

**The Homeland Security Bill Fiasco**  
**November 17, 2002, Washington, D.C.**

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## **The Homeland Security Bill Fiasco**

HR 5710, the Homeland Security Act of 2002 passed the House on November 13. Several provisions, not germane to the Legislation were inserted without the knowledge of some who voted to approve this Bill – and without discussion or debate. Given the contentious nature and the broad reaching effects of these provisions, it would be prudent to remove Sections 1714, 1715, 1716 and 1717 from the Senate Bill. These issues, all public health related, should be taken up for full discussion, debate and public input in the new 108<sup>th</sup> Congress.

According to media reports, these provisions were inserted by retiring Representative Richard Arney at the request of the White House.

Senator Lieberman has introduced an amendment to strip the Bill of all the provisions that are not pertinent to the creation of the Department of Homeland Security (about 8 provisions that appear to have been inserted by the White House).

Section 1714-1717 affect the National Vaccine Injury Compensation Act do not protect Americans from a terrorist threat, or affect the Department of Homeland Security, rather they protect large domestic chemical companies from potential civil liability to hundreds of thousands of vaccine injured children in the United States. Amending the Vaccine Act through this legislation is inappropriate. If the desire is to protect manufacturers of the components of any smallpox vaccine, the date of enactment should not suspend any currently filed cases which are not related to smallpox but to thimerosal.

## **The National Vaccine Injury Compensation Program**

The compensation program was created through an excise tax from the sale of vaccines, the chemical companies who manufacture components of vaccines such as thimerosal do not contribute to this fund. In fact, they are being offered a free ride, no liability, no discussion and debate, no opportunity for the public or the Special Masters who hear these cases to weigh in.

Sections 1714-1717 will have a devastating effect on the families of children who were injured from their thimerosal-containing vaccines and suffered damage to their central nervous system, resulting in diagnosis of autism spectrum disorder, speech and language delays, or neurodevelopmental delays.

Section 1714 offers protection for the manufacturers of all ingredients of vaccines rather than simply the vaccine manufacturers from litigation from individuals who have not yet gone through the National Vaccine Injury Compensation Program. Eli Lilly and other companies that

are co-defenders in ongoing thimerosal-related litigation (and who have made no financial contribution to the vaccine trust fund) will be indemnified from all vaccine ingredient lawsuits.

It is clear that by including a retroactive date of effective date while not including an extension of the statute of limitation, that the intent was to stop all ongoing litigation that has not yet gone to judgement that this action was taken to protect these companies.

The current statute of limitations for filing cases with the National Vaccine Injury Compensation Program is 3 years. HR 3741 included a provision to extend the statute of limitations from 3 to 6 years. Additionally, the bill also included a 2 year look-back provision to allow those who had missed the statute of limitation and not filed in the program (for post 1988 cases only) 2 years to file a claim in the program.

Given that the program was intended to be a compassionate, no-fault, compensation program that quickly compensate individuals who suffer serious adverse reactions to vaccines. The program was intended to rule in favor of the injured when it was a close call in determining whether the science supported the vaccine injury claim. HHS admits that it has not done as good a job as they could have to inform the public about the existence of the program, and that bringing these cases through the program further protects the companies, the look-back provision was included in HR 3741.

Inserting the provision to protect industry, without opening the program up to those whose children were injured during the time when thimerosal was most heavily used in children's vaccines is extremely unjust.

Over the last two decades the number of vaccines given to infants and young children has risen dramatically. In fact, most children are given 26 doses or more of vaccines before they go to kindergarten. Three years ago, the FDA realized that children, in the first six months of life were being injected with more mercury through their immunizations that was considered safe according to at least one of three Federal standards. The preservative, thimerosal, which is 50 percent mercury and 50 percent thiosalicylic acid is being phased out. However, under the current law, children who may have been injured from 1988 until 1999 would have no legal recourse if this bill passes if their parents have not already filed a claim. It is likely that a significant number of the plaintiffs in the pending cases will lose all legal recourse because of these four Sections.

### **Proposed Changes – (bolded sections are the proposed inserts)**

#### **TITLE 42 - THE PUBLIC HEALTH AND WELFARE CHAPTER 6A - PUBLIC HEALTH SERVICE SUBCHAPTER XIX - VACCINES**

Part 2 - National Vaccine Injury Compensation Program subpart d - general provisions

Sec. 300aa-33. Definitions

-STATUTE-

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies,

and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes ~~under its label any vaccine set forth in the Vaccine Injury Table~~, any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine except that, for purposes of section 300aa-28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine including any component or ingredient of any such vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa-19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa-14 of this title.

(7) The term `vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.

Effective Date:

The amendments made by sections 1714, 1715, and 1716 shall apply to all actions or proceedings pending on or after the date of enactment of this Act, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding.

## **The Exact Amendments**

### **SEC. 1714. CLARIFICATION OF DEFINITION OF MANUFACTURER.**

Section 2133(3) of the Public Health Service Act (42 U.S.C. 300aa-33(3)) is amended--

(1) in the first sentence, by striking `under its label any vaccine set forth in the Vaccine Injury Table' and inserting `any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine'; and

(2) in the second sentence, by inserting `including any component or ingredient of any such vaccine' before the period.

### **SEC. 1715. CLARIFICATION OF DEFINITION OF VACCINE-RELATED INJURY OR DEATH.**

Section 2133(5) of the Public Health Service Act (42 U.S.C. 300aa-33(5)) is amended by adding at the end the following: 'For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.'

#### **SEC. 1716. CLARIFICATION OF DEFINITION OF VACCINE.**

Section 2133 of the Public Health Service Act (42 U.S.C. 300aa-33) is amended by adding at the end the following:

'(7) The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.'

#### **SEC. 1717. EFFECTIVE DATE.**

The amendments made by sections 1714, 1715, and 1716 shall apply to all actions or proceedings pending on or after the date of enactment of this Act, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding.

## **Vaccine Injury Compensation Program Investigation and Proposed Legislation**

The Committee on Government Reform, over the last two years has conducted an extensive investigation into the Vaccine Injury Compensation Program. After six months of negotiations, on February 13, Chairman Dan Burton and Ranking Minority Member Henry Waxman in collaboration with Congressman (and physician) Dave Weldon, and broad bipartisan group of Congressmen introduced, HR 3471, the National Vaccine Injury Compensation Program Improvement Act of 2002.

#### **This Bill would:**

- Increase compensation for future lost earnings for injured children. Under current law, compensation is based on the average weekly earnings of full and part-time workers as determined by the Bureau of Labor Statistics. This bill would specify that only full-time workers should be used in the calculation.
- Increase the level of compensation to a family after a vaccine-related death from \$250,000 to \$300,000. The death benefit has remained unchanged since the program's inception in 1986.
- Allow families of vaccine-injured children to be compensated for the costs of family counseling and creating and maintaining a guardianship to administer the funds.
- Allow for the payment of interim attorneys fees and legal costs while a petition is being adjudicated. The costs of assembling the necessary medical records and obtaining expert witnesses are substantial. Under current law, these costs, as well as attorney's fees, are not reimbursed until a case is fully resolved, which oftentimes takes years..

- Extend the statute of limitations for seeking compensation to six years from the date of injury. Under current law, families must file within two years of a child's death or three years of a child's injury.
- Provide a one-time, two-year period for families to file a petition if they were previously excluded from doing so because they missed the statute of limitations.

Senator Frist and Congressman Greenwood have introduced similar bills that appear to protect industry, while whittling down families opportunities to receive compensation through the program. These provisions include the ones inserted by the White House as well as a provision to Federalize a finding in a New Jersey case that found that individuals who missed the statute of limitations in the Federal program would have missed the statute of limitation in the state as well. This in essence prevents tolling for minors, and prevents cases from being filed for individuals who did not know about the program in time to file in the Federal program. While these Bills appear to have the Administration Support, they do not have the support of the vaccine injured.

## **What Does the Science Say About Thimerosal?**

Thimerosal has been used in some vaccines as a preservative since the 1930's. Thimerosal is reported to be effective in killing bacteria in opened multi-dose bottles. The Food and Drug Administration Modernization Act of 1997 called for an FDA review of all mercury containing food and drugs which included a review of vaccines that contain Thimerosal. This review was completed in 1999. The FDA recognized that some children could be exposed to a cumulative level of mercury over the first 6 months of life that exceed the federal guidelines on methyl mercury. Thimerosal contains 49.6% mercury by weight and is metabolized to ethyl mercury and thiosalicylate.

All guidelines for safe mercury intake are related to methyl-mercury, not ethyl-mercury. Methyl mercury is associated with neurotoxicity in high doses. The Center for Biologic Evaluation and Research (CBER) at the FDA had to assume that the toxicity of the two compounds were equivalent. At the time of the review, CBER realized that Thimerosal was present in over 30 licensed vaccines in the United States. According to CBER calculations, a 6-month old baby that received all the vaccines on schedule would receive 75 micrograms of mercury from three doses of DTaP, 75 micrograms of mercury from three doses of Hib and 37.5 micrograms from three doses of hepatitis B vaccine. The total of 187.5 micrograms exceeds the suggested safe limits published by the EPA.<sup>1</sup>

Various agencies have developed guidelines for safe exposure to methylmercury, including the U.S. Environmental Protection Agency, U.S. Agency for Toxic Substances and Disease Registry, the FDA, and the World Health Organization (WHO 1996). These exposure levels range from 0.1 µg/kg body weight/day (EPA) to 0.47 µg/kg body weight/day (WHO). The range of recommendations is due to varying safety margins, differing emphasis placed on various sources of data, the different missions of the agencies and the population that the guideline is intended to protect. All guidelines, however, fall within the same order of magnitude. While these guidelines

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<sup>1</sup> Centers for Disease Control. Summer 1999, The Hepatitis Control Report

may be used as screening tools in risk assessment to evaluate the “safety” of mercury exposures, they are not meant to be bright lines above which toxicity will occur. However, as exposure levels increase in multiples of these guidelines, there is increasing concern on the part of the public health community that adverse health consequences may occur.

To address the issue of conflicting methylmercury exposure guidelines, Congress asked the National Academy of Sciences to study the toxicological effects of methylmercury and provide recommendations on the establishment of a scientifically appropriate methylmercury reference dose (RfD) (National Research Council 2000; <http://www.nap.edu/catalog/9899.html>).

**Their report concluded that the EPA’s current reference dose, the RfD, for methylmercury, 0.1 µg/kg/day is a scientifically justifiable level for the protection of human health.**

For a ten pound child for instance, (10 pounds X 2.2 = 22 kilograms of body weight. 22 X 0.1 micrograms = 2.2 micrograms per day.

