

VACCINE EPIDEMIC

**How Corporate Greed, Biased Science, and
Coercive Government Threaten Our Human
Rights, Our Health, and Our Children**

Edited by
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Chapter Seven

AN URGENT CALL FOR MORE RESEARCH

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Note: The authors would like to thank Louise Kuo Habakus for her contributions to this chapter.

THE NEED FOR SCIENCE

Science lies at the heart of the vaccine controversy, and there can be no substitute for it. The ethical practice of medicine requires full and informed consent. It is not possible to have the *informed* part of informed consent without the science. That vaccine safety science has been and remains inadequate is not in dispute.

The National Academy of Sciences chartered the Institute of Medicine (IOM) in 1970 to serve as an adviser to the federal government on issues affecting public health and to act independently on issues of medical care, research, and education¹ through the analysis and evaluation of evidence-based information. The IOM has played an important role in guiding vaccine policy over the past several decades. Excerpts from a succession of IOM reports over a fifteen-year period illustrate the continued lack of progress in addressing the paucity of research on vaccine safety.

Institute of Medicine Reports on Vaccine Safety

In 1991:

In the course of its review, the committee encountered many *gaps and limitations in knowledge* bearing directly and indirectly on the safety of vaccines. These include *inadequate understanding* of the biologic mechanisms underlying adverse events following natural infection or immunization, *insufficient or inconsistent information* from case reports and case series, *inadequate size or length of follow-up* of many population-based epidemiologic studies, and *limited capacity of existing surveillance systems* of vaccine injury to provide persuasive evidence of causation. The committee found *few experimental studies* published in relation to the number of epidemiologic [*sic*] studies published. Clearly, *if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped.*² (emphasis added)

In 1994:

Committee members were struck by the *lack of evidence*. . . For about two-thirds of the relations evaluated, the committees found either that there was *no evidence* bearing on the question of causality or that the available evidence was *insufficient or inadequate* to make a determination about causality.³

Clinical trials for evaluating vaccine efficacy generally *do not include sufficient sample sizes* to permit adequate evaluations of the risk of adverse reactions. Participants expressed dismay that post-marketing studies of vaccines are generally *not randomized controlled trials*. The role of clinical trials for assessing adverse reactions is *limited*.⁴

Discussion arose about the issue of the *lack of unvaccinated controls* in the studies under consideration. Some participants felt that *a true control group* in a study of vaccines and adverse events would consist of never-vaccinated children (whereas now, control groups often consist of children who had not been vaccinated *recently [sic]*). *It would then be possible* to look at the frequencies of adverse events and disease in these children in comparison with the frequencies in those who had been vaccinated. This *might be particularly relevant* in studying adverse events with long latencies from the time of vaccination.⁵ (emphasis added)

In 1997:

A number of factors make it *difficult to detect adverse events* associated with the administration of a vaccine: (1) the *need to study* multiple exposures and mul-

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tiple outcomes, (2) the lack of unique vaccine-associated syndromes, making it *difficult to establish causality*, (3) the *need for large sample sizes and lack of large computerized immunization databases* with individual level data including vaccine lot number, (4) brief exposure periods for each individual, (5) high vaccination coverage makes unvaccinated individuals highly selected.⁶

More research could be done on potential long-term adverse events from vaccines as well as the potential of vaccines to induce or worsen immune disorders. *Research also could usefully address* such questions as whether age is a factor in the adverse events experienced following vaccination and whether some groups of individuals are more prone to such adverse effects than others.⁷ (emphasis added)

In 2001:

Little is known about ethylmercury (the active component in thimerosal) compared to methylmercury.⁸

There are *no data* that elucidate how much, if any, mercury exposure from all sources contributes to the prevalence of autism, ADHD, or speech or language delay.⁹

As noted in previous IOM reports (IOM, 1994 a, b, 2001), a positive ecological correlation constitutes only *weak evidence* of causality, and *additional research would be needed* to establish a causal association.¹⁰

The available case reports are *uninformative* with respect to causality. There are *no published epidemiological studies* examining the potential association between thimerosal-containing vaccines and neurodevelopmental disorders. The *unpublished and limited* epidemiological studies provide *weak and inconclusive* evidence. . . .¹¹

The committee has found *inadequate* evidence to accept or reject a causal relationship between thimerosal-containing vaccines and neurodevelopmental disorders. Although the available evidence is *indirect and incomplete*, and the relationship is not established, it is biologically plausible. Because thimerosal was used in millions of vaccine doses over several decades, it is *important that additional research be done* to understand the nature of the risk, if any, from this exposure to thimerosal.¹² (emphasis added)

