Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:
Preservatives, to prevent contamination. For example, thimerosal.
Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These include:
Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts, current as of January 6, 2017.
If in doubt about whether a PI has been updated since then, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
Adenovirus	human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, microcrystalline cellulose, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, 2-phenoxyethanol
DTaP (Infanrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, ammonium sulfate aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

Vaccine	Contains
DTaP-HepB-IPV (Pediarix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. glutaraldehyde, MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hib/Mening. CY (MenHibrix)	saline, semi-synthetic media, formaldehyde, sucrose, tris (trometamol)-HCl
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, CTAB (cetyltrimethylammonium bromide), formaldehyde
Influenza (Fluarix) Trivalent & Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Trivalent & Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone
Influenza (Flulaval) Trivalent & Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials)
Influenza (Fluvirin)	ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal
Influenza (Fluzone) Quadrivalent	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, sucrose
Influenza (Fluzone) Intradermal	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, sucrose
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MPSV4-Menomune)	Mueller Hinton casein agar, Watson Scherp casamino acid media, thimerosal (multi-dose vials), lactose
Meningococcal (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, histidine buffered saline.
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone
Rabies (RabAvert)	chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*
Rotavirus (Rotarix)	amino acids, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-250 glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*
Smallpox (Vaccinia – ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, human serum albumin, sodium chloride, neomycin, polymyxin B, Glycerin, phenol

Vaccine	Contains
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
Tdap (Boostrix)	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (inactivated – Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, EDTA (Ethylenediaminetetraacetic acid), neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles – Zostavax) *Frozen*	sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; MRC-5 cells, neomycin, bovine calf serum
Zoster (Shingles – Zostavax) *Refrigerator Stable*	sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 cells, neomycin, bovine calf serum

A table listing vaccine excipients and media *by excipient* can be found in:

Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs* – 2013 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.

Attachment 2

108 scientific studies that you, as managers, authorities and decision makers should know about

Researchers have found that vaccines and their ingredients can cause underlying medical conditions that committed physicians and researchers commonly find in children with diagnosis – especially who have been given an autism diagnosis. These conditions include gastrointestinal damage, immune system impairment, chronic infections, mitochondrial disorders, autoimmune conditions, neurological regression, glial cell activation, brain inflammation, damage to the blood–brain barrier, seizures, synaptic dysfunction, dendritic cell dysfunction, mercury poisoning, aluminum toxicity, gene activation and alteration, glutathione depletion, impaired methylation, oxidative stress, endocrine dysfunction, cellular apoptosis, and other disorders. Here is a little part of all studies that has been carried out, all indicating that vaccines are harmful.
We also show that adjuvants with aluminum and mercury are very toxic to humans and to the human brain and nerves.

1. YALE SCIENTISTS FIND STRONG ASSOCIATION BETWEEN VACCINATIONS AND ANOREXIA, OCD, AND ANXIETY DISORDER

Temporal Association of Certain Neuropsychiatric Disorders Following Vaccination of Children and Adolescents: A Pilot Case-Control Study
Frontiers in Psychiatry, January 2017, Douglas L. Leslie, Robert A. Kobre, Brian J. Richmand

Summary: "Subjects with newly diagnosed anorexia nervosa were more likely than controls to have had any vaccination in the previous 3 months [hazard ratio (HR) 1.80, 95% confidence interval 1.21-2.68]. Influenza vaccinations during the prior 3, 6, and 12 months were also associated with incident diagnoses of AN, OCD, and an anxiety disorder. Several other associations were also significant with HRs greater than 1.40 (hepatitis A with OCD and AN; hepatitis B with AN; and meningitis with AN and chronic tic disorder). This pilot epidemiologic analysis implies that the onset of some neuropsychiatric disorders may be temporally related to prior vaccinations in a subset of individuals."

2. ITALIAN SCIENTISTS FIND UNEXPECTED CONTAMINANTS IN ALL PEDIATRIC VACCINES, INCLUDING LEAD, STAINLESS STEEL, TUNGSTEN, IRON, AND CHROMIUM

New Quality-Control Investigations on Vaccines: Micro- and Nanocontamination
International Journal of Vaccines and Vaccination, January 2017, Dr. Antonietta M. Gatti, Stefano Montanari

Summary: Scientists found contaminants in all vaccines that are not listed on the label of the vaccines. "The analyses carried out show that in all samples checked vaccines contain non biocompatible and bio-persistent foreign bodies which are not declared by the Producers, against which the body reacts in any case. This new investigation represents a new quality control that can be adopted to assess the safety of a vaccine. Our hypothesis is that this contamination is unintentional, since it is probably due to polluted components or procedures of industrial processes (e.g. filtrations) used to produce vaccines, not investigated and not detected by the Producers. If our hypothesis is actually the case, a close inspection of the working places and the full knowledge of the whole procedure of vaccine preparation would probably allow to eliminate the problem."