The 1999 Schedule recommended 5 shots be given at 2, 4, and 6 months. The average child would receive about 62.5 micrograms of mercury in one doctor’s visit. (This was 28 times higher than a daily exposure should have been.)

Thimerosal also known as mercurachrome and merthiolate was used in over-the-counter (OTC) topical ointments and ophthalmic solutions. However, many of these products were banned from the market in the 1980’s when the FDA determined that they were no longer “generally recognized as safe.”<sup>2</sup> As early as 1945 Eli Lilly recommended a patch test before using eye ointments that contained thimerosal to insure patients would not suffer an allergic response.

Thimerosal has been eliminated from latex paints, and Merthiolate, a concentrated form of Thimerosal used as an antiseptic, is no longer used because of serious toxic effects from these products in infants.<sup>3</sup> The American Academy of Pediatrics state: “Mercury in all forms is toxic to the fetus and children, and efforts should be made to reduce exposure to the extent possible to pregnant women and children as well as the general population”<sup>4</sup>

## **The Institute of Medicine’s Findings on Thimerosal**

**On October 1, 2001, the Institute of Medicine’s Immunization Safety Review Committee released a report entitled *Thimerosal Containing Vaccines and Neurodevelopmental Outcomes*. The report stated, “...the committee recommends the use of Thimerosal-free DTaP,**

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<sup>2</sup> Food And Drug Administration. December 14, 1998, Mercury Compounds in Drugs and Food; Request for Data and Information.

<sup>3</sup> Halsey, Neal A. November 10, 1999, Vol 282, No 18, Journal of the American Medical Association.

<sup>4</sup> Goldman, Lynn. July, 2001, Technical Report: Mercury in the Environment: Implications for Pediatricians, Pediatrics.

HIB, hepatitis B vaccines in the United States, despite the fact that there might be remaining supplies of Thimerosal-containing vaccine available. The committee could not explore mechanisms by which this could be accomplished. However, the committee is concerned that, because of meeting schedules and other requirements- for example the development of official statements on this issue by advisory groups such as the Red Book Committee of the AAP or the ACIP – might delay action. The removal of Thimerosal as a preservative from vaccines on the recommended childhood immunization schedule does not eliminate exposure to Thimerosal from other vaccines, such as DT or influenza, that some infants, children and pregnant women receive. Therefore, the committee recommends that full consideration be given by appropriate professional societies and government agencies to removing Thimerosal from vaccines administered to infants, or pregnant women in the United States.”<sup>5</sup>

**Dr. Marie McCormick, IOM Committee Chair made the following statement:**

“Because mercury at high doses is known to pose risks, some parents and researchers are concerned that thimerosal in vaccines puts children at increased risk for developmental disorders such as autism. Preliminary data from a few studies have suggested that thimerosal-containing vaccines could possibly -- very minimally -- affect some measures of normal child development. But the data are inconclusive....Our committee has reviewed the limited body of toxicological, clinical, and epidemiological literature on ethylmercury and the more exposures are associated with neurological damage. There is also toxicological and epidemiological literature suggesting that methylmercury is a toxicant to the developing nervous system. Some children who received the maximum number of thimerosal-containing vaccines on the recommended childhood immunization schedule had exposures to ethylmercury that exceeded some safe exposure guidelines for methylmercury. In addition, some children could be particularly vulnerable or susceptible to mercury exposures because of genetic or other differences.... It was viewed as feasible as well as consistent with the public health goal of decreasing mercury exposures in general, as much as possible. Mathematical calculations also suggested that some infants received a total amount of mercury from vaccines that exceeded some federal agency guidelines for safe mercury exposure. It should be noted that exceeding the guidelines for safe exposure does not mean that harm is certain to occur. These guidelines take into account safety factors to protect sensitive populations, such as children. In addition, they were set for methylmercury exposure, which occurs primarily from eating fish, and their relevance to ethylmercury in vaccines is unclear... Based on information from these sources, our study has come to the following conclusion: The hypothesis that thimerosal exposure through the recommended childhood immunization schedule causes neurodevelopmental disorders is not supported by clinical or experimental evidence. Existing epidemiological evidence is inadequate to either accept or reject a causal relationship between exposure to thimerosal from vaccines and the neurodevelopmental disorders of autism, ADHD, and speech or language delay. However, there are some indirect associations concerning biological plausibility, which refers to a theoretical but unproven possibility. For example, high-dose thimerosal.

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<sup>5</sup> The Institute of Medicine October 1, 2001, Immunization Safety Review Thimerosal Containing Vaccines and Neurodevelopmental Outcomes



## **What is Thimerosal:**

Thimerosal is a preservative that is approximately 50 % ethylmercury and 50 % thiosalicylic acid (TSA – sometimes referenced in the literature as a salt). First licensed in 1930 by Eli Lilly and Company, it has been used both in the manufacturing process of vaccines and as a preservative in single and multi-dose vials. Over the last 20 years the FDA determined that single dose vials would not require a preservative.

(A preservative is used in multi-dose vials because it is conjectured that repeated punctures with needles into the multi-dose vial may introduce contaminants that could cause molds or bacteria to grow in the vaccine.)

The important issue remains that over the course of 70 years, the FDA was in the loop of the allergen and toxicity issues and chose not to take action – not to require further testing on the possible harm of thimerosal injected in children over time – knowing that from animal studies that use over time was directly related to increased sensitization, knowing that through animal and human studies that there is a delayed adverse reaction. From all available data, it appears that the FDA was asleep at the switch and never made the possible connection between the dangers in thimerosal in OTC and the potential for problems with the ever increasing amounts of thimerosal being injected into infants through their immunizations. If they were not asleep at the switch and were aware of the possible problem, then it begs the question of why they chose not to act.

## **Why did the FDA wait until mandated by Congress under FDAMA 1997 to examine the use of preservatives containing mercury?**

Several factors led to examination of mercury-containing preservatives in childhood vaccines. Over the past decade there has been increased attention focused on the health effects of human exposure to mercury, particularly methyl mercury. In 1994, the EPA revised its Reference Dose (RfD) for methylmercury exposure, lowering its guideline for safe exposure from 0.3 to 0.1 microgram per kilogram body weight per day. Prospective studies (in the Seychelles, Faroe Islands and others) of the effects of low dose exposure to methylmercury in the diet have been published during the past few years. Some studies have raised concern that neurodevelopmental outcomes in children may be subtly affected when their mothers were exposed methylmercury from dietary sources at levels that were previously thought to be safe. Also in the past decade, the CDC's Advisory Committee on Immunization Practices (ACIP) and other recommending bodies have added new vaccines containing thimerosal as a preservative such as hepatitis B and Hib vaccines to the routine childhood immunization schedule. Additionally, beginning in 1996, the replacement of whole cell DTP-Hib combination vaccines with separately administered DTaP and Hib vaccines increased the amount of thimerosal that some infants might receive (depending on vaccine formulation(s) received). In light of efforts by various federal agencies to decrease human exposure to mercury from all sources, and the potential increase in infant exposure to thimerosal from vaccines, FDA undertook review of this issue.

Thus, while enactment of FDAMA 1997 provided an official mechanism for review of this issue, the use of thimerosal as a preservative in vaccines had already begun to be considered by the FDA. During the past ten years, the FDA has provided informal and formal advice to

manufacturers recommending that new vaccines under development be formulated without thimerosal as a preservative.

The FDA had previously reviewed thimerosal use in biological products, including vaccines, in 1976. This review evaluated exposure to thimerosal from biological products using the 1974 American Academy of Pediatrics “Red Book” immunization schedule and concluded that, with the exception of long term immune globulin replacement therapy, “no dangerous quantity of mercury is likely to be received from biologic products in a lifetime.” Of note, immune globulin products manufactured in the U.S. no longer use thimerosal as a preservative.

## **What Do We Know From the Peer-Reviewed Scientific Literature About Thimerosal?**

1. We know that in 1947, 31.5 % of cases of contact dermatitis was due to thimerosal. Of these 75% was confirmed to be related to the TSA and 12.5% confirmed to be related to mercury. We know that the authors of the 1947 paper questioned the wisdom of injecting thimerosal.

A 1947 paper<sup>6</sup> reports on a series of case reports. The author makes reference to a 1942 test in which 1 of 6 patients tested were sensitive to merthiolate (16.7%). It also references a 1945 test which found that 8 patients were treated for contact dermatitis use related to merthiolate. Six of these were tested for TSA and reacted. (75%). An 8<sup>th</sup> patient proved to be sensitive to mercury (12.5 %). The article goes on to state that 35 % of contact dermatitis (in general) is due to therapeutic agents (i.e. from putting a medication on the skin). Of those 35%, 90 % were due to merthiolate. Therefore, it meant that 31.5 % of contact dermatitis (in general) was due to merthiolate (i.e. TSA and mercury) While much of the focus has been on the mercury component of thimerosal, the article points to the high level of allergic response due to the TSA component. Given that thimerosal = ethylmercury + TSA, it doesn't really matter whether it is TSA or the mercury that causes the problem.

Dr. Vera Stejskal, a noted European researcher testified before the House Committee on Government Reform that it is not simply the toxicity of the mercury, but also the sustained allergic response to mercury and TSA that can lead to a systemic response – which can include a swelling of the brain.

### **Notable quotes from paper:**

- “No eruptions or reactions have been observed or reported to merthiolate internally, but it may be dangerous to inject a serum containing merthiolate into a patient sensitive to merthiolate.”
- “The thiosalicylic acid radical is the usual sensitizing factor in merthiolate sensitivity.”
- “Only one patient who had merthiolate dermatitis gave a negative patch test to thiosalicylic acid.”

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<sup>6</sup> Francis A. Ellis, M.D., The Sensitizing Factor in Merthiolate, 18 J. Allergy 212-213 (1947)

2. We know that in 1948 there were frequent reports of adverse reactions related to topical application of thimerosal.

A 1948 paper<sup>7</sup> reports on a 1947 case in which a 45-year-old woman suffered multiple reactions to merthiolate applied to her skin prior to surgery. She suffered fever and chills and had small vesicles and erythema in the area of merthiolate application. After her recovery, the patient indicated that the ulcer for which she was being surgically treated appeared after repeated applications of a tincture of merthiolate. Thinking she was treating the skin itch, she applied merthiolate daily. She continued the application until the skin became too raw and painful to continue use – then sought medical care. After the surgery, she developed pruritis in the area of the reaction. Two months later upon an office visit, the patient’s pruritis and crusting of the skin continued, while the erythema had almost subsided.