In 2002:

The committee concludes that the epidemiological and clinical *evidence is inadequate* to accept or reject a causal relationship between multiple immunizations and an increased risk of allergic disease, particularly asthma.¹³

The committee was *unable to address* the concern of some that repeated exposure of a susceptible or fragile child to multiple vaccines over the developmental period may also produce atypical or nonspecific immune or nervous system injury that could lead to severe disability or death. Such adverse health outcomes may not be “classical” diseases but variants of diseases . . . there are *no epidemiological studies that address this*, either in terms of exposure or outcome. That is, there is *no study that compares an unvaccinated control group* with children exposed to the complete immunization schedule, *nor are there any studies* that looked at health outcomes other than those classically defined, such as infections, allergy or diabetes. Thus, *the committee recognizes with some discomfort* that this report *addresses only part of the overall set of concerns* of some who are most wary about the safety of childhood vaccines.¹⁴

Research on the developing human immune system, especially in relation to vaccines, is *limited*.¹⁵ (emphasis added)

As the immunization schedule expanded, the IOM acknowledged a concomitant “dramatic increase in the complexity of immunization safety issues.”¹⁶ Although the IOM identified this complexity and these inadequacies and recommended more research over a fifteen-year period, critical questions about vaccine safety remain unanswered.

In addition, funding for vaccine safety has been and remains insufficient, despite urgent, unanswered questions. In 1995, Dr. Robert Chen, chief of Vaccine Safety and Development at the CDC, said,

The only line item for vaccine safety research is, I think, on the order of a little less than \$2 million per year. That basically covers operation of VAERS (Vaccine Adverse Events Reporting System) period, and nothing else.¹⁷

In 2008, almost fifteen years later, Dr. Louis Cooper, vaccine inventor and a former president of the American Academy of Pediatrics, wrote that the total vaccine safety science research budget was \$20 million or 0.5 percent of the \$4 billion total vaccine budget for purchase, promotion, and delivery of vaccines.¹⁸ Despite insufficient scientific knowledge and funding for safety research, the compulsory vaccination program continues to expand.

THE last duty of parents to their children is that of giving them an education suitable to their station in life: a duty pointed out by reason, and of far the greatest importance of any. For, as Pufendorf very well observes, it is not easy to imagine or allow, that a parent has conferred any considerable benefit upon his child, by bringing him into the world; if he afterward entirely neglects his culture and education, and suffers him to grow up like a mere beast, to lead a life useless to others, and shameful to himself.

- 6 *Pierce v. Society of Sisters*, 268 U.S. 510 (1925).
 7 *Wisconsin v. Yoder*, 406 U.S. 205 (1972).
 8 See e.g., the Declaration of Independence.
 9 The state-mandated vaccination progeny of the Supreme Court decision *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), is a case in point. In the midst of a national smallpox epidemic, the Supreme Court upheld a government mandated adult vaccination program. The *Jacobson* Court opined that “the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to [government] restraint . . . as the safety of the general public may demand.” 197 U. S. at 26. Chapter 1 explains how governments subsequently relied on this decision improperly to justify mandated vaccinations for exponentially milder public safety interests.

CHAPTER 7: AN URGENT CALL FOR MORE RESEARCH
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- 1 Institute of Medicine, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (Inst. of Med., 2002), ix.
 2 Institute of Medicine (1991) ‘Adverse Effects of Pertussis and Rubella Vaccines’, *Institute of Medicine*, 8.
 3 Institute of Medicine, *Research Strategies for Assessing Adverse Events Associated with Vaccines*, (Inst. of Med., 1994), 1.
 4 *Ibid*, 16.
 5 *Ibid*, 16–17.
 6 Institute of Medicine, *Vaccine Safety Forum: Summaries of Two Workshops* (Inst. of Med., 1997), 1.
 7 *Ibid*, 2.
 8 Institute of Medicine, *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders* (Inst. of Med., 2001), 82.
 9 *Ibid*, 74.
 10 *Ibid*, 65.
 11 *Ibid*, 66.
 12 *Ibid*, 75.
 13 Institute of Medicine, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (Inst. of Med., 2002), 18.
 14 *Ibid*, 36.
 15 *Ibid*, 14.
 16 Institute of Medicine *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction*, (Inst. of Med., 2002), 2.