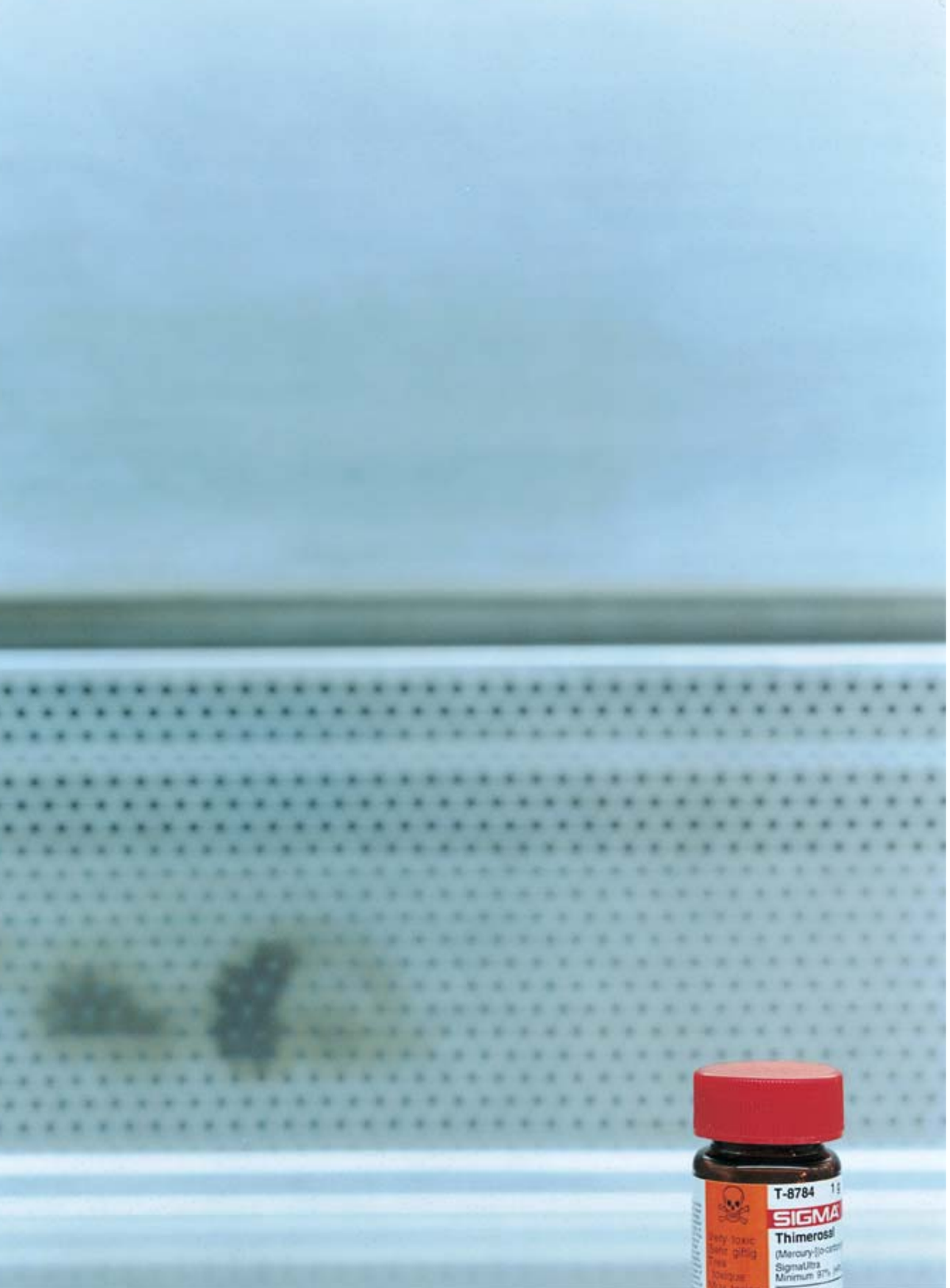

The Rise Against Mercury

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.

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 50 percent mercury by weight.

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*

ber of swing voters to oppose Bush in order to tip the scales of the election. In 2000, Al Gore lost by a grand total of five electoral points, and the votes within the states that determined these electoral points were incredibly narrow. Bush's win in Florida was decided by 537 votes; in New Mexico Gore won by 366 votes; and in Wisconsin Gore won by 5,708 votes. In almost half of all the states in the nation, a candidate's win was decided by fewer than 10,000 votes.

