Drug Test

By Daniel Schulman

On May 18, 2004, the Institute of Medicine, a branch of the prestigious National Academies, delivered its eighth and final report on vaccine safety, seeking to end a scientific controversy that had built to a slow boil over the previous five years: whether a mercury-containing vaccine preservative called thimerosal was to blame for an alarming spike in autism cases among a generation of children. After three years of reviewing this and other immunization safety questions on behalf of the Centers for Disease Control and Prevention, the institute’s fourteen-member panel rejected the thimerosal link, and, in a powerful policy statement, recommended that research funding in this area be shifted toward other, more promising lines of inquiry. Under headlines such as this one from The Washington Post, EXPERTS FIND NO VACCINE-AUTISM LINK; PANEL SAYS MORE RESEARCH ON POSSIBLE CONNECTION MAY NOT BE WORTHWHILE, the press dutifully reported the IOM’s conclusions, perhaps as eager to lay the question to rest as the IOM panel itself.

For a time it appeared the controversy over thimerosal would end there. It didn’t. Over the past seven months, it has gained traction again, leaving journalists in an awkward position. The thimerosal question — scientifically, politically, and emotionally complex — is proving to be a test for journalism, and the successes and failures are evident in the coverage.

David Kirby, a Brooklyn-based writer, jumpstarted the debate in April with the publication of his book, Evidence of Harm, which lays out a compelling case for a connection between thimerosal and autism. Then, in June, Robert Kennedy Jr. followed with a more pointed — some say over-the-top — article, co-published by Rolling Stone and Salon.com, that alleges what amounts to a government cover-up of the harmful properties of thimerosal in the interest of buffering vaccine manufacturers from a cascade of lawsuits and maintaining public confidence in the national immunization program.
Still, the bulk of the scientific establishment denies the autism link, citing the conclusions of the IOM panel, and views believers as crackpots, conspiracy theorists, or zealots — a perspective many medical experts barely conceal in conversations with reporters. In an interview with Myron Levin of the Los Angeles Times after the publication of the IOM report, Dr. Stephen Cochi, the head of the CDC’s national immunization program, dismissed supporters of the thimerosal theory as “junk scientists and charlatans.” If so, then such universities as Harvard and Columbia, among others, employ charlatans — scientists who believe that a link between mercury exposure and autism is plausible. Even so, the perception that only distraught, activist parents and disreputable scientists back the thimerosal theory has seeped into the collective consciousness of the news media, which, in general, have been reluctant to cover the controversy.

Both sides in the debate make convincing arguments to support their cases, and in the cacophony of competing claims each is guilty of using data selectively. What is known is this:

Since the late 1980s the number of children diagnosed with autism has increased sixty-fold, from one in every 10,000 in 1987 to one in every 166 in 2003. Much of this spike overlaps with a period when, due to recommendations by the CDC and the Food and Drug Administration, the number of suggested immunizations on the childhood vaccination schedule more than doubled, raising the doses of mercury that some children received to levels that far surpassed federal standards for mercury exposure. (The standards were based on methylmercury, the type emitted by coal-burning power plants. Ethylmercury, which makes up nearly half of thimerosal by weight, is a closely related compound. To date, ethylmercury has received far less study, and scientists disagree on whether it’s as harmful as methylmercury, though both are considered neurotoxins.) Until the late 1990s, health officials were unaware of the total amount of mercury children were receiving in their vaccinations. It’s not unreasonable to ask how this went unnoticed, and unreported, for so long. The answer is simple: no one had ever done the arithmetic. When scientists did, the U.S. Public Health Service recommended that vaccine manufacturers phase out thimerosal from children’s vaccines in 1999 as a precaution. It was careful to note, however, that “there are no data or evidence of any harm.” As it stands, the preservative, which allowed drug manufacturers to supply vaccines in multidose vials (the thimerosal-free, single-dose versions are costlier), has been eliminated from most immunizations, excluding some flu and tetanus shots. During 1999 and 2000, the thimerosal link was quietly under study by the CDC, and, as shown in internal memos and meeting minutes, health officials were deeply concerned about what they might find.

