Bush administration moves to suppress documents on vaccines

Joanne Laurier
10 December 2002

The Bush administration asked a federal claims court on November 26 to seal documents relating to hundreds of cases of autism allegedly caused by a mercury-based preservative, thimerosal, used in childhood vaccines.

The government's legal action comes on the heels of an insertion into the Homeland Security bill that protects Eli Lilly, the drug company giant that developed thimerosal, from lawsuits involving the additive. The bill removes all liability from the pharmaceutical industry and health officials for the injuries and death resulting from the preservative.

The connections between the Bush administration and the pharmaceutical company are extensive. Eli Lilly's chairman and CEO, Sidney Taurel, was recently given a seat on the president's Advisory Council on Homeland Security and Mitch Daniels, former president of Lilly's North American operations, is currently the White House budget director. Former president George Bush sat on Eli Lilly's board of directors.

In asking for the documents to be sealed November 26, Department of Justice (DOJ) lawyers asked a special master in the US Court of Federal Claims for a protective order on behalf of Tommy G. Thompson, the secretary of Health and Human Services, whose department administers a government fund to compensate people injured by vaccines. DOJ lawyers claim that the law creating the fund gives the secretary jurisdiction over which information is released and they argue that automatic disclosure of the documents would take away that right. The claims are being heard by Special Master George Hastings in a 'vaccine court'—part of the National Vaccine Injury Compensation Program (NVIC)—that was created in 1986, when the government fund was established.

The vaccine court was set up to speed compensation claims and help protect vaccine makers from having to pay large punitive awards decided by juries in state civil courts. Claims must be filed within three years of a child's first symptoms (autism, however, is typically not diagnosed until 18 months after the first symptoms appear) and the program grants a maximum of $250,000 for proof of injury—a sum considerably lower than the typical award for autism in a state court. It also takes four to five years to reach a decision under NVIC, according to Portland lawyer Mike Williams, who represents hundreds of families in suits against the pharmaceutical companies.

The court is currently hearing approximately 1,100 claims brought by the families of autistic children, who claim that thimerosal has caused autism and other neurological disorders in children.

The request by the Bush administration would prevent plaintiffs who later go to civil court from using evidence gathered during the required vaccine court proceedings.

"There is no secret here. What the petitioners are arguing for are enhanced rights in a subsequent civil action," complained Justice Department attorney Vincent Matanoski to *Reuters Health*.

The order, which amounts to punishing of the families of injured children, will require that plaintiffs incur the time and expense of regenerating evidence in a civil suit.

"The vaccine program is a public health program—every child has to get inoculated," Sallie Bernard of the parental advocacy group Safe Minds told the WSWS. "Therefore the public has the right to know every aspect of the program."

Mercury-based thimerosal was added to vaccines to safeguard against production-related contamination. The Federal Drug Administration began urging vaccine makers to eliminate the substance in mid-1999, as did the Public Health Service and the American Academy of Pediatrics. The World Health Organization still defends thimerosal, which is currently being manufactured in vaccines sent to the underdeveloped countries. Thimerosal helps vaccines survive dirty storage conditions and allows for cheaper packaging in multi-dose bottles, as opposed to single-dose vials.

In 1999 the Institute of Medicine, an associated organization of the National Academy of Sciences, concluded that the evidence was "inadequate to accept or reject a causal relationship between thimerosal exposures from childhood vaccines and the neurodevelopmental disorders of autism" and other problems, but added, "However, data on mercury toxicity more generally suggests that the hypothesis is biologically plausible."

In the midst of the heated response by advocacy groups and law firms involved with the thimerosal controversy to the DOJ's attempt to seal documents, a study was published November 30 in the British medical journal *The Lancet*. Its findings claimed that infants who received vaccines containing thimerosal had levels of mercury in their blood that were within the federal safety limits. The study examined 33 infants from two to six months who were injected with thimerosal-laced vaccines and 15 infants that were administered mercury-free vaccines.

Sallie Bernard of Safe Minds commented on the report: "Thirty-three blood draws cannot do justice to a known neurotoxin. One major shortcoming of a small sample size is the low chance of

including infants who are especially sensitive to mercury's effects, or who may have detoxification difficulties. The blood was not drawn at peak levels, and the samples were not randomly drawn, but were convenience samples and therefore not representative of all infants in terms of health status, socioeconomic status, ethnicity and other potentially important factors. Also the amount of the dosage used in the study was considerably less that the typical dosage administered throughout the 1990s."