Both Democratic and Republicans strategists agree that though the political landscape has changed dramatically since 2000, the voter breakdown between Democrats and Republicans has not: "All the polls and political analysis shows that it's going to be an incredibly close race—just as close as the last one," says Frank Luntz. Which is why environmental organizations are developing their campaign strategies around critical swing states. "Just by getting a hundred votes here and a thousand votes there in certain swing states, we can decide the fate of the presidential election," said Mark Longabaugh, a senior vice president at the LCV.

Those small pockets of voters shouldn't be hard to find: A total of 10 million people in America are signed up as members of green organizations—which makes them a group as numerous as the organized labor force. "The environment is surprisingly a big-tent issue in politics—with broad reach," says Adam Werbach of CADF. And despite assumptions that most environmentalists are motivated voters, many, in fact, are not. According to Joe Fox, a deputy political director at the Sierra Club, "People who are active on environmental issues are only slightly more likely to vote than the average American [in the 2000 elections about 55 percent of Americans voted]. These are the people we're targeting to get to the polls."

But even in today's heated political climate, environmental groups are wary of the so-called "halo effect" that often surrounds the environment: While fully 85 percent of Americans typically say they support strong environmental protections, less than 5 percent actually give money to the cause, and an even smaller percentage consistently vote for it. Green groups are aiming to close this gap by making their best case to voters where it really matters—at home. Of the 12 most important swing states, many are predisposed to environmental concerns: Oregon, Florida, New Hampshire, Arizona, and New Mexico, for instance, are naturally beautiful regions with tourism industries that rely on their environmental well-being. Other politically significant states have unique environmental problems, such as Nevada, which is grappling with nuclear waste disposal at Yucca Mountain, and Michigan, which struggles with pollution in the Great Lakes. To wit, environmental groups are putting a lot of emphasis on local messages in their 2004 campaign strategies: "Our biggest concern is making our messages feel personally relevant to voters. We don't focus just on sweeping concerns like Bush's effort to destroy the Clean Air Act or Clean Water Act. We show how these national decisions will affect people in their back yards," says Carol Browner, who has already begun actively campaigning in Florida and New Hampshire on local issues for Environment2004.

Strategies like "microtargeting"—an eerily sophisticated art of tailoring messages to specific voters based on their personal concerns and geographical location—enable organizations to develop highly targeted grassroots campaigns on direct voter contact via mail, phone calls, and door-to-door canvassing. The LCV, for instance, plans to deploy a force of 25,000 volunteers in seven swing states to knock on a total of 1.5 million doors. "There is no more persuasive way to convince someone to vote than to talk to people face-to-face on their doorsteps, porches, driveways, and front yards," says LCV's Longabaugh.

Sierra Club President Carl Pope concurs: "We've changed from a primary emphasis on paid advertising to direct voter contact," he says. "The 2002 congressional elections proved that paid advertising gets lost in all the media clutter. There were 25,000 political ads that ran nationwide in the three months leading up to the election, and they all basically cancelled each other out."

Most of this kind of person-to-person outreach won't get underway until three months before the election—the messages are all but useless unless they're fresh in voters' minds on the day they cast their ballots. But the development of the basic grassroots infrastructure began during the presidential primaries, some with only crowds as small as ten to 20 people in local libraries, homes, and coffee shops.

E'04 has taken a more top-down approach, organizing media events with high-profile politicians, scientists, and visionaries, including Carol Browner, Florida Senator Bob Graham, architect William McDonough, and author Jeremy Leggett, as well as local doctors and business leaders in each state who draw local media coverage.

At the Common Assets Defense Fund, Adam Werbach has also used access to politically minded celebrities such as the Beastie Boys and Alanis Morissette to get his message out. Werbach leaves it up to his celeb-studded "Creative Council" to decide which environmental campaign subjects will have the broadest appeal—a matter pop stars are well-equipped to evaluate. Every six weeks or so he presents them with a list of ideas, and they promote the campaigns of their choice on their personal Web sites. One popular campaign, called "Fire Griles" (FireGriles.com), set out to oust deputy secretary of the interior and environmental foe J. Steven Griles. A former energy lobbyist, Griles was paid $284,000 a year during his first several years in office by his former lobbying firm where he represented mining companies. Despite the widespread outrage over this conflict of interest, and the more than 350,000 signatures of protest that Werbach managed to pull in, Griles was exonerated of any wrongdoing by the Department of Interior's Inspector General Office in March.