Thimerosal activists point to this history: In June 2000, the CDC convened a closed meeting at the Simpsonwood Convention Center in Norcross, Georgia, to discuss, among other things,
preliminary findings on thimerosal. In addition to the health officials, researchers, and vaccine experts in attendance were representatives from GlaxoSmithKline, Merck, Wyeth, and Aventis Pasteur, the vaccine manufacturers who had the most to lose if an autism link were proven. During one session of the two-day meeting, the CDC epidemiologist Thomas Verstraeten presented the results of an analysis of the CDC’s Vaccine Safety Datalink, a database that contains the vaccination histories of more than seven million Americans. His study, at least at that stage, appeared to support a connection between thimerosal and neurodevelopmental disorders, showing what Verstraeten described as “statistically significant relationships between exposures and outcomes.” The presentation caused one physician in attendance to remark, “the medical legal findings in this study, causal or not, are horrendous.” Attendees were instructed that what they’d heard that day was to be considered “embargoed.”

Known as the Simpsonwood transcripts, the minutes of this meeting are widely available on the Internet thanks to a Freedom of Information Act request by the autism advocacy group SafeMinds. Some advocates of the thimerosal theory point to Simpsonwood as proof that the government buried evidence of an autism link. In the minds of some supporters of the theory, the perception of conspiracy was heightened when Verstraeten’s study, published three years later, no longer indicated an association between thimerosal and neurological maladies, including autism. Adding to their suspicion is the fact that in the study, published in the journal *Pediatrics*, Verstraeten was listed as a CDC researcher, when in fact he had been hired away by GlaxoSmithKline two years earlier. (Nor did they find it any less suspicious when a midnight rider turned up in a 2002 bill creating the Department of Homeland Security that sought to protect vaccine manufactures from thimerosal-related lawsuits. The measure was eventually removed.)

But Simpsonwood is not a smoking gun. Nor are other documents that purport to be, including the transcript of a private session of the Institute of Medicine’s Immunization Safety Review Committee from 2001, in which the committee’s chairwoman, Dr. Marie McCormick, referring to the vaccine-thimerosal issue, says that the CDC “wants us to declare, well, these things are pretty safe on a population basis.” It is a statement that indicates to some that the IOM had already decided where it was going to come down on thimerosal. If transcripts of both meetings are not damning, the comments of some attendees are striking, particularly when they are quick to note the legal ramifications should a connection be established. As McCormick makes plain during the 2001 meeting, attendees were aware of the conclusion that the CDC wanted them to reach, but that isn’t proof that the institute manipulated data to reach that end, as some allege.
When the IOM panel released its final report in 2004, it had analyzed more than 200 studies and based its conclusions largely on five recent epidemiological papers that appeared to debunk the autism connection, including Verstraeten’s and one from Denmark that shows autism cases rising after thimerosal was removed from that country’s vaccine supply. Excluded was much of the biological research that supports a link, which the IOM deemed speculative.

Those are the facts, though they are interpreted in radically different ways by each side. Even the question of whether the nation is currently experiencing an autism epidemic is subject to debate. Detractors posit that the increase in cases is a red herring, that the numbers reflect changes in how autism is diagnosed and reported. As for the IOM report — the nail in the coffin for the autism link as far as many scientists are concerned — believers hold that the studies that the panel relied on were flawed. For example, as David Kirby reports in Evidence of Harm, the researchers on the Danish study examined autism cases both before and after 1992, when thimerosal was removed, but used two different data sets in doing so, tallying inpatient cases through 1994 and adding outpatient cases to their count thereafter, a factor that could explain the increase they observed. According to Kirby, even the study’s authors conceded, in their own words, that they “may have spuriously increased the apparent number of autism cases.” Verstraeten, for his part, seemed to grow tired of how his findings were being interpreted by both sides. In an April 2004 letter to Pediatrics, he wrote that his study “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.” He went on to call allegations of a potential conflict of interest an “insult,” saying that he remained on the study only in an advisory capacity after he went to work for Glaxo. “Did the CDC water down the original results? It did not.”

