases in Norwich, and 64 cases in Northampton during the last three months” - without something along these lines, surely you can have no real idea about the incidence of disease and therefore it is slightly irresponsible to be warning about possible epidemics?

Chris Bradley was coy about giving figures, explaining that they are in the process of compiling a database on these reports and saying that it’s hard to be definitive about the prevalence of the disease. In fact, the only statistical report he could cite was a 1991 UK serological survey of more than 500 unvaccinated strays in Edinburgh and Glasgow. This study revealed that between 23.5 per cent and 27.5 per cent had antibodies to Leptospirosis (got infected, survived and now carry the disease). Note, though, that these were stray dogs and not pampered pets, with very different lifestyles. It seems to suggest that even in unvaccinated dogs, about 25 per cent would have the disease (although naturally, this does not take into account the percentage of dogs that were infected and subsequently died) - and 75 per cent would have escaped infection. Is this disease really that common after all?

Intervet argues that regardless of how common the disease is, it is important to vaccinate as infection with Leptospirosis can lead to a horrible death for the dog. This would certainly play on most owners’ emotions but again, it is really a question of numbers.

In the majority of cases, Leptospirosis presents as a chronic, low-grade illness, which may lead to renal failure in old age, but usually the dog recovers to become simply a carrier of the disease.

In certain acute cases, the disease will be more aggressive and dogs will suffer a rapid, horrible death. This is certainly something we all want to avoid - but just how common are these acute cases? After all, chicken pox is a disease that can, on rare occasions, lead to severe complications (such as potentially fatal bacteraemia and pneumonia) but this doesn't stop most parents from just letting their children itch their way through an infection. Could the situation not be similar for Leptospirosis? If the disease only causes acute illness and death in a very small percentage of dogs, is it worth vaccinating against it?

Catherine O'Driscoll points out, "If you look at the Edinburgh study, it showed that dogs had antibodies to Leptospirosis, but they didn't have the full-blown disease, and they had survived. This, to me, indicates that most dogs survive Leptospirosis, and in most cases, frequently undiagnosed, the dog may have the runs. And then the high acid in the dog's system will neutralise the bacteria. It is my contention that healthy dogs won't be overly threatened by Leptospirosis. Several studies have shown that an organism given adequate and appropriate nutrition will withstand viral and bacterial disease."

It would help if we had some idea of how many dogs would suffer acute Leptospirosis. Again, Intervet was unable to provide any figures and the information does not seem to be available anywhere else. I find it astounding that there is currently not even a rudimentary system to record incidence of Leptospirosis. Surely if this disease is meant to be so deadly to our dogs and so dangerous to humans, there would be some kind of recording system in place? How can pharmaceutical companies fighting something that is supposedly so serious, rely purely on anecdotal reporting? Unfortunately, unless there is a formal reporting scheme for infectious disease in dogs, which provides independent data (free from both pro- and anti-vaccine bias) about the incidence of cases, we will never really know how common a disease Leptospirosis is.

So if we're not sure how prevalent the disease is, maybe we should vaccinate anyway, just to be safe? But according to many veterinary experts, the vaccine itself may carry risks. It is the one most likely to trigger serious side effects, especially in puppies and toy breeds, possibly because it has the highest amount of added 'adjuvants' to stimulate the immune system. Some vets in the United States will not give the Leptospirosis vaccine to dogs under 10lb, due to the risk of severe anaphylaxis.

Rare risks

Intervet UK has strongly countered this by referring to the 2004 Animal Health Trust study and saying, "We appreciate that, on rare occasions, vaccination may adversely affect canine health. Our pharmacovigilance monitoring does demonstrate that adverse reactions such as transient malaise, lumps at the site of injection or even anaphylaxis can occur rarely. These rare outcomes however must be weighed up against the risks of the animal not being vaccinated and thus be left vulnerable to disease."

This is cold comfort to someone like Allison who had to put her 12-week-old German Shepherd puppy to sleep, following his Leptospirosis vaccine. The night Cougar was brought home from his first shots, he started worrying his tail and showing distress.

Allison tried to dismiss it as puppy behaviour but her concern turned to panic when Cougar began displaying signs of fear and aggression – first attacking Allison's six-year-old daughter who he had previously adored and then the older dogs in the household, before finally attempting to bite Allison when she tried to comfort him. After consultation with three different vets, Allison was told that Cougar was brain damaged and the only option was to put him to sleep.

"At the point of having Cougar put to sleep, I walked out of the vet's and had to sit on the step as my legs gave way. My husband took me straight to my mother's who gave me brandy, as I was shaking with shock. After all, you don't expect to buy a puppy and then have him put to sleep three weeks later! It totally devastated me. I was offered other puppies but I just couldn't bring myself to have them. It's taken me eight years to get the courage to have another."

Stories like Allison's are heartwrenching but the vaccine industry would argue that, while tragic, Allison's case is in a negligible minority. Chris Bradley from Intervet insists that he believes their vaccines are safe, with very few adverse reactions recorded to their Nobivac Lepto-2 vaccine, based on their pharmacovigilance monitoring from member vets who are obliged to report any incidences of adverse reactions. Despite the evidence from studies that show a link between vaccines and illnesses like autoimmune haemolytic anaemia, Chris Bradley is sceptical of any real risk from vaccines.

"I don't discount that there are cases of haemolytic anaemia or injection site cancers, but there is no clear evidence that it is definitely caused by the vaccine. For example, with the injection site cancers, the scruff of the neck - where the tumour is detected - is also the place for a lot of other procedures, such as steroid and antibiotic injections and topical flea applications. In an animal that is genetically susceptible, any of these causes could lead to the formation of a tumour - it is not necessarily the vaccine. Yes, there is the odd case that may have a possible link to vaccines but the incidence is so low, it's not considered significant. Our pharmacovigilance database has had no recorded incidence of anaphylactic shock in dogs, from our vaccine and very little record of other reactions. Obviously, if certain dogs were particularly susceptible - like certain humans with bee stings - then the vets would warn the client and perhaps recommend a different vaccination schedule. But I firmly believe that, in the majority of cases, the benefits of vaccination far outweigh the risks."

Catherine O'Driscoll, however, has a different perspective. "The 'monitoring' is at present the SARRS [Suspected Adverse Reaction Reporting] scheme. It calls for vets to voluntarily report suspected reactions. The words, 'voluntarily' and 'suspected' are key. Time after time we are contacted by dog owners whose dogs suffered epilepsy, brain damage, skin problems, allergies etc, immediately

after vaccination, and the vet denies there is any vaccine link. Therefore, no adverse reaction report is filed. If a report is filed, then a committee sticks its finger in the air and makes a subjective decision - and many of the 'experts' at the VMD [Veterinary Medicines Directorate] and the VPC [Veterinary Products Committee] are paid consultants for vaccine companies.