The article notes that there are many severe reactions reported following the use of mercurial ointments and a lesser number due to antiseptics containing mercurials. recommended further research to determine if harm would result following its subcutaneous or intravenous injection in skin sensitive individuals. The article also notes that most of the references to reactions to thimerosal are published in dermatology journals which general practitioners would not be reading, and thus not be alerted to the problems.

**Notable quotes from paper:**

“Merthiolate is such a commonly used preservative for biologicals, plasma, cartilage etc, that it would seem important to determine whether harm would result following its subcutaneous or intravenous injection in skin sensitive individuals.”

“It seems more logical, therefore, to ascribe most of the reactions of merthiolate to the thiosalicylate rather than the mercuric compound it contains.”

A 1950 research paper published in the New York Academy of Science<sup>8</sup> found that mercury bichloride (which is not merthiolate) was toxic when injected, that it caused dermatitis if used on the skin too long, and that it could not be used in chemotherapy.

Additionally, this article provides an historical perspective of the use of mercurials to prevent sepsis. It also mentions that much of the early work conducted on these products was inadequate to make the claim. The research conducted for this paper was specifically to disprove the claims of high germicidal and sporicidal activity increasingly being touted in textbooks.

3. A 1963 research publication<sup>9</sup> reported that a patient who is sensitive to merthiolate should not be injected with thimerosal. It notes that a patch test exists – and has

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<sup>7</sup> H.D. Cogswell, M.D., et al., *Reaction Following the Use of Tr. Merthiolate*, 5 Arizona Med. 42-43 (1948)

<sup>8</sup> John H. Brewer, *Mercurials as Antiseptics*, 53 N.Y. Acad. Sci. 221-291(1950)

existed for decades, but there has never been routine testing of infants or children to determine if there is an allergic response. Allergic responses are often overlooked. While the article states that individuals who are allergic to merthiolate are usually sensitive to the TSA, it also mentions that some are sensitive to the mercurial component.

The article also stipulates that in determining who will be sensitized, the frequency the topical ointment is used seems to affect the numbers who become allergic. If this argument upholds, it could be extrapolated to mean that the early and frequent use of thimerosal in childhood vaccines could make newer generations more susceptible to allergic responses to TSA and mercury. The paper reports that patients react differently – there is a dermal and epidermal reaction (possibly a systemic response).

Of particular concern from this paper is that if this is true, that with new and increasing recommendations from the CDC to given adults booster shots from childhood immunization and to give flu and other vaccines that adults may begin to suffer similar allergic (and systemic) reactions to thimerosal in vaccines.

#### **Notable quotes from paper:**

“There is another point of practical significance: does the parental injection of merthiolate-containing fluids cause disturbances in merthiolate-sensitive patients.” “It is known that persons that are contact sensitive to a drug may tolerate the same medications internally, but it seems advisable to use a preservative other than merthiolate for injections in merthiolate sensitive people.”

“Patch and intradermal tests of Merthiolate “do not produce reactions in normal, nonsensitive persons, according to the literature and my own experience.”

Test results present “a picture of allergic reaction and corresponds to those reactions seen in contact dermatitis.”

“It is generally recognized sensitivity to Merthiolate usually is not due to its mercurial component but to the thiosalicylate part of the molecule...although some patients who are allergic to Merthiolate also react to other mercurials.”

“The intradermal injection of Merthiolate from numerous intradermal tests in my cases did not seem to cause any systemic reactions.”

4. A 1973 report<sup>10</sup> of skin burns resulting from a chemical reaction of thimerosal and aluminum resulted in Lilly adding a new warning to the label in 1973.

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<sup>9</sup> Stephen Epstein, M.D., et al., *Sensitivity to Merthiolate: A Cause of False Delayed Intradermal Reactions*, 34 J. Allergy 225-234 (1963)

<sup>10</sup> Jones, H.T., “Dangers of Skin Burns from Thimerosal,” 2 Brit. Med. J. 505-505, 1972.

Through multiple tests it was learned that thimerosal acted as a catalyst to the oxidation of aluminum. Blisters on the skin resulted. It was suggested in this article that thimerosal and aluminum should not be used together. (However, aluminum is another ingredient in many children's vaccines.)

**Notable quotes from paper:**

- 1972 British Medical Journal reports cases of skin burns resulting from the chemical reaction of thimerosal and aluminum. “Mercury is known to act as a catalyst and to cause aluminum to oxidize rapidly, with the production of heat.” The manufacturers who supply us with thimerosal have been informed.
5. A 1972 paper<sup>11</sup> reports on six patients who died as a result of subacute mercury poisoning from merthiolate. The doses of merthiolate were likely 1,000 higher than expected doses.

This article is important in that it shows that there is indeed a level in which merthiolate (thimerosal) can be toxic. A dose of 1,000 times the intended dose is now proven to be deadly. (We have not seen any research that indicates the exact dose that it would become toxic.) The LD50 (the dose at which 50 % of the test animals die) for rats is 60 mg/kg of body weight.

The article references the subacute nature of the poisoning – i.e. showing that the death was not rapid, but that death occurred after the cellular enzyme was poisoned by the mercuric ion.

The article notes that in chronic poisoning, where small amounts of mercury are ingested over a long period, that the symptoms were mostly neurologic.

In immediate forms of poisoning, the kidneys were the affected area.

While merthiolate was used in blood plasma products extensively in WWII, it was learned that that a higher concentration of merthiolate resulted in the destruction of red blood cells, which was a noted issue in several of the cases reported in this paper.

**Notable quotes from paper:**

- “The case histories of four children and two adults who were accidentally given toxic amounts of Merthiolate are recorded.”
- “Five out of the six patients died, and necropsy showed extensive renal tubular necrosis in each case, and in two, evidence of diffuse intravascular coagulation.”
- “Merthiolate (Thimerosal, Thiomersal) is an organo-mercurial compound widely used as an antiseptic agent. Its main application in medicine has been as a skin antiseptic, and it has also been incorporated as a preservative in attenuated polio and influenza virus preparations.

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<sup>11</sup> J.H.M. Axton, M.B., M.R.C.P., D.C.H., *Six Cases of Poisoning After a Parental Organic Mercurial Compound (Merthiolate)*, 48 Post Grad. M.J., 417-421 (1972)

Similarly, vials of antibiotic preparation may contain Merthiolate as a bactericidal agent to allow such vials to be used for several doses.”

- “Toxic effects in man have been confirmed mainly to skin reactions, which on occasions may be severe.”
  - “Intravenous Merthiolate has been used in the treatment of subacute bacterial endocarditis with no apparent ill effects. (Powell & Jamieson 1931). However, the doses used were very small.”
  - “The amount of Merthiolate in each vial was 1,000 times too much.”
  - “The LD50 (lethal dose for 50% of test population) for Merthiolate in man is unknown. However, these six patients received between two and six times the LD50 for rats (LD50 60 mg/kg)”
5. In 1982, the FDA published an Advance Notice of Proposed Rulemaking to ban the use of thimerosal in OTC products.

This FDA generated documents<sup>12</sup> that lists the high level of toxicity of thimerosal in their proposed rule for OTCs. The announcement noted delayed hypersensitivity in 10 of 20 guinea pigs (50%) tested indicating that thimerosal is highly allergenic and that it is reasonable to expect humans to be equally allergenic.

The report also notes a Swedish study found in healthy subjects the following had hypersensitivity to thimerosal:

- 10 % of school children,
- 16 % of military recruits,
- 18 % of twins, and
- 26% of medical students

The FDA concludes that while it has been suggested that hypersensitivity may be due to the TSA portion of the molecule and not the mercury, that this was not confirmed. The FDA succeeded in their move to ban OTC products with thimerosal.

Notable quotes from paper:

“At the cellular level, thimerosal has been found to be more toxic for human epithelial cells in vitro than mercuric chloride, mercuric nitrate, and merbromim (mercurichrom),” “It was found to be 35.3 times more toxic for embryonic chick heart tissue than for staphylococcus aureus.” 1950 study showed that thimerosal was no better than water in protecting mice from potential fatal streptococcal infection.

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<sup>12</sup> 01/05/82 FDA’s Advance Notice of Proposed Rulemaking Regarding Thimerosal

“The Panel concludes that thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed.”

6. Occupational Safety Materials<sup>13</sup> give the following warnings:

- Primary Physical & Reproduction Effects: Nervous System and Reproduction Effect.
- Effects of exposure include fetal changes.
- Exposure in children may cause mild to severe retardation.
- Hypersensitivity to mercury is a medical condition aggravated by exposure.
- CERCA Hazardous substance – toxic waste disposal.

The MSDS statement states that the primary physical and health hazards include that it is toxic, a mutagen, an allergen, and can have nervous system and reproductive effects.

Early signs of mercury poisoning in adults include: narrowing of the visual field and numbness in the extremities.

Exposure to mercury in utero may cause mild to severe mental retardation and mild to severe motor coordinating impairment.

In the toxicological section it was noted that in rats, an intravenous dose of greater than 45 mg/kg was needed for mortality.

7. A 1973 paper on the toxicology of thimerosal<sup>14</sup> notes, “as with other chemicals of its generation, information relating to safety and efficacy of thimerosal in animal models is sparse.”

The article reviews the existing animal studies:

- In mice, all injections of 150 mg of thimerosal per kg of body weight were lethal within 1 hour.
- A 1937 study performed by Lilly gave 20 mice 30 to 50 mc/kg of a 1% solution of thimerosal. The lethal dose of 50% of the mice was found to be  $40.9 \pm 1.2$  mg/kg.
- A 1945 study was done in mice. Doses ranging from 40-62 mc/kg of thimerosal was given intravenously. Most deaths occurred 3 days later, however a few mice died as late as 9 days later. The Lethal dose of 50% was calculated at  $55 \pm 3$  mg/kg.
- In a rat study, 45 mc/kg was the tolerated intravenous dose. Autopsy revealed definite kidney lesions, consisting principally of tubular changes, necrosis of the epithelium (Membranous tissue composed of one or more layers of cells separated by very little intercellular substance and forming the covering of most internal and external surfaces of the body and its organs.), inclusion of masses of debris in the lumen (The inner open space or cavity of a tubular organ, as of a blood vessel or an intestine. ) and congested and

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<sup>13</sup> Eli Lilly and Company Material Safety Data Sheet (MSDS) December 8, 1999

<sup>14</sup> W. D. Broddle and W.R. Gibson, Toxologic Studies of Sodium Ethylmercurithiosalicylate “Thimerosal, Lilly In Laboratory Animals, February 1973.

hemorrhagic regions throughout the cortex (The outer layer of an internal organ or body structure, as of the kidney or adrenal gland / The outer layer of gray matter that covers the surface of the cerebral hemisphere.)