Steeped in controversy and intrigue, the thimerosal debate has all the makings of a compelling news story, yet it has been approached with caution by the news media, which, more often than not, don’t portray it as a legitimate scientific debate. “I’m putting my faith . . . in the Institute of Medicine,” ABC’s medical editor, Dr. Timothy Johnson, told viewers during a segment on thimerosal in July. At the conclusion of an NBC report on the debate last winter, the science correspondent Robert Bazell was careful to note that “if we stop vaccinating our children, we run the risk of having these horrible diseases come back . . . . And the evidence right now is that vaccines do not cause autism.”

There is a very real fear that taking the thimerosal theory seriously will prompt antivaccine blowback. Myron Levin, the Los Angeles Times reporter, said that some journalists have been cowed by the notion that “by the mere act of covering this, they will instill panic in the
vaccination-getting public, or feed mindless phobias that cause people to refuse to let their kids get shots.” That concern is reflected in the coverage and has implications for how deeply the story is reported. “I think many news organizations have held back and given the story short shrift,” Levin said.

On June 25, The New York Times addressed the thimerosal controversy in a front-page article, the product of five months of reporting by Gardiner Harris and Anahad O’Connor. Appearing less than two weeks after Robert Kennedy’s piece, which would later have a list of corrections and clarifications appended to it, the Times article had been eagerly awaited by proponents of the thimerosal link, some of whom had been communicating regularly with the Times reporters over the previous months. Believing that the heft of the paper’s reputation would help to propel their cause into the mainstream, they expected a proper airing of both sides of the question — that, after all, was the impression O’Connor gave at least one of his sources, the mother of an autistic child and a member of an autism advocacy organization, when he approached her in late January. “I’m thinking of a 2,000-word story, essentially saying that an array of studies over the years (the Institute of Medicine report, I would think, being the most prominent) were intended to settle the issue of autism and vaccines once and for all,” he wrote in an e-mail. “Yet it seems that the question is still very much open . . . and evidence for the case against vaccines has been mounting, despite many researchers’ insistence that the issue is dead. I think, for now at least, I’d like to just present the evidence on both sides and let the readers decide.”

The result was much more one-sided. Headlined ON AUTISM’S CAUSE, IT’S PARENTS VS. RESEARCH, the story cast the thimerosal connection as a fringe theory, without scientific merit, held aloft by angry, desperate parents. The notion that supporters of the theory were disregarding irrefutable scientific findings was an underlying theme, drilled home several times. “It’s really terrifying, the scientific illiteracy that supports these suspicions,” Dr. Marie McCormick told the Times. Readers were left with little option but to believe that the case against thimerosal was scientifically unsound.

The piece did note the work of Mark and David Geier, a father-son research team who believe that mercury exposure is linked to autism. The Geiers’s research has been a lightning rod for criticism, and their methodology has been called into question by some in the scientific community. But before the reporters even discussed the Geiers’s science, they had already painted the researchers as eccentric outsiders: “He and his son live and work in a two-story house in suburban Maryland. Past the kitchen and down the stairs is a room with cast-off, unplugged laboratory equipment, wall-to-wall carpeting and faux wood paneling that Dr. Geier calls ‘a world-class lab — every bit as good as anything at N.I.H.’”
the story was the work of Dr. Mady Hornig, a Columbia University epidemiologist; Richard Deth, a Northeastern University pharmacologist; Jill James, a professor of pediatrics at the University of Arkansas; and others whose work suggests that thimerosal may cause neurodevelopmental disorders in a subset of susceptible children (those who are not able to eliminate mercury from the body in the ways that most people do). The story alluded to Boyd Haley, chairman of the department of chemistry at the University of Kentucky and an ally of thimerosal activists, in the same sentence as a Louisiana physician who believes “that God spoke to her through an 87-year-old priest and told her that vaccines caused autism” — leaving Haley, it would seem, guilty by association of lunacy. Several reporters I spoke with who have covered the thimerosal controversy described the Times story as a smear. One called it a “hit piece.”

The Times’s O’Connor told me he had looked at the research linking thimerosal with autism, including the work of Hornig, Deth, and James, but ultimately found the epidemiological studies cited by the IOM more persuasive. “The larger scientific community has rejected a link between thimerosal and autism,” he said. “You do have some scientists who are convinced that there’s a link, but then you have the American Academy of Pediatrics, the World Health Organization — it’s not a stretch to say that the scientific community has rejected this link.”

