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House Bill 1306
Industry, Business and Labor
January 19, 2021, 2:45 p.m.

Good Morning Chairman Weisz and members of the House Human Services Committee. My name is Molly Howell and I am the Immunization Director of for the North Dakota Department of Health. I do not have testimony for HB1306 but want to let you know I am available virtually to answer questions, if needed. Additionally, attached is a list of studies that have been previously published regarding vaccines, autism and SIDS. Thank You.

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Vaccine-Related Science: Autism and SIDS

No Causal Association Found

Autism

Literature Reviews: Autism and Vaccines

1. Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study
   PDF available here
   Annals of Internal Medicine
   March 2019
   The study strongly supports that MMR vaccination does not increase the risk for autism, does not trigger autism in susceptible children, and is not associated with clustering of autism cases after vaccination. It adds to previous studies through significant additional statistical power and by addressing hypotheses of susceptible subgroups and clustering of cases.
2. Autism Occurrence by MMR Vaccine Status Among US Children With Older Siblings With and Without Autism
   http://jama.jamanetwork.com/article.aspx?articleid=2275444
   The Journal of the American Medical Association
   April 2015
   In this large sample of privately insured children with older siblings, receipt of the MMR vaccine was not associated with increased risk of ASD, regardless of whether older siblings had ASD. These findings indicate no harmful association between MMR vaccine receipt and ASD even among children already at higher risk for ASD.
3. Safety of Vaccines Used for Routine Immunization of U.S. Children: A Systematic Review
   http://www.ncbi.nlm.nih.gov/pubmed/25086160
   Pediatrics
   August 2014
   We found evidence that some vaccines are associated with serious AEs; however, these events are extremely rare and must be weighed against the protective benefits that vaccines provide.
4. Vaccines are Not Associated with Autism: An Evidence-Based Meta-Analysis of Case-Control and Cohort Studies

http://www.ncbi.nlm.nih.gov/pubmed/24814559
Vaccine
June 2014
Findings of this meta-analysis suggest that vaccinations are not associated with the development of autism or autism spectrum disorder. Furthermore, the components of the vaccines (thimerosal or mercury) or multiple vaccines (MMR) are not associated with the development of autism or autism spectrum disorder.

5. On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes
   http://pediatrics.aappublications.org/cgi/content/abstract/125/6/1134
   Pediatrics
   Smith, M and Woods, C
   June 2010
   Timely vaccination during infancy has no adverse effect on neuropsychological outcomes 7 to 10 years later. These data may reassure parents who are concerned that children receive too many vaccines too soon.
6. Vaccines and Autism: A Tale of Shifting Hypotheses
   http://www.journals.uchicago.edu/doi/full/10.1086/596476
   Clinical Infectious Diseases
   Offit, Paul and Gerber, Jeffrey S.
   February 2009
   Twenty epidemiologic studies have shown that neither thimerosal nor MMR vaccine causes autism. These studies have been performed in several countries by many different investigators who have employed a multitude of epidemiologic and statistical methods. The large size of the studied populations has afforded a level of statistical power sufficient to detect even rare associations. These studies, in concert with the biological implausibility that vaccines overwhelm a child's immune system, have effectively dismissed the notion that vaccines cause autism. Further studies on the cause or causes of autism should focus on more-promising leads.
7. Immunization Safety Review: Vaccines and Autism
   http://www.iom.edu/reports/2004/immunization-safety-review-vaccines-and-autism.aspx
   Institute of Medicine
   May 2004

8. Adverse Effects of Pertussis and Rubella Vaccines: A Report of the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines
http://www.nap.edu/catalog/1815/adverse-effects-of-pertussis-and-rubella-vaccines
Institute of Medicine
1991

Too Many Too Soon?

9. Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?
http://pediatrics.aappublications.org/cgi/content/full/109/1/124
Pediatrics
Offit, Paul A., Quarles, Jessica, et al.
2002
Current studies do not support the hypothesis that multiple vaccines overwhelm, weaken, or "use up" the immune system. On the contrary, young infants have an enormous capacity to respond to multiple vaccines, as well as to the many other challenges present in the environment. By providing protection against a number of bacterial and viral pathogens, vaccines prevent the "weakening" of the immune system and consequent secondary bacterial infections occasionally caused by natural infection.
10. Immunization Safety Review: Multiple Immunizations and Immune Dysfunction
http://www.iom.edu/reports/2002/immunization-safety-review-multiple-immunizations-and-immune-dysfunction.aspx
Institute of Medicine
February 2002
11. Cellular Immune Responses in Neonates
http://www.ncbi.nlm.nih.gov/pubmed/10763708
International Reviews of Immunology
Fadel S, Sarazotti M.
2000
12. Neonatal and Early Life Vaccinology
http://www.ncbi.nlm.nih.gov/pubmed/11348697
Vaccine

Siegrist CA.
2001

13. The Problem with Dr. Bob's Alternative Vaccine Schedule
    http://pediatrics.aappublications.org/content/123/1/e164.abstract
    Pediatrics
    Offit, Paul A. and Moser, Charlotte A.
    January 2009

Thimerosal and Autism Studies

14. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containing vaccines.
    https://pediatrics.aappublications.org/content/123/2/475?
    Pediatrics
    Tozzi AE, Bisiacchi P, Tarantino V, De Mei B, D'Elia L, Chariotti F, Salmaso S.
    January 2009
    Given the large number of statistical comparisons performed, the few associations found between thimerosal exposure and neuropsychological development might be attributable to chance. The associations found, although statistically significant, were based on small differences in mean test scores, and their clinical relevance remains to be determined.
15. Continuing Increases in Autism Reported to California's Developmental Services System
    http://archpsyc.ama-assn.org/cgi/content/full/65/1/19
    Archives of General Psychiatry
    Robert Schechter, MD, MSc and Judith K. Grether, PhD
    January 2008
    The DDS data do not show any recent decrease in autism in California despite the exclusion of more than trace levels of thimerosal from nearly all childhood vaccines. The DDS data do not support the hypothesis that exposure to thimerosal during childhood is a primary cause of autism.
16. Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years
    http://content.nejm.org/cgi/content/full/357/13/1281
    New England Journal of Medicine
    Thompson WW, Price C, Goodson B, et al.
    September 2007

17. Lack of Association Between Rh Status, Rh Immune Globulin in Pregnancy and Autism
    http://www3.interscience.wiley.com/cgi-bin/abstract/114264055/ABSTRACT
    American Journal of Medical Genetics
    Judith H. Miles and T. Nicole Takahashi
    May 2007
18. Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16079072&query_hl=1
    Environmental Health Perspectives
    Thomas M. Burbacher, PhD
    April 2005
    The results indicate that MeHg is not a suitable reference for risk assessment from exposure to thimerosal-derived Hg. Knowledge of the toxicokinetics and developmental toxicity of thimerosal is needed to afford a meaningful assessment of the developmental effects of thimerosal-containing vaccines.
19. Thimerosal Exposure in Infants and Developmental Disorders: A Prospective Cohort Study in the United Kingdom Does Not Support a Causal Association
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15342824&query_hl=5
    Pediatrics
    John Heron and Nick Andrews, PhD and Jean Golding, DSc
    September 2004
    We could find no convincing evidence that early exposure to thimerosal had any deleterious effect on neurologic or psychological outcome.
20. Neurotoxic Effects of Postnatal Thimerosal Are Mouse Strain Dependent
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15184908&query_hl=10
    Molecular Psychiatry
    M Hornig, M
    June 2004
21. Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Database
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dop

t=Abstract&list_uids=14595043&query_hl=59
Pediatrics
Thomas Verstraeten, MD
November 2003
No consistent significant associations were found between TCVs and neurodevelopmental outcomes. Conflicting results were found at different HMOs for certain outcomes. For resolving the conflicting findings, studies with uniform neurodevelopmental assessments of children with a range of cumulative thimerosal exposures are needed.

