

**IOM Opening Statement
Immunization Safety Review: Vaccines and Autism
Institute of Medicine**

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**Opening Statement:
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Good afternoon. On behalf of the Institute of Medicine and the entire committee, I would like to welcome reporters and guests to the release of our report, Vaccines and Autism. I am joined by fellow committee member Steven Goodman.

The Committee on Immunization Safety Review was established in January 2001 in response to a request from the Centers for Disease Control and Prevention and the National Institutes of Health, both of which recognized the need for an independent group of scientists to address growing concerns about vaccine safety in a timely and objective manner. The committee consists of 13 members with expertise in a variety of relevant public health and medical disciplines.

Since its inception, the committee has issued seven reports. In this eighth and final report, we were asked to revisit concerns about vaccines and autism, specifically whether the vaccine preservative thimerosal or the measles-mumps-rubella -- or MMR -- vaccine are causally related to autism. The current report follows up two reports examining the role of vaccines in autism that the committee issued in 2001. One reviewed the hypothesized causal association between the MMR vaccine and autism, which the committee rejected based on the evidence at the time. The second report reviewed the hypothesized link between thimerosal-containing vaccines and a broad range of neurodevelopmental disorders including autism. The committee concluded that the evidence available at the time was inadequate to accept or reject a causal relationship between thimerosal and neurodevelopmental disorders.

The report we are releasing today incorporates new epidemiological evidence and studies of biological mechanisms related to vaccines and autism that have emerged since the earlier reports. The committee wishes to emphasize that this report focuses only on autism and does not address other neurodevelopmental disorders.

Scientists generally agree that most cases of autism likely result from events in the prenatal period or shortly after birth. But there are concerns about the MMR vaccine because autistic symptoms typically do not emerge until the child's second year of life, which is about the same time that the MMR vaccine is first administered. In addition, some point to the apparent increase in the number of reported cases of autism, and question whether this rise may be due, in part, to widespread use of the MMR vaccine and thimerosal-containing vaccines.

Thimerosal has been used as a preservative to prevent bacterial contamination in multidose vials of several childhood and adult vaccines. The active ingredient in thimerosal is ethylmercury, a close chemical relative of methylmercury. Many forms of mercury are known to damage the nervous system in high doses, although ethylmercury has been studied less than other forms of mercury. In 1999 thimerosal began to be removed from vaccines. This action was taken as a precaution to decrease mercury exposures, despite the absence of data at that time to suggest that thimerosal was in fact dangerous at the levels present in vaccines. As of mid-2000, all childhood vaccines recommended for universal use were available free of thimerosal as a preservative.

On the issue of whether thimerosal is associated with autism, epidemiological studies in the United States, the United Kingdom, Denmark, and Sweden that have been published since our earlier study provided significant evidence that there is no association between thimerosal-containing vaccines and autism. Based on these studies, the committee concluded that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.

To assess whether the MMR vaccine is associated with autism, the committee looked at the large number of epidemiological studies that have examined this issue. Let me note that the MMR vaccine does not contain and has never contained thimerosal. Fourteen large, well-designed epidemiological studies consistently showed no association between the MMR vaccine and autism. Based on this body of evidence, the committee saw no reason to change its 2001 conclusion that the evidence favors rejection of a causal relationship between the MMR vaccine and autism.

The committee also reviewed the potential biological mechanisms that have been put forth as possible explanations for how vaccines might cause autism. These hypothesized mechanisms include:

- The release of chemicals into the brain due to disruption of intestinal function by the MMR vaccine.
- Triggering of abnormalities in the immune system that are indicative of damage to the central nervous system induced by vaccines.
- Increased accumulation of mercury and decreased excretion of the element from the brains of a subgroup of children.
- The effects of thimerosal on a variety of biochemical pathways.

The evidence offered for these various hypotheses includes data from in vitro experimental systems, clinical observations, and analogies between rodent behavior and human behavior. While the laboratory observations of the toxic effects of mercury are important in understanding how this metal may cause damage, these observations do not explain how specific exposures in a rapidly developing infant affect certain tissues but not others where these mechanisms are also active. The laboratory studies also have not shown how these effects lead to autism. The committee does not dispute that mercury-containing compounds, including thimerosal, can be very damaging to the nervous system. The question is whether these damaging effects are related to the development of autism.

While the committee agreed that the studies raise interesting questions, they do not address the specifics of how these mechanisms result in the symptoms of autism. It is difficult to establish a link between vaccine components and this disorder because scientific understanding about the causes of autism is only in an early stage. Autism is not a single condition but rather a complex set of disorders. It is possible, and perhaps even likely, that autism will be found to have many different causes. It is possible that some people with autism also have abnormal immune reactions, or abnormalities in the way they metabolize mercury. But it is also possible that vaccination does not cause these abnormalities, and likewise that the abnormalities do not lead to autism.

In the absence of experimental or human evidence that either the MMR vaccine or vaccines containing thimerosal affect metabolic, developmental, immune, or other physiological or molecular mechanisms that are causally related to the development of autism, the committee concludes that the hypotheses generated to date are theoretical only.

The committee recommends a public health response that fully supports an array of vaccine safety activities. While the committee strongly supports research that focuses on achieving a better understanding of autism, we recommend that future research be directed toward other lines of inquiry that are supported by current knowledge and evidence, and that offer more

promise for finding an answer. Given the current evidence, the vaccine hypothesis doesn't offer that promise.

The committee also believes that communication with the public about vaccine safety issues needs to be improved. To that end, we recommend developing programs to increase public participation in research on vaccine safety and in policy decisions about the issue. Efforts are also needed to enhance the skills and willingness of scientists and government officials to engage in constructive dialogue with the public about research findings and their policy implications.

This concludes my opening statement. My colleague Steven Goodman and I will now take your questions. We anticipate that there will be a lot of questions, and would like to get to as many as possible during the time remaining in this hour, so we urge you to state your questions as succinctly as possible. Thank you.

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