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"A Dragon By The Tail"

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By Lisa Reagan
March 7, 2005

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On January 24, 2005 -- the same day the Global Alliance for Vaccines and Immunization (GAVI) announced the receipt of $750 million for its historic world vaccination campaign -- seven US Senators introduced a bill to protect vaccine manufacturers from thousands of pending federal lawsuits filed by parents of vaccine-damaged children.

The unprecedented act named Senate Bill 3, extends comprehensive liability protections to vaccine manufacturers, restricts Freedom of Information Acts on drug/vaccine safety, and preempts 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 has ordered the worlds' "big five" vaccine manufacturers to "produce any and all documents relating to payments made to, or stock ownership" by the seventeen members of the Institute of Medicine's Immunization and Safety Review Committee who issued a report last year denying a link between childhood vaccines and the country's autism epidemic.

The judge issued the order after receiving a leaked internal transcript in the first civil juried lawsuit against the vaccine manufacturers that allegedly proves the Institutes of Medicine's committee members ***"predetermined the necessity of not finding causality between vaccines and autism and/or neurological injury"*** in its official reports on the issue.

Judge T. John Ward also ordered the vaccine manufacturers to produce all communications with "members of the World Health Organization, the Center for Disease Control, the Food and Drug Administration, the Institute of Medicine, the Brighton Collaboration, or the Global Alliance for Vaccines and Immunization relating to the issue whether the thimerosal contained in pediatric vaccines causes autism or other neurological disorders."

The vaccine manufacturer's legal counsel balked at the amount of expense involved in producing such extensive documentation for the court; however, Judge Ward reassured the defense that the process could be useful for the more than 300 pending lawsuits waiting to be tried in the US .

Vaccine manufacturers Aventis Pasteur, Merck, GlaxoSmithKline, Wyeth and Eli Lilly and Co. are cited as defendants in the lawsuit brought by the parents of a child who developed autism after receiving mandatory routine childhood immunizations.

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

- to endorse standardized case definitions for Adverse Events Following Immunizations for "global dissemination";

- 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 defense for dismissing over 4,500 petitions 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 influenced by allegedly "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 Immunization 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 Microsoft billionaire Bill Gates through his Seattle-based Bill and Melinda Gates Foundation, GAVI's partnership of international governments and vaccine manufacturers salvaged lagging sales through an overhauled world vaccination campaign that placed GAVI, headquartered in Geneva, Switzerland, at the center of the reorganized alliance.

Also formed in 1999 were the international Brighton Collaboration and the WHO Global Advisory Committee on Vaccine Safety.

Brighton's sole purpose was to create standardized case definitions for Adverse Events Following Immunizations for "global dissemination". Brighton's steering committee members

currently hail from the US FDA, CDC, and Aventis Pasteur, a vaccine manufacturer and federal lawsuit defendant.

Brighton's website does not include autism among its listed adverse events.

The WHO Global Advisory Committee on Vaccine Safety has " concluded that there is currently no evidence of mercury toxicity in infants, children, or adults exposed to thimerosal in vaccines" and "that current WHO immunization policy with respect to thimerosal containing vaccines should not be changed."

The Brighton Collaboration has been cited as being "fraught with pitfalls and merges regulators and the regulated into an indistinguishable group."

" I am very concerned about the development of the Brighton Collaboration," stated US Congressional Representative Dave Weldon, MD, (R-FL) at an Autism One Conference in May 2004. "Particularly troubling is the fact that serving on the panels defining what constitutes an adverse reaction to a vaccine, are vaccine manufacturers. What is even worse is the fact that some of these committees are chaired by vaccine manufacturers. It is totally inappropriate for a manufacturer of vaccines to be put in the position of determining what is and is not an adverse reaction to their product. Do we allow GM, Ford and Chrysler to define the safety of their automobiles?"

In 1999, with GAVI's international partnership and Bill Gates' billions on the way to rescue the industry, the CDC hired the IOM's Immunizations and Safety Review Committee to examine multiple "vaccine safety challenges".

In its public report, the CDC specifically sited 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 has been denounced by a three year long US 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, under-powered, 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 Immunization 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 increased immunization rates," states the congressional report. (View the report at **http://www.nomercury.org/science/documents/GRC_6-15-00.pdf**)

"They serve as their own watchdog -- neither common nor desirable when seeking unbiased research," Weldon has stated in 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 a conclusion about ourselves? Yet, this is what the CDC is asked to do," Weldon said.

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

The IOM stated "no comment" to *byronchild* about the leaked transcript or its use in the pending civil court case.