- Rabbit study – 25 mg/kg was usually tolerated dose. Pre-death signs of toxicity included prostration (total exhaustion or weakness; collapse ) and diarrhea. Death occurred 1-6 days post-treatment and cause of death was attributable to mercurial poisoning, including kidney and intestinal lesions.
- Another rabbit study tested 20 or 60 mg/kg intravenous dose of thimerosal. Onset of side effects and death occurred at both doses and varied with dose and rate of injection. Side effects noted were drowsiness, ataxia (Loss of the ability to coordinate muscular movement), weight loss, and oliguria (production of an abnormally small amount of urine). Animals receiving a dose of 60 mg/kg showed a progressive fall in serum potassium and an elevation in urinary potassium excretion. Histopathology included kidney tubular necrosis but no glomerular (glomeruli: A tuft of capillaries situated within a Bowman's capsule at the end of a renal tubule in the vertebrate kidney that filters waste products from the blood and thus initiates urine formation) lesions
- In a series studies that tested the oral delivery of thimerosal in rats, the lethal dose of thimerosal was estimated to be greater than 50 mg/kg but less than 100 mg/kg. Side effects preceding death included ptosis (Abnormal lowering or drooping of an organ or a part, especially a drooping of the upper eyelid caused by muscle weakness or paralysis.), chromorhinorrhea (miscolorated nasal discharge), poor grooming, and weakness
- These studies which originally lasted 7 days were extended 14 days and showed that there is a delayed toxicity in thimerosal. This is also shown in other studies previously discussed. This raises a large number of questions about the lack of safety studies in this area. Toxicity death prior to 3 days in one study only occurred at the 125 mg/kg level. The 50% death rate after 7 days was calculated at  $88.8 \pm 5.7$  mg/kg but additional deaths occurred during the second week resulting in a 14 day 50 % death rate of  $72.7 \pm 5.4$  mg/kg.
- An intraperitoneal (inside the area that holds the abdominal organs) study on guinea pigs tested injections of varying thimerosal solution strengths. No abnormal responses were seen at the 0.0125% or 0.025 %. Those treated with 0.05% or 0.1% evidenced irritation and pain, and autopsy revealed congestion (excessive fluid) and hemorrhage in the peritoneum.
- Intracutaneous studies in rabbits found that some of the animals became irritated and others did not. In a guinea pig study found similar response and showed that the level of response was dose related.
- As an extension of the intracutaneous study, a subcutaneous test was done on 3 rabbits. After 24 hours, no irritation was noted on the skin. The animals were sacrificed and examined. A few of the injection sites had caused small sites of hyperemia. The cause of this was unclear (thimerosal or needle puncture of small vessels).
- A dermal study of rabbits found no dermal irritation.
- In an ocular study with rabbits, tincture merthiolate (thimerosal, alcohol, and acetone) was found to be an eye irritant, damaging both the iris and the conjunctiva. The study was consistent with other studies on alcohol ocular irritation. In another study of mercurialentis, an ocular study of rats and guinea pigs (30 days) found no corneal toxicity. However, they found measurable levels of mercury in both eyes (test was in one eye) and in peripheral blood of rats.



- In a Subacute toxicity study in dogs given thimerosal intravenously. None of the dogs died from the 2 mg/kg of thimerosal.

## Cancer Data From the World Health Organization

While this report makes no reference to exposure to mercury through thiomersal or vaccines, it offers valuable insights about what is known about mercury and cancer.

According to a review of the International Agency for Research on Cancer (IARC) which is part of the World Health Organization<sup>15</sup>, the following is known about the carcinogenicity of metallic mercury and inorganic mercury compounds:

### Exposure data

Mercury occurs at low concentrations in the Earth's crust, mainly in sulfide ores (cinnabar), from which it has been extracted for a variety of uses for many centuries. Common applications of metallic mercury are as a cathode in the electrolytic production of chlorine, in dental amalgams, in the extraction of gold from ore concentrates, in electrical equipment and in devices for measuring temperature and pressure. Mercury compounds have been used as fungicides in paints and on seeds and grains, as antiseptics, in electrical applications, and as catalysts and intermediates.

Workers are exposed to mercury by inhalation, principally to metallic mercury but also to inorganic and organic mercury compounds. Occupations in which the highest exposures occur include mercury mining, work in chloralkali and alkaline battery plants and production of devices for measuring temperature and pressure. Lower exposures have been measured for people employed in hospital laboratories and dental clinics. Exposures have been measured by both ambient air monitoring and biological monitoring.

Nonoccupational sources of exposure to mercury include food (methylmercury compounds, mainly in aquatic organisms) and dental amalgam fillings (metallic mercury). These exposure levels are usually lower than those typically detected in occupational settings.

- A cohort study in a nuclear weapons factory in the USA on exposure to metallic mercury showed no difference in risk for lung cancer in exposed and unexposed subcohorts from the same factory.
- In a nested case-control study at two nuclear facilities in the USA, the risk for cancers of the central nervous system was not associated with estimated levels of exposure to mercury.
- A cohort study of chloralkali workers in Sweden identified a two-fold, significant excess risk for lung cancer and some nonsignificant excess risks for cancers of the brain and kidney.
- Lung cancers also occurred in an almost two-fold excess in Norwegian chloralkali workers, whereas the numbers of cases of cancer of the brain and kidney were close to those expected. In both studies, asbestos and smoking were judged to be the main determinants of the excess risk for lung cancer.
- In a study of male and female dentists and female dental nurses in Sweden, a two-fold risk for brain tumours was found in each of the three cohorts.

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<sup>15</sup> <http://193.51.164.11/htdocs/monographs/vol58/mono58-3.htm>

- No such risk appeared among dentists or medical and dental technicians in a US study of military veterans; these groups had excess risks for pancreatic and colon cancer, respectively.
- In an Australian case-control study of brain tumours and amalgam fillings, there was a decreased risk for gliomas and no effect was seen with regard to meningiomas.
- The risk for lung cancer was found to be higher among individuals with silicosis who had been working in US mercury mines than in subjects with silicosis who had worked elsewhere. This finding was based on small numbers, however, and the confidence limits overlapped.
- A case-control study in Italy indicated an excess risk for lung cancer among women in the felt-hat industry who had heavy exposure to mercury but also to arsenic.
- In a population-based case-control study from Canada, risk for prostatic cancer was associated with exposure to mercury compounds in general and the risk for lung cancer with exposure to metallic mercury.

### **Organomercury compounds**

Studies in Minamata, Japan, on causes of death in populations with high exposure to mercury included areas with a high prevalence of methylmercury poisoning.

- The only clear indication of an increased cancer risk was in the most informative of these studies, in which excess mortality from cancer of the liver and cancer of the oesophagus was found in the area with the highest exposure, together with an increased risk for chronic liver disease and cirrhosis. Consumption of alcoholic beverages was known to be higher than average in the area.
- A cohort study of individuals in Sweden with a license for seed disinfecting with mercury compounds and other agents found no excess of brain cancer. Of the three Swedish case-control studies on exposure to mercury seed dressings and soft-tissue sarcomas, only one showed an odds ratio above unity; in all three studies, the confidence intervals included unity. For malignant lymphomas, there was a slightly but nonsignificantly elevated odds ratio for exposure to mercury seed dressings, but other exposures had higher odds ratios and, consequently, potential confounding.

### **Animal carcinogenicity data**

- Mercuric chloride was tested for carcinogenicity in two studies in mice, by oral gavage and by administration in the drinking-water; only the study by gavage was adequate for an evaluation of carcinogenicity. Mercuric chloride was also tested in one study in rats by oral gavage. In mice, a few renal adenomas and adenocarcinomas occurred in males only.
- In rats, a few renal adenomas occurred in females; there was a dose-related increase in the incidence of squamous-cell papilloma of the forestomach in males, and a few papillomas were seen in females.
- Dose-related hyperplasia of the forestomach was seen in both males and females.
- Methylmercury chloride was tested for carcinogenicity in three studies in mice and two studies in rats by oral administration in the diet. In all three studies in mice, the incidence of renal adenomas and adenocarcinomas was increased in males. In the two studies in rats, no increase in tumour incidence was reported.

- In another study in mice given methylmercury chloride, a significant number of renal tumours was found in intact male mice and a few renal tumours were found in gonadectomized male and female mice that also received testosterone propionate; no renal tumour was found in male or female gonadectomized mice that did not receive testosterone propionate.

### **Other Relevant Data Noted in the Report**

- After inhalation, about 70-80% of metallic mercury vapour is retained and absorbed.
- Little metallic mercury is taken up in the gastrointestinal tract, and less than 10% is absorbed.
- Metallic mercury passes into the brain and fetus. In the body, metallic mercury is oxidized to mercuric mercury, which binds to reduced sulfhydryl groups.
- The kidney is the main depository following exposure to both metallic and mercuric mercury.
- Mercuric mercury is eliminated mainly in urine and faeces; it is also excreted in milk. In humans, inorganic mercury compounds have two half-times: one lasts for days or weeks and the other much longer.
- Mercury concentrations in urine, blood and plasma are useful for biological monitoring.
- Methylmercury compounds present in seafood are almost completely absorbed from the gastrointestinal tract and are distributed to most tissues.
- The methylmercury compounds bind to reduced sulfhydryl groups; a fraction is converted to mercuric mercury, the extent of conversion differing among species. Methylmercury compounds are excreted mainly in the bile; in the intestine, some mercury is biotransformed into inorganic mercury compounds and excreted in the faeces.
- Methylmercury compounds pass into the fetus and are excreted in milk.
- In humans, methylmercury compounds have a single biological half-time of approximately two months.
- Concentrations in blood and hair are useful for monitoring exposure to methylmercury compounds.
- Following intense exposure to metallic mercury vapour, lung damage occurs; gastrointestinal and renal tubular necrosis occur after ingestion of mercuric mercury.
- Long-term exposure to metallic mercury causes encephalopathy and renal damage; chronic exposure to mercuric mercury causes renal tubular damage. Immunologically based glomerulonephritis can occur.
- In rats, mercuric chloride may cause immunosuppression.
- Effects on the immune system vary considerably among rodent strains.
- Inorganic mercury is a cause of allergic contact dermatitis.
- The nervous system is the main target organ for methylmercury compounds, but interspecies differences exist; in some species, there are also effects on the kidney. Some selenium compounds affect the kinetics of inorganic and methylmercury compounds and have a protective effect against their toxicity.
- In several studies of female dental assistants, no increased risk for spontaneous abortion or birth defects was seen.

