

A *byronchild* world exclusive

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# A Dragon by the Tail

By Lisa Reagan

On the eve of an historic, billion-dollar world vaccination campaign, a leaked transcript ignites questions of vaccine safety and research corruption. Meanwhile US senators fast-track a bill to protect vaccine manufacturers from litigation. With millions of children's lives at stake, and billions of dollars to lose, will a merger of philanthropy, big business and compromised science win an epic race between medical ethics and institutional agendas?

In this world exclusive, *byronchild* exposes how the most powerful medical research bodies in the United States compromise their vaccine safety research for vested interests, as they assist in a global vaccine policy, while a federal bill looms in the background to protect it all. Though the race takes place in America, it suggests consequences to public health and civil rights around the world.

On January 24, 2005 — the same day the Global Alliance for Vaccines and Immunisation (GAVI) announced the receipt of \$750 million for its historic world vaccination campaign — seven US Senators introduced Senate Bill 3. The bill is an unprecedented Act giving comprehensive liability protections to vaccine manufacturers, restricting Freedom of Information Acts on drug/vaccine safety, and pre-empting states' rights to ban mercury from children's vaccines, all under the bill's

official title: 'Protecting America in the War on Terror Act of 2005'.

Meanwhile in Texas, a US District Court judge presiding over the first juried civil lawsuit against vaccine manufacturers for vaccine injury awaited the subpoenaed depositions of members of the Institute of Medicine (IOM), and the Centers for Disease Control and Prevention (CDC), regarding a closed meeting transcript.

The transcript, a court document alleges, proves the members of the IOM's Immunisation and Safety Review Committee, 'predetermined the necessity of not finding causality between vaccines and autism and/or neurological injury' in their official reports on the issue.

The same IOM reports denouncing a link between vaccines and the country's autism epidemic have been used:

- to formulate standardised case definitions for Adverse Events Following Immunisations, for 'global dissemination' through GAVI;
- as justification for Senate Bill 3's sweeping provisions and protections;
- as a cause for no further federal monies to be spent on research of the potential vaccine/autism link;
- as a reason to silence media inquiries into vaccine safety issues; and
- as a defence for dismissing over 8,000 claims for vaccine injuries in a federal court.

*Is it possible that a closed meeting transcript alleged as proof of a ploy to ignore vaccine risks, a near billion dollar grant for a global vaccination campaign, emerging lawsuits for vaccine injuries and a sweeping federal bill to protect vaccine manufacturers are unrelated?*

*Is it possible that in spite of US Congressional hearings and reports citing widespread conflicts of interest between federal policy makers and the vaccine industry that Senate Bill 3 will defy the US Constitution's provisions for state and civil rights in order to shield vaccine manufacturers from liability?*

*And finally, how will a world vaccine policy formed with alleged 'predetermined' safety reports implemented through a global alliance of international governments and vaccine manufacturers with a fund of billions headquartered in Geneva, Switzerland, support or protect the health and human rights of targeted Third-World country peoples?*

## History of the IOM's Immunisation and Safety Review Committee

Insight to these questions may lie in the pivotal year of 1999, a year preceded by a decade of declining vaccine sales, major breakups within the manufacturing industry, increased requirements for routine childhood vaccines, a growing autism epidemic, and researchers and media reports questioning the safety of vaccines and their possible link to autism.

In 1999, as a US Congressional Government Reform Committee initiated an investigation into the rampant conflicts of interest between federal vaccine policy makers and manufacturers, a global rescue effort of the sinking vaccine industry began with the formation of GAVI.

Originally funded by the Bill and Melinda Gates Foundation, GAVI's partnership of international governments and vaccine manufacturers salvaged lagging sales through an overhauled billion dollar world vaccination campaign that placed GAVI, headquartered in Geneva, Switzerland, at the centre of the reorganised alliance.

Also formed in 1999 was the international Brighton Collaboration whose sole purpose was to create standardised case definitions for Adverse Events Following Immunisations for 'global dissemination'. Brighton lists its secretariats in Switzerland and at the CDC in Atlanta, Georgia.