3. ISRAELI AND ITALIAN SCIENTISTS WARN THAT VACCINE ADJUVANTS (ALUMINUM) ARE CAUSING A WIDE-RANGE OF AUTOIMMUNE CONDITIONS, INCLUDING SJOGREN'S SYNDROME

Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Sjogren's Syndrome

IMAJ VOL 18, March-April 2016, Serena Colafrancesco, Carlo Perricone, Yehuda Shoenfeld

Summary: "Several case reports have suggested that both vaccines and silicone may trigger the development of SS [Sjogren's syndrome], a chronic systemic autoimmune inflammatory condition involving the exocrine glands]. Aluminum is one of the principal adjuvants used in vaccine formulation and may be responsible for the development of ASIA syndrome. It seems that its ability to behave as an adjuvant might be related to evidence that aluminum salts seem to both induce the activation of dendritic cells and complement components and increase the level of chemokine secretion at the injection site... other vaccines including Bacillus Calmette Guerin (BCG), hepatitis A and/or B and human papillomavirus, should be avoided or considered only in selected patients... There is considerable evidence raising the possibility of vaccine-triggered autoimmunity"

4. INFANTS VACCINATED WITH MULTIPLE VACCINES AT ONCE HAVE MUCH HIGHER HOSPITALIZATIONS AND DEATH RATES THAN INFANTS WHO RECEIVE FEWER SIMULTANEOUS VACCINES

Combining Childhood Vaccines at One Visit Is Not Safe
Journal of American Physicians and Surgeons, Summer 2016, Neil Z. Miller

Summary: "Our study showed that infants who receive several vaccines concurrently, as recommended by CDC, are significantly more likely to be hospitalized or die when compared with infants who receive fewer vaccines simultaneously. It also showed that reported adverse effects were more likely to lead to hospitalization or death in younger infants. The safety of CDC's childhood vaccination schedule was never affirmed in clinical studies. Vaccines are administered to millions of infants every year, yet health authorities have no scientific data from synergistic toxicity studies on all combinations of vaccines that infants are likely to receive. National vaccination campaigns must be supported by scientific evidence."

5. ISRAELI, CANADIAN, AND COLOMBIAN SCIENTISTS SHOW THAT GARDASIL VACCINE TRIGGERS BRAIN INFLAMMATION AND AUTOIMMUNITY IN MICE

Behavioral abnormalities in female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil
Immunol Res, July 2016, Rotem Inbar, Ronen Weiss, Lucija Tomljenovic, Maria-Teresa Arango, Yael Deri, Christopher A, Shaw, Joab Chapman, Miri Blank, Yehuda Shoenfeld

Summary: "Vaccine adjuvants and vaccines may induce autoimmune and inflammatory manifestations in susceptible individuals. To date most human vaccine trials utilize aluminum (Al) adjuvants as placebos despite much evidence showing that Al in vaccine-relevant exposures can be toxic to humans and animals...It appears that Gardasil via its Al adjuvant and HPV antigens has the ability to trigger neuroinflammation and autoimmune reactions, further leading to behavioral changes...In light of these findings, this study highlights the necessity of proceeding with caution with respect to further mass-immunization practices with a vaccine of yet unproven long-term clinical benefit in cervical cancer prevention"

6. ALUMINUM IN VACCINES IS HIGHLY NEUROTOXIC AND EXPOSURE LEVELS GIVEN TO INFANTS HAVE DRAMATICALLY INCREASED

Aluminum in Childhood Vaccines Is Unsafe
Journal of American Physicians and Surgeons, Winter 2016, Neil Z. Miller

Summary: "Infants and young children throughout the world receive high quantities of aluminum from multiple inoculations. Incremental changes to the vaccination schedule during the past several years significantly increased the quantity of aluminum in childhood shots. Numerous studies provide compelling evidence that injected aluminum can be detrimental to health. Aluminum is capable of remaining in cells long after vaccination and may cause neurologic and autoimmune disorders. During early development, the child's brain is more susceptible to toxins and the kidneys are less able to eliminate them. Thus, children have a greater risk than adults of adverse reactions to aluminum in vaccines. Millions of children every year are injected with vaccines containing mercury and aluminum despite well-established experimental evidence of the potential for additive or synergistic toxicity when an organism is exposed to two or more toxic metals."