The article prompted a massive reader response. One organization, known as A-Champ (Advocates for Children’s Health Affected by Mercury Poisoning), organized an e-mail campaign directed at top editors at the Times, as well as the public editor, Byron Calame. O’Connor personally received dozens of e-mails and letters. “There were a couple that were threatening. There were some that were pretty harsh and others saying that I was part of the conspiracy. A lot of people responded saying there must be some link between the Times and the pharmaceutical industry.”

Responding to the complaints of one group, Calame wrote: “I have carefully reviewed your e-mail and spent several hours with the editors and reporters who prepared the article . . . . This has left me convinced that the article isn’t intellectually dishonest. Nor are the omissions staggering. Nor is there a pervasive editorial bias. I find the article fair and accurate.”

As it turned out, the story had angered members of the epidemiology department at Columbia’s Mailman School of Public Health, including the department’s chair, Dr. Ezra Susser. Since some of their work, including that of Dr. W. Ian Lipkin, a highly regarded neurologist, and Mady Hornig, explored the connection between environmental mercury exposure and autism, including exposure through thimerosal-carrying vaccines, they felt that they had been lumped into the category of scientific illiterates. Responding to the article in a
June 28 letter to the *Times* (never published), signed by Susser, Lipkin, Hornig, and the epidemiologist Michaeline Bresnahan, the researchers wrote that “scientists pursuing research on mercury and autism are caricaturized as immune to the ‘correct’ interpretation of existing studies. Researchers rejecting a link are depicted as the sole voices of reason . . . . Whether mercury in any form (or any of several factors recently introduced to our environment) has anything to do with autism can and should be resolved with rigorous studies and respectful discourse, not moral indictments and denunciations.”

Journalists agree that the thimerosal story is one of the most explosive they’ve ever encountered. In addition to the vitriolic response Anahad O’Connor drew from readers, he also said he received a number of e-mails praising him and Harris from fellow reporters who had been interested in covering the thimerosal controversy, but had “gotten scared away from really tackling the subject . . . they were afraid of getting hate mail.”

Some reporters who have portrayed this as an ongoing scientific controversy have been discouraged by colleagues and their superiors from pursuing the story. A reporter for a major media outlet, who did not want to be identified for fear of retribution, told me that covering the thimerosal controversy had been nearly “career-ending” and described butting heads with superiors who believed that the reporter’s coverage — in treating the issue as a two-sided debate — legitimized a crackpot theory and risked influencing parents to stop vaccinating their children or to seek out experimental treatments for their autistic sons and daughters. The reporter has decided against pursuing stories on thimerosal, at least for the time being. “For some reason giving any sort of credence to the side that says there’s a legitimate question here — I don’t know how it becomes this untouchable story, I mean that’s what we do, so I don’t understand why this story is more touchy than any story I’ve ever done.”

Pursuing this story is unattractive for other reasons, too. The issue is exceedingly complex and easily oversimplified. “It took me two and a half years and four hundred pages to tell this story, and I’m sure I made some mistakes,” David Kirby told me, adding that the complexity convinced him to write a book.

The fact that the bulk of the public health establishment dismisses the thimerosal theory is also daunting, particularly for science reporters who rely on the same pool of medical experts and health officials regularly. “They depend on these people in this symbiotic relationship that they have,” said Steve Wilson, an investigative reporter for the local ABC affiliate in Detroit, WXYZ, whose three-part series on thimerosal won an Emmy. “They’ve come to trust them and respect them and to believe when they tell them, ‘Look, you’re barking up the wrong tree here; these parents are just looking for somebody to blame.’”
Some of the most enterprising journalistic contributions to the thimerosal debate have come from the once prestigious, now flagging news wire United Press International, which is owned, along with the Washington Times, by the Reverend Sun Myung Moon’s Unification Church. On my desk, UPI senior editor Dan Olmsted’s “Age of Autism” series, which he began late last winter, occupies a file that at this writing is more than an inch thick and growing. He averages two columns a week on the topic. Aside from the Washington Times, though, not a single U.S. paper that Olmsted knows of has run any part of the series. It has, however, been widely disseminated on the Internet.

