

# New Kennedy Book Calls for Thimerosal-Free Vaccines

Robert Lowes | August 07, 2014

Does the mercury-based preservative called thimerosal in seasonal influenza vaccines cause neurodevelopmental disorders in children? The scientific establishment says no, but environmental activist Robert F. Kennedy Jr. argues in a new book that thimerosal should be removed from the vaccines to protect children's brains.

Critics say that his book, published August 4, could harm children and adults alike by supplying everyone with more bogus reasons to avoid immunization.

Making vaccines thimerosal-free is a cause that the 60-year-old Kennedy has championed for a long time. In 2005, *Rolling Stone* magazine published a piece of his titled "Deadly Immunity," claiming that "government health agencies colluded with Big Pharma to hide the risks of thimerosal from the public." The risk that Kennedy cited the most was autism, the rates of which grew explosively in the 1990s, he wrote, just as more thimerosal-containing vaccines were introduced to the childhood immunization schedule (the preservative has since been removed or lowered to trace amounts in all childhood vaccines in the early 2000s).

Kennedy's book, titled *Thimerosal: Let the Science Speak*, expands on the *Rolling Stone* article with references to hundreds of studies while adopting a less inflammatory tone. It mutes the conspiracy-theory angle and generally substitutes neurodevelopmental disorders for autism when speaking of the public health threat. Kennedy told *Medscape Medical News* that his editorial team deleted a chapter connecting thimerosal and autism just before publication.

"They took out everything that was controversial and just made it pure science," said Kennedy, who is not a medical researcher or clinician.

Kennedy is used to being on the popular side of controversial causes. *Time* magazine named him one of its "Heroes of the Planet" in 2010 for helping to clean up the Hudson River. He fights polluters as a senior attorney for the National Resource Defense Council, a blue-chip institution in the environmental movement. And it doesn't hurt to have a famous name.

When it comes to thimerosal, however, Kennedy finds himself a pariah.

"He's become the cheerleader for the antiscience movement," said Michael Osterholm, PhD, MPH, director of the University of Minnesota Center for Infectious Disease Research and Policy, in an interview with *Medscape Medical News*. "His work has no credibility." A recent opinion piece in *Time*, once Kennedy's booster, said the son of the late Robert F. Kennedy "has taken a disreputable plunge into the world of anti-science."

"Every parent he frightens into skipping vaccinations means one more child who is in danger," wrote *Time* editor-at-large Jeffrey Kluger, in charge of the magazine's science and technology coverage.

Equally as harsh, Steven Salzberg, PhD, a professor of medicine, computer science, and biostatistics at Johns Hopkins University, wrote in *Forbes* last month that Kennedy's "advocacy of bad science will cost lives, if it hasn't already."



**Robert F. Kennedy Jr. *Wikimedia Commons***

Kennedy portrays himself as a lone prophet who has endured a verbal stoning or two.

"This has been nothing but agony for me," Kennedy said. "I've been called anti-vaccine. I've been called anti-science. It's said that I am a true believer who has some kind of psychological problem that makes me believe in this fairy tale.

"All I'm doing is reading science. Show me where I'm wrong on the science. Show me the study that shows thimerosal is safe," he said.

### "A Settled Issue"

The US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), among other entities, say they can point to the studies exonerating thimerosal.

Chief among them is a 2004 review of published and unpublished studies by the Institute of Medicine (IOM). It concluded that "the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." A [study](#) published in *Pediatrics* in 2010 likewise found that prenatal and infant exposure to thimerosal did not increase the risk for autism spectrum disorder. Coauthor Frank DeStefano, MD, MPH, the CDC's director of immunization safety, told *Medscape Medical News* at the time that "further studies are not warranted."

Dr. DeStefano reiterated that the safety of thimerosal is a "settled issue" in another interview with *Medscape Medical News* last week. "The weight of the evidence is that there is not an association" with neurodevelopmental disorders, including autism, he said.

The public health community wasn't as sure about thimerosal in the late 1990s when its safety first started to come under intense questioning, as [detailed](#) on the FDA Web site. The Environmental Protection Agency (EPA) understood the risks of methylmercury — the kind of mercury found in seafood — enough to establish exposure guidelines, according to the FDA. However, no such guidelines existed for ethylmercury, the form used in thimerosal.