Still, the Fire Griles campaign represents an important voter-outreach strategy: "Most of us—especially the growing set of younger voters—have a hunch that the Bush Administration has a bad environmental record, but often we can't pin it down to specific allegations," said Werbach. "They need a villain, and Griles is a clear-cut environmental Darth Vadar. He personifies the larger problem into something more personal that people can grasp."

Werbach illustrated the campaign with hipster-friendly street art—showing a sensitivity to shrewd marketing that most other environmental organizations have not. He identifies marketing savvy as one of the most critical strategies for encouraging the growing political participation of younger voters. A recent MTV survey showed a 30 percent increase since 2000 in young people who say they will "definitely" vote this year. In Iowa, four times the number of younger voters turned out than in 2000 (17 percent of caucusgoers overall), setting record numbers. In the 2000 presidential election, only about one third of the 40 million young adults between the ages of 18 and 29 eligible to vote fulfilled their civic duty. If even 2 million more vote in November, it could tip the election. Which means that environmental groups face two voter-recruitment strategies—one aimed simply at exhorting their less politically active constituency to take the trip to the voting booth, and one that would convince new converts that the environment matters. Certainly there has never been a better time for green groups to amass a larger support base than now.

But will it all be enough to counter the Bush-Cheney campaign strategy, which essentially boils down to de-emphasizing the environment in favor of seemingly more "personal" issues? Can the environment really be made a non-issue by virtue of exclusion? The question can't be answered until November, surely, but it seems inevitable that Kerry will force Bush to face the storm of criticism against his environmental record. When pressed to explain how Republican strategists are advising Bush to respond to the criticism, RNC spokesperson Mary Ellen Grant was curt: "The president has shown principled leadership on the environment. He has a very strong record in this area and is prepared to defend it."

The White House statements on the Bush Administration's environmental vision are couched in a grand theory of ushering in a "new era of environmentalism" with "market-based initiatives." And while such economically pragmatic solutions have certainly been lauded in theory by many environmentalists, a serious disconnect has been exposed between the Bush Administration's stated philosophies and its practices. Indeed, the Bush Administration's claims of espousing a "new environmentalism" has come to be seen as just another fig leaf to cover up their abysmal track record.

"They're running from it," says Kerry spokesperson Chad Clanton. "They're running from a horrible and embarrassing record." But the more they run, the more vulnerable they become, says Clanton, "and you bet we're going to make them face it whether they like it or not."

But while Kerry will certainly do well to discredit the Bush environmental record, he would also be wise to balance the mudslinging with a positive message about the future. "It's a time when clean-energy industries are exploding," says Werbach. "Clean cars, clean energy, green building. Not just companies but entire nations are innovating to reduce their environmental impact. Kerry has already shown that he believes this revolution in sustainability can do great things for our job market and our national security." Indeed, the energy issue has been one of Kerry's key platform issues. "I have a strategy to make America energy independent with investments in renewables and the energy technologies of the future," he announced in March when he introduced his plan to create 10 million new jobs during his first term in office. "This strategy will lead to 500,000 new jobs [in the clean-energy sector]—not counting its benefits in keeping energy costs down and making American businesses more competitive." In other words, the message that there is hope for the future could be as compelling to voters as the observation that the Bush Administration's environmental policy spells doom.

Even Al Gore was careful to temper his vitriolic speech in New York City by ending on a positive note: "Our world is now confronting a five-alarm fire that calls for bold moral and political leadership from the United States of America," he said from the Beacon Theatre stage. "With such leadership, there is no doubt that we could solve [our escalating environmental problems]. After all, we brought down communism, won wars in the Pacific and Europe simultaneously, enacted the Marshall Plan, found a cure for polio, and put men on the moon. When we set our sights on a visionary goal and are unified in pursuing it, there is very little we cannot accomplish."

Now that Kerry and an increasingly unified front of environmental activists have set their sights on tipping a narrow election in November, "saving the Earth" might just make it on the list. ◊

What happens when Bush and Kerry meet in the Rockies for a few brief moments of environmental sincerity? Find out, and get more Election '04 coverage at seedmagazine.com

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The Rise Against Mercury
Continued from page 81

I believe that I am currently employed by a company that has the same high ethical standards as myself. Therefore, any suggestion that GlaxoSmithKline intended to have me manipulate this data is nothing short of an insult to both my and the company's intergrity."