"Further, vets are not trained in college to look for such reactions. They are only trained to look for anaphylaxis. They are also unaware of latest research. For example, one lady who contacted the Canine Health Concern - her dog had vaccine-site cancer but the vet said it's only seen in cats so must therefore have another cause. Yet in August 2003, the *Journal of Veterinary Medicine* published a report to say that vaccines also cause vaccine-site cancer in dogs!"

But putting the issue of safety aside, what about the effectiveness of the vaccine itself? After all, if it is really good and effective, then it can be argued that it is worth giving, in spite of the risks.

In fact, the vaccine has been heavily criticised, as it appears to give only limited immunity because it does not protect against all the strains of Leptospirosis a dog might meet in the field. Like many bacteria, Leptospira exists in hundreds of different strains - called serovars - with two common strains in Britain being Leptospira canicola (dog as host) and Leptospira icterohaemorrhagiae (rodent as host), as well as two other strains, which use the pig and cattle as host, and many other rarer strains. The current vaccine only contains two serovars (L. canicola and L. icterohaemorrhagiae), which means that the dog is not protected if it meets any of the other serovars in the field. To someone like Catherine O'Driscoll, this seems crazy - to subject the dog to the high risks of the vaccine but then not give it the full spread of immunity needed.

Intervet insists, however, that anecdotal reports from veterinary laboratories show that L. icterohaemorrhagiae and L. canicola are still the antibodies most often found in blood tests on infected dogs (although they acknowledge that L. Bratislava seems to be increasing). Thus they believe that L. icterohaemo-rrhagiae and L. canicola are the two strains dogs are most likely to meet and, therefore, the two strains they use in the vaccine.

They do admit that they do not have any real epidemiological data regarding the strains dogs are exposed to or infected with. Without proper statistical data, how can they be so sure dogs are never infected with other strains if they only base their knowledge on anecdotal cases of Leptospirosis? Chris Bradley had already admitted to me earlier that most cases are under-reported and usually only acute cases would merit any owner deciding to have a diagnostic post-mortem or blood tests. Therefore, one could argue that maybe the reason why you only see L. icterohaemorrhagiae and L. canicola as the most common antibodies is because they are the ones that cause the acute cases.

Stresses and strains

There might be other strains out there, such as L. bratislava (which Intervet has admitted is increasing), which are also infecting dogs, but because they cause chronic infection, rather than acute, they are never picked up because those dogs would not be presented for post-mortems or blood tests. But meanwhile, the dogs are still being infected with Leptospirosis, despite being vaccinated, and still running the risk of both getting renal failure in later life and also adverse vaccine reactions.

In the United States, neglect to include other strains in the vaccine has led to serious outbreaks across the country from newly emerging serovars, despite dogs being already vaccinated for Leptospirosis with the two old serovars that had been believed to be dominant.

Nevertheless, Chris Bradley says that there is little evidence of L. bratislava causing clinical disease in dogs; he is confident that the situation in the UK is different from the United States - although it is difficult to see the reason for his confidence when there is no epidemiological data to support it.

The other criticism of the Leptospirosis vaccine is the length of immunity. According to Dr Jean Dodds, a leading veterinarian and expert on canine vaccines, challenge studies from the United States show that immunity only lasts for three to six months, which means that even the recommended annual boosters may leave a dog unprotected for half the year or more.

Intervet claims that its 2003 updated Leptospirosis vaccine, Nobivac Lepto-2, does guarantee immunity for 12 months, based on its own challenge studies, the results of which were published in *Veterinary Microbiology, Vol 95 (2003).* In this study, only half the test dogs were vaccinated and then all the dogs were ‘challenged’ with infection from Leptospirosis at five-, 22- and 56-week intervals.

The results showed that the vaccinated dogs withstood infection, even after 12 months, and Intervet suggests that immunity may last even longer in some dogs but yearly boosters are the safest upper limit, to cover all dogs.

What is puzzling is how the UK vaccine can give such different immunity levels to the US vaccine? According to Dr Jean Dodds, the core vaccine is the same and even though the American vaccine contains two more serovars than the UK one, “that wouldn’t explain the US and UK difference in claims for longevity. Further, it has long been known that the two-way Lepto vaccines last no longer than six months.”

Chris Bradley at Intervet claims that the difference lies in the way immunity is assessed - ie, the US is assessing immunity by measuring antibodies to Leptospirosis in the blood. However, dogs can still be immune to the disease, even if they do not show any antibodies - thus the American studies may not record any antibodies after six months, leading them to assume immunity only lasts for six months, when in reality the vaccinated dogs may still be immune. Conversely, the UK vaccine immunity is measured by actually challenging the animals with the disease and seeing if they succumb.

This is nonsense, says Dr Jean Dodds, insisting that the animals in the US are also challenged by the actual disease. Chris Bradley admits that he is unclear about the exact nature of vaccines in the US so he is unable to really explain the difference.

Small sample

Certainly, challenge studies are not infallible - Dr Dodds points out that, “The problem with experimental challenge studies is that only a small number of animals are required to license a new vaccine” - and Chris Bradley admits that the Intervet challenge studies only used 24 dogs but maintains that this was statistically robust and that they did not use more dogs for welfare reasons.

The final issue with the Leptospirosis vaccine is that of ‘herd immunity’ or lack of, in this case. While the vaccine may protect a dog from the clinical development of the disease, it does not prevent it carrying and shedding the infectious Leptospires into the environment.

Thus, this is one vaccine that does not protect the population, only the individual dog. Having said that, Intervet insists that its 2003 updated vaccine does confer reduced renal shedding and therefore does help towards herd immunity.

This does not impress Catherine O’Driscoll. “Herd immunity refers to the fact that once 67 per cent of a population has been exposed to a disease, then epidemics die out (as with the human plague). As shown in the Edinburgh survey, only around 25 per cent of city dogs had been exposed to Leptospirosis, which shows that herd immunity cannot be claimed at this time. Even so, we still don’t have lots of dogs coming down with Lepto and, again, the high acid content of a healthy dog’s stomach will put a stop to acute infection.”

The American Animal Hospital Association Guidelines for vets places Leptospirosis in their ‘non-core’ (optional) category, with special mention of its high incidence of post-vaccination reactions and advises that, “Annual boosters are not routinely recommended for all dogs. Vaccination should be restricted to use in areas where a reasonable risk of exposure has been established.”

Should we adopt a similar strategy for the UK? No, says Intervet’s Chris Bradley, because everywhere in the UK is potentially an area of high risk due to the “booming rodent population”, which provides a reservoir for infection.