With GAVI's international partnerships and Bill Gates' billions on the way to rescue the industry, the CDC hired the

IOM's Immunisations and Safety Review Committee to examine multiple 'vaccine safety challenges'. The CDC specifically cited a 1998 British Lancet study recommending more research into a potential link between the measles, mumps, rubella (MMR) vaccine and autism, negative press, public information vaccine conferences, the Rotavirus vaccine recall and seven congressional hearings questioning vaccine safety as impetus to employ the IOM.

However, the CDC's ability to objectively and fairly evaluate vaccine risks was denounced by a three year long congressional investigation. 'To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, underpowered, and fatally flawed. The CDC's rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations...

'The CDC in general and the National Immunisation Program in particular are conflicted in their duties to monitor the safety of vaccines, while also charged with the responsibility of purchasing vaccines for resale as well as promoting

## side bar 1

### More cause for concern

The 2001 IOM transcript is not the first document to be leaked to the public. Another closed meeting transcript from June of 2000 recorded 53 scientists from the CDC, FDA, and the vaccine industry at the Simpsonwood Retreat Center in Georgia to review the findings of a statistically significant correlation between mercury-containing vaccines and neurological conditions. The discovery was made by CDC employee Thomas Verstraeten, MD, using the CDC's own data. The meeting was not open to the public or announced in the Federal Register, and the CDC has still not made their findings public. Verstraeten has since left the CDC to work for a vaccine manufacturer in Belgium. He has also not responded to a US Congressional subpoena.

However, the meeting transcript was included in the 'Mercury in Medicine: Taking Unnecessary Risks?' a report which was the result of a three-year investigation by the US Congress' Subcommittee on Human Rights and Wellness, Committee on Government Reform's Report published in April 2003. The Simpsonwood meeting was presided over by Walter Orenstein, MD, the Director of the National Immunisation Program at the CDC. Orenstein presented the public charge to the IOM Committee on January 11, 2001, the day before the closed organisational meeting.

(To read transcript go to: <http://www.autismhelpforyou.com/simpsonwood.pdf>)

increased immunisation rates,' states the congressional report *Mercury in Medicine*.

'They serve as their own watchdog — neither common nor desirable when seeking unbiased research,' stated US Congressional Representative Dave Weldon, MD, (R-FL) describing the CDC.

'An association between vaccines and autism would force CDC officials to admit that their policies irreparably damaged thousands of children. Who among us would easily accept such

of Strategic Planning for the Vaccine Research Center at the National Institutes of Health (NIH) the IOM Committee was hired by the CDC to 'rule out the proposed links'. The NIH serves as America's medical research agency.

Douglas stated in a Princeton University lecture summary that, 'Four current studies are taking place at the CDC in collaboration with the NIH to rule out the proposed links between immunisations and autism, immunisations and possible developmental regression, inflammatory bowel disease and the MMR vaccine, and thimerosal and the risk of autism. In order to undo the harmful effects of research claiming to link the MMR vaccine to an elevated risk of autism, we need to conduct and publicise additional studies, strengthen the program to assure parents of MMR's safety, and further educate pediatricians and primary care physicians.'

Formerly Douglas served as the president of vaccine manufacturer and federal lawsuit defendant Merck Vaccines from 1991 to 1999. According to a *LA Times* story on February 8, 2005, while serving as president of Merck, Douglas received a memo from Maurice R. Hilleman, MD, an internationally renowned vaccinologist, who told Douglas that six-month-old babies



Photo by Katrina Folkwell

a conclusion about ourselves? Yet, this is what the CDC is asked to do. Also, the relationship between the CDC and vaccine manufacturers has become extremely close. If a conflict of interest does not exist here, then we certainly have the appearance of one,' Weldon said.

When *byronchild* asked CDC spokesperson Curtis Allen for a copy of the contract between the IOM and the CDC, Allen stated that the contract would be available only in a heavily 'redacted' or blacked-out format.