GlaxoSmithKline also did not respond to *Seed*'s requests for an interview.

Conflicts of interest, such as Dr. Verstraeten's, are all too common in vaccine research. Scientists armed with pharmaceutical or CDC grants conduct nearly all vaccine research in this country, and independent corroboration is the anomaly. This raises the question of whether such researchers can fairly evaluate the safety of products, such as vaccines, and whether their affiliations have played into the thimerosal debate. These tangled relationships provide ample fodder for those who believe that the CDC is trying to cover its tracks regarding thimerosal. They also undermine studies that point to the safety of the preservative. A case in point is the large-scale Danish study, published in *Journal of the American Medical Society (JAMA)* in September 2003, which found no link between thimerosal and autism. The study is routinely cited as proof that the preservative is safe in vaccines. Soon after its publication, however, it was revealed that *JAMA* failed to disclose that the study's authors work for Denmark's largest maker and distributor of childhood vaccines—another company that could face lawsuits over thimerosal.

Given these conflicted reports and apparent conflicts of interest, Mark and David Geier's work became more urgent, as they are the only *self-funded* scientists who have examined the CDC's vaccine databases.

Mark Geier has a long history of forging into uncharted territory. When he was 23, he corrected a genetic disorder in a tissue culture, gaining distinction as one of the founders of the field of genetic engineering. The discovery earned him front-page stories in *The New York Times* and *The London Times,* and a call from President Nixon. Anything but a fringe player, he holds an MD and a PhD in genetics—which he earned while on a tennis scholarship at George Washington University. He then spent ten years at the National Institutes of Health and several more as a professor at Johns Hopkins University before opening the genetic laboratory and clinical practice that he co-owns today.

In addition to tending to a full roster of patients, Mark has testified before the IOM on five occasions, as well as the US

House of Representatives Committee on Government Reform; and he has been certified as an expert witness on vaccines in federal, state, Canadian, and English courts. He was one of the original architects of the National Childhood Vaccine Injury Act, which created the national program that compensates children who have been injured by vaccines.

He works with his only child, David, 23, who is currently pursuing graduate studies in biochemistry at George Washington University and is a ranked tennis player himself. David is quiet and self-deprecating, and routinely embarrassed when Mark points out his accomplishments. He finishes his father's sentences and jumps in to correct him when a detail is omitted during one of the numerous presentations they make together. In the past five years alone, they have published more than 30 peer-reviewed research articles in many top scientific journals; David has actually published more articles than several of his professors in graduate school.

The Geiers live in the house where David grew up and work most nights and weekends on side-by-side computers in the study. The entire basement has been converted into a work area—a Ping-Pong table in the family room is covered with stacks of articles, binders of their research notes, and scholarly books.

Despite Mark's long track record of studying vaccine safety, he did not see the thimerosal debate coming. In fact, when frantic parents originally asked him to explore the possible link in 2001, he believed it was a case of wishful thinking, as there was simply no good science to back it up.

There were other reasons to be hesitant: The Geiers are adamantly provaccine—and have learned through experience that questioning the immunization program can make scientists extremely unpopular with their peers. In the early '90s, Mark was assailed for criticizing the whole-cell pertussis vaccine and arguing that it should be taken off the market. The attacks only abated in 1995, once the FDA recommended its removal and replacement with a safer version of the vaccine. The pattern is repeating with thimerosal. The AAP took the unusual step of posting a document on its Web site in 2003 that was highly critical of the Geiers' research; more recently, the Geiers have been faulted for their use of VAERS, a database that some researchers feel is too subjective (almost anyone can report a health problem, and they may incorrectly link the problem to a vaccine), and for their vociferous objections against thimerosal.

A more material reason for proceeding with caution is the risk of mass declines in vaccination rates due to heightened fears. Anyone interested in vaccine safety is well aware of Britain's recent experience with this. As concerns escalated about a potential link between autism and the MMR vaccine, the country saw immunization rates fall by 10 percent—and disease rates increase.

As I sat at the dining room table in the Geiers' house in Maryland during my first visit with them, several clear themes emerged from their story: Working with the US government is neither fast nor easy; it's tough to gain trust as an outsider; and people don't appreciate you poking around something as important to the national interest as vaccines. Roadblocks were to be expected, but at some point they became nearly insurmountable.

