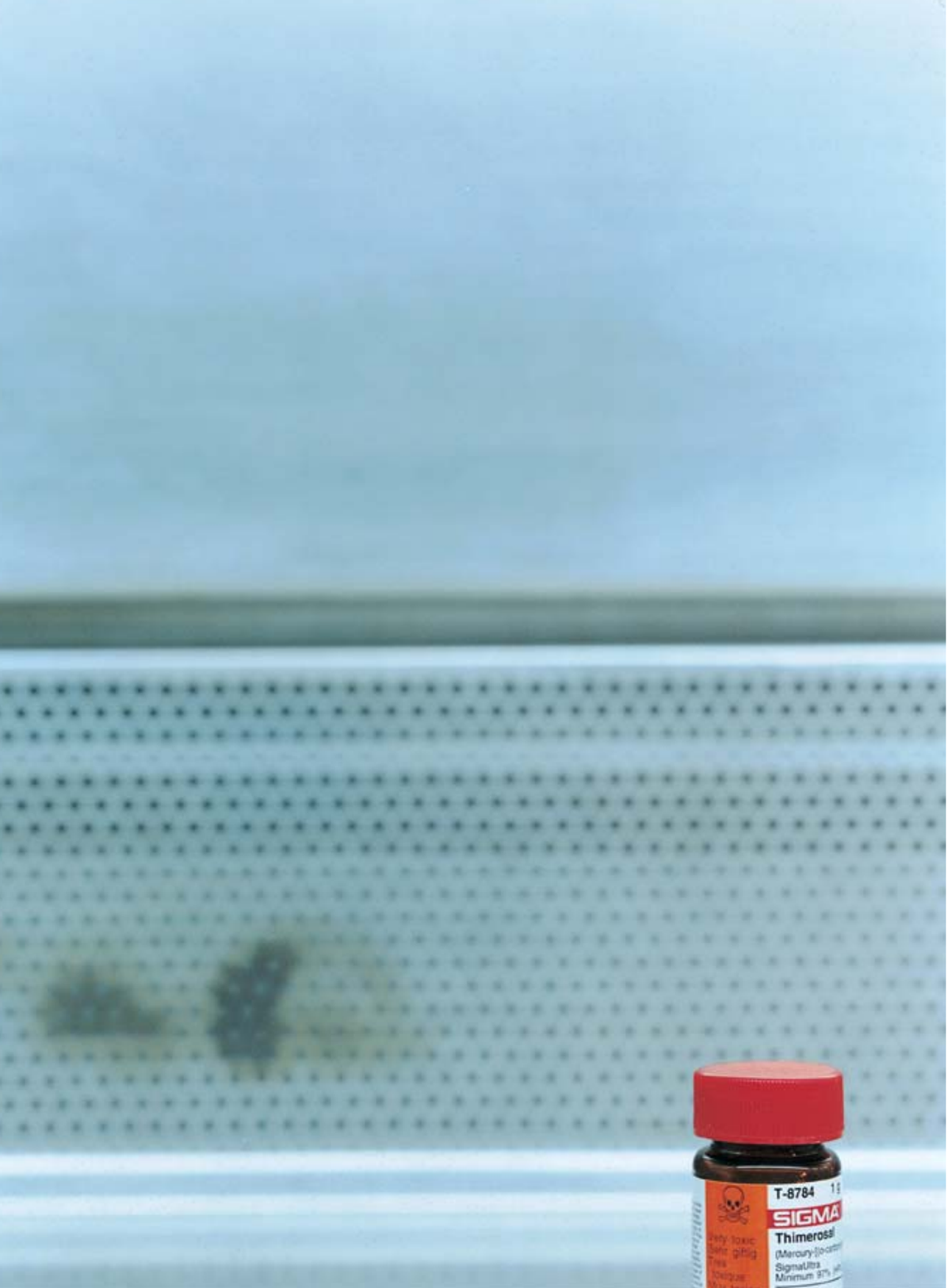

The Rise Against Mercury

Is the nation's spiraling rate of autism caused by the mercury in vaccines? With over four thousand cases pending, a trillion dollars at stake, and public trust on the line, a firestorm is sweeping from the halls of science to the boardrooms of Big Pharma to the steps of the Capitol. **Sarah Bridges** spends nine months with a father-and-son team of researchers on the frontline.