Now, this might be true but it does beg the question that if rats are so numerous and such a dangerous source of disease, why are humans not vaccinated for Leptospirosis? And why - if we are not and not all dogs are vaccinated - are we not all succumbing to the disease, in spite of the high risk of exposure from rats everywhere?

Catherine O’Driscoll says, “Actually, it is said that all of us live within 20ft of rats. They are everywhere, and especially in cities where they live in the sewage network and feast on our rubbish. The rats aren’t vaccinated, of

course, but the human population is NOT beset and besieged by a Leptospirosis epidemic. How many people are vaccinated against Leptospirosis, despite all these rats? Are farm workers vaccinated against Lepto - where it seems the greatest threat lies?"

It would be safe to assume that if the United States – arguably equally overrun with rats - can define geographical areas of high risk for Leptospirosis, then the UK should be able to do the same. After all, it seems - from Defra and HPA [Health Protection Agency] information on the disease - that even though there are rats everywhere, the risk for humans is only high for people who work with farm animals, who spend large amounts of time in possibly contaminated bodies of water and in areas of flooding. So the situation should be similar for dogs, shouldn't it? At the very least, not all dogs could have the same risk of exposure and there is some argument for only vaccinating the dogs in high-risk areas.

No change

Despite conflicting evidence, annual boosting for Leptospirosis remains the recommendation in the UK and something most vets will push for, as they have little support from the veterinary community if they opt not to vaccinate and the dog subsequently becomes ill. In spite of support from scientific research, it seems that most vets still feel obliged to adhere to the vaccine data sheet recommendations.

Liz Jay was one such owner who came to bitterly regret her vet's advice to repeat the Leptospirosis vaccine on her Bearded Collie, Lulu. Following her booster, Lulu developed extremely itchy, peeling skin while her hair fell out in clumps until she was about two-thirds bald. She also developed a series of minor infections - ears, eyes, anal glands, nails - and occasional bouts of seizures and vomiting. Things came to a head when Lulu collapsed at a show, bleeding internally, and was diagnosed with haemangiosarcoma, with tumours from her ovaries to her heart. Liz couldn't even wake her up to say goodbye.

So it seems that we are back at square one, with the vaccine companies saying that there is a real need for protection and that the Leptospirosis vaccine is a good product that carries negligible risk. Meanwhile, the sceptics, like Catherine O'Driscoll, cynically believe in more financial motives, saying, "The fact that it is dangerous and practically useless, and fighting a disease that is barely a problem, doesn't much matter to them."

Perhaps the best we can hope for is informed consent: make sure your vet explains the dangers of the vaccine to you; find out about the length and coverage of immunity of the vaccine he is using; ask him about the real risk of Leptospirosis in your area; and weigh up the risk benefit ratio before you subject your dog to 'just a little prick'. ::

Intervet was not very pleased with the *Dogs Today* article, and wrote to the editor to tell her that the publication could no longer rely upon its advertising support. The editor published the letter for all to see.

The following referenced paper was written by veterinarian Patricia Jordan and published in *Dogs… Naturally!* magazine during 2010. It again explains why the British government through the VMD should not base its advice on vaccine industry publicity propaganda.

There is a problem with Leptospirosis Vaccines
Beware the Smoke and Mirrors
By Patricia Jordan, DVM

In several vaccine lectures that I have attended in the past four years, the most current information from our premiere veterinary vaccine researchers, Dr. Ronald Schultz (Immunologist) and Dr. Richard Ford, (Infectious Disease Professor, Clinical Director of NC College of Veterinary Medicine), is that Leptospirosis vaccines are not recommended vaccines.[1, 2] Dr. Ron Schultz, who lives in a Leptospira endemic area of the country, still does not recommend the Leptospira vaccines and does not vaccinate his own dogs.[3]

First let us look at information from the CDC website on the disease of Leptospirosis as it stands here in the United States. The most current CDC fact sheet states that Leptospirosis in humans is not a reportable disease in the United States. The few cases that occur are mostly traced to Hawaii which is not a part of the continental United States. The disease does occur more in tropical climates and is reported to have a fatality rate worldwide in humans of 1-5%. With most of the cases in the US occurring in Hawaii or in travellers that went to tropical destinations we can put the exposure of Leptospirosis in the US into proper perspective.[4]

Indeed while I requested the epidemiological information on Leptospirosis in the Commonwealth of Massachusetts prior to a lecture promoting Leptospirosis vaccines in dogs, I found that Massachusetts had never had even one case of Leptospirosis reported in humans since they started looking for Leptospirosis .[5] There were no cases of Leptospirosis reports in dogs documented and confirmed for the Commonwealth of Massachusetts.

Again, I gathered this information for the purpose of properly understanding the true status of the Leptospirosis disease and the need for a preventative program within the veterinary clinical setting.

Researching the areas of the world that are trouble spots of Leptospira exposure - Okinawa, Philippines, Sri Lanka, Malaysia, Indonesia, Brazil, Cuba, Guatemala, Borneo - most of the areas that suffer from this disease in a natural setting, have a number of common environmental parameters. One is standing water or flooding, post hurricane flooding and in tropical areas of increased water fall. US military personnel have seen infections with Leptospira when at duty in stations in tropical and subtropical locations. Another factor to consider with Leptospirosis is the presence of rat infestations. This can be found in slums of Brazil and the crowded areas of rat infested alleys of the NY Bronx, to the rat infested prisons of Malaysia. Sewer workers in China are exposed to Leptospirosis; post flood waters from hurricanes in Cuba bring predictable exposure to Leptospira.

There is also a seasonality of autumn associated with the disease. People and animals exposed to infected areas of water, ponds and smaller lakes, hunters and people taking part in water sports are at risk in selected reservoirs harbouring pathogenic serovars of Leptospira. Occupations exposing the workers to animals - as in butchers and slaughterhouse workers - are at increased risk, as are veterinarians and farmers. One dairy maid in the UK lost a pregnancy at 23 weeks due to the first known case of human intrauterine exposure to Leptospirosis.[6] A caution to handling the tissues of any animals that could become infected with pathogenic strains of Leptospirosis would be prudent to note; namely in cows, pigs, and dogs. Understanding the factors that increase the risk of exposure to Leptospirosis is necessary in understanding how to avoid Leptospirosis exposure.

Last year there was a report of the use of Leptospirosis as a biological warfare weapon in Somalia, the pathogen being added to the drinking water supply of soldiers.[7] A newly reported reservoir of Leptospira in bats is also a matter of study .[8] California sea lions and harbour seals have been found to carry Leptospira and Japan has found Leptospira in flying squirrels imported from the United States as pets from Texas.[9,10] Other than these aforementioned areas, the fact is that the typical veterinary patient in the continental United States will not be at risk nor exposed to a pathogenic serovar of this organism that is nevertheless listed as the most rapidly growing zoonosis in the world.