The Transcript of the First Organizational Meeting of the IOM Committee

On January 11, 2001, the IOM's Immunization and Safety Review committee members gathered for its first organizational meeting in Washington, DC. It is this meeting's transcript that has been submitted as an exhibit by Waters and Kraus, a Dallas, Texas law firm.

During the IOM's *open* meeting, Walter Orenstein, MD, the Director of the National Immunization 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 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 immunizations and autism, immunizations 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 publicize 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 an 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 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 side bar 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, immunization, 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."

Instead of focusing on scientific data which could possibly tarnish the current routine childhood vaccine policy, "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 t he court document.

Specifically sited are statements by the IOM's study director Kathleen Stratton, PhD, and committee chair Marie McCormick, MD. These statements, the law firm says, strongly suggest

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

Dr. McCormick, for example, in speaking of the CDC, noted that the agency "wants us to declare, well, these things are pretty safe on a population basis." (See Exhibit 1 at page 33).

"The committee's bias and predetermination of the causality issues presented are found at page 74 in a comment from Dr. Statton:

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, at 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.

At 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 and parents petitioned the IOM Committee to delay their final meeting and report last year until an animal study demonstrating a link between mercury and autism by Mady Hornig, MD, an associate professor at Columbia University, could be completed.

The IOM refused to delay their final meeting and issued their "no link" report on May 2004. The Columbia University study confirming the link between mercury and autism was completed and presented to the public in June 2004.

"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 nonprofit organization. "The IOM was well aware that studies like these were due for release, but chose to ignore them…The findings in this study make clear that the IOM was more interested in regurgitating CDC spin than incorporating hard science like Dr. Hornig's report. Such information would force the government to face the reality of the mercury threat and take definitive action to protect countless children from potential neurological damage."

The US Office of Special Counsel (OSC) – an independent investigative and prosecutorial agency that serves as a channel for whistleblowers -- forwarded hundreds of disclosures "alleging public health and safety concerns about childhood vaccines that include a mercury-based preservative known as thimerosal, and its possible link to neurological disorders, including autism" to the US Congress on May 20, 2004, the day after the IOM issued its "no link" report.

The OSC letter requesting congressional action was addressed to US Senator Judd Gregg (R-NH) – who introduced Senate Bill 3 and its provisions for liability protection for vaccine manufacturers on January 24, 2005.

The OSC's letter to Gregg stated, "it appears there may be sufficient evidence to find a substantial likelihood of a substantial and specific danger to public health caused by the use of thimerosal/mercury in vaccines because of its inherent toxicity…"

"Due to the gravity of the allegations, I am forwarding a copy of the information disclosed to you in your capacity as Chairmen of the Senate Committee and House Committee with oversight authority for HHS. I hope that you will review these important issues and press HHS for a response to this very serious public health danger," states the OSC letter to Gregg.

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 the world's sixth largest charitable gift of $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.

Lilly is the single biggest contributor to the Republican Party from the pharmaceutical industry donating $1.6 million in the last US election.

Senate Majority Leader Bill Frist (R-TN), co-sponsor of Senate Bill 3, was the author of a controversial bill that contained a provision that would protect Eli Lilly and other vaccine manufacturers from lawsuits over mercury in the 2002 Homeland Security Act.

Frist's other notable tie to Lilly is the fact that the vaccine manufacturer bought 5,000 copies of the senator's book on bioterrorism and distributed them to physicians after September 11, 2001.

The basis of the Frist family fortune is the Hospital Corporation of America (HCA), the largest for-profit hospital chain in the country, which was founded by Frist's father and brother. (For more on Senator Frist **see sidebar 3**).

GAVI – Using Corrupt Research to Vaccinate the World?

GAVI's public and private sector partners include governments in industrialized and developing countries, UNICEF, the World Health Organization, WHO, the World Bank, non-governmental organizations, 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 immunization rate by 2010 for all of its 70 underdeveloped countries/grantees.

For vaccine manufacturers, the Gates' billions for GAVI represent a guaranteed pipeline of money. For governments of undeveloped countries, the funds may be used for any aspect of health as long as their country's vaccine rate increases. If the rates drop, so do the funds.

According to GAVI figures, 4 million children have been vaccinated for diphtheria, tetanus, and whooping cough; 42 million more children have been vaccinated with hepatitis B; and 991 million single-use disposable syringes have been produced for the program.

" GAVI relies on technical and scientific information and advice from the Global Advisory Committee on Vaccine Safety. Based on the committee's findings, GAVI and its partners will continue to support the use of vaccines that contain thimerosal," responded Gates Foundation spokesperson Jenny Sorensen to *byronchild's* inquiry.