The air in the meeting room had grown stale as the afternoon wore on, but Minnesota Attorney General Mike Hatch listened intently, puzzling his way through the data. Leaning forward at the head of the oak table that dominated the room, he asked, "Are you saying there is still mercury in vaccines today?"

After a quick glance at his attaché case, Dr. Mark Geier replied, "In several of them—we have the bottles here to show you."

"I thought the Federal and Drug Administration required it to be removed," countered Hatch.

Mark Geier sighed. "They *recommended* it be removed. Many of our children are still being injected with mercury at their well-baby checkups."

Mercury is the main component of thimerosal, an antibacterial preservative that until recently was used in most vaccines. It has become a lightening rod in an escalating debate over the cause of the nation's rising rates of autism. It has entangled parents, health care providers, legislators, attorneys, public health officials, and drug makers, prompting them to ask one central question: Is thimerosal the mark of colossal government negligence or merely a symbol of parental desperation?

This debate became more than a theoretical one for me the day I received a call from the office of Congressman David Weldon (R-Florida), asking me if I was writing anything about thimerosal. Stuart Burns, Weldon's deputy chief of staff, was calling in response to an article I wrote in *The Washington Post Magazine*, detailing the government's acknowledgement of my son's brain damage from a vaccine. Mr. Burns gave me the name of Dr. Mark Geier and Dr. Geier's son David, saying, "They are the only self-funded researchers publishing in peer-reviewed journals on thimerosal and autism, using CDC data . You should talk with them." Twenty-four hours later, I was on the phone with the Geiers. I was doubtful about what I'd hear as I dialed their number. We started speaking at 9:30 on a Saturday night. We didn't finish until after midnight.

In the course of that call—and a two-day visit to their home a few weeks later—I heard a story that sounded more like a whodunit than a typical scientific investigation. They detailed their evidence linking thimerosal with the autism epidemic, and it was compelling. I had to hear more and told them I'd come visit in order to fully understand the issue.

Almost everybody knows of someone with autism today—but it wasn't always like that. In the years between 1970 and the late '90s, the autism rates in America rose from 1 in 10,000 children to 1 in 166. The Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) sent out an *Autism A.L.A.R.M.* to pediatricians across the country in March 2004, warning them that the disorder "is prevalent" and must be treated early and aggres-

Photography by Jason Gould

sively. A scan of the US Department of Education data on autism in children makes the surge obvious: In the decade between 1992 and 2002, the rate of autism was up an average of 1,000 percent in all 50 states. Recent articles in *The Journal of the American Medical Association* and *Pediatrics* contend that that the increase is real—that it is not an issue of increased reporting or shifting demographics. The related disorders of attention deficit hyperactivity and speech delays have spiked as well. The question is, why?

Since autism was first described by Dr. Leo Kanner in 1943, numerous theories have emerged to explain its etiology, ranging from bad mothering to microwave ovens to faulty genetics. "At first they talked about 'refrigerator mothers' and then the Measles, Mumps, and Rubella (MMR) vaccine," said Dr. Adrian Sandler, chairperson for the AAP. "The field of autism is littered with the carcasses of false causes." Several recent studies have linked autism to particular genes; however, the role of the environment in the epidemic must be factored in, as genetics alone cannot account for the rapid increase in the prevalence of the disease. Most scientists agree that epigenetics—an interaction between genes and the environment—will ultimately be identified as the cause.

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In the mid '90s, concerned scientists, parents, and politicians began questioning the link between the skyrocketing incidence of neurological problems in children and thimerosal, a drug that is approximately 50 percent mercury by weight. Thimerosal was first trademarked by Eli Lilly and Company in April 1930 and was added to childhood vaccines a few years later. Due to the comparatively lax safety standards of the time, it never underwent animal testing or long-term safety trials.