Last year, the predictable season of post hurricane flooding and Leptospira exposure in Cuba was handled with the public prescription and use of homeopathy. This successful use of homeopathy for public health is documented with over 2.4 million people in Cuba administered two doses of homeoprophylaxis in 2007 by the Ministry of Health in Cuba. The doses of Leptospira nosode had been prepared at the Finlay Institute, a centre dedicated to development and production of vaccines. Finlay Institute is a WHO qualified facility dedicated to research, production and development and produces high quality homeopathic products in addition to vaccines.[11] Understanding that there are much safer ways to address exposure to Leptospira in the example of a chemoprophylaxis also is important when the record of adverse events from Leptospira vaccines are discussed.[12,13]

Outside the United States where recognized pathogenic serovars of Leptospira exist and certain workers are at higher risk for Leptospira infections, except for a few weak references of sewer workers and agricultural workers in Asia, people are simply not vaccinated against Leptospirosis. The reasons are:

#1 the vaccines do not work to prevent infections
#2 the vaccine is associated with adverse events that preclude their use[14]

So, if exposure to Leptospirosis is so specific, if there are known adverse events, and if there is a lack of protection from the vaccines in humans, why are Leptospira vaccines promoted for dogs in the United States, or in the United Kingdom or in Australia?

THE BAD VACCINE

There are over 230 serovars of Leptospirosis, only a few which are pathogenic.[15] The vaccines are serovar specific and several factors are impacted by this information.[16] First of all, any vaccine administered for specific serovars will only create agglutinating antibody to those specific serovars.[17]

Once vaccinated, the patient's serum can no longer be a useful record for diagnostic tests, as the serum antibody titre from the vaccine cannot be distinguished from antibody caused by natural infection. This leads to interpretation problems when trying to diagnose the presence of infection or disease.[18]

Records of multivalent vaccines lead to test results of antibody generation against serovars that were not even included in the vaccine to begin with.[19] This, of course, means that antibodies came from natural exposure, and not from the vaccine. This leads to problems using the MAT titre test to even try and determine beyond doubt which serovar was the serovar of infectivity, if any.[20] If the production of antibody following vaccination were synonymous with immunity (which it is not) or immunization (which it is not) the obvious conclusion of this information is that vaccination does not even result in protection.[21]

Due to molecular mimicry with antigens, the unsettling factor for disease presence is complicated with cross reactivity of the antigens with many different disease organisms such as Syphilis, Lyme, Legionaries, HIV and autoimmune disease.[22] Put simply, this means that it is difficult to distinguish between antibodies to this range of diseases. Testing of the patient suspected with a Leptospirosis disease is now done via the PCR DNA test for the actual organism retrieved from either blood or urine.

Oregon State Veterinary Diagnostic laboratory and IDEXX now both advertise this PCR testing on the DNA of the actual organism.[23, 24] One problem with the tests is to understand that you should not administer any treatment prior to obtaining test samples if you want a chance at retrieving useful information - as even one dose of antibiotics is able to turn a positive case to negative on the PCR test following treatment.[25] Any treatment will also render a test taken at a later date negative.

This would be a good time to let you know how easily Leptospirosis can be treated. Doxycycline is the antibiotic of choice. This antibiotic has the ability, even in renal compromise, to sterilize the urinary tract of Leptospira infection. Doxycycline can be administered to dogs with renal insufficiency and is effective in both the infection of the blood or urine stage, clearing the organism from the kidneys.[26]

Since there are so many Leptospirosis serovars out there, and since the pathogenic strains vary, and since the vaccines cannot guarantee protection from infection, it would make better sense to not inject your dog with any Leptospira vaccines.

The trade offs to avoiding adverse events from vaccination - not the least of which can be renal failure within 48 hours of injection, or four years of dermatitis and puritis - would be the human caretakers actually knowing their dog is sick with a pathogenic strain and having their dog presented immediately for treatment.[27] To do this, animal guardians need to be aware of the symptoms of Leptospirosis in the dog.

Antibiotic treatment is quickly effective. The possibility of human infection from their dog disappears after the first day of treatment with antibiotics, so early detection of a real problem impacts human public health issues as well.[28] Doxycycline (chemoprophylaxis) is also used successfully to prevent human infections (weekly 200 mg for military personnel without previous exposure to Leptospirosis who are going for jungle training) when taken prior to the possibility of Leptospira exposure.[29]

Vaccination with Leptospira is fraught with problems. Leptospira vaccines cannot even protect the dog from infection with Leptospira or renal colonization. Leptospira vaccines have little effect on the maintenance and transmission of the disease in the animal populations in which they are applied.[30] The Leptospira becomes the very source of infection of the humans in contact with the Leptospirosis vaccinated dog.[31] There are several cases that I am personally aware of that, in the end, I could not say beyond any doubt that the Leptospira vaccine administered to the dog was not the actual reason for subclinical infection. Chronic shedding of the Leptospira in turn infected the humans living in the same household!

Read the paper on the use and overuse of veterinary vaccines leading to emerging public health issues and realize that use of Leptospira vaccines in dogs is an obstacle to public health![32]

In the case of a duck hunter contracting a case of Leptospirosis, following the epidemiological field study undertaken by the state of California and the inability to recover any Leptospira from the bodies of water, the question needs to be answered if the man became infected through transmission of the Leptospira from his vaccinated dog.[33]

There is a cost associated with monitoring the environment to continue to assess the extent of any purported Leptospirosis serovars causing disease in a given population. To date there are no such programs set up as the scarcity of the disease economically makes Leptospira not a “priority” disease, not one that even needs to be tackled with vaccination. A successful vaccination program requires that the epidemiological studies are done to assess the extent of a problem and this is currently not even being performed.[34]

The public and the veterinary doctors usually do not know that this vaccine does not confer immunity. Challenge studies are rarely done and the studies I have evaluated are conflicted and ineffective in measuring immunity in vivo[35, 36] Production of Leptospira vaccines are expensive and labour intensive to the drug companies who must recoup the precious monies spent to have brought them to market. Is this enough of a reason to allow the adverse events that follow use of this troubled vaccine?

Most information available to the animal caretakers that come from self proclaimed “dog experts” on the internet are false. The marketing misinformation that recommends this vaccine is everywhere. Unfortunately this includes most of the advice available from veterinary run websites on the internet, and in the veterinary office in the brochures available to clients. I found one very fair column on the subject of Leptospirosis written by a retired veterinarian in Oklahoma, and a great article that even listed the contraindications for the Leptospira vaccines in dogs by a veterinarian in Bali - one place that has a serious Leptospirosis problem.[37, 38] Why is this? The truth is that veterinarians are painfully inept at discussing the facts surrounding Leptospirosis because the bulk of their information comes from the very drug companies that stand to profit or at least recoup the many monies this troubled vaccine has cost their corporations.