"It started," said David, "when we asked the CDC for data on the net distribution of all vaccines given to American adults by year, which is something we needed to accurately calculate vaccine reactions. They told us it didn't exist. However, a month later an anonymous CDC employee secretly faxed photocopies of the data to us."

The Geiers believed it was crucial to reexamine the very data that Dr. Verstraeten and his colleagues used to study thimerosal. Up to that point in time the CDC had refused to allow independent researchers to view the data they used to publish vaccine safety studies. Under intense lobbying by Congress, the agency announced in August 2002 that outside researchers would be allowed to analyze the VSD database. The Geiers immediately applied.

Just as quickly, their proposal was rejected.

At first, the CDC denied their application on the basis of the configuration of their proposed studies. The Geiers rewrote their requests and applied again, beginning a five-month process of back-and-forth with the CDC comprised of new proposals, new rejections, new requirements, and further rejections. Ultimately, the logjam was broken only through weekly intervention by Rep. David Weldon, who is a physician himself and an advocate of independent research.

Over the course of the reapplication process, the Geiers incurred thousands of dollars worth of fees and their proposal grew to more than 200 pages as they incorporated suggestions from the CDC's half-dozen rejection letters.

The delays continued as the CDC proved incapable of tracking down some of its own data. "First they said we couldn't have a particular data set because an outside researcher did not want to share it," Mark said. "After Dr. Weldon intervened, the CDC said we couldn't have it because it was on obsolete media—and after further pressure, they stated that it was lost."

In December 2002, the Geiers' proposals were finally accepted, though they were still ten months from actually seeing the data. In the interim, the CDC required them to correspond with HMO review boards and to take lessons in patient confidentiality.

"The course on confidentiality was the last straw," recounted Mark. "I've taught patient confidentiality at Johns Hopkins University, the National Institutes of Health, and Sarah Lawrence College, but they still required a 12-module course through the University of Miami. The bigger issue was the fact that no patient names, addresses, or clinic locations are in the database, so you couldn't identify patients even if you wanted to."

The CDC initially turned down *Seed*'s interview requests regarding thimerosal but eventually agreed to answer questions via e-mail. Curtis Allen, of the CDC's National Immunization Program, passed over queries about the Simpsonwood meeting and whether it violated the Sunshine Act (a law requiring that meetings of government agencies be open to the public), the Geiers' difficulty gaining access to the VSD, and Rep. Weldon's requisite lobbying on their behalf. Instead, he commented that, "Replication of studies and findings is a fundamental component of science and scientific research.... The staff who have developed the data-sharing program have been working diligently to ensure that the program is successful and to ensure that VSD data be made available, as appropriate, to external scientific researchers, while maintaining confidentiality."

The agency's reluctance to discuss its thimerosal research comes as no surprise. Much is on the line for the CDC. If a thimerosal-autism link is firmly established, the revelation will shake public confidence in the agency and its vaccination protocol and may prompt litigation aimed at the CDC and individual researchers within its ranks.

As the Geiers got closer to viewing the actual VSD data, Rep. Weldon asked the agency to release all data sets from the different phases of Dr. Verstraeten's study—in order for the Geiers to examine how refinement of the data over the years may have affected results. Of particular interest was the study discussed at the Simpsonwood meeting, which indicated a statistically significant link between thimerosal and numerous neurological problems. The CDC agreed to provide the information, though the Geiers still had not received the data several months later. Rep. Weldon continued to intervene on the Geiers' behalf. "To date, only those with a conflict of interest have had access to the database," he explained before sending another letter to the CDC's director, Dr. Julie Gerberding, and others, asking about the hold up. A month later he heard back—and was told that previous data sets no longer existed.

"Aside from the fact that they promised to maintain the data, it is standard practice to do it so that others can analyze what you leave in and what you take out," Mark Geier said. "Unfortunately, that can never be done in this case."

David Geier's frustration with the situation was palpable: "The CDC only allowed outside researchers into the VSD because Congress demanded it, though it was obvious by the endless hurdles that they don't want us looking at their data."

But Dr. Robert Davis, who along with Dr. Verstraeten and several other researchers co-authored the VSD study, insisted that interpreting the changing and lost data as a cover-up is silly. "Of course the data changed from one phase of the VSD study to another," he said. "It evolved. If Congressmen Weldon questions that, then he doesn't fully understand the proper approach to scientific research."

He continued, "Science is best left to scientists."