The growing interest in thimerosal sprang from multiple avenues: biological plausibility (the effects of mercury toxicity have been studied through a series of industrial accidents), the Environmental Protection Agency's (EPA) classification of mercury as a potent neurotoxin, and research from other medical disciplines demonstrating thimerosal's toxicity.

There was another reason thimerosal was suspect: the linear correlation between increasing rates of autism and the amount of thimerosal children received during the '90s. With the number of routine thimerosal-containing vaccines rising from eight to nearly 40 in that decade, federal health officials realized that some children were receiving many times the EPA's safe limit for mercury—the daily limit of allowable mercury based on evaluation of documented human mercury exposure—on given days in the first six months of life. Essentially, it appeared that the more thimerosal given to a child in a year, the more likely he or she was to develop autism or a related neurological disorder.

Following up on my promise to the Geiers, I flew to the East Coast last fall to meet with them. The subway ride from Washington, D.C., was humid and long as the train sped past a blur of high-rise buildings and emptied out in the Maryland suburbs. I spotted Mark Geier on the platform—middle-aged with practical glasses, slightly unruly hair, and an easy grin. No flash, I thought, but exuding confidence.

"I'm Mark," he said, extending a hand before climbing into the driver's seat of a car with "Geier 4" spelled out on the license plate.

"What happened to Geier 1, 2, and 3?" I asked.

"My wife and son have those," he replied.

We traveled through a residential neighborhood to his modest two-story home. He chatted amiably as we drove and told me a story about his attempt to have thimerosal delivered to his house so that he could study it in one of his labs.

"A day after I ordered it," he said, "I received a frantic call from the FedEx office. The woman on the other end said they would not be able to deliver thimerosal to my home." He continued, "She said, 'It's too dangerous—it needs to be handled in a secure lab with protective clothing.' She wasn't overreacting, though—there was an incident a few years ago when a researcher from Dartmouth spilled a *drop* of dimethyl mercury on her gloved hand. They did everything they could to treat her. She died a few months later." He paused and looked over at me. "This is the same stuff we are injecting into our kids."

I didn't respond. Despite the severe reaction my son Porter had to the pertussis (whooping cough) vaccine, I am a firm believer in immunizations. I've had two children since Porter's injury, and both of them have been fully vaccinated. The mercury-poisoning theory of autism reminded me too much of the preposterous Mad Hatter in *Alice in Wonderland*. The training I did for my PhD in experimental psychology taught me to be skeptical, and it was working well at the moment.

Mark must have seen the look on my face.

"I know it's hard to believe," he said. "Spend a few days with us, and we'll tell you about thimerosal. We'll show you the research and studies and data. Decide for yourself when we're done."

I spent the next two days with them. Here is what I learned.

In 1999, the American Academy of Pediatrics (AAP) and the US Public Health Service took the unexpected step of recommending that thimerosal be removed from childhood vaccines. In a recent interview, Dr. Thomas Saari, spokesperson for the AAP, interpreted the decision this way: "I think everyone recognizes that removing heavy metals like mercury or thallium from our environment is a good thing.... We project over the next ten years that we'll add one to two new vaccines a year, so you need to be concerned about the total amount of thimerosal children would ultimately get if the newer vaccines use thimerosal as a preservative as well." He continued, "While I could not say that there is or is not a relationship to autism in some children, the AAP was on the forefront of raising this issue and suggesting that we remove thimerosal out of an abundance of caution."

This move was not unfounded. It followed the Food and Drug Administration's (FDA) Modernization Act of 1997, legislation that, among other regulations and improvements, required the FDA to review the amount of mercury that was added to products for use in

humans. In 1999, the review was completed, and the FDA required the removal of thimerosal from over-the-counter drugs. The same year, once the amount of thimerosal in childhood vaccines was finally tallied, the FDA discovered that children were receiving more than 100 times the EPA's safe limit for mercury by 18 months of age. The agency also acknowledged that long-term safety trials for thimerosal had never been conducted.