Olmsted, a former assistant national editor at USA Today, found his way into thimerosal through another medical side-effect story. It involved an antimalarial drug called Lariam, which was prescribed to Peace Corps volunteers, travelers to third-world countries, and more recently to U.S. troops stationed in Iraq and Afghanistan. As Olmsted and his UPI colleague Mark Benjamin (now a national correspondent at Salon.com) detailed in an investigation that spanned more than two years, starting in 2002, Lariam, which had been approved by the FDA and recommended by the CDC, also appeared strongly linked to psychosis, including homicidal and suicidal behavior. Partly because of their reporting, the effects of Lariam are now under study by the Pentagon. “If it hadn’t been for Lariam, I don’t think I would have ever thought twice about autism,” Olmsted told me. “With Lariam, CDC officials said many times that there’s absolutely no problem with side effects from this drug, it’s extraordinarily safe. That’s just not true.”

Instead of wading directly into the thimerosal controversy, Olmsted approached it, as he puts it, “sideways.” By this he means that after reading what had been written on autism and noticing a relative dearth of material about its origins, he set out to write a natural history of the disorder.

Eventually, Olmsted began thinking of ways to test the thimerosal theory. He wondered whether researchers had ever examined the prevalence of autism in an unvaccinated population, such as the Amish. That, it would seem, would be the most likely way to determine whether the vaccine link held water. If the number of autism cases among the unvaccinated mirrored the national average, then it would seem that thimerosal played no role. Olmsted found that though researchers had discussed such a study, none had ever been done. “That’s an expensive study,” he said, “but for a journalist all you have to do is get on the phone and start asking.” After spending weeks searching for cases among the Amish of Lancaster County, Pennsylvania, he managed to find three children with autism, two of whom had been vaccinated, a rarity in that community. “The cases among the Amish that I’ve
identified over the past several weeks appear to have at least one link — a link made of mercury,” Olmsted wrote in a column on May 20, referring to the vaccinated children. “That’s not something I expected to encounter.” Looking at other large Amish populations in the Midwest, such as those in Middlefield, Ohio, and Goshen, Indiana, Olmsted found similarly low autism rates. He admits that his findings are not scientific. “I could be getting a completely wrong impression from what I’m finding, but it’s interesting,” Olmsted told me. Interesting enough to get the attention of members of Congress, including Representative Dave Weldon of Florida and Senator Joseph Lieberman of Connecticut; officials at the Department of Health and Human Services; and researchers, including Mady Hornig, the Columbia epidemiologist, who now hopes to devise a study looking at the Amish.

Privately, two reporters told me that, while intriguing, Olmsted’s reporting on the Amish is misguided, since it may simply reflect genetic differences among an isolated gene pool (Hornig, however, said that a study on the Amish may still be valuable should the prevalence of autism in that community indeed be low, allowing researchers to study the genetics of people who are not susceptible to the disorder). Both reporters believed that Olmsted has made up his mind on the question and is reporting the facts that support his conclusions.

“I’ve just tried to find a way to get into this that adds something to the debate and is original,” Olmsted said.

Among major newspapers, the Los Angeles Times’s coverage of thimerosal stands out. It has taken the story seriously and devoted significant coverage to it, partly because through the summer and fall of 2004 a bill to ban thimerosal from all vaccines given to infants and pregnant women was making its way through the California legislature. Strongly opposed by the vaccine manufacturer Aventis Pasteur and the American Academy of Pediatrics, the measure was signed into law by Governor Arnold Schwarzenegger in late September of that year.

The reporter Myron Levin entered the fray in April 2004 with a piece that revealed that while the CDC would add flu shots to its list of suggested vaccines for children, it would not recommend that parents seek the available thimerosal-free version. He followed in August with a long feature on the attempts of parents who believed their children’s autism was caused by mercury-containing shots to win compensation through a little known branch of federal claims court for the exorbitant costs of caring for their kids. (This “vaccine court,” which pays out claims from a federal trust funded by revenue from a vaccine surcharge, was established during the mid-1980s as a means to protect drug companies from civil suits.) It was while covering this story, in which Levin captured both sides of the debate, as well as the devastating realities of raising a child with autism, that the CDC’s Stephen Cochi referred to
supporters of the thimerosal link as “junk scientists and charlatans.”