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 undeveloped 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.

WEF panelists were not convinced that GAVI's goals were realistic or a panacea for the complex needs of underdeveloped countries.

"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."

The World Economic Forum is a global community of business, political, intellectual and other leaders of society. The forum is an independent international organization incorporated as a Swiss not-for-profit foundation and has NGO consultative status with the Economic and Social Council of the United Nations.

Autism – An Epidemic Too Big To Ignore

During the years that the IOM reports were drafted, 2001 to 2004, more than 4,500 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.

In the last four years alone, the number of cases of autism has nearly doubled in California. "It is growing much faster than the growth of the population and other forms of childhood disabilities," states Cliff Allenby, director of the State Department of Development Services.

A report by the independent Environmental Working Group issued in December 2004 found that autistic children had less glutathione, an antioxidant that helps rid the body of toxic metals, when compared to a sample of healthy children. The study, led by Jill James, PhD, a professor of biochemistry and pediatrics at the University of Arkansas for Medical Sciences, found that a glutathione deficit "may contribute to the development and clinical manifestation of autism."

Autism is not a disease but a 'condition' often characterized by a failure to bond, lack of social interaction, avoidance of eye-to-eye contact, difficulties in language development, and repetitive behaviors 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.

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 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 percent 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 Swcharzenegger signed his state's mercury ban last year 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 4** for a complete list of the bill's proposals.)

Senate Bill 3 – Dissolution of Civil Rights?

Citing the IOM reports' 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."

"The war on terror is a different kind of war and requires a different kind of preparedness," US Senator Judd Gregg (R-NH) said in a press release about the bill. "Specifically, this bill encourages development of products needed to protect the nation against biological, radiological or nuclear agents as well as infectious diseases. It expands the availability and accessibility of vaccines. Finally, it strengthens capacity and coordination, so we can respond effectively during public health emergencies."

"This bill is labeled as an 'anti-terror' bill, but it is 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 vaccine safety and consumer watchdog organization the National Vaccine Information Center.

"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."

An internationally renowned bio-ethicist who has previously spoken on vaccine policy issues at the National Vaccine Information Center conference, told *byronchild* magazine that people should not be surprised by the contents of the IOM transcript or Senate Bill 3. 'Old paradigms do not die easily,' he said. 'This is just the nature of the beast.'

Side Bar 1: Not The First Leaked Transcript

The 2001 IOM transcript is not the first 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?" report that 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 Immunization Program at the CDC. Orenstein presented the public charge to the IOM committee on January 11, 2001, the day before the closed organizational meeting.

Side Bar 2: 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 yearlong 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 ethics reform.

The NIH announcement came after a year-long investigation in to 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."

Sidebar 3: Who is Senate Majority Leader Bill Frist (R-TN), co-sponsor of Senate Bill 3?

According to the Center for Justice and Democracy, these are some facts about Senator Bill Frist, MD:

- The basis of the Frist family fortune is the Hospital Corporation of America (HCA), the largest for-profit hospital chain in the country, which was founded by Frist's father and brother.

- Frist and his wife have $26 million in HCA stock in a so-called "blind trust."

- HCA has agreed to pay the federal government more than $1.7 billion in civil and criminal penalties, the largest health care settlement in history, for massive Medicare, Medicaid and Tricare billing fraud.

• Frist has gotten more than $2.3 million from doctors, health insurers, drug companies and others in the health care industry, roughly 20 percent of all the contributions to his two Senate races, raising more cash from health-care interests than 98 percent of his colleagues.

• Frist has voted against patients' rights to sue their HMOs for failure to provide adequate treatment while supporting tax subsidies to HMOs and insurance companies to offer prescription drugs to seniors, rather than providing them through Medicare. Frist has received $123,750 in campaign cash from HMOS.

• To date, Frist has received $265,023 from the pharmaceutical industry. The pharmaceutical industry was also the largest single contributor to the National Republican Senatorial Campaign Committee that Frist chaired, giving about $4 million — and Lilly was the single biggest contributor to the GOP from that industry, having given $1.6 million in the last election cycle.

• In 2002, Frist engineered the insertion of a provision into the Homeland Security bill that would protect Eli Lilly and other pharmaceutical giants from lawsuits over mercury in vaccines. Not long after Frist introduced the legislation, the Pharmaceutical Research and Manufacturers of America, the drug industry's trade group, gave $10,000 to his political action committee.

Side Bar 4: Senate Bill 3 – What It Could Do

Of major concern to vaccine safety and civil rights 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 defense 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.

S. 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.