After 14 months of petitioning, the Geiers got their chance to review the VSD. They drove to an address a few miles from their house. The building they arrived at was nondescript from the outside and tucked behind a strip mall.

After taking the elevator up to the fourth floor, they stepped into a long hallway dotted with offices on either side. Each door had a padlock but was propped open with books or cups. "The building seemed deserted," David remembered. The Geiers followed the hall to a windowless room in the building's interior—in which a single computer sat on a card table. Behind it was a second small table, where a woman from the CDC was sitting quietly waiting for them.

The rules for viewing the data were laid out: no phones, no tapes, no copies, no cell phones. Every keystroke the Geiers made would be recorded. Their data would be printed in a locked room and examined by the CDC observer—and some pieces of it would be deleted with Liquid Paper before they were allowed to see it. The CDC promised not to analyze the Geiers' data but would keep a copy of it to ensure patient confidentiality.


The Geiers at work in their home office

On the computer were specific data sets corresponding to the Geiers' proposed studies. They got to work, spending their first day at the site organizing the information so they could compare children who had received different amounts of thimerosal. The key lay in examining recipients of two kinds of DTaP vaccines—one containing 25 micrograms of thimerosal per dose and one containing none. From medical records, they were able to identify which type of vaccine each child had received. They knew that fully vaccinated children had received four DTaP shots by the age of 18 months, making it possible to segregate the children into five groups—from those who received virtually no thimerosal (the control) to those who were given four doses of it.

Next, they programmed the computer to search for the International Code of Disease for autism in the children's files and to count up the number of children with the diagnosis of autism in each of the five groups. The value of this design was that it did not require case ascertainment, as there would be equal accuracy in labeling autistic children in all groups. Interpreting the results from the control group was easy. The children who received no thimerosal had no autism. Things began to change as they viewed data from the higher-dose groups.

"At first I didn't think it was right," David said. "I ran the program several times, and each time it turned out the same—the kids in group five [receiving 100 micrograms of thimerosal] were over ten times more likely to have autism than the kids in group one [with no mercury]."

The results of the Geiers' VSD study were accepted for publication in *Expert Review of Vaccines*, a peer-reviewed journal in which the CDC frequently publishes. An October 22, 2003 e-mail from the journal's editor, Elisa Manzotti, thanked the Geiers for an "excellent revision" in response to the peer-review and outlined information on obtaining reprints of the published article. But on November 11, 2003, Manzotti e-mailed them again. All bets were off. The editors had abruptly reversed themselves, stating that they could not publish the Geiers' work due to the concerns voiced by a new, anonymous reviewer.

"When we called the editor, she was very apologetic and said that after 20 years in the field, it was a first for her," said Mark, who has published more than 70 peer-reviewed articles in the course of his career and has never had an article withdrawn. *Expert Review of Vaccines* did not reply to repeated requests for comment. Rep. Weldon is currently working with the Geiers to get the study published in another leading journal. Meanwhile, the results remain in limbo.

While scientists debated the thimerosal issue, the topic surfaced in the political realm as well. In mid 2003, the Geiers were invited to present their research to multiple state attorneys

general, and I accompanied them. Interest on the part of the attorneys general is just one indication of how high the stakes have become. The National Vaccine Injury Compensation Program in Washington, D.C., the vaccine court through which my son won his claim, has been besieged by nearly 4,000 thimerosal cases, with more filed daily. It was established in 1986 to shield vaccine makers from liability while providing legal recourse and compensation for vaccine-injured children. Parents are required to start there but may opt out after 240 days to pursue civil litigation. At present, thimerosal suits are on hold while the court determines causation for all cases, which have been lumped together as the "Omnibus Autism Case."

To date, approximately 25 suits have been filed against five drug makers outside the vaccine court. The claims begin at $1 million and increase from there, depending on the seriousness of the injury. Although the number is small, primarily because litigants are required to start with the National Vaccine Injury Compensation Program, potential liability for the pharmaceutical industry is astronomical. "When you multiply the number of autistic children in the Department of Education data by the typical cost over a lifetime, you quickly exceed a trillion dollars," said Mark. "Others have told us these estimates are conservative since we don't factor in children with related neurological disorders."

But it is likely that the states themselves have the most skin in the game, as the cost of educating and caring for an autistic child throughout his or her lifetime is estimated to be $5 million to $10 million, an expense carried largely by taxpayers.

"One in eighty males is diagnosed with autism today," said Mark in one of his recent presentations. "Many of them will not be able to work. How are we going to pay for their care?"