Cochi’s lack of diplomacy stunned Levin. “When government officials talk to reporters, they are usually beyond cautious and it can be really hard getting them to opine on anything,” he told me. “To attack opponents in those terms shows the raw emotion that has infused this whole issue.”

From his introduction to the thimerosal issue toward the end of 2003, Levin found it striking that a neurotoxin had ever been put into vaccines given to infants, even newborns. He wondered how health officials had failed for so long to consider the repercussions of injecting children with mercury-carrying vaccines.

As Levin reported last winter, the question of whether children were receiving too much mercury from their inoculations had been considered by Merck in the early 1990s. The front-page story — which reverberated through autism circles but drew little attention from the rest of the press — reported the contents of a leaked memo written by Dr. Maurice Hilleman, then the president of Merck’s vaccine division. While public health officials had yet to recognize the total mercury load infants would receive from all of their suggested immunizations, Hilleman had done the math. “When viewed in this way, the mercury load appears rather large,” he wrote in the 1991 memo, suggesting that thimerosal should probably be removed from vaccines administered to young children when possible. Levin kept the heat on Merck, reporting in March that the company had likely misled the public when it assured consumers in 1999 that its “infant vaccine line . . . is free of all preservatives.” Merck had in fact continued supplying vaccines containing thimerosal until the fall of 2001.

Interestingly, this scoop had first been offered to The New York Times in February by a source who provided evidence to back up the claim. Gardiner Harris, then working on the story that turned out to be dismissive of the thimerosal debate that would run in June, blew off the tip, signing off his e-mailed response to the source, “I’ll let Myron bite this apple.”

Levin’s reporting has drawn the ire of some in the pharmaceutical industry. Wyeth officials met with Levin and his editor in late July. “They have said there are problems with the tone, and that we seem to take too seriously an idea that they say is absurd and has been disproved by the IOM,” Levin told me. (Douglas Petkus, a Wyeth spokesman who attended the meeting along with two lawyers who represent the firm, declined to discuss the particulars of the conversation.)

In late August, the Pittsburgh Post-Gazette reported the death of a five-year-old boy whose heart seized while he underwent an unproven autism treatment known as “chelation.” Used
for purging the body of heavy metals, particularly in cases of acute lead poisoning, it can prove damaging to internal organs by leeching certain necessary elements, such as calcium, from the system. While chelation has been embraced by some supporters of the thimerosal theory, who report that their children’s conditions have improved as mercury was drawn from their bodies, the medical establishment has cautioned against it as a means of treating autism. To journalists, for whom the perils of covering thimerosal have been purely theoretical, this incident could only underscore the potential dangers of lending any credibility to the autism link.

The day the boy’s death was reported, Craig Westover, a columnist at the St. Paul Pioneer Press, who writes frequently about thimerosal, received acid comments from readers on his blog. One reader, writing under the name Credenza, wrote, “They finally did it Mr. Westover, they killed a little boy trying to get that satanic mercury out of his little body. You have some blood on your hands. Like it or not you do. There has been no autism epidemic and thimerosal doesn’t cause autism . . . . I hope the parents of this boy point the finger at you and scream murder.”

“I really do try to walk a middle line on this,” Westover told me that day, as he mulled his response to the reader. “You have to go out and investigate this and be able to come to some sort of conclusion. Not definitely that thimerosal does or does not cause autism, but you have to come to the question of whether this theory is plausible or not. Otherwise, I think you’re doing a disservice to your reader.” The evidence has led Westover to believe that a connection is possible. He realizes, moreover, that what he writes may influence others to believe the same.

To the reader who blamed him for the boy’s death, Westover ultimately wrote, “That is the risk of a sin of commission, and one I considered long and hard before I wrote my first article on this topic . . . . I will stand on what I believe and accept the risk and the consequences if I am wrong.”

Whether the thimerosal theory is proved right or wrong, there will be consequences — for the public health apparatus and vaccine manufacturers, for parents and their children, even for journalists. But with science left to be done and scientists eager to do it, it seems too soon for the press to shut the door on the debate.

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