- Parenteral administration of mercury salts to pregnant rodents induces fetal growth retardation, malformations and death; altered placental transport of nutrients may be involved.
- Methylmercury compounds induce adverse effects on human development - most notably microcephaly and deficits in neurological development. Similar effects have been shown in many laboratory species.
- The conceptus appears to be more sensitive than the maternal organism.
- The dose levels of methylmercury compounds that affect reproduction and development are generally lower than those of inorganic mercury and affect a wider range of end-points.
- The findings of 14 studies of cytogenetic effects, such as sister chromatid exchange, micronucleus formation, structural chromosomal aberrations, aneuploidy and polyploidy, in peripheral lymphocytes of individuals exposed to metallic mercury and various mercury compounds are controversial and uncertain. Thus, four studies involving subjects exposed to methylmercury compounds from contaminated seal or fish meat were either inconclusive or indicated slight chromosomal effects.
- Nine studies in individuals exposed from occupational sources to metallic mercury, amalgams, alkyl- and arylmercury compounds or mercury fulminate gave either negative or borderline results, or the exact role of mercury in any positive result was uncertain.
- A slight yet significant increase in the frequency of sister chromatid exchange was observed in only one subset of children intoxicated with phenyl-mercury acetate used for disinfecting diapers.
- Several organomercury compounds and fungicides containing organomercury compounds were assayed in a variety of short-term tests.
- Tests for unscheduled DNA synthesis, sister chromatid exchange, chromosomal aberrations and dominant lethal mutations in mammals *in vivo* gave conflicting results. Tests for clastogenicity in fish and amphibians gave more convincingly positive results. All studies of induction of c-mitosis (spindle disturbances), sister chromatid exchange, structural chromosomal aberrations and aneuploidy in cultured human lymphocytes gave positive results. The results of the majority of studies of the induction of forward mutations, c-mitosis and polyploidy in cultured mammalian (non-human) cells were positive, and those of one study on micronucleus induction in cultured fish cells were also positive. In *Drosophila melanogaster* and other insects, the majority of mercury compounds induced sex-linked recessive lethal mutation and nondisjunction (aneuploidy) but did not induce dominant lethal mutation. The assessment of nuclear or mitochondrial DNA mutations, mitotic recombination and gene conversion in the yeast *Saccharomyces cerevisiae* led to conflicting results. Most of the few studies available in bacteria (investigating differential killing in *rec<sup>-</sup> Bacillus subtilis* or reversion in *his<sup>-</sup> Salmonella typhimurium* or *trp<sup>-</sup> Escherichia coli*) gave negative results.
- There were fewer studies of inorganic mercury compounds (mostly mercuric chloride), and a minority compared inorganic and organic compounds.
- No experimental study was available on metallic mercury.
- As in studies with organomercury compounds, studies in rodents treated *in vivo* with mercuric chloride gave weakly positive results for dominant lethal mutation.
- Studies on the induction of chromosomal aberrations in rodents yielded conflicting results. One study on chromosomal effects in amphibians gave positive results for mercuric chloride and methylmercury chloride at similar doses. Chromosomal alterations were reported in cultured human lymphocytes.

- The dose of mercuric chloride required to induce sister chromatid exchange in cultured human lymphocytes was 5-25 times higher than those needed of methylmercury chloride.
- Mercuric acetate did not induce anchorage-independent growth in human cells.
- Five to ten times higher doses of mercuric chloride than methylmercury chloride were required to induce polyploidy. DNA damage has been induced repeatedly in mammalian cells by mercuric chloride. Although the information comes from single studies, this compound also induced sister chromatid exchange, chromosomal aberrations, aneuploidy (spindle disturbances) and enhancement of virus-induced morphological transformation. Unlike organomercury compounds, mercuric chloride failed to enhance the frequency of micronuclei in cultured fish cells.
- Mercuric chloride failed to enhance lethality in a DNA repair-deficient strain of *E. coli*.

### Conclusions

- There is *inadequate evidence* in humans for the carcinogenicity of mercury and mercury compounds.
- There is *inadequate evidence* in experimental animals for the carcinogenicity of metallic mercury.
- There is *limited evidence* in experimental animals for the carcinogenicity of mercuric chloride.
- There is *sufficient evidence* in experimental animals for the carcinogenicity of methylmercury chloride.
- In making the overall evaluation, the Working Group took into account evidence that methylmercury compounds are similar with regard to absorption, distribution, metabolism, excretion, genotoxicity and other forms of toxicity.

## **Autism: a Novel Form of Mercury Poisoning**

July, 2000

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### **Summary**

Autism is a syndrome characterized by impairments in social relatedness and communication, repetitive behaviors, abnormal movements, and sensory dysfunction. Recent epidemiological studies suggest that autism may affect 1 in 150 U. S. children. Exposure to mercury can cause immune, sensory, neurological, motor, and behavioral dysfunctions similar to traits defining or associated with autism, and the similarities extend to neuroanatomy, neurotransmitters, and biochemistry. Thimerosal, a preservative added to many vaccines, has become a major source of mercury in children who, within their first two years, may have received a quantity of mercury that exceeds safety guidelines. A review of medical literature and U.S. government data suggests that (i) many cases of idiopathic autism are induced by early mercury exposure from thimerosal; (ii) this type of autism represents an unrecognized mercurial syndrome; and (iii) genetic and non-genetic factors establish a predisposition whereby thimerosal's adverse effects occur only in some children.

### **INTRODUCTION**

Autistic Spectrum Disorder (ASD) is a neurodevelopmental syndrome with onset prior to age 36 months. Diagnostic criteria consist of impairments in sociality and communication plus repetitive and stereotypic behaviors (1). Traits strongly associated with autism include movement disorders and sensory dysfunctions (2). Although autism may be apparent soon after birth, most autistic children experience at least several months, even a year or more of normal development -- followed by regression, defined as loss of function or failure to progress (2,3,4).

The neurotoxicity of mercury (Hg) has long been recognized (5). Primary data derive from victims of contaminated fish (Japan – Minamata Disease) or grain (Iraq, Guatemala, Russia); from acrodynia (Pink Disease) induced by Hg in teething powders; and from individual instances of mercury poisoning (HgP), many occurring in occupational settings (e.g., Mad Hatter's Disease). Animal and in vitro studies also provide insights into the mechanisms of Hg toxicity. More recently, the Food and Drug Administration (FDA) and the American Academy of Pediatrics (AAP) have determined that the typical amount of Hg injected into infants and toddlers via childhood immunizations has exceeded government safety guidelines on an individual (6) and cumulative vaccine basis (7). The mercury in vaccines derives from thimerosal (TMS), a preservative which is 49.6% ethylmercury (eHg) (7).

Past cases of HgP have presented with much inter-individual variation, depending on the dose, type of mercury, method of administration, duration of exposure, and individual sensitivity. Thus, while commonalities exist across the various instances of HgP, each set of variables has given rise to a different disease manifestation (8,9,10,11). It is hypothesized that the regressive form of autism represents another form of mercury poisoning, based on a thorough correspondence between autistic and HgP traits and physiological abnormalities, as well as on the known exposure to mercury through vaccines. Furthermore, other phenomena are consistent with a causal Hg-ASD relationship. These include (a) symptom onset shortly after immunization; (b) ASD prevalence increases corresponding to vaccination increases; (c) similar sex ratios of affected individuals; (d) a high heritability rate for autism paralleling a genetic predisposition to Hg sensitivity at low doses; and (e) parental reports of autistic children with elevated Hg.

### **TRAIT COMPARISON**

ASD manifests a constellation of symptoms with much inter-individual variation (3,4). A comparison of traits defining, nearly universal to, or commonly found in autism with those known to arise from mercury poisoning is given in Table I. The characteristics defining or strongly associated with autism are also more fully described.

Autism has been conceived primarily as a psychiatric condition; and two of its three diagnostic criteria are based upon the observable traits of (a) impairments in sociality, most commonly social withdrawal or aloofness, and (b) a variety of perseverative or stereotypic behaviors and the need for sameness, which strongly resemble obsessive-compulsive tendencies. Differential diagnosis may include childhood schizophrenia, depression, obsessive-compulsive disorder (OCD), anxiety disorder, and other neuroses. Related behaviors commonly found in ASD individuals are irrational fears, poor eye contact, aggressive behaviors, temper tantrums, irritability, and inexplicable changes in mood (1,2,12-17). Mercury poisoning, when undetected, is often initially diagnosed as a psychiatric disorder (18). Commonly occurring symptoms include (a) "extreme shyness," indifference to others, active avoidance of others, or "a desire to be alone"; (b) depression, "lack of interest" and "mental confusion;" (c) irritability, aggression, and tantrums in children and adults; (d) anxiety and fearfulness; and (e) emotional lability. Neuroses, including schizoid and obsessive-compulsive traits, problems in inhibition of perseveration, and stereotyped behaviors, have been reported in a number of cases; and lack of eye contact was observed in one 12 year old girl with mercury vapor poisoning (18-35).

The third diagnostic criterion for ASD is impairment in communication (1). Historically, about half of those with classic autism failed to develop meaningful speech (2), and articulation difficulties are common (3). Higher functioning individuals may have language fluency but still show semantic and pragmatic errors (3,36). In many cases of ASD, verbal IQ is lower than performance IQ (3). Similarly, mercury-exposed children and adults show a marked difficulty with speech (9,19,37). In milder cases scores on language tests may be lower than those of unexposed controls (31,38). Iraqi children who were postnatally poisoned developed articulation problems, from slow, slurred word production to an inability to generate meaningful speech; while Iraqi babies exposed prenatally either failed to develop language or presented with severe



language deficits in childhood (23,24,39). Workers with Mad Hatter's disease had word retrieval and articulation difficulties (21).