The Geiers' trip to Minnesota Attorney General Mike Hatch's office took place in September and was of particular interest due to Hatch's prominent role in tobacco litigation. We arrived at the domed state capitol building early and waited for Hatch in a high-ceilinged meeting room.

A woman with a fixed smile popped her head out from the office and led us past the flags and official portraits to a room with a long oak table. A few minutes later, Hatch bustled in with coffee in hand, making apologies for being late. The Geiers launched into their presentation. It was scheduled for 45 minutes, but the conversation became intense and the meeting stretched to more than three hours. Hatch's press secretary looked anxious and repeatedly tapped his watch and raised his eyebrows at his boss, but the Attorney General only nodded back.

The Geiers fielded numerous questions from Hatch and his staff: "Are there other studies besides your research that show thimerosal is a problem?"

Before answering, David tapped a foot-high pile of papers on the table next to him. "Do your own Medline search—they're easy to find. We've turned up 5,000 peer-reviewed articles so far that discuss thimerosal's toxicity, which come out of all lines of medicine, agriculture, and other areas from scientists across the globe. A dozen of these are written by scientists within the CDC and FDA."

Another question: "I've heard thimerosal is safe because it doesn't cross, the blood-brain barrier."

"That's not true," said Mark. "And you don't have to take my word for it—Dr. William Slikker from the FDA wrote a recent *Neurotoxicology* article and said that it does cross, and accumulates in the brain."

But the questioner wasn't satisfied. "I read that ethyl and methyl mercury are different—the kind of mercury kids get is safe."

"That's not what Dr. Leslie Ball from the FDA wrote in 2001—and she's just one of many stating it," Mark replied. (Thimerosal contains ethyl mercury. The difference between ethyl and methyl mercury in terms of toxicity to humans is still unclear.)

More questions, more answers—each with complete references to specific articles, authors, and journals.

This was actually the Geiers' second meeting with Hatch, and the Attorney General had done his homework. Between their visits, he'd invited pharmaceutical representatives to Minnesota to present their side of the thimerosal debate. Similarly, when we met with Nebraska Attorney General Jon Bruning two months later, he had met with representatives from pharmaceutical giants Wyeth and Eli Lilly and Company.

Ed Sagebiel, spokesperson for Eli Lilly and Company, which first patented thimerosal and continues to receive money from licensing agreements with other drug makers, stated that legal action over thimerosal is misguided—although he was unwilling to answer questions about long-term safety studies and was unfamiliar with recent molecular, DNA, and animal studies of the chemical. Still, he continued, "There is no scientifically credible evidence that links thimerosal to autism." He preferred not to comment on the Geiers' research but forwarded a two-page document, created by the company, that outlined why Mark Geier should be discredited.

In a six-week period around the beginning of this year, the Geiers traveled to Kansas, Nebraska, New York, South Carolina, North Carolina, Virginia, and California in rapid succession. In early December, I met them in Lincoln, Nebraska. It was wintry and cold, and Mark was wearing a parka with ski tickets dangling from the zipper. A local doctor and businessman were instrumental in getting the meeting arranged, and they drove us through the countryside to the Attorney General Bruning's office.

Bruning, who at age 34 could easily pass for Tom Hanks in *Big*, strode into the room smiling and sat directly across from the Geiers at a crowded table. Before the meeting began, a staff member unhooked a picture from the wall so the Geiers would have a place to project their PowerPoint presentation. We were scheduled for 45 minutes, and again the meeting lasted three or more hours. Afterwards, the Geiers' day proceeded apace—a presentation to the University of Nebraska medical school and a public talk, followed by more presentations and a radio interview the next morning.

A meeting in New York took place three weeks later. I followed the Geiers through the Empire State Building's security check, past a group of arguing teens, and up a creaking elevator to Attorney General Eliot Spitzer's office. As usual, the presentation ran long. "I was intrigued by the Geiers," Joseph Baker, deputy health bureau chief, told me a month later. "We are pursuing it."

The visit to the California attorney general's office was different than the others, as the state already has a law requiring that products containing harmful substances have warning labels—and thimerosal is on the chemical hit list. However, the state recently lost a lawsuit that would have required thimerosal-containing vaccines to have such warnings—because federal law is considered adequate for prescription-drug warnings, explained Ed Weil, supervising deputy attorney general in California. "The court ruled that FDA standards are sufficient. If they say thimerosal doesn't need a warning, we can't add one to vaccines.