22. Association Between Thimerosal-Containing Vaccine and Autism
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14519711&query_hl=16
Journal of the American Medical Association
Anders Hviid, MSc
October 2003
The results do not support a causal relationship between childhood vaccination with thimerosal-containing vaccines and development of autistic-spectrum disorders.
23. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15496004&query_hl=19
Pediatrics
Kreesten M. Madsen, MD
September 2003
24. "Autism and Thimerosal-Containing Vaccines: Lack of Consistent Evidence for an Association"
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12880876&query_hl=21
American Journal of Preventive Medicine
Paul Stehr-Green, DrPh, MPH
August 2003
The body of existing data, including the ecologic data presented herein, is not consistent with the hypothesis that increased exposure to Thimerosal-containing

vaccines is responsible for the apparent increase in the rates of autism in young children being observed worldwide.

25. Thimerosal and Autism?
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12612255&query_hl=22
    Pediatrics
    Karen Nelson, MD
    March 2003
26. Mercury concentrations and metabolism in infants receiving vaccines containing thiomersal: A descriptive study
    http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12480426&query_hl=30
    The Lancet
    Michael Pichichero, MD
    November 2002
    Administration of vaccines containing thiomersal does not seem to raise blood concentrations of mercury above safe values in infants. Ethylmercury seems to be eliminated from blood rapidly via the stools after parenteral administration of thiomersal in vaccines.

Measles-Mumps-Rubella (MMR) Vaccine and Autism Studies

27. Examination of the Safety of Pediatric Vaccine Schedules in a Non-Human Primate Model: Assessments of Neurodevelopment, Learning, and Social Behavior
    http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/2/ehp.1408257.acco.pdf
    Environmental Health Perspectives
    February 2015
28. Early Exposure to the Combined Measles-Mumps-Rubella Vaccine and Thimerosal-Containing Vaccines and Risk of Autism Spectrum Disorder
    http://www.ncbi.nlm.nih.gov/pubmed/25562790
    Vaccine
    January 3, 2015
    No convincing evidence was found in this study that MMR vaccination and increasing thimerosal dose were associated with an increased risk of ASD onset.

29. Lack of Association Between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study
http://www.plosone.org/article/info%3Adoi/10.1371/journal.pone.0003140
PLoS One
Hornig M, Briese T, Buie T, Bauman ML, Lauwers G, et al.
September 2008
This study provides strong evidence against association of autism with persistent MV RNA in the GI tract or MMR exposure. Autism with GI disturbances is associated with elevated rates of regression in language or other skills and may represent an endophenotype distinct from other ASD.
30. Measles Vaccination and Antibody Response in Autism Spectrum Disorders
https://adc.bmj.com/content/93/10/832.abstract?
Archives of Disease in Childhood
Gillian Baird, F.R.C.Paed.
February 2008
No association between measles vaccination and ASD was shown.
31. Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links With Immunizations
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=16818529&query_hl=2&itool=pubmed_docsum
Pediatrics
Eric Fombonne, MD
July 2006
The prevalence of pervasive developmental disorder in Montreal was high, increasing in recent birth cohorts as found in most countries. Factors accounting for the increase include a broadening of diagnostic concepts and criteria, increased awareness and, therefore, better identification of children with pervasive developmental disorders in communities and epidemiologic surveys, and improved access to services. The findings ruled out an association between pervasive developmental disorder and either high levels of ethylmercury exposure comparable with those experienced in the United States in the 1990s or 1- or 2-dose measles-mumps-rubella vaccinations.
32. MMR Vaccination and Pervasive Developmental Disorders: A Case-Control Study
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15364187&query_hl=38

The Lancet
Liam Smeeth, MRCGP
September 11, 2004
Our findings suggest that MMR vaccination is not associated with an increased risk of pervasive developmental disorders.