Nearly all cases of ASD and HgP involve disorders of physical movement (2,30,40). Clumsiness or lack of coordination has been described in many higher functioning ASD individuals (41). Infants and toddlers later diagnosed with autism may fail to crawl properly or may fall over while sitting or standing; and the movement disturbances typically occur on the right side of the body (42). Problems with intentional movement and imitation are common in ASD, as are a variety of unusual stereotypic behaviors such as toe walking, rocking, abnormal postures, choreiform movements, spinning; and hand flapping (2,3,43,44). Noteworthy because of similarities to autism are reports in Hg literature of (a) children in Iraq and Japan who were unable to stand, sit, or crawl (34,39); (b) Minamata disease patients whose movement disturbances were localized to one side of the body, and a girl exposed to Hg vapor who tended to fall to the right (18,34); (c) flapping motions in an infant poisoned from contaminated pork (37) and in a man injected with thimerosal (27); (d) choreiform movements in mercury vapor intoxication (19); (e) toe walking in a moderately poisoned Minamata child (34); (f) poor coordination and clumsiness among victims of acrodynia (45); (g) rocking among infants with acrodynia (11); and (h) unusual postures observed in both acrodynia and mercury vapor poisoning (11,31). The presence of flapping motions in both diseases is of interest because it is such an unusual behavior that it has been recommended as a diagnostic marker for autism (46).

Virtually all ASD subjects show a variety of sensory abnormalities (2). Auditory deficits are present in a minority of individuals and can range from mild to profound hearing loss (2,47). Over- or under-reaction to sound is nearly universal (2,48), and deficits in language comprehension are often present (3). Pain sensitivity or insensitivity is common, as is a general aversion to touch; abnormal sensation in the extremities and mouth may also be present and has been detected even in toddlers under 12 months old (2,49). There may be a variety of visual disturbances, including sensitivity to light (2,50,51,52). As in autism, sensory issues are reported in virtually all instances of Hg toxicity (40). HgP can lead to mild to profound hearing loss (40); speech discrimination is especially impaired (9,34). Iraqi babies exposed prenatally showed exaggerated reaction to noise (23), while in acrodynia, patients reported noise sensitivity (45). Abnormal sensation in the extremities and mouth is the most common sensory disturbance (25,28). Acrodynia sufferers and prenatally exposed Iraqi babies exhibited excessive pain when bumping limbs and an aversion to touch (23,24,45,53). A range of visual problems has been reported, including photophobia (18,23,34).

## **COMPARISON OF BIOLOGICAL ABNORMALITIES**

The biological abnormalities commonly found in autism are listed in Table II, along with the corresponding pathologies arising from mercury exposure. Especially noteworthy similarities are described.

Autism is a neurodevelopmental disorder which has been characterized as "a disorder of neuronal organization, that is, the development of the dendritic tree, synaptogenesis, and the

development of the complex connectivity within and between brain regions" (54). Depressed expression of neural cell adhesion molecules (NCAMs), which are critical during brain development for proper synaptic structuring, has been found in one study of autism (55). Organic mercury, which readily crosses the blood-brain barrier, preferentially targets nerve cells and nerve fibers (56); primates accumulate the highest Hg-levels in the brain relative to other organs (40). Furthermore, although most cells respond to mercurial injury by modulating levels of glutathione (GSH), metallothionein, hemoxygenase, and other stress proteins, neurons tend to be "markedly deficient in these responses" and thus are less able to remove Hg and more prone to Hg-induced injury (56). In the developing brain, mercury interferes with neuronal migration, depresses cell division, disrupts microtubule function, and reduces NCAMs (28,57-59).

While damage has been observed in a number of brain areas in autism, many nuclei and functions are spared (36). HgP's damage is similarly selective (40). Numerous studies link autism with neuronal atypicalities within the amygdala, hippocampi, basal ganglia, the Purkinje and granule cells of the cerebellum, brainstem, basal ganglia, and cerebral cortex (36,60-69). Each of these areas can be affected by HgP (10,34,40,70-73). Migration of Hg, including eHg, into the amygdala is particularly noteworthy, because in primates this brain region has neurons specific for eye contact (74) and it is implicated in autism and in social behaviors (65,66,75).

Autistic brains show neurotransmitter irregularities which are virtually identical to those arising from Hg exposure: both high or low serotonin and dopamine, depending on the subjects studied; elevated epinephrine and norepinephrine in plasma and brain; elevated glutamate; and acetylcholine deficiency in hippocampus (2,21,76-83).

Gillberg and Coleman (2) estimate that 35-45% of autistics eventually develop epilepsy. A recent MEG study reported epileptiform activity in 82% of 50 regressive autistic children; in another study, half the autistic children expressed abnormal EEG activity during sleep (84). Autistic EEG abnormalities tend to be non-specific and have a variety of patterns (85). Unusual epileptiform activity has been found in a number of mercury poisoning cases (18,27,34,86-88). Early mHg exposure enhances tendencies toward epileptiform activity with a reduced level of seizure-discharge amplitude (89), a finding consistent with the subtlety of seizures in many autism spectrum children (84,85). The fact that Hg increases extracellular glutamate would also contribute to epileptiform activity (90).

Some autistic children show a low capacity to oxidize sulfur compounds and low levels of sulfate (91,92). These findings may be linked with HgP because (a) Hg preferentially binds to sulfhydryl molecules (-SH) such as cysteine and GSH, thereby impairing various cellular functions (40), and (b) mercury can irreversibly block the sulfate transporter NaSi cotransporter NaSi-1, present in kidneys and intestines, thus reducing sulfate absorption (93). Besides low sulfate, many autistics have low GSH levels, abnormal GSH-peroxidase activity within erythrocytes, and decreased hepatic ability to detoxify xenobiotics (91,94,95). GSH participates in cellular detoxification of heavy metals (96); hepatic GSH is a primary substrate for organic-Hg clearance from the human (40); and intraneuronal GSH participates in various protective responses against Hg in the CNS (56). By preferentially binding with GSH, preventing absorption of sulfate, or inhibiting the enzymes of glutathione metabolism (97), Hg might diminish GSH bioavailability. Low GSH can also derive from chronic infection (98,99), which

would be more likely in the presence of immune impairments arising from mercury (100). Furthermore, mercury disrupts purine and pyrimidine metabolism (97,10). Altered purine or pyrimidine metabolism can induce autistic features and classical autism (2,101,102), suggesting another mechanism by which Hg can contribute to autistic traits.

Autistics are more likely to have allergies, asthma, selective IgA deficiency (sIgAd), enhanced expression of HLA-DR antigen, and an absence of interleukin-2 receptors, as well as familial autoimmunity and a variety of autoimmune phenomena. These include elevated serum IgG and ANA titers, IgM and IgG brain antibodies, and myelin basic protein (MBP) antibodies (103-110). Similarly, atypical responses to Hg have been ascribed to allergic or autoimmune reactions (8), and genetic predisposition to such reactions may explain why Hg sensitivity varies so widely by individual (88,111). Children who developed acrodynia were more likely to have asthma and other allergies (11); IgG brain autoantibodies, MBP, and ANA have been found in HgP subjects (18,111,112); and mice genetically prone to develop autoimmune diseases "are highly susceptible to mercury-induced immunopathological alterations" even at the lowest doses (113). Additionally, many autistics have reduced natural killer cell (NK) function, as well as immune-cell subsets shifted in a Th2 direction and increased urine neopterin levels, indicating immune system activation (103,114-116). Depending upon genetic predisposition, Hg can induce immune activation, an expansion of Th2 subsets, and decreased NK activity (117-120).

## **POPULATION CHARACTERISTICS**

In most affected children, autistic symptoms emerge gradually, although there are cases of sudden onset (3). The earliest abnormalities have been detected in 4 month olds and consist of subtle movement disturbances; subtle motor-sensory disturbances have been observed in 9 month olds (49). More overt speech and hearing difficulties become noticeable to parents and pediatricians between 12 and 18 months (2). TMS vaccines have been given in repeated intervals starting from infancy and continuing until 12 to 18 months. While HgP symptoms, may arise suddenly in especially sensitive individuals (11), usually there is a preclinical "silent stage" in which subtle neurological changes are occurring (121) and then a gradual emergence of symptoms. The first symptoms are typically sensory- and motor-related, which are followed by speech and hearing deficits, and finally the full array of HgP characteristics (40). Thus, both the timing and nature of symptom emergence in ASD are fully consistent with a vaccinal Hg etiology. This parallel is reinforced by parental reports of excessive amounts of mercury in urine or hair from younger autistic children, as well as some improvement in symptoms with standard chelation therapy (122).

The discovery and rise in prevalence of ASD mirrors the introduction and spread of TMS in vaccines. Autism was first described in 1943 among children born in the 1930s (123). Thimerosal was first introduced into vaccines in the 1930s (7). In studies conducted prior to 1970, autism prevalence was estimated, at 1 in 2000; in studies from 1970 to 1990 it averaged 1 in 1000 (124). This was a period of increased vaccination rates of the TMS-containing DPT vaccines among children in the developed world. In the early 1990s, the prevalence of autism was found to be 1 in 500 (125), and in 2000 the CDC found 1 in 150 children affected in one community, which was consistent with reports from other areas in the country (126). In the late

1980s and early 1990s, two new TMS vaccines, the HIB and Hepatitis B, were added to the recommended schedule (7).

Nearly all US children are immunized, yet only a small proportion develop autism. A pertinent characteristic of mercury is the great variability in its effects by individual, so that at the same exposure level, some will be affected severely while others will be asymptomatic (9,11,28). An example is acrodynia, which arose in the early 20th Century from mercury in teething powders and afflicted only 1 in 500-1000 children given the same low dose (28). Studies in mice as well as humans indicate that susceptibility to Hg effects arises from genetic status, in some cases including a propensity to autoimmune disorders (113,34,40). ASD exhibits a strong genetic component, with high concordance in monozygotic twins and a higher than expected incidence among siblings (4); autism is also more prevalent in families with autoimmune disorders (106).

Additionally, autism is more prevalent among boys than girls, with the ratio estimated at 4:1 (2). Mercury studies in mice and humans consistently report greater effects on males than females, except for kidney damage (57). At high doses, both sexes are affected equally; at low doses only males are affected (38,40,127).

## **DISCUSSION**

We have shown that every major characteristic of autism has been exhibited in at least several cases of documented mercury poisoning. Recently, the FDA and AAP have revealed that the amount of mercury given to infants from vaccinations has exceeded safety levels. The timing of mercury administration via vaccines coincides with the onset of autistic symptoms. Parental reports of autistic children with measurable mercury levels in hair and urine indicate a history of mercury exposure. Thus the standard primary criteria for a diagnosis of mercury poisoning - observable symptoms, known exposure at the time of symptom onset, and detectable levels in biologic samples (11,31) - have been met in autism. As such, mercury toxicity may be a significant etiological factor in at least some cases of regressive autism. Further, each known form of HgP in the past has resulted in a unique variation of mercurialism – e.g., Minamata disease, acrodynia, Mad Hatter's disease – none of which has been autism, suggesting that the Hg source which may be involved in ASD has not yet been characterized; given that most infants receive eHg via vaccines, and given that the effect on infants of eHg in vaccines has never been studied (129), vaccinal thimerosal should be considered a probable source. It is also possible that vaccinal eHg may be additive to a prenatal mercury load derived from maternal amalgams, immune globulin injections, or fish consumption, and environmental sources.