"The recognition caused a huge stir," Barbara Loe Fisher said. Fisher is the cofounder and president of the National Vaccine Advisory Committee and served for four years on the FDA Vaccines and Related Biological Products Advisory Committee, a group that advises the CDC on vaccine issues. She also has a son she believes was harmed by a vaccine. "I stood in the back of the room when they announced [the amount of mercury], and you could hear the sighs—people were obviously upset. They worried that a crisis of public confidence would jeopardize the vaccine program."

In 2001, the Institute of Medicine (IOM), an impartial advisory board to Congress, stated that a link between thimerosal and autism was "biologically plausible" and reaffirmed the recommendation to remove it from vaccines. Curtis Allen, of the CDC's National Immunization Program, said in a recent e-mail that "at present, all routinely recommended vaccines manufactured for administration to US infants are either thimerosal-free or contain only trace amounts of thimerosal that are a byproduct of the manufacturing process."

In contrast, a review of FDA documents, acquired by Rep. Weldon, reveals that some of the Influenza, Meningitis, and Diptheria-Tetanus and Acellular Pertussis (DTaP) vaccines given to children today still contain thimerosal. For example, the DTaP multi-dose vaccine still contains "standard" levels (25 micrograms per dose), although thimerosal has been removed from DTaP single-dose vials. The agency also acknowledged that the final stock of many thimerosal-containing immunization didn't expire until the end of 2002. The FDA did not respond to *Seed*'s repeated requests for an interview.

The Geiers' home has been transformed by their research. They even have a fumehood, purchased on ebay

Soon after, the Geiers began to investigate thimerosal—and grew increasingly concerned. "Once we understood the data well enough, we were frightened," recalled David.

Prompted by concerned parents they had met through their work on vaccine safety, they examined the CDC and FDA's Vaccine Adverse Reporting System (VAERS)—a database where doctors and parents report vaccine side effects. Over the course of two years, the Geiers published six peer-reviewed correlational studies based on the VAERS data, with startling results: The more thimerosal children received, the higher the incidence of neurological problems, including autism. Next they tackled the US Department of Education data and conducted a statistical comparison of yearly autism rates with the amount of thimerosal given to children. Again, a tight lockstep between the two was revealed.

But this data only took them so far. "Correlation only means a relationship," explained David. "The autism epidemic of the '90s also coincided with increased television-watching among children. But none of us are arguing that TV is the cause."

To resolve this issue, the Geiers wanted to reanalyze the CDC's Vaccine Safety Datalink (VSD)—a database of medical records purchased from seven Health Maintenance Organizations (HMOs) for study purposes at a cost of more than $30 million. Analysis of the VSD by CDC researchers began in 1999 and revealed a statistically significant relationship between thimerosal and several neurological problems in approximately 110,000 children. CDC scientists continued analyzing the data, and e-mails they exchanged, obtained through the Freedom of Information Act (FOIA), revealed that despite "running, rethinking, rerunning and rethinking" their analyses, the thimerosal effect did not disappear. As the subject line of lead researcher Dr. Thomas Verstraeten's e-mail to colleagues read, "It just won't go away."

These early findings were kept from the public, though they were presented to representatives from the CDC, the FDA, the AAP, and vaccine makers at a private meeting at the Simpsonwood Conference Center in Georgia in 2000. Copies of the data shared at the meeting, also obtained through the FOIA, showed a linear correlation between thimerosal exposure and neurological problems, including autism. The meeting transcript revealed that several participants were concerned about thimerosal's alleged neurologically toxic effects—and the impact the information might have on America's immunization program.

Dr. Bill Weil, a consultant to the AAP and a conference participant, commented on thimerosal, saying, "You can play with this all you want. [The results] are statistically significant."