"This study is an example of the fact that as yet there has not been enough time or resources allocated to complete much-needed, genuine investigations," stated Bernard, who expressed alarm at the prominence *The Lancet* had given to the finding.

She further questioned the objectivity of the study's author, Dr. Michael E. Pichichero of the University of Rochester, who has extensive ties to the vaccine manufacturers. In a disclosure statement for an article in the American Academy of Family Physicians newsletter of April 2000, Pichichero admits to receiving research grants and/or honoraria from Abbot Laboratories, Bristol-Myers Squibb, Eli Lilly, Merck, Pfizer Labs, Roche, among a host of others. Pichichero's work has been cited in 21 vaccine patent applications. Bernard pointed out that the University of Rochester web site describes Dr. Pichichero as an immunologist, not a toxicologist.

Thimerosal came under scrutiny due to the dramatic rise in autism throughout the 1990s. Early on in the decade several new thimerosal-based vaccines were added to the standard childhood schedule, leading to an augmentation of two to three times the doses of multiple vaccines. According to the Federal Drug Administration's (FDA) web site, prior to the recent initiatives by the agency to reduce or eliminate thimerosal from vaccines, the maximum cumulative exposure to mercury via routine childhood vaccinations during the first six months of life was 187.5 micrograms. The FDA states that "an exposure to more than 62.5 micrograms within the first three months of life significantly increases a child's risk of developing autism." An FDA review conducted in 1998 revealed that children who had received the full complement of childhood vaccines were potentially exposed to mercury levels 30 to 50 times the acceptable levels established by the Environmental Protection Agency (EPA).

The number of children who have been affected by autism leaped from 1 in 2,000 in 1970 to 1 in 250 in 2000. (The National Vaccine Information Center reports clusters in areas of New Jersey and California of 1 in 150). Concurrently, the number of children diagnosed with learning disabilities has now reached 1 in 5.

Another Safe Minds advocate, Lyn Redwood, a nurse practitioner whose husband is a physician, told the WSWS the story of her son Will. "He was normal until his second year of life. He then began to regress—he lost speech, eye contact and became withdrawn and despondent." When Will was diagnosed with autism she began investigating her son's quantity of mercury exposure and discovered it was 125 times the allowed level. It is her belief that Will suffered from delayed neurotoxicity which led to the onset of autism.

"In the early 1990s, two new vaccines were added to the vaccine protocol for the first six months of life. I believe that caused what we see now as an epidemic of autism in children. You can see that most clearly in California, the state with the best tracking records," said Ms. Redwood. California recorded an increase of 273 percent between 1987 and 1998 in the number of children entering the California development services system with a professional diagnosis of autism, according to the California Department of Developmental Services.

She continued: "The Homeland Security Bill has now moved all cases to the National Vaccine Injury Compensation Act, which has a three year limitation. My case was in the batch of 1,000 cases, but the statute of limitation has closed the door on us and also the majority of parents who remain unaware of the statute."

The Houston-based law firm of Waters & Kraus filed the first known lawsuit alleging thimerosal's connection to autism. The firm is leading a consortium of 10 firms nationwide that are actively prosecuting cases of this nature.

The lead attorney for the consortium, Andy Waters, obtained through Safe Minds an unreleased confidential report by scientists of the Centers for Disease Control (CDC) which states: "As for the exposure evaluated at 3 months of age, we found increasing risks of 'neurological developmental disorders' with the increasing cumulative exposure to thimerosal ... within the group of 'developmental disorders' ... for the subgroup called 'specific delays,' and within this subgroup for the specific disorder 'developmental speech disorder,' and for 'autism' 'stuttering' and 'attention deficit disorder.'"

Mr. Waters told the WSWS: "It defies coincidence between double the vaccines and the dramatic upsurge in autism. But this should come as no surprise, given that the government and its allies are in control of public policy. Eli Lilly gave more money to the Republican campaign than any other pharmaceutical company in an industry that gave $20-40 million. The DOJ and the administration are owned by the pharmaceutical companies. They want to seal the files to prevent proving the case against these companies. [Attorney General John] Ashcroft is owned by the industry and the Democrats are waffling all over the place, so the administration's move comes as no real surprise."

"With the cases sealed, Eli Lilly will move for a dismissal and all my cases are filed against Eli Lilly," Waters continued. "This will be a long battle against people who have all the resources and motivation. They control the pier-reviewed medical and scientific journals and all the research money. It will be a long and difficult fight."

Waters added that "no amount of money can give these children back the potential that they were born with, and no amount of money will comfort the parents that watched helplessly as their children literally just slipped away."