## **CONCLUSION**

The history of acrodynia illustrates that a severe disorder, afflicting a small but significant percentage of children, can arise from a seemingly benign application of low doses of mercury. This review establishes the likelihood that Hg may likewise be etiological in ASD, with the Hg derived from thimerosal in vaccines rather than teething powders. Due to the extensive parallels between autism and HgP, the likelihood of a causal relationship is great. Given this possibility, TMS should be removed from all childhood vaccines, and the mechanisms of Hg toxicity in autism should be thoroughly investigated. With perhaps 1 in 150 children now

diagnosed with ASD, development of HgP-related treatments, such as chelation, would prove beneficial for this large and seemingly growing population.

### **Table I: Summary Comparison of Traits**

of Autism & Mercury Poisoning

(ASD references in bold; HgP references in italics)

#### Psychiatric Disturbances

Social deficits, shyness, social withdrawal (1,2,130,131; 21,31,45,53,132)

Repetitive, perseverative, stereotypic behaviors; obsessive-compulsive tendencies  
(1,2,43,48,133; 20,33-35,132)

Depression/depressive traits, mood swings, flat affect; impaired face recognition (14,15,17,103,  
134,135; 19,21,24,26,31)

Anxiety; schizoid tendencies; irrational fears (2,15,16; 21,27,29,31)

Irritability, aggression, temper tantrums (12,13,43; 18,21,22,25)

Lacks eye contact; impaired visual fixation (HgP)/ problems in joint attention (ASD)  
(3,36,136,137; 18,19,34)

#### Speech and Language Deficits

Loss of speech, delayed language, failure to develop speech (1-3,138,139; 11,23,24,27,30,37)

Dysarthria; articulation problems (3; 21,25,27,39)

Speech comprehension deficits (3,4,140; 9,25,34,38)

Verbalizing and word retrieval problems (HgP); echolalia, word use and pragmatic errors (ASD)  
(1,3,36; 21,27,70)

#### Sensory Abnormalities

Abnormal sensation in mouth and extremities (2,49; 25,28,34,39)

Sound sensitivity; mild to profound hearing loss (2,47,48; 19,23-25,39,40)

Abnormal touch sensations; touch aversion (2,49; 23,24,45,53)

Over-sensitivity to light; blurred vision (2,50,51; 18,23,31,34,45)

## Motor Disorders

Flapping, myoclonal jerks, choreiform movements, circling, rocking, toe walking, unusual postures (2,3,43,44; 11,19,27,30,31,34,39)

Deficits in eye-hand coordination; limb apraxia; intention tremors (HgP)/problems with intentional movement or imitation (ASD) (2,3,36,181; 25,29,32,38,70,87)

Abnormal gait and posture, clumsiness and incoordination; difficulties sitting, lying, crawling, and walking; problem on one side of body (4,41,42,123; 18,25,31,34,39,45)

## Cognitive Impairments

Borderline intelligence, mental retardation – some cases reversible (2,3,151,152; 19,25,31,39,70)

Poor concentration, attention, response inhibition (HgP)/shifting attention (ASD) (4,36,153; 21,25,31,38,141)

Uneven performance on IQ subtests; verbal IQ higher than performance IQ (3,4,36; 31,38)

Poor short term, verbal, and auditory memory (36,140; 21,29,31,35,38,87,141)

Poor visual and perceptual motor skills; impairment in simple reaction time (HgP)/ lower performance on timed tests (ASD) (4,140,181; 21,29,142)

Deficits in understanding abstract ideas & symbolism; degeneration of higher mental powers (HgP)/sequencing, planning & organizing (ASD); difficulty carrying out complex commands (3,4,36,153; 9,18,37,57,142)

## Unusual Behaviors

Self injurious behavior, e.g. head banging (3,154; 11,18,53)

ADHD traits (2,36,155; 35,70)

Agitation, unprovoked crying, grimacing, staring spells (3,154; 11,23,37,88)

Sleep difficulties (2,156,157; 11,22,31)

## Physical Disturbances

Hyper- or hypotonia; abnormal reflexes; decreased muscle strength, especially upper body; incontinence; problems chewing, swallowing (3,42,145,181; 19,27,31,32,39)

Rashes, dermatitis, eczema, itching (107,146; 22,26,143)

Diarrhea; abdominal pain/discomfort, constipation, “colitis” (107,147-149; 18,23,26,27,31,32)

Anorexia; nausea (HgP)/vomiting (ASD); poor appetite (HgP)/restricted diet (ASD) (2,123; 18,22)

Lesions of ileum and colon; increased gut permeability (147,150; 57,144)

## **Table II: Summary Comparison of Biological Abnormalities**

in Autism & Mercury Exposure

Mercury Exposure  
Autism

Biochemistry

Binds -SH groups; blocks sulfate transporter in intestines, kidneys (40,93)  
Low sulfate levels (91,92)

Reduces glutathione availability; inhibits enzymes of glutathione metabolism; glutathione needed in neurons, cells, and liver to detoxify heavy metals; reduces glutathione peroxidase and reductase (97,100,161,162)

Low levels of glutathione; decreased ability of liver to detoxify xenobiotics; abnormal glutathione peroxidase activity in erythrocytes (91,94,95)

Disrupts purine and pyrimidine metabolism (10,97,158,159)  
Purine and pyrimidine metabolism errors lead to autistic features (2,101,102)

Disrupts mitochondrial activities, especially in brain (160,163,164)  
Mitochondrial dysfunction, especially in brain (76,172)

Immune System

Sensitive individuals more likely to have allergies, asthma, autoimmune-like symptoms, especially rheumatoid-like ones (8,11,18,24,28,31,111,113)  
More likely to have allergies and asthma; familial presence of autoimmune diseases, especially rheumatoid arthritis; IgA deficiencies (103,106-109,115)

Can produce an immune response in CNS; causes brain/MBP autoantibodies (18,111,165)

On-going immune response in CNS; brain/MBP autoantibodies present (104,105,109,110)

Causes overproduction of Th2 subset; kills/inhibits lymphocytes, T-cells, and monocytes;  
decreases NK T-cell activity; induces or suppresses IFN $\gamma$  & IL-2 (100,112,117-120,166)

Skewed immune-cell subset in the Th2 direction; decreased responses to T-cell mitogens;  
reduced NK T-cell function; increased IFN $\gamma$  & IL-12 (103,108,114-116,173,174)

#### CNS Structure

Selectively targets brain areas unable to detoxify or reduce Hg-induced oxidative stress  
(40,56,161)

Specific areas of brain pathology; many functions spared (36)

Accumulates in amygdala, hippocampus, basal ganglia, cerebral cortex; damages Purkinje and  
granule cells in cerebellum; brain stem defects in some cases (10,34,40,70-73)

Pathology in amygdala, hippocampus, basal ganglia, cerebral cortex; damage to Purkinje and  
granule cells in cerebellum; brain stem defects in some cases (36,60-69)

Causes abnormal neuronal cytoarchitecture; disrupts neuronal migration, microtubules, and cell  
division; reduces NCAMs (10,28,57-59,161)

Neuronal disorganization; increased neuronal cell replication, increased glial cells; depressed  
expression of NCAMs (4,54,55)

Progressive microcephaly (24)

Progressive microcephaly and macrocephaly (175)

#### Neuro-chemistry

Prevents presynaptic serotonin release and inhibits serotonin transport; causes calcium  
disruptions (78,79,163,167,168)

Decreased serotonin synthesis in children; abnormal calcium metabolism (76,77,103,179)

Alters dopamine systems; peroxidase deficiency in rats resembles mercurialism in humans (8,80)

Either high or low dopamine levels; positive response to peroxidase, which lowers dopamine  
levels (2,177,178)

Elevates epinephrine and norepinephrine levels by blocking enzyme that degrades epinephrine  
(81,160)

Elevated norepinephrine and epinephrine (2)

Elevates glutamate (21,171)

Elevated glutamate and aspartate (82,176)



Leads to cortical acetylcholine deficiency; increases muscarinic receptor density in hippocampus and cerebellum (57,170)

Cortical acetylcholine deficiency; reduced muscarinic receptor binding in hippocampus (83)

Causes demyelinating neuropathy (22,169)

Demyelination in brain (105)

## Neurophysiology

Causes abnormal EEGs, epileptiform activity, variable patterns, e.g., subtle, low amplitude seizure activities (27,31,34,86-89)

Abnormal EEGs, epileptiform activity, variable patterns, including subtle, low amplitude seizure activities (2,4,84,85)

Causes abnormal vestibular nystagmus responses; loss of sense of position in space (9,19,34,70)

Abnormal vestibular nystagmus responses; loss of sense of position in space (27,180)

Results in autonomic disturbance: excessive sweating, poor circulation, elevated heart rate (11,18,31,45)

Autonomic disturbance: unusual sweating, poor circulation, elevated heart rate (17,180)

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## News Articles on Homeland Security Bill Fiasco

### HOMELAND INSECURITY

#### **Doctors: Bill allows forced vaccinations**

#### **Physicians' group decries legislation establishing new Cabinet agency**

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**Posted: November 16, 2002**

**1:00 a.m. Eastern**

**By Jon Dougherty**

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A physicians' group is among a growing number of critics imploring the Senate to scrap portions of a proposed homeland security bill they say will seriously undermine civil liberties and grant the federal government unprecedented – and unconstitutional – power.

The [American Association of Physicians and Surgeons](#) said yesterday that one section of the legislation would allow the head of the Health and Human Services department to order Americans to receive potentially deadly smallpox vaccines against their will.

The bill gives "the HHS secretary virtually unlimited powers to declare an emergency and order smallpox treatment that could include forced immunizations, detainment and quarantines," said AAPS.

The 480-page bill passed the House Wednesday night on a 299-121 vote and is currently on the fast track to Senate passage. But as more details of the bill become known, the number of critics who oppose all or part of it also increase, including members of both parties as well as liberal and conservative analysts.

New York Times columnist William Safire, in an editorial Thursday entitled, "You Are a Suspect," attacked the entire measure, claiming a provision in the bill that establishes a broad Defense Department-administered database of information on every American is akin to author George Orwell's book "1984."