Dr. Richard Johnston, an immunologist and pediatrician, was concerned enough to consider his own family members. "My gut feeling? It worries me enough," he said. "Forgive this personal comment, but I got called out for an emergency, and my daughter-in-law delivered a son by C-section... and I do not want that grandson to get a thimerosal-containing vaccine until we know better what is going on."

The group's final discussion centered on how best to guard the incendiary findings from the public. "Consider this embargoed information," said Dr. Roger Bernier, the associate director for science at the National Immunization Program, to the group. The participants took his caution seriously, and the findings remained out of the public eye until they were released to Safe Minds, a nonprofit group founded by parents concerned about the role of mercury in disease, under the FOIA in July 2001.

Following the Simpsonwood conference, Dr. Thomas Verstraeten, the lead author of the VSD study, was concerned about how refinement of the thimerosal data might jeopardize scientific rigor. In an e-mail to Robert Chen, chief of the Immunization Safety Branch of the CDC's National Immunization Program, and others, he wrote, "I do not wish to be the advocate of the anti-vaccine lobby and sound as if I am convinced that thimerosal is or was harmful; but at least I feel that we should use sound scientific argumentation and not let our standards be dictated by our desire to disprove an unpleasant theory."

Nonetheless, the thimerosal effect did go away. Three years later, when Dr. Verstraeten and peers published the research in a November 2003 issue of *Pediatrics*, the results no longer showed a link between thimerosal and autism. The results took four years to publish, due to refinement of the VSD data, including the addition of some children to the database and the removal of others.

Dr. Thomas Saari from the AAP defended the study's changing data and said they were understandable if one looked more closely. "I've talked to Dr. Verstraeten a number of times on this matter at different stages of the maturation of the study," he said. "I believe he thought he did see a weak signal with thimerosal concerning some neurodevelopmental conditions in the beginning stages of the study." But once the CDC group reworked the data in response to reviewers concerns, "the effect was less apparent and seemingly restricted to a couple of conditions, like tics and language delays." He explained that the changing data represented "attempts at more accurate case-ascertainment and improving the quality of the data to be analyzed."

"I've studied thimerosal and talked to people on both sides of the issue. There is enough evidence I've seen to make it clear to me that we need to get thimerosal out of the products we give to our children."

Others felt this explanation didn't go far enough.

"Good case ascertainment had already been done before Simpsonwood—in fact, they talk about it quite a bit in the transcript," David Geier said. "The data shuffling was so extreme in the four years after the initial study that they actually found in their article that thimerosal may be *protective* for certain neurological problems. I find it hard to fathom that a scientist could actually claim that a potent neurotoxic substance like mercury is good for the developing brain."

Dr. Verstaeten hasn't responded to a congressional subpoena to be questioned about the VSD data, although he continues to publish with the CDC. His current employer, GlaxoSmithKline, stated that he is not granting interviews at this time. But Dr. Verstraeten responded to criticisms of his work via a Letter to the Editor in the April 2004 issue of *Pediatrics*, the journal in which the CDC study was first published.

Dr. Verstraeten wrote, "The CDC screening study of thimerosal-containing vaccines was perceived at first as a positive study that found an association between thimerosal and some neurodevelopmental outcomes. This was the perception both independent scientists and anti-vaccine lobbyists had at the conclusion of the first phase of the study. It was foreseen from the very start that any positive outcome would lead to a second phase.

"Because the findings of the first phase were not replicated in the second phase, the perception of the study changed from a positive to a neutral study. Surprisingly, however, the study is being interpreted now as negative by many, including anti-vaccine lobbyists. The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come."

Further muddying the water for some, *Pediatrics* failed to reveal that Dr. Verstraeten worked for GlaxoSmithKline, a vaccine maker that may be vulnerable to lawsuits over thimerosal. He joined the pharmaceutical company in 2001, on the day he presented his thimerosal findings to the IOM. In his Letter to the Editor, Dr. Verstraeten also addressed this issue, stating, "I regard myself as a professional scientist who puts ethical value before any person or material gains. *Continued on page 107*