7. ALZHEIMER'S VICTIMS HAVE VERY HIGH BRAIN ALUMINUM LEVELS, A POTENT NEUROTOXIN

Aluminium in brain tissue in familial Alzheimer's disease
Journal of Trace Elements in Medicine and Biology, November 2016, Ambreen Mirza, Andrew King, Claire Troakes, Christopher Exley

Summary: "Aluminium has been shown to be present in brain tissue in sporadic Alzheimer's disease. We have made the first ever measurements of aluminium in brain tissue from 12 donors diagnosed with familial Alzheimer's disease. The concentrations of aluminium were extremely high, for example, there were values in excess of 10mg/g tissue dry wt. in 5 of the 12 individuals. Overall, the concentrations were higher than all previous measurements of brain aluminium except cases of known aluminium-induced encephalopathy. We have supported our quantitative analyses using a novel method of aluminium-selective fluorescence microscopy to visualise aluminium in all lobes of every brain investigated. The unique quantitative data and the stunning images of aluminium in familial Alzheimer's disease brain tissue raise the spectre of aluminium's role in this devastating disease."

8. VACCINES IMPLICATED IN EPIDEMIC OF FOOD ALLERGIES

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy
Journal of Developing Drugs, 2015, Vinu Arumugham

Summary: "Numerous studies have demonstrated that food proteins contained in vaccines/injections induce food allergy. The IOM's authoritative report has concluded the same. Allergen quantities in vaccines are unregulated. Today kids are more atopic. C-section births bias the newborn's immune system towards IgE synthesis due to sub-optimal gut microbiome [19]. C-section birth rates have gone up 50% in the last few decades. The vaccine schedule has increased the number of vaccine shots to 30-40 and up to five vaccines are simultaneously administered to children. Vaccines also contain adjuvants such as aluminum compounds and pertussis toxin that bias towards IgE synthesis. Given these conditions, the predictable and observed outcome is a food allergy epidemic."

9. CHINESE SCIENTISTS FIND MICE INJECTED WITH THIMEROSAL (VACCINE MERCURY) HAVE BEHAVIORAL IMPAIRMENTS SIMILAR TO AUTISM

Transcriptomic Analyses of Neurotoxic Effects in Mouse Brain After Intermittent Neonatal Administration of Thimerosal,
Toxicological Sciences, March 2014, Xialong Li, Fengqin Qu, Wenjuan Xe, Fengli Wang, Hongmei Lui

Summary: "Thimerosal-treated mice exhibited neural development delay, social interaction deficiency, and inclination of depression. Apparent neuropathological changes were also observed in adult mice neonatally treated with thimerosal. High-throughput RNA sequencing of autistic-behaved mice brains revealed the alternation of a number of canonical path- ways involving neuronal development, neuronal synaptic function, and the dysregulation of endocrine system."

10. NEURODEVELOPMENTAL DISORDERS ARE MUCH MORE COMMON IN CHILDREN WHO RECEIVED MERCURY-CONTAINING VACCINES

A Dose-Response Relationship between Organic Mercury Exposure from Thimerosal-Containing Vaccines and Neurodevelopmental Disorders
Int. J. Environ. Res. Public Health, 2014, David A. Geier, Brian S. Hooker, Janet K. Kern, Paul G. King, Lisa K. Sykes and Mark R. Geier

Summary: "On a per microgram of organic-Hg basis, PDD (odds ratio (OR) = 1.054), specific developmental delay (OR = 1.035), tic disorder (OR = 1.034) and hyperkinetic syndrome of childhood (OR = 1.05) cases were significantly more likely than controls to receive increased organic-Hg exposure. This study provides new epidemiological evidence supporting a significant relationship between increasing organic-Hg exposure from TCVs and the subsequent risk of an ND diagnosis."

11. FULLY VACCINATED CHILDREN REQUIRE MUCH MORE EMERGENCY CARE THAN UNDERVACCINATED CHILDREN

A Population-Based Cohort Study of Undervaccination in 8 Managed Care Organizations Across the United States
JAMA Pediatrics, January 2013, Jason M. Glanz, PhD; Sophia R. Newcomer, MPH; Komal J. Narwaney, MD, PhD; Simon J. Hambidge, MD, PhD; Matthew F. Daley, MD; Nicole M. Wagner, MPH

Summary: "Children who were undervaccinated because of pa- rental choice had lower rates of outpatient visits, lower rates of ED [emergency room] encounters.. undervaccinated children had lower outpatient visit rates compared with children who were age-appropriately vaccinated."