### The transcript of the first organisational meeting of the IOM Committee

On January 11, 2001, the IOM's Immunisation and Safety Review Committee members gathered for its first organisational meeting in Washington, DC. It is this meeting's transcript that has been submitted by Waters and Kraus, a Dallas, Texas law firm as *Exhibit One* in the first juried civil trial against the 'big five' vaccine manufacturers, Aventis Pasteur, Merck, GlaxoSmithKline, Wyeth and Eli Lilly and Co. for vaccine injuries to a now autistic child. The trial was slated to begin March 7, 2005.

During the IOM's open meeting, Walter Orenstein, MD, the Director of the National Immunisation Program at the CDC, charged the committee to specifically address: 'the causal relationship between the vaccine and adverse effect; the biologic mechanisms that could account for the adverse effect; and the significance of the safety concern in the context of society at large.' (Orenstein presided over another leaked CDC transcript from June 2000, see sidebar 1.)

However, according to Gordon Douglas, MD, Director

... how will a world vaccine policy formed with alleged 'predetermined' safety reports ... support or protect the health, and human rights of targeted Third-World country people?



who received their vaccines on schedule would receive a mercury dose **87 times higher** than the Environmental Protection Agency

deemed safe. (The NIH announced a 'sweeping ethics reform' on February 1, 2005, see sidebar 2.)

From the beginning of the IOM Committee's meeting behind the closed doors of the National Academies of Science building on January 12, 2001, committee members repeatedly expressed their 'need for reassurance' and concern over their charge, evidence, methodology, and public communication goals, especially to parents.

'We've got a dragon by the tail here,' states a committee member in the transcript. 'At the end of the line, what we know is — and I agree — that the more negative that presentation [the report] is, the less likely people are to use vaccination, immunisation, and we know what the results of that will be. We are kind of caught in a trap. How we work our way out of the trap, I think, is the charge.'

'The transcript sets forth in significant detail stated biases, preferences and/or predetermination of various committee members in January, 2001, i.e. *before any medical or scientific evidence had been presented to the committee* (emphasis added),' states the court document referencing the IOM transcript as *Exhibit One*.

The court document specifically points out statements by the IOM's study director Kathleen Stratton, PhD, and committee chair Marie McCormick, MD. These statements, the law

## Sweeping Ethics Reform to End Culture of Corruption

Drug industry influence on medical research and practice and on the prescribing of drugs is pervasive. After a year-long investigation into the 'culture' of conflicts of interest between its scientists and manufacturers, on February 1, 2005, the National Institutes of Health, the US leading agency for medical research, announced a 'sweeping ethics reform'.

Under the new rules which reversed a 1995 decision that allowed 'moonlighting' between the scientists and industry, all NIH employees have been prohibited from engaging in employment with pharmaceutical and biotechnology companies, supported research institutions, including NIH grantees, health care providers and insurers. NIH employees were also required to sell their stock in any of the above.

In a 'town hall' meeting for employees on February 3, 2005, NIH director Elias A. Zerhouni, MD, announced the need for a summit of government and academic leaders to address conflicts of interest throughout American medical research as part of the need for ethics reform. The NIH ethics reform came after a year-long investigation into conflicts of interest and the 'discovery, made by congressional investigators, that more than 100 NIH employees had not disclosed various relationships they had with pharmaceutical and biotech companies, in violation of government ethics rules' according to a *Washington Post* article on February 3, 2005.

'I came to the conclusion that we have a systemic problem,' Zerhouni said in an *LA Times* interview on February 12, 2005. 'They were not just isolated events. They reflected the complete set of rules that had been adopted over the years, which had transformed the culture. I said, if that's the case, let's bring back the culture to where it needs to be: That is, public first.

'That's the hardest part,' he said. 'It's easy to come up with regulations. It's not easy to change a culture.'