"To this computerized dossier on your private life from commercial sources, add every piece of information that government has about you – passport application, driver's license and bridge toll records, judicial and divorce records, complaints from nosy neighbors to the FBI, your lifetime paper trail plus the latest hidden camera surveillance – and you have the supersnoop's dream: a 'Total Information Awareness' about every U.S. citizen," Safire wrote.

Called the Defense Department's Total Information Awareness program, it would be administered by a totally new department called the Security Advanced Research Projects Agency.

AAPS said the dubious medical emergency language is contained in Section 304, titled, "Administration of Counter Measures Against Smallpox."

The bill gives HHS authority to declare an actual or potential bio-terrorist incident while giving the secretary the power to "administer 'countermeasures'" – like forced immunizations – to "a category of individuals or everyone." Also, the bill gives HHS the power to "continually extend" the emergency declaration indefinitely, without Congress' consent.

"Also, if you are harmed" by the countermeasures, "you cannot sue or take any other civil remedy," AAPS said.

"This section will give the [HHS] secretary unlimited power to define a real or potential threat, to take any measures he decides and to do it for as long as he wants," said Kathryn Serkes, a spokeswoman for the group. "It's 'Alice in Wonderland' time again – an emergency is just what [the secretary] says it is."

Some lawmakers are also alarmed at the scope of the bill.

The legislation "gives the federal government new powers and increases federal expenditures, completely contradicting what members were told about the bill," said Rep. Ron Paul, R-Texas, on the House floor before the vote Wednesday.

"Furthermore," he continued, "these new power grabs are being rushed through Congress without giving members the ability to debate, or even properly study, this proposal.

"I must oppose this bill and urge my colleagues to do the same," he said.

Sen. Robert Byrd, D-W.Va., also opposes the legislation.

"We're making a huge mistake passing the bill at this time," he said Thursday. "There has not been a single hearing" on its contents.

Expressing concern about the manner in which the bill was being fast-tracked, Byrd added: "If necessity is the mother of invention, then politics is the mother of bureaucracy."

Other problems with the bill, AAPS says, "include centralized database provisions, airport security, unchecked power to Cabinet officials, extent of the new bureaucracy, concentration of power in the Executive Branch, suspension of the rule that prohibits secret advisory committee meetings, limited public access to information and failure to address border security and immigration issues, such as [the] tracking of foreign students."

Serkes said the provision dealing with HHS reminds her of similar emergency legislation directed at empowering governors.

[The Model State Emergency Health Powers Act](#), WorldNetDaily reported in January, gives governors the power to order the collection of all data and records on citizens, ban firearms, take control of private property and quarantine entire cities, under the auspices of protecting "the health and safety of citizens from epidemics and bioterrorism," according to one analysis.

The version of the bill either under consideration or adopted by the majority of states thus far was drafted in October 2001, just a month after the Sept. 11 terrorist attacks, by The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, in collaboration with several other organizations.

"Just remove 'governor' from the old bill and insert 'secretary' and magically you have a federal bill that was firmly rejected by voters across the country," said Serkes.

Of the homeland security measure, Serkes added: "We need an honest accounting of how this will work. It's too frightening to allow it to be rammed through."

In response to some of the concerns, Senate Democrats are proposing amendments to the bill that would eliminate the liability protections in the House version for vaccine makers. The White House says it supports the amendments to an extent.

White House spokesman Scott McClellan said yesterday there are provisions in the bill that "still allow people the right to compensation or the right to sue if they believe they've been harmed by the use of a particular vaccine." But, he said, the provisions "only require that individuals seeking compensation begin by seeking resolution through the Vaccine Injury and Compensation Program."

"If an individual is not satisfied with the award that is offered through that system, then they always have the right to proceed and sue the manufacturer," he said. "But, in short, the vaccine

manufacturers will still be subject to liability. We just want to close loopholes, where people can circumvent that process."

If you'd like to sound off on this issue, please take part in the [WorldNetDaily poll](#).

*[Jon E. Dougherty](#) is a staff reporter and columnist for WorldNetDaily, and author of the special report, ["Election 2000: How the Military Vote Was Suppressed."](#)*

## **Homeland Bill Rider Aids Drugmakers Measure Would Block Suits Over Vaccines; FBI Powers Also Would Grow**

By Dan Morgan

Washington Post Staff Writer

Friday, November 15, 2002; Page A07

Riding along on legislation to create a new federal Department of Homeland Security is a White House-backed provision that could head off dozens of potential lawsuits against Eli Lilly and Co. and other pharmaceutical giants.

Elsewhere in the sprawling measure is language that would help the FBI obtain customer information from Internet service providers and increase the penalties for computer hacking. These and other last-minute additions to the bill by Republican leaders could have implications well beyond the measure's immediate goal of protecting the homeland, congressional officials said yesterday.

Lawyers for parents of autistic children suing pharmaceutical companies over childhood vaccines charged yesterday that a new section in the homeland bill -- passed on Wednesday by the House and now before the Senate -- would keep the lawsuits out of state courts, ruling out huge judgments and lengthy litigation. Complaints, instead, would be channeled to a federal program set up 14 years ago to provide liability protection for vaccine manufacturers. The program, funded through a surcharge on vaccines, compensates persons injured by such vaccines, to a maximum of \$250,000.

"The industry has seized the opportunity presented by a Republican House and Senate to immediately pass legislation to get the industry off the hook," said Dallas lawyer Andrew Waters. "To me, it looks like payback for the fact that the industry spent millions bankrolling Republican campaigns."

GOP officials said the provisions are merely aimed at protecting companies working on life-saving products from being dragged into costly litigation by trial lawyers. Pharmaceutical companies were among the largest contributors to Republicans in this year's elections, while trial lawyers heavily backed Democrats.

In the past several years, some families have alleged a connection between their children's autism and vaccines using the preservative Thimerosal, which contains mercury. Medical studies have not proven a connection between Thimerosal and autism, but companies stopped using the preservative several years ago.

Eli Lilly, once the largest maker of Thimerosal, is a major target in a spate of lawsuits filed since 2000. The company stopped making the product in 1980 but continued to buy it from other manufacturers and to resell it for another decade.

Company spokesman Edward Sagebiel said Lilly was "surprised when the language was inserted" because it had not actively lobbied for it in recent months. But he said the company "believes it is a positive step to help assure that manufacturers are protected from lawsuits that are without merit or scientific evidence."

Richard Diamond, a spokesman for retiring House Majority Leader Richard K. Armey (R-Tex.), said the provision was inserted because "it was something the White House wanted. It wasn't [Armey's] idea." But Diamond said the principle is good. "We don't want companies to be steered away from the business of making things that can save lives," he said. Elsewhere in the bill, Republicans incorporated the entire Cyber Security Enhancement Act, which the House passed overwhelmingly in July but which made little progress in the Democratic-controlled Senate. To strengthen law enforcement's hand in protecting the security of computer communications, the legislation would increase penalties for hacking and other malicious computing. Privacy advocates have criticized some provisions, particularly those that would lower the threshold for Internet service providers to give law enforcement agencies customer communications without a court order.

The bill would make hacking punishable by as much as life in prison if the offender "knowingly or recklessly causes or attempts to cause death."

Cut from the bill was a Democratic-backed provision that would have prevented the new federal agency from giving contracts to U.S.-based companies that use offshore addresses to avoid corporate taxes.

GOP aides said the language originally offered by Rep. Tom DeLay (R-Tex.), and now incorporated in the bill, gives Texas A&M the inside track in hosting the first university center on homeland security, to be established within one year. DeLay was elected Wednesday to serve as the House majority leader in the 108th Congress.

Yesterday, Senate Democrats were considering trying to strip non-relevant provisions from the homeland security bill during the final debate. If successful, such a move could derail Congress's timetable for adjourning, by forcing a new round of House-Senate negotiations to resolve differences in the legislation.

*Staff writer Jonathan Krim contributed to this report.*

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## Democrats see a larded security bill, *The Washington Times*

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Senate Democrats said yesterday they would try to strip what they called Republican special-interest provisions from the homeland security bill, a move Republicans said might kill the measure already passed by the House and advocated relentlessly by the White House.

"If this is a homeland security bill, let's keep it homeland-security related and let's take out all this terrible special-interest legislation that has nothing to do with homeland security," said outgoing Senate Majority Leader Tom Daschle, South Dakota Democrat.

But Republicans denied their provisions were unrelated to homeland security. They also said if Senate Democrats succeeded in their changes, the Republican-controlled House then would have to vote again — and the House left for the year early yesterday morning.

Also, if the homeland security bill fails, it will take longer to get a final vote on a terrorism insurance provision, said Sen. Phil Gramm, Texas Republican.

"I just think it's a risk we shouldn't take," he said.

The fight is over an amendment offered by Mr. Daschle and Sen. Joseph I. Lieberman, Connecticut Democrat, that would strip seven provisions from the legislation approved by the House on Wednesday that would create a new Homeland Security Department.

"In the dead of night with no one watching, after we thought we'd made the compromise, a few things were snuck into the bill," said Sen. Barbara Boxer, California Democrat.

Included is language that would create at least one new university-based homeland security research center at a major university — Democrats say it was intended for Texas A&M University, a favorite of Mr. Gramm's and incoming House Majority Leader Tom Delay, Texas Republican. Republicans say it could go to any number of universities including Texas A&M. Also, Democrats say there is language in the bill that would protect pharmaceutical companies from lawsuits over the vaccines they create and their side effects, including wiping out lawsuits already in court.

The provision "provides liability protection for pharmaceutical companies that actually make mercury-based vaccine preservatives that actually have caused autism in children. It wipes out all of the litigation," Mr. Daschle said. "I can't understand why we would put a provision in there relating to that kind of liability protection."

Republicans deny that the provision would wipe out current lawsuits, and say future liability protection is needed to ensure that pharmaceutical companies will produce the vaccines that America needs to fight the war on terrorism.

"Why would [companies] stand out totally exposed for making a medicine that is lifesaving but one that, with one lawsuit, can wipe out their whole development process, their whole manufacturing process today?" said Sen. Bill Frist, Tennessee Republican, the Senate's only doctor.

After the Senate finishes with the homeland security bill on Monday, it will move on to the terrorism insurance legislation passed by the House.

Under that bill, the government would cover up to \$90 billion annually in insurance claims from any future terrorist attacks for the next three years. The government would cover up to 90 percent of insured losses from major attacks, with the insurance industry covering up to the first \$15 billion in annual claims.

The measure does not cover last year's terrorist attacks, which generated an estimated \$40 billion in claims that insurers had to cover.

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