33. Association of Autistic Spectrum Disorder and the Measles, Mumps, and Rubella Vaccine
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12860782&query_hl=40
Archives of Pediatrics & Adolescent Medicine
Kumanan Wilson, MD, MSc, FRCP
July 2003
The current literature does not suggest an association between ASD and the MMR vaccine; however, limited epidemiological evidence exists to rule out a link between a rare variant form of ASD and the MMR vaccine. Given the real risks of not vaccinating and that the risks and existence of variant ASD remain theoretical, current policies should continue to advocate the use of the MMR vaccine.
34. Neurologic Disorders After Measles-Mumps-Rubella Vaccination
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12415036&query_hl=64
Pediatrics
Annamari Makela, MD
November 2002
We did not identify any association between MMR vaccination and encephalitis, aseptic meningitis, or autism.
35. No Evidence for a New Variant of Measles-Mumps-Rubella-Induced Autism
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=11581466&query_hl=66
Pediatrics
Eric Fombonne, FRCPsych
October 2001
No evidence was found to support a distinct syndrome of MMR-induced autism or of "autistic enterocolitis." These results add to the recent accumulation of large-scale epidemiologic studies that all failed to support an association between MMR and autism at population level. When combined, the current

findings do not argue for changes in current immunization programs and recommendations.

36. Vaccines for Measles, Mumps, rubella and varicella in children
    Vaccines for measles, mumps, rubella, and varicella in children - Di Pietrantonj, C - 2020 | Cochrane Library
    Cochrane Review
    Di Pietrantonj, C, et al.
    April 2020
    This study assessed currently available literature and analyzed the evidence regarding how effective MMR, MMR+V and MMRV vaccines are and if they cause unwanted effects. They found 138 studies with more than 23 million children to analyze. Overall, the studies found that MMR, MMRV, and MMR+V vaccine did not cause autism (2 studies 1,194,764 children). Our review shows that MMR, MMRV and MMR+V vaccines are effective in preventing the infection of children by measles, mumps, rubella and chickenpox, with no evidence of an increased risk of autism or encephalitis and a small risk of febrile seizure.

Vaccines and SIDS

1. Yang YT and Shaw J. Sudden infant death syndrome, attention-deficit/hyperactivity disorder and vaccines: longitudinal population analyses. Vaccine 2018;36:595-598.
   The authors analyzed six years of vaccine uptake data for 3-month-olds from the National Immunization Survey and state-level National Vital Statistics SIDS reports and found vaccination coverage for routinely used childhood vaccines was not associated with an increased risk of SIDS.
2. Moro PL, Arana J, Cano M, Lewis P, Shimabukuro TT. Deaths reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013. CID 2015;61:980-987.
   The authors examined deaths reported to VAERS in the United States during a 16-year period, with nearly half of the deaths attributed to SIDS. As with the previous 2001 study, SIDS reports progressively decreased over time, during which the addition of seven-valent pneumococcal vaccine and rotavirus vaccine were added to the recommended vaccine schedule, and the DTaP-HepB-IPV combination vaccine was licensed for use.