<http://www.nih.gov/news/pr/feb2005/od-01.htm>

firm says, strongly suggest Stratton and McCormick deliberately railroaded their committee into specific outcomes (all in italics directly from court document):

*'The committee's bias and predetermination of the causality issues presented are found on page 74 in a comment from Dr. Stratton:*

*Dr. Stratton: 'We said this before you got here, and I think we said this yesterday, the point of no return, the line we will not cross in public policy is to pull the vaccine, change the schedule. We could say it is time to revisit this but we will never recommend that level. Even recommending research is recommendations for policy. We wouldn't say compensate, we wouldn't say pull the vaccine, we wouldn't say stop the program.'*

*Similarly, Dr. McCormick, on page 97 in discussing whether autism could be associated with vaccines, stated that 'we are not ever going to come down that it is a true side effect,' despite the fact that the committee had not yet considered any evidence on this issue.*

*On page 123, Dr. Stratton indicated that, despite not having heard any of the evidence, the probable conclusion was going to be that the evidence was 'inadequate to accept or reject a causal relation'. 'Chances are, when all is said and done, we are still going to be in this category. It is just a general feeling that we probably still are not going to be able to make a statement.'*

Stratton joined the IOM in 1990 and was later awarded the IOM's Cecil Research Award for her contributions to vaccine safety. McCormick is the Sumner and Esther Feldberg Professor of Maternal and Child Health at the Harvard School of Public Health.

Congressmen, researchers, activists and parents petitioned the IOM Committee to delay their final meeting and report last year until a study by Mady Hornig MD, an associate professor at Columbia University, demonstrating a link between mercury and autism could be completed. The IOM refused to delay their final meeting and issued their 'no link' report on May 2004. In June 2004, the Columbia University study confirming the link between mercury and autism was completed and presented to the public.

'This is a perfect example of the scientific findings that the IOM ignored when creating their recent report on the potential of the vaccine-autism link,' stated Lyn Redwood, RN, MSN, NP, president of Safeminds, an independent research nonprofit organisation.

### Conflict of interest in IOM Governing Council

Currently, members of the IOM's Governing Council include, among 19 others, Gail H. Cassell, PhD, of Eli Lilly and Company and Helene D. Gayle, MD, from the Bill and Melinda Gates Foundation — the same foundation that donated over \$1.5 billion to create and sustain GAVI.

Lilly is the original manufacturer of thimerosal, a mercury derivative used in childhood vaccines as a preservative. The result of a discovery process by law firm Waters and Kraus, showed that Lilly knew of mercury's toxicity as early as 1930 but nonetheless 'secretly sponsored a human toxicity study on patients already known to be dying of meningococcal meningitis.'

'Lilly then cited this study repeatedly for decades as proof that thimerosal was of low toxicity and harmless to humans,' states a press release from the law firm.

While Lilly ceased the sale of thimerosal in 1991, their licensing agreements demonstrate continued profits from the product until at least 2010. The FDA has never issued an official recall of thimerosal/mercury-containing vaccines.

## Senate Bill 3 – what it could do

Of major concern to vaccine safety advocates, are the following provisions in Senate Bill 3:

- Eliminates a state's right to more strictly regulate vaccines and drugs and more fully inform their citizens about vaccine and drug risks than does the Federal government. Laws already passed in California and Iowa limiting mercury content in vaccines would be repealed.
- Gives comprehensive liability protections to drug companies. Eliminates a citizen's right to seek justice in state courts for drug and vaccine injuries and deaths and limits awards in federal courts. Gives tax credits, grants and patent extensions to the drug industry.
- Allows the Department of Health and Department of Justice, the defendants in the federal Vaccine Injury Compensation Program, to write the terms of their own defence in order to further limit awards to vaccine-injured children.
- Creates and funds a mandatory, national electronic tracking system operated by the Centers for Disease Control (CDC) to monitor vital records of citizens relating to both notifiable and non-notifiable diseases and 'new trends' and 'patterns in public health'.
- Creates penalties for states and health care providers not reporting in a 'timely manner' to the national tracking system. There are no provisions for mandatory reporting of serious health problems following vaccine and prescription drug use or punishments for not reporting serious side effects.

Senate Bill 3 is being promoted by sponsors as a military veteran benefit bill because it raises the death benefits and other financial support for the families of soldiers who lost their lives in the war in Iraq.