One serious problem veterinarians face is marketing conflict material for the drug companies. I have seen this misinformation published - not only in the local newspapers but also on the worldwide web. A Reidsville, NC veterinary facility that promoted the Leptospira vaccine in partnership with Pfizer was the source of one particular case.[39] The advice of our professional medical experts is seriously compromised and devalued when they do not perform due diligence in the release of misinformation marketing material. The conflict material included a telephone number to the veterinary facility, so I made a telephone call and heard the veterinary receptionist continue to disperse marketing misinformation. Where is truth in advertising? Truth is not even found at the very facilities that administer the jab!

Who then will be held accountable for the adverse events that follow the administration of Leptospira vaccines? Certainly not the corporations that make the vaccine, they have no license to censure.

I am including pictures of animals harmed by the Leptospira vaccines and a listing of those adverse events reported by the clients. Anaphylaxis, anorexia, fever, dehydration, autoimmune disease, digestive issues, limping, loud vocalization following vaccination, acute organ failure, renal failure, liver failure, pancreatitis, death, dermatitis, puritis, cancer, degeneration of soft tissue - all of these are reports following administration of the Leptospira vaccine.

Here is another important fact of vaccine use in general…….vaccines are being linked to death, disease and chronic disability. Vaccines - because of the immunopathology they activate once the jab has been delivered - are responsible for the disease that results in those receiving the jab. Immune reaction to the soup of ingredients delivered in the jab result in autoantibody production.[40] Microbial antigens can also elicit autoantibody production.[41]

Indeed vaccines are now found to be responsible for autoantibody production, autoimmune disease, and cancer! The immunogenetics of autoantibody and autoimmune diseases are under genetic control; however the inciting disturbance to elicit gene response is from the jab itself.[42] Vaccines lead to mutations of the genome, autoimmune disease in one generation leads to genetic disease in the next.

Vaccines generate genetic impact that not only determines the severity of the immune response in natural infections but also dictates response from tissue histocompatibility markers and the expression of autoimmune disease with repeated exposure to antigens with subsequent vaccine administrations. The histocompatibility markers on the tissues are also reactive to the results of the jab. The genetic compromise that occurs to anyone's genome receiving the jab has never been researched by the drug manufacturers that produce vaccines and therefore prove that vaccine safety and efficacy have never been determined by the government regulatory agencies that license and unleash these products upon the populations.

Indeed, research is now available to show how the histocompatibility sites of human and animal tissues are reacting with vaccine-injected antigens that in turn are responsible for the adverse, lethal disease pathology that kills or dis eases the patient.[43] Indeed there are examples of the very vaccine antigen to immune cell response with both Leptospira and Lyme disease vaccines producing the same pathology as the natural infection itself.[44, 45, 46]

To clarify, these vaccines can cause the disease pathology that we are vaccinating against. In some cases with viral vaccines they can even result in the viral disease itself.

This brings more understanding to the statement in the book 'Vaccination Examining the Record' by Judith A. DeCava: "a person not vaccinated has ONE RISK, catching the disease, where a vaccinated person has TWO RISKS; catching the disease and damage from the vaccine".[47] We now know that the vaccines have not been safety tested and they have not really been proven effective in providing true immunity. The immune system reactivity vaccines are responsible for can be the expression of the adverse events and diseases that follow vaccine administration.[48]

Specific Leptospirosis severity may be associated with the intensity of the humoral immune response. Vaccines and previous natural exposure would determine this humoral immune response.[49] Therefore the "gene environment" which is impacted by every jab delivered can determine the T cell activation and immune complexes, auto antibodies and cytokine cascade that results not only with future natural exposure to antigen but with every additional jab delivered. The making of a "super antigen" and lethal consequences would at the hands of the vaccine administrators.[50] This is why Dr. Ron Schultz is on record with a minimal vaccine protocol and has said you better have a good reason for injecting because any time you inject you could kill the patient.

The hypothesis is that the disease of Leptospirosis is in actuality immune mediated. I believe I have support of this in the reporting by doctors of the use of pulsed steroid treatment to save the kidney in cases where the symptoms are the very description of immune mediated dis ease itself. Patients that were treated with pulsed steroids were too far from immediate medical facilities and were treated in the field situations with high doses of pulsed steroid. Immunosuppressive dosing of steroids was able to save them from renal failure and the immune mediated pathology of the disease until they were able to reach critical care facilities and fluid support for the kidneys.[51] This means the antigens

in the vaccine are just as capable of producing disease as in the natural infection because of the interaction of the antigen and the immune cells, is the dis ease!

Another factor now understood is that in direct opposition to the germ theory of Pasteur, it appears this is another example of the proof that Microbiologist Antoine Bechamp was correct about disease and the theory of “terrain”. Terrain theory states that it is the individual’s system that determines dis ease and the individual response to presentation of the antigen to the patient’s immune cells. However, multiple administrations of vaccines hyper sensitize the patient to a real crisis, and when antigen and immune cells collide, disease results.

So beware the medical professionals that are not Leptospirosis literate and are just promoting corporate marketing information. Misinformation seems to me to be the majority of Leptospirosis information available. Marketers - especially now in this tight economy - are engaging all of their “business resources” in order to generate revenue. Adverse event associated vaccine administration are a real boon to the coffers when the adverse events follow the cost of vaccinations.

Pfizer sponsored ”scientific” papers on Leptospira are sponsored with “educational “grants in order to produce recommendations for vaccination of the dog without proof that the vaccine is safe or effective. They use words like “likely” and “appears’ to expotentialize the nonexistent benefit of vaccination. They are “reaching” in their efforts to provide a benefit for vaccine use. They say these vaccines “appear” to be effective. They write off any adverse events from the vaccines stating “published data to validate these concerns are lacking because there is no independent mechanism to report vaccine reactions in the US”.[52]

The drug companies and the veterinarians that are paid as corporate mouthpieces can all hide behind this statement and all help keep independent mechanisms for reporting adverse vaccine events from manifesting by influencing government. The repeatable phenomena that continue to follow vaccinations are not merely “coincidences”.

A Pfizer mouthpiece states that “they would advise to strongly consider vaccination” because “they appear to work”, yearly boosters “appear to be necessary”. They admit that the weak spot is “vaccine development” and “diagnostic assays”, that re-emergence of this disease could very well be the result of vaccine programs! [53]

When I pressed for the proof from Merial that their Leptospira vaccines did indeed provide an entire year of “immunity” they finally sent me an article that did not even test their vaccines. The company forwarded work from Intervet in the Netherlands. Intervet is the source of much conflict in the UK for mounting yearly marketing campaigns in order to advocate yearly vaccinations of pets, despite the fact this is not a recommendation from the World Small Animal Veterinary Association or our AVMA or AAHA, or in Australia. The paper that was supposed to prove the worthiness of the Leptospira vaccines was conflict material that also failed to properly test vaccinates in a method that would prove immunity.