3. Traversa G, Spila-Alegiani S, Bianchi C, Ciofi degli Atti M, Frova L, et al. Sudden unexpected deaths and vaccinations during the first two years of life in Italy: a case series study. PLoS ONE 2011;6(1):e16363.
The authors found no increased risk for sudden unexplained death (SUD) and any vaccination in the time windows of 0-7 days or 0-14 days after vaccine receipt.
4. Vennemann, MMT, Butterfab-Bahloul T, Jorch G, et al. Sudden infant death syndrome: no increased risk after immunisation. Vaccine 2007;25: 336-340.
The authors investigated the risk of SIDS with immunization in the first year of life, particularly with a hexavalent vaccine containing 15 different antigens. They found no increased risk of SIDS in the 14 days after immunization. As with previous studies, patients with SIDS were vaccinated less frequently and later than those infants without SIDS.
5. Eriksen EM, Perlman JA, Miller A, Marcy SM, Lee H, et al. Lack of association between hepatitis B birth immunization and neonatal death: A population-based study from the Vaccine Safety Datalink Project. Pediatr Infect Dis J 2004;23:656-661.
The authors evaluated more than 360,000 births during a five-year period to determine if a correlation existed between hepatitis B vaccine receipt at birth and neonatal death. The authors found no relationship between hepatitis B vaccine receipt at birth and neonatal death, and the proportion of deaths from unexpected causes (e.g., SIDS) was not different between vaccinated and unvaccinated infants.
6. Fleming PJ, Blair PS, Platt MW, Tripp J, Smith IJ, et al. The UK accelerated immunisation programme and sudden unexpected death in infancy: case-control study. BMJ 2001;322:1-5.
In the early 1990s, the schedule for routine infant immunizations in the United Kingdom was accelerated to give the vaccines at an earlier age. The authors found that the accelerated immunization program did not increase the risk of SIDS in a study population of 17.7 million infants. Immunization uptake was lowest among the infants who died from SIDS.
7. Jonville-Bera AP, Autret-Leca E, Barbeillon, Paris-Llado J and the French Reference Centers for SIDS. Sudden unexpected death in infants under 3 months of age and vaccination status – a case-control study. Br J Clin Pharmacol 2001;51:271-276.
The authors conducted a two-year prospective study on the vaccination status of infants with SIDS who died between 1 and 3 months of age to assess whether

vaccination increased the risk of SIDS in this population in France. The authors found DTPP ± Hib immunization did not increase the risk of SIDS.

8. Silvers LE, Ellenberg SS, Wise RP, Varricchio FE, Mootrey GT, et al. The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System 1990-1997. Pharmacoepidemiol Drug Saf 2001; 279-285.
   The authors examined fatalities reported to VAERS in the United States during a seven-year period and found that reports peaked in 1992-1993 and then declined, with nearly half of the deaths attributed to SIDS. The trend in decreasing SIDS rates correlated with the 1992 American Academy of Pediatrics recommendation for infants to sleep on their side or back and the National Institute of Child Health and Human Development "Back to Sleep" campaign in 1994. The authors concluded that these data support findings of past controlled studies showing that the temporal association between infant vaccination and SIDS is coincidental and not causal.
9. Griffin MR, Ray WA, Livengood JR, Schaffner W. Risk of sudden infant death syndrome after immunization with the diphtheria-tetanus-pertussis vaccine. New Engl J Med 1988;319(10):618-623.
   The authors evaluated recent immunization with DTP as a possible risk factor for SIDS during a 10-year period in Tennessee. They found no increase in the risk of SIDS after immunization with DTP vaccine and no correlation between SIDS and age at first immunization. Additionally, the rate of SIDS decreased in the first week after immunization.
10. Hoffman HJ, Hunter JC, Damus K, Pakter J, Peterson DR, et al. Diphtheria-tetanus-pertussis immunization and sudden infant death: results of the National Institute of Child Health and Human Development Cooperative Epidemiological Study of Sudden Infant Death Syndrome Risk Factors. Pediatrics 1987;79:598-611.
    The authors investigated the possible association between diphtheria-tetanus-pertussis (DTP) immunization and subsequent occurrence of sudden infant death in the United States using data from a national SIDS epidemiological database. They found no temporal association between SIDS and DTP vaccine receipt. Infants with SIDS were less likely to have been immunized than infants without SIDS.
11. Keens TG, Davidson Ward SL, Gates EP, Andree DI, Hart LD. Ventilatory pattern following diphtheria-tetanus-pertussis immunization in infants at risk for sudden infant death syndrome. AJDC 1985;139:991-994.

The authors evaluated the effects of DTP immunization on the ventilatory pattern during sleep in infants at increased risk for SIDS, including those with unexplained apnea and those who were siblings of SIDS victims. Overnight pneumograms were recorded the night before and the night following DTP immunization. The authors found that DTP immunization did not increase abnormalities of the ventilatory pattern in infants at increased risk for SIDS.