From the National Vaccine Information Center's website. For a point by point examination of the bill, visit the site at [www.nvic.org](http://www.nvic.org).

## GAVI — Using corrupt research to vaccinate the world?

GAVI's public and private sector partners include governments in industrialised and developing countries, UNICEF, the World Health Organisation, WHO, the World Bank, non-governmental organisations, foundations, vaccine manufacturers, and public health and research institutions. WHO and GAVI's headquarters are both in Geneva, Switzerland.

To date a total of almost \$1.3 billion, in addition to the Gates

endowment, has been raised from international governments and private sources as well as an additional \$1.19 billion in pledges toward GAVI's goal of a 90% routine immunisation rate by 2010 for all of its 70 underdeveloped countries/grantees.

In their global vaccine campaign, GAVI's allies utilise the Brighton Collaboration, a multi-international government partnership whose sole purpose is to develop standardised case definitions for Adverse Events Following Immunisation.

The IOM's reports — now accused of being 'predetermined' to find no link between routine childhood vaccines and autism — were provided to Brighton to assist in developing its standardised case definitions of Adverse Events Following Immunisation for 'global dissemination'. Brighton's website does not include autism among its listed adverse events.

If the accusation that the IOM 'predetermined' the outcome of their reports is true, what does this bode for a worldwide vaccine policy that is now being routinely employed through GAVI's partners and the governments of under developed countries who rely on the IOM's vaccine safety information to be accurate?

## World Economic Forum questions GAVI's global vaccine campaign

Is the solution for creating a healthy world a global vaccine campaign? During the World Economic Forum's 2003 Annual Meeting in Davos, Switzerland, GAVI's global vaccine campaign was intensely debated by panelists. The World Economic Forum is a global community of business, political, intellectual and other leaders of society. The forum is an independent international organisation incorporated as a Swiss not-for-profit foundation and has NGO (non-governmental organisation) consultative status with the Economic and Social Council of the United Nations.

WEF panelists were not convinced that GAVI's goals were realistic or a panacea for the complex needs of underdeveloped countries: (WEF notes in all italics)

*'There is a strong tendency to see vaccines as a cure-all that can work in isolation,' said Geoffrey Foster, founder and consultant, International Child Welfare and Health, Family AIDS Caring Trust, FACT, Zimbabwe, and Social Entrepreneur. 'Instead, vaccines must be set firmly within a realistic and holistic context. In the past, in Europe, death and disease dropped because of nutrition and education. Vaccines must accompany poverty alleviation or children will be stunted both physically and intellectually.'*

## Autism — An epidemic too big to ignore

During the years that the IOM reports were drafted, 2001 to 2004, more than 8,000 petitions for 'vaccine injuries resulting in autism spectrum disorder', piled up in an Omnibus Autism Proceeding with the US Court of Federal Claims.

Currently, autism is the fastest growing developmental disability in the United States, with one in 166 US children diagnosed with Autism Spectrum Disorder, up from 1 in 2500 a decade ago, and over 1.77 million affected. Over 30,000 Australian children have autism, with a dramatic increase of more than 200% in diagnoses over the past 10 years in Australia.

Autism is not a disease but a 'condition', often characterised by a failure to bond, lack of social interaction, avoidance of eye-to-eye contact, difficulties in language development, and repetitive behaviours known as stimming (self-stimulation). Milder forms of autism are Asperger's Syndrome, Pervasive Developmental Disorder and Attention Deficit/Hyperactivity Disorder. Collectively they are known as Autism Spectrum Disorder, ASD.

In September 2004, California Governor Arnold Schwarzenegger signed his state's mercury ban, saying, 'I believe that an abundance of caution merits the acceleration of the process already under way to remove thimerosal from the last few vaccines that contain it.'



### States take matters into their own hands

After multiple congressional hearings on conflicts of interest within the vaccine industry and government, repeated IOM reports stating no link between vaccines and autism, and with no official FDA recall for mercury containing vaccines, US citizens and state legislators took matters into their own hands and in May 2004, Iowa became the first state to ban mercury in vaccines.