The paper was also not even using the Merial vaccines in their study. The conflict work was performed at the Dept. of Bacteriological R & D for Intervet International BV in the Netherlands.[54]

If you read the paper A Shot in the Dark about the scandal surrounding the push to vaccinate dogs in the UK with Leptospirosis vaccines, despite the lack of proof of the existence of a Leptospirosis problem. You will find out that the drug companies conspired to format a market for their product with only anecdotal evidence of the existence of any Leptospirosis problems.[55] What truthful information or facts do we really have to base due diligence on?

This problem of the drug company making a market for their product when a risk for the disease does not exist, or when there is a risk of vaccine induced adverse events, is not beneficial to the animals and is counter-productive for animal welfare. A few examples of this happening in human medicine with Glaxo Smith Kline and the Hep B vaccine, the Merck Gardasil vaccine and the Bird Flu and Swine flu vaccines have all resulted in a call for investigations and criminal charges to be brought against the WHO.[56, 57]

The WHO Vaccine Advisor, Juhane Eskola made over 6 million Euros researching vaccines; he then advised the WHO to recommend for the recent swine flu “pandemic”. Similarly, the CDC Childhood Vaccine Advisor, Dr. Paul Offit made so much money with Merck making a rotavirus vaccine that he said “it was like winning the lottery”. Now Professor Ulrich Keil Director of WHO Collaborative Center for Epidemiology is admitting to PACE investigation that the vaccine advisors are often employees of the pharmaceutical companies and the WHO is only a screen for unearned commercial promotion of pharmaceutical products.

Indeed, even the US courts hearing the case of Lymerix vaccine damage and ordering the recall of the adverse event associated vaccine stated that the federal employees should never be allowed to consult in areas where they set federal policy. In veterinary medicine, many researchers are indeed employees of the pharmaceutical companies they become the mouthpiece for. Despite being on faculties of our leading veterinary institutions, many have their research grants supplied to them from the pharmaceutical industry.

Vaccine adverse events will remain anecdotal so long as government and industry continue to protect vaccine use. When the only safety or effectiveness studies come from conflict sources - those that stand to profit from the sale and use of the vaccines - we need to understand that corporate integrity or lack thereof is the only unit of measure.

This year another effort by Canine Health Concern in the UK is once again trying to stop the unethical marketing of vaccine protocols that are not within the standard of care for veterinary medicine and constitute fraud. This letter of concern has been signed by many veterinary professionals in the hopes that unsafe and dangerous vaccines are not promoted to the public from drug marketers.[58]

The Leptospira vaccines are not safe. Pfizer gives 'immunization support guarantees" and this says, 'buy ours, it is the best". As they talk about "serovar shifts" and discuss that "diagnostic assays are wrought with problems"; that they cannot explain how high MAT titres are obtained against serovars not even in the vaccines, that the vaccine itself can produce disease in the dog, you see quickly over a dozen ways to beat the 'immunization guarantee".[59]

Cornell helped Pfizer with the "educational" paper and now, we see Cornell has a" better vaccine" as they have yet another idea how to make an effective Leptospira vaccine. Cornell disses the aluminium adjuvant used for a century in veterinary vaccines. The aluminium adjuvant; which has been in all the Leptospira vaccines even now to this very day, despite being found to cause cancer. Cornell is now reporting that the aluminium adjuvant used for five decades is now known to be "unreliable". They say it "destroys the antigens structure" and that it" degrades amino acid sequence ".[60] Did the aluminium do this to the genomes of the victims receiving these adjuvants? Apparently so as the WHO in 1999 declared these adjuvants, the same found in children's vaccines, as "carcinogenic" in the IARC.[61]

Cornell wants to take a whack at putting yet another Leptospira vaccine out there. Cornell's Baker Institute of Animal Vaccines will make yet another type of vaccine and this one will be better, this one is made with genetically engineered bacteria genes from E. coli, this one will be safe, try this one.[62] (January 25, 2010)

Understand that there is no backbone for support of vaccination. The most widely used statement from disease illiterate professionals marketing the vaccines is: "the long history of well established success that vaccines have been responsible for the control of infectious disease" is as long as the history of vaccine use and as much a figment of the promoter's imagination as I have ever seen consistently appear as defence for vaccinologists. There is no proof that vaccines create immunity. Vaccines are linked to the generations of immune reaction diseases that now plague highly vaccinated populations. As my colleague Dr. Stephen Blake has said over and over,"never before in the history of man has there ever been a greater medical assumption more responsible for the death and disease than the use of vaccines as we know them today".

Know the risks for natural infection, seek immediate treatment if your dog gets sick, and realize the germ is not the problem; the individual's immune system is the determinant. Optimal nutrition is the key to immune health .Prior genetic damage from vaccines should be considered. Become proactive in the search for truth, never assume the medical professional performs due diligence. Poison is poison no matter if injections contain toxins, chemicals, heavy metals, viruses and microbial protein, antibiotics and fungi stats or genetically engineered monsters.

Having the "new thing" with genetically engineered products will not be proven any safer than the earlier poisons. Know the promoters will not perform due diligence in establishing safety, that our government to date accepts safety studies from this conflict source and provides for no independent testing, that the vaccine-promoting professionals, the doctors, will not be expected to perform due

diligence in the researching of these products and at this time still do not recognize the vaccine induced disease and adverse events nor report them to any independent monitoring system. Understand that they will unleash this vaccine without really knowing if the vaccine is safe or effective, just as they have for all the vaccines that have come before.

Intervet Schering Plough is revving up for their annual vaccine propaganda marketing in the UK again, promoting unsafe vaccines on the anecdotal evidence that there is even a need for the vaccine in the first place.[63] The only protection from this marketing mania is to know the lack of science behind both the making and administration of these vaccines. Understand that the client will not have recourse against these marketing giants when their pets become ill. Understand that drug companies are responsible and yet are unable to be held accountable. To the vaccinologists out there, Dr. Ron Schultz says it is an indefensible practice. Culpable responsibility does lie in the hands of the administrator of the jab. Only the informed animal owner will understand this so pass the information forward!

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KENNEL COUGH

Once again, we will quote the VMD's position paper:

> **Before a veterinary vaccine can be placed on the UK market it undergoes a rigorous independent scientific assessment to ensure the product meets the required standards. In the UK the standards are set by the European legislation. Independent assessment seeks to ensure three major factors are in place before any vaccine is made available for use:**

1. vaccines are manufactured to a consistent and acceptable quality using high grade materials and are uncontaminated with potentially harmful infectious agents or other toxic substances;

2. **vaccines are safe to be administered to young and older animals where relevant, and pose no risk to the owner, their families or other animals and persons coming in contact with vaccinated animals. Where necessary, specific warnings are added to the product literature to minimise any risk of an adverse reaction following administration of the product;**

3. high quality scientific data is available to support the primary and any revaccination (booster) schedule and this has been assessed to ensure the vaccine can be expected to provide the required onset and duration of immunity claimed by the manufacturer to protect animals against disease.