Using the EPA's methylmercury guidelines, the FDA determined that cumulative ethylmercury levels in some infants during their first 6 months could exceed the safety threshold, "depending on the vaccine formulations used and the weight of the infant." Accordingly, the FDA, the CDC, and other government agencies asked vaccine makers to eliminate or reduce thimerosal in childhood vaccines in what the FDA called "a precautionary measure."

Since then, Dr. DeStefano said, studies have shown that ethylmercury is not as dangerous as methylmercury because it is broken down and excreted much more quickly. Further clinching the argument for thimerosal's safety, he noted, is the [continued rise](#) in autism rates well after the disappearance of thimerosal from childhood vaccines. To Dr. DeStefano and others, pulling the preservative from these vaccines more than 12 years ago was prudent at the time, but not necessary after all in hindsight. "We know there's no need to eliminate thimerosal [from vaccines] at any age," he said.

All along, thimerosal has remained in multidose vials of inactivated influenza vaccine. Such vials need a preservative to prevent contamination by repeated needle punctures, said Dr. DeStefano. Theoretically, all inactivated influenza vaccine could be packaged in single-dose vials that do not require a preservative, but that is a less efficient and costlier manufacturing route, especially during a flu pandemic when there's a rush to vaccinate the public. He noted that wary Americans always can choose a thimerosal-free version of the seasonal flu vaccine.

Unlike the CDC, the FDA did not agree to an interview on thimerosal, but did issue a statement. The agency said that it continues to review research on vaccine safety and finds that the data "support the safety of vaccines licensed in the US, and they do not support a link between...thimerosal-containing vaccines and autism." Broadening this reassurance, the FDA said that research over the past 15 years "has failed to yield any evidence of harm, including serious neurodevelopmental disorders, from the use of thimerosal in vaccines."

So is the matter settled? Noted autism researcher Iva Hertz-Picciotto, PhD, MPH, asserts that there is no evidence supporting a thimerosal-autism association. "Do I think people should get their vaccines? Absolutely," said Dr. Hertz-Picciotto, an epidemiologist and professor at the University of California–Davis and its MIND Institute. "But I would distinguish between 'no evidence of a link' and 'evidence of no link.' To prove there is not an association is not so easy to do."

Dr. Hertz-Picciotto told *Medscape Medical News* that she agrees with some of Kennedy's criticisms of studies about thimerosal cited by the CDC and FDA, characterizing some as apple-and-orange comparisons and others as highly massaged. "There is not strong evidence of no link," she said.

Nailing down a causal relationship between thimerosal and autism, however, is not her top priority, said Dr. Hertz-Picciotto. "I don't think this is the most important issue in autism." Like other scientists, and Kennedy himself, she views autism as a multifactorial disorder. Her own research has found possible links to air pollution, prenatal exposure to pesticides, the lack of prenatal vitamin supplements, advanced maternal and paternal age, and maternal metabolic conditions such as obesity and diabetes, for example.

At the same time, she said she's reluctant to study thimerosal and autism because such research is a "career destroyer," marking someone as antivaccine and opposed to science. "This is an issue that people are afraid to come out on," she said. "I think the combination of the CDC and the pharmaceutical industry has dug in its heels and made it virtually impossible to discuss this issue."

### **Not About Autism, But...**

In his new book, Kennedy maintains that he is pro-vaccine just as much as he is pro-science. The presence of thimerosal in flu vaccines keeps some people from getting a shot. Removing the preservative, Kennedy said, would "help boost confidence in vaccines in general."

The book's case against thimerosal, which often reads like a legal brief, points to evidence suggesting that the ethylmercury in the preservative may be just as toxic as methylmercury. There's no reason to include thimerosal in inactivated flu vaccines in the first place if they are packaged in single-dose vials, which would be more economical than the FDA thinks, Kennedy contends. And if public health agencies insist on multidose vials, pharmaceutical companies can make vaccines with safer, more effective preservatives than thimerosal, such as 2-phenoxyethanol, according to Kennedy.

The book counterattacks the notion that rising autism rates after the removal of thimerosal from childhood vaccines blows the causation theory. The advent of administering seasonal flu vaccine to pregnant women during any trimester and children over the age of 6 months — not recommended until the early 2000s — has replaced most of the thimerosal exposure that children once had when the preservative was still in childhood vaccines.

Kennedy told *Medscape Medical News* that his book is not about autism, however. "The jury is still out about that," he said. Instead, the work ostensibly looks at a broad range of neurodevelopmental disorders that include attention deficit hyperactivity disorder, learning disabilities, neuromotor problems, and mental retardation.