During the same three-year period that the IOM Committee reviewed its data on the vaccines and autism link, the Iowa Human Resources Committee reviewed scientific and biological data from independent researchers.

'After three years of review, I became convinced there was sufficient credible research to show a link between mercury and the increased incidents in autism,' said Iowa Senator Ken Veenstra. 'The fact that Iowa's 700% increase in autism began in the 90s, right after more and more vaccines were added to the children's vaccine schedules, is solid evidence alone... The IOM has not convinced me this action is not needed. I feel strongly we need to pursue a use of alternative vaccines.'

US Congressional Representative Dave Weldon, MD, (R-FL), called the IOM reports 'heavily biased and unrepresentative of all the available scientific and medical research'. Weldon said the reports discounted the biological evidence presented by US Congressional investigative reports and university studies. It also discounted thousands of parent activists who pointed to the parallel increase in vaccination requirements and the rise in autism rates starting in the early 1990s.

California Governor Arnold Schwarzenegger also signed his state's mercury ban and more than a dozen other states are currently considering their own bans.

Senate Bill 3 would seek to repeal the current states' bans and to prohibit more states from enacting their own bans on mercury, a violation of the US Constitution's Tenth Amendment. (See side bar 3 for a complete list of the bill's proposals.)

### Senate Bill 3 — Dissolution of Civil Rights?

Sighting the IOM report's green light to justify the Act's proposed sweeping protections for the vaccine industry, the bill states that, 'After considering recent changes in the litigation environment with respect to vaccines as well as recent scientific evidence and reports by the *Institute of Medicine* (italics added) and others with respect to the safety of vaccines and their components and ingredients, the Secretary of Health and Human Services and the Attorney General shall, not later than 6 months after the date of enactment of this Act, jointly submit recommendations to the appropriate committees of Congress concerning necessary modifications to the Vaccine Injury Compensation Program and Federal rules regarding litigation involving vaccines.'

'This bill is labelled as an "anti-terror" bill, but it is a power grab by the federal government and an assault on self-governance and the informed consent ethic. It takes away the freedom of the people to make their voices heard through their elected state representatives and protect themselves from unsafe drugs, such as Celebrex and Vioxx, and unsafe vaccines, such as those that contain high levels of mercury. It gives unprecedented liability protection to the drug industry and broad powers to federal officials to hide the truth from the people about vaccine and prescription drug risks,' said Barbara Loe Fisher, president of America's largest and oldest consumer watchdog organisation the National Vaccine Information Center, in a press release. ([www.nvic.org](http://www.nvic.org))

'Protecting the public health was not delegated to the federal government and public health laws, including laws governing use of vaccines, have always been under the control of citizens residing in each state,' said Fisher. 'The irony of this bill is that it is using the families of citizens who have given their lives to defend our nation's freedom in order to take rights and freedoms away from other families. Military veterans should not be used to protect the drug industry and take away the freedom for all Americans to have their voices heard through their elected state representatives... This bill does not serve justice or freedom.'

A well-known international bio-ethicist who has spoken on vaccine policy issues at the National Vaccine Information Center conference, said recently to *byronchild* magazine that people should not be surprised by the contents of the IOM transcript. 'Old paradigms do not die easily,' he said. 'This is just the nature of the beast.' ☹

### Resources

- National Vaccine Information Center, [www.nvic.org](http://www.nvic.org)
- No Mercury, [www.nomercury.org](http://www.nomercury.org)
- Safeminds, [www.safeminds.org](http://www.safeminds.org)
- Autism Research Institute, [www.autismwebsite.com/ari/](http://www.autismwebsite.com/ari/)
- CDC's Autism Alert, [www.medicalhomeinfo.org/screening/Autism%20downloads/AlarmFinal1.jpg](http://www.medicalhomeinfo.org/screening/Autism%20downloads/AlarmFinal1.jpg)
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- *Conflicts of Interest in Vaccine Policy Making*. Majority Staff Report Committee on Government Reform, U.S. House of Representatives June 15, 2000 [www.whale.to/v/staff.html](http://www.whale.to/v/staff.html)