We refer specifically to point 2 above.

We also quote another statement from the VMD's position paper, in particular regard to the VMD's ambition to reduce dissemination (spread) of disease:

> **Immunity therefore does not necessarily signify a freedom from disease. With some vaccines the ambition is simply to reduce the severity of the disease (e.g. Kennel Cough vaccine) rather than to protect fully the animal from the symptoms of the disease. In some cases the ambition is to reduce the dissemination of the disease causing organism.**

Bordetella bronchiseptico (kennel cough) infection can be transmitted from animals to humans and so it is a Zoonosis.

Bordetella bronchiseptico – <u>from the vaccine</u> - can be transmitted to adult humans with compromised immune systems, and also to human infants. Bordetella is closely related to whooping cough in humans.

Kennel cough vaccines, when administered to dogs, are not entirely safe for the humans living with those dogs. Yet they are still licensed, and no document is available for pet owners so that they can understand the risks – except, of course, the datasheets which are retained by vets and which are jargonistic and therefore largely unintelligible to the ordinary layman.

The problem is that the product literature is rarely made available to veterinary clients. Informed consent is not sought. The above statement from the VMD is not reflective of the truth when viewed alongside the following information relating to kennel cough vaccines. Further, the kennel cough vaccine is capable of initiating kennel cough outbreaks.

Whilst the VMD claims in its position paper that the kennel cough vaccine can reduce the amount of viral shedding, datasheets approved by the VMD for kennel cough vaccines include the following warnings:

> Canigen KC: "Vaccinated animals can spread the Bordetella bronchiseptico vaccine strain for six weeks and the Canine parainfluenza vaccine strain for a few days after vaccination. It is therefore advisable to avoid close contact between immunocompromised humans and vaccinated animals during this period.
>
> "Immunocompromised individuals should avoid any contact with the vaccine and vaccinated dogs up to six weeks after vaccination."
>
> Bronchi Shield: "Vaccinated dogs may excrete the vaccine strain of Bordetella bronchiseptico up to seven weeks following vaccination. During this time, immunosuppressed persons are advised to avoid contact with vaccinated dogs. Similar precautions are also applicable to unvaccinated in-contact or immunosuppressed animals."
>
> Intrac: "Immunosuppressed individuals should avoid any contact with the vaccine and vaccinated dogs."
>
> Nobivac KC: "Vaccinated animals can spread the Bordetella bronchiseptico vaccine strain for six weeks and the canine parainfluenza vaccine strain for a few days after vaccination.
>
> "Immunocompromised individuals should avoid any contact with the vaccine and vaccinated dogs up to six weeks after vaccination."

It should be noted that Intervet's website - http://www.future-of-vaccination.co.uk/kennel-cough-vaccination.asp - uses significantly different wording in its advice to pet owners with regard to their kennel cough vaccine. Intervet manufactures Nobivac KC, whose datasheet contraindications were given above.

> "There is one vaccine that provides year round protection against both the major causes of this disease, with full onset of immunity within three days of administration. It is recommended that you require all clients to have their dogs vaccinated at least three days prior to admission. However, for dogs which have not previously been vaccinated against this disease, it is advisable to allow 14 days between vaccinations and admission to your kennel. This avoids the risk of animals being boarded that may be incubating the disease at the time of vaccination."

Information for clients is given somewhat lightly on this website, is it not, claiming that the concern is that animals may be incubating the disease? No mention of risk to immunocompromised humans, and no mention of the fact that the vaccine itself can give rise to the animal contracting the disease and spreading infection.

Datasheet information is not shared with dog owners by vets who routinely retain and dispose of the datasheets.

The government needs to prepare a document which is given to veterinary clients, and which includes this information so that informed consent is obtained from pet owners.

If the kennel cough vaccine is capable of causing disease in humans and other animals, routine and unnecessary use of the vaccine could well add to the costs borne by the National Health Service, and the costs faced by pet owners. It could also keep the disease in the ecosystem.

Apart from treatment costs for humans infected via the canine kennel cough vaccine, perhaps the VMD could advise whether there are also costs borne by the British public that are associated with Bordetella vaccines for humans, which themselves attempt to protect the British public from zoonotic diseases caused by canine vaccines?

Are we paying for vaccines which cause outbreaks in animals, which are then transmitted to humans? And are we then paying for vaccines for humans to allegedly protect us against diseases caused by animal vaccines? If so, it is no wonder the vaccine industry is so wealthy!

"Paws for Thought", the official newsletter of the British Kennel and Cattery Association, part of the Pet Care Trust, Spring 2010, carries the experiences of two kennel owners, which is consistent with the experiences of CHC members who also own kennels.

Christine Sandford, Hazel Corner Boarding Kennels stated: "We recommend the kennel cough vaccine but do not make it mandatory. However, for the last 3-4 years I have insisted that they be done a minimum of one month before the dog(s) come into kennels. We have had no kennel cough outbreaks since we introduced this policy."

Pam Gee, Daisy Bank Kennels stated: "Our experience has been that outbreaks of kennel cough often originate from dogs that have been recently vaccinated. Therefore, as much as ten years ago we began to advise our clients that they should not have their dogs vaccinated less than six weeks prior to them entering the kennels. This is included in our boarding contract."

Neither CPi nor Bordetella bronchiseptico vaccines are hugely effective, reducing symptoms at best, frequently failing to protect, and even causing outbreaks. Since Kennel Cough is a disease most seen in kennel situations, this is not a vaccine which should be routinely used. This is why it is deemed a non-core vaccine by bodies such as the World Small Animal Veterinary Association.

The WSAVA also states that revaccination against CPi should occur at one year, and then no more often than every three years. The MLV Bordetella vaccine is required annually or more often in very high risk animals, although it is known that veterinarians often avoid this vaccine due to the distress it causes to animals, and the subsequent breakdown in trust between animal and vet. This is reflective of the WSAVA's suggestion that animals should be assessed as individuals, and not routinely vaccinated for the sake of it.

Other side effects of kennel cough vaccines are the same as with other vaccines, namely diarrhoea, vomiting, pale gums, increased heart rate, seizures, anaphylaxis and death.

It seems, therefore, that there is a very strong case for refraining from the routine annual administration of kennel cough vaccine.