Following the attorneys general meetings, the Geiers met with bipartisan senate offices, including staff members for senators Stabinow, Cantwell, Kennedy, Clinton, and Kerry, and with Senator Edwards himself. Concurrently, lawmakers in Iowa, Missouri, Nebraska, and Kansas presented legislation to ban thimerosal in childhood vaccines. Interestingly, while the thimerosal issue is often painted as the terrain of liberal trial lawyers, Republican lawmakers are actually leading the charge to ban the preservative's use. A case in point is Senator Roy Holand (R-Missouri), a physician by training who presented a bill to Missouri's legislators to prohibit thimerosal in childhood vaccines in his state. On March 10, the bill passed the Missouri state House of Representatives by 152 to four, the biggest landslide victory in recent state history. Those who testified against the bill included the Department of Health and Human Services and the Pharmaceutical Research Manufacturers of America, among others.

"As a physician, I've been concerned about the rising levels of autism, and the more I've learned about thimerosal, the more convinced I am that it causes neurological damage," said Holand. "Mercury has no place being injected into children."

Senator Ken Veenstra (R-Iowa), who introduced a similar bill to Iowa's Senate Human Resources Committee, put it just as simply: "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." The Iowa senate committee voted in favor of the ban on March 1.

A month later, on April 5, Rep. Weldon and Rep. Carolyn Murphy (D-New York) introduced legislation to ban mercury from vaccines at the federal level. HR 4169 requires that by January 1, 2005, no childhood vaccine have more than one microgram of mercury and that by January 1, 2006, mercury be removed from all childhood and adolescent vaccines. In a statement, Rep. Weldon said, "We can eliminate this exposure now, and it is inexcusable not to."

As I followed the Geiers around the country, I tracked down one of the participants from the Simpsonwood meeting in Georgia, and he agreed to speak with me on the condition of anonymity.

Before I could ask my first question, he cut in: "Just tell me first—are you one of those anti-vaccine militants?"

"No," I responded. "Are you one of those pro-pharmaceutical extremists?" He laughed, and it broke the ice. I told him about my son Porter's brain damage and about my other vaccinated children. I am not anti-vaccine, I said, but what about Simpsonwood and the data you saw there that showed a link with neurological problems?

"Thimerosal is a potent neurotoxin—no one would dispute that," he told me. "The question is whether the amount children receive has any clinical significance."

"Does it?" I asked.

"In all honesty, we may not know for a while," he said. "Medicine works that way. Here's an example: We used to give oxygen to newborns. We thought that was a good thing to do. Ten thousand children went blind from it. We may not know about thimerosal for five to ten years."

Dr. Thomas Saari of the American Academy of Pediatrics agreed that time will tell: "I am keeping an open mind [about thimerosal]. I am glad a lot of research is going on, and we'll see in five years where things shake out."

In Februrary, the Institute of Medicine (IOM) convened a meeting to review thimerosal's safety, and numerous scientists on both sides of the debate presented data, including the Geiers. The IOM is expected to render its opinion sometime this month.

Within two weeks of sharing their VSD findings at the IOM meeting, however, the Geiers received a letter from the CDC stating that due to "potential issues of patient confidentiality," they would no longer be granted access to the data.

"I am very concerned about this action and find that it fits the pattern," said Rep. Weldon. "It took me over a year of working with the CDC to get Mark Geier access in the first place. I am committed to working to see that access is restored."

Rep. Weldon, with the backing of a bipartisan contingent of Congressional members, is currently looking into the matter.

"These roadblocks won't stop progress," said Mark, seemingly undeterred. "Due to the epidemic of neurological problems, even the government has officially put autism research on the national agenda. We're moving past database studies anyway—fascinating new research is being done by scientists from Tufts, Johns Hopkins, University of Kentucky, the United States' Department of Agriculture, and other places, showing through double-blind clinical trials that autistic children have very little ability to eliminate mercury. Others at Northeastern and Baylor University have shown how thimerosal damages DNA. This adds more potential evidence to the theory that children cannot get rid of it when given large doses. Dr. Mady Hornig [a professor of epidemiology] from Columbia University also just announced her findings that she can make mice act like they have a disorder like autism by treating them with thimerosal in a regiment similar to that used in infants.

"If VSD studies are no longer possible, we will continue to pursue the other avenues of research. We, and many of the children, don't have five years to wait." ◊

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