Still, the subject of autism comes up frequently in the Kennedy book and figures heavily in some of its arguments. For example, it claims that the \$300 million cost of switching from multidose vials of vaccine to single-dose vials worldwide — and forgoing thimerosal — pales in comparison with the \$137 billion in autism's annual economic costs in the United States. The argument falls flat if one doesn't believe that thimerosal causes autism.

### **"They Did Not Want Their Names Listed"**

In his campaign against thimerosal, Kennedy has to overcome not only the views of mainstream science, but also the issue of his own credibility on the subject. Case in point is the 2005 article in *Rolling Stone*, which was

simultaneously published online in *Salon*. Within a few days both publications corrected half a dozen errors, which *Salon* said "went far in undermining Kennedy's expose." In 2011, *Salon* pulled the article off its site, explaining at the time that continued criticism "further eroded any faith we had in the story's value." The [story](#) remains on *Rolling Stone's* Web site.

Kennedy's choice of publisher, Skyhorse Publishing, for his new book has come under criticism in terms of guilt by association. Skyhorse also has published 2 books on autism by discredited British researcher Andrew Wakefield, whose 1998 article in *The Lancet* rang alarm bells about a connection between the measles, mumps, and rubella (MMR) vaccine and autism. In 2011, a series of articles and editorials in *BMJ* painted the study as a fraud. *The Lancet* had retracted the article the previous year. Wakefield was stripped of his medical license.

Some of the researchers cited in Kennedy's book have the same taint. About a dozen studies purporting to show a correlation between thimerosal and neurodevelopmental disorders such as autism were authored by Mark Geier, MD, and his son David Geier. Dr. Geier's treatment of autistic children with leuprolide (*Lupron*) — approved to treat precocious puberty as well as several conditions in adults, including cancer — and chelation therapy got him in trouble with the Maryland State Board of Physicians. It revoked his license in 2012 after finding that "his actions toward patients were not those of an honest or competent physician, nor do they appear to be those of an objective and ethical researcher." Other states where Dr. Geier was licensed followed suit. Meanwhile, that same year, the Maryland medical board fined David Geier \$10,000 for practicing medicine without a license.

As for the Geiers' studies, "they're just trash," said Dr. Hertz-Picciotto. "It's appalling that they actually got published."

Kennedy counters that he has not found anyone who has discredited the research by the father-son team. "The Geiers have become lightning rods like anybody else who writes about this issue," he told *Medscape Medical News*. "The Geiers were a difficult issue for us, but their studies were worthwhile, we thought."

## Two Physicians on Record

Kennedy's use of the plural "we" and "us" raises yet another question of credibility about the book — who exactly wrote it? Kennedy is listed as its editor. So whom did he edit? Who are the contributing authors? In his "editor's introduction," Kennedy wrote that he "engaged a crack team of respected scientific researchers to review the voluminous, peer-reviewed literature related to thimerosal and human health." However, the book does not identify the members of this editorial team. Kennedy said they requested anonymity.

Again, the lightning-rod phenomenon.

"They did not want their name listed," Kennedy said. "They think that their careers will be injured, that they won't be able to get grants, that they'll be cut off by the CDC, the NIH [National Institutes of Health], and all the others."

The book features a preface and introduction by 2 physicians who were willing to go on the record in their support of Kennedy's cause. The author of the preface is Mark Hyman, MD, the founder and medical director of the UltraWellness Center in Lenox, Massachusetts, and author of several books including *The Blood Sugar Solution* and *The UltraMind Solution*. Dr. Hyman wrote that he was involved in "reviewing and contributing ideas and scientific references to this manuscript."

The introduction is by Martha Herbert, MD, PhD, an assistant professor of neurology at Harvard Medical School. "You can be pro-vaccine and at the same time seek to improve the vaccine program," she wrote. "Why do we persist in putting a potent toxin into a vital medical product when we don't need to?"

Kennedy told *Medscape Medical News* that the sooner public health agencies resolve that question, the better for children, and him.

"I hate this issue. I want to get away from it," he said. "It has isolated me and it has made it easy for people to call me names.

"Just get somebody to show me where I've missed something, or got a blind spot, or whatever, so I can do my job. I'm not getting paid for this. It's not something that other people are supporting me on," Kennedy said. "I just feel that if children are getting poisoned unnecessarily, I ought to do something about it."

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