See also *Human Illness Associated with Use of Veterinary Vaccines*, Ruth L. Berkelman, CID 2003:37 (1 August), Emerging Infections, which discusses the potential dangers of, amongst other vaccines, the aerosol Bordetella vaccine.

It is worth also noting here that vaccines against influenza in humans are also notoriously ineffective.

> To determine the value of flu vaccines for children, Tom Jefferson, MD, and colleagues at the Cochrane Collaboration looked at over a thousand studies. They selected 14 high-quality clinical trials in which vaccinated children had been compared with unvaccinated children.
>
> The combined results of these 14 trials were reported in *The Lancet* (2/26/05). The conclusion: "We recorded no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, and community transmission of influenza.
>
> "Though the U.S. Centers for Disease Control (CDC) and Prevention advises flu vaccines for babies 6-23 months because they tend to suffer more complications once they get the flu, no evidence supports the recommendation."
>
> Another comprehensive study cast doubt on the widespread belief that flu vaccines save adult lives (*Archives of Internal Medicine*, 2/14/05).
>
> Lone Simonsen, PhD, and colleagues at the National Institute of Allergy and Infectious Diseases conducted a review of 33 consecutive flu seasons, from 1968 to 2001. Dr. Simonsen and colleagues found: The number of flu-related

deaths among elderly Americans increased steadily during the 33-year-period, despite the fact that their acceptance of flu vaccinations also steadily increased.

Another study, reported in *Science Daily* (May 20, 2009) showed that the inactivated flu vaccine does not appear to be effective in preventing influenza-related hospitalizations in children, especially the ones with asthma. In fact, children who get the flu vaccine are three times more at risk for hospitalization than their peers who do not get the vaccine.

With regard to adults receiving flu vaccines: In a review of 48 reports (more than 66,000 adults), "Vaccination of healthy adults only reduced risk of influenza by 6% and reduced the number of missed work days by less than one day (0.16) days. It did not change the number of people needing to go to hospital or take time off work." Reference: *"Vaccines for preventing influenza in healthy adults."* The Cochrane Database of Systematic Reviews. 1 (2006).

Withdraw the Kennel Cough Vaccines from the Market

As the kennel cough vaccine is known to shed and spread disease in both animals and humans, and as it is known to cause outbreaks in kennels, and as it is not known to reduce the incidence of kennel cough in dogs, what use is this vaccine?

CORE VACCINES

With regard to the core MLV vaccines, it is well known that vaccine shedding can pose a risk, either/or to humans and animals. In humans the distemper vaccine should be of particular concern as distemper and measles are closely related.

For example, see *Bone.* 1991;12(3):195-201. *Canine distemper virus localised in bone cells of patients with Paget's disease*.

> This study showed that in 41% of Paget's patients, CDV could be detected in osteoclasts, osteoblasts, and osteocytes, but not in controls. The authors suggest that CDV may in some cases play a role in the aetiology of Paget's disease.

We would suggest that canine distemper is now a very rare disease, and human exposure to the disease is more likely to be through shed vaccine from family dogs rather than through field exposure.

To remind the VMD of one of their points:

> **high quality scientific data is available to support the primary and any revaccination (booster) schedule and this has been assessed to ensure the vaccine can be expected to provide the required onset and duration of immunity claimed by the manufacturer to protect animals against disease.**

QUESTIONS FOR THE VMD:

1. Why do we not vaccinate children against viral disease every year?

2. What are the differences between human viral diseases and animal viral diseases that should make it necessary to vaccinate dogs and cats against viral disease on an annual basis, but not children?

3. Did regulators require proof of efficacy on a year-by-year basis for human vaccines before the medical community was asked not to re-vaccinate children every year?

4. Where did annual vaccination for dogs and other animals come from?

5. Why was the distemper vaccine not boosted annually prior to circa 1978, and what new science appeared to make annual vaccination against distemper necessary?

6. Where is the science to actively support annual or three-yearly booster vaccination against parvovirus?

7. Where is the science to actively support booster vaccination against canine adenovirus?

8. Upon what scientific basis was it historically deemed necessary to prove efficacy against canine parvovirus, distemper and adenovirus for only one year?

9. Whilst we accept that the VMD must be assured that each manufacturer's vaccine is efficacious, where is the science to support the assumption that each vaccine type and brand must be tested to show longer duration of immunity? Does immunity not go into memory with some vaccines?

10. Where is the logic, or ethics, in saying that in order to vaccinate less frequently, dogs must be challenged in the laboratory to establish longer duration of immunity?

11. Why is there a difference in scientific principle between childhood vaccines and pet vaccines regarding length of immunity?

12. Where is the science to show that immunity, once stimulated by natural infection or vaccination (i.e., where circulating antibodies have been established), will not prevail for years or the life in greater than 95% of animals? In other words, who dreamt up the need to prove year-by-year efficacy on a product-by-product basis, and where is the science upon which this need is based?

The VMD also stated in its position document:

> **Each and every authorised vaccine in the EU must be supported by its own specific data package submitted by the manufacturer. Each vaccine strain of a particular manufacturer is considered to have unique biological properties and, therefore, must have its own corresponding quality, safety and efficacy package to support the authorisation. The WSAVA Guidelines appear to assume common biological properties for certain groups of canine vaccines and could only be used to support data packages if applicants can demonstrate relevance to their particular vaccine product. An assumption that all vaccines are the same would ignore basic principles of immunology and vaccinology.**

Please could the VMD support the last sentence, viz., "*An assumption that all vaccines are the same would ignore basic principles of immunology and vaccinology".*

Is the VMD suggesting that there are different forms of distemper in Australia, Japan, America and the UK? Elsewhere in its document the VMD asserted that current UK vaccines protect against the various forms of parvovirus, seen in different parts of the world, in the UK. Are there different forms of parvovirus elsewhere in the world that are not covered by UK vaccines? This would seem to contradict the VMD's earlier statement.

Or is the VMD buying time for the <u>international</u> veterinary vaccine producers in their UK market by suggesting that the trials are too expensive and inhumane

to conduct for UK vaccines, or that the principle that once immune to viral disease, a dog (and cat) is immune for years or life only applies in America where the principle has been established?

If there is reliable science to show that specific MLV vaccine brands stimulate antibodies which disappear within a year, or even seven years, without stimulating immunity in memory, then please let the pet owning public have this brand-related information so that we may ask our veterinarians not to use them. The VMD uses reverse logic.

Alternatively, it is more probable and scientifically sound to accept that all vaccines for core viral diseases, if they are able to stimulate immunity at all, will do so for years or life – as shown by DOI studies conducted by independent scientists who have long expressed concern about, and therefore taken action to resolve, the over-vaccination of companion animals.

Once immunity exists against viral disease, it persists for years or life. Only someone wishing to maintain or increase vaccine company income would suggest otherwise.