12. ISRAELI AND ITALIAN RESEARCHERS DEMONSTRATE THAT EXPOSURE TO ALUMINUM IN VACCINES CAN LEAD TO AUTOIMMUNE AND BRAIN DYSFUNCTION

Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) 2013: Unveiling the pathogenic, clinical and diagnostic aspects
Journal of Autoimmunity, October 2013, Carlo Perricone, Serena Colafrancesco, Roei D. Mazor, Alessandra Soriano, Yehuda Shoenfeld

Summary: "The data herein illustrate the critical role of environmental factors in the induction of autoimmunity. Indeed, it is the interplay of genetic susceptibility and environment that is the major player for the initiation of breach of tolerance. Several neurologic demyelinating diseases have been reported following vaccination, the main being Guillaine Barre? syndrome (GBS). Another demyelinating disease associated with vaccines is the acute disseminated encephalomyelitis (ADEM). This is an inflammatory disease of the central nervous system frequently occurring post-vaccination. Rabies, diphtheria tetanus polio, smallpox, measles, mumps, rubella, Japanese B encephalitis, pertussis, influ-enza, hepatitis B, and the Hog vaccines have been called to be involved."

13. CANADIAN RESEARCHERS: ALUMINUM IN VACCINES CAN CAUSE BOTH AUTOIMMUNITY AND NEUROLOGICAL DAMAGE

Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity
Immunol Res, 2013, Chris Shaw, L. Tomljenovic

Summary: "In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. Many of the features of aluminum- induced neurotoxicity may arise, in part, from autoimmune reactions, as part of the ASIA syndrome. Aluminum is added to vaccines to help the vaccine work more effectively, but unlike dietary aluminum which will usually clear rapidly from the body, aluminum used in vaccines and injected is designed to provide a long-lasting cellular exposure. Thus, the problem with vaccine- derived aluminum is really twofold: It drives the immune response even in the absence of a viral or bacterial threat and it can make its way into the central nervous system. It is not really a matter of much debate that aluminum in various forms can be neurotoxic."

14. SCIENTISTS FROM MEXICO AND ISRAEL EXPLAIN ADJUVANTS (ALUMINUM) USED IN VACCINES CAN INDUCE AUTOIMMUNITY

Autoimmune/inflammatory syndrome induced by adjuvants (Shoenfeld's syndrome): clinical and immunological spectrum
Expert Rev. Clin. Immunol. 2013 Olga Vera-Lastra, Gabriela Medina, Maria Del-Pilar Cruz Dominguez, Luis J Jara

Summary: "The activation of the immune system by adjuvants, a desirable effect, could trigger manifestations of autoimmunity or autoimmune disease. Recently, a new syndrome was introduced, autoimmune/inflammatory syndrome induced by adjuvants (ASIA), that includes postvaccination phenomena, macrophagic myofasciitis, Gulf War syndrome and siliconosis. Various adjuvants used in vaccines enhance a specific immune response against antigens and may produce autoimmunity and AID both in experimental models and humans. The clinical and laboratory data support an association between adjuvants and autoimmune diseases."

15. INFANTS RECEIVING MERCURY-CONTAINING VACCINES HAD MUCH HIGHER RATES OF AUTISM THAN INFANTS RECEIVING VACCINES WITHOUT MERCURY

A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States
Translational Neurodegeneration, David A. Geier, Brian S. Hooker, Janet K. Kern, Paul G. King, Lisa K. Sykes, Mark R. Geier

Summary: "The present study provides new epidemiological evidence supporting an association between increasing organic-Hg [mercury] exposure from Thimerosal-containing childhood vaccines and the subsequent risk of ASD [autism] diagnosis."

16. BRITISH SCIENTISTS SOUNDS THE ALARM ON ALUMINUM TOXICITY AND QUESTIONS LACK OF RESEARCH ON ALUMINUM USED IN VACCINES

Human exposure to aluminium
Environmental Science Processes & Impacts, 2013, Christopher Exley

Summary: "The immunopotency of aluminium has been known for at least 100 years and still today forms the basis for the use of aluminium salts as adjuvants in vaccinations and allergy therapies. What is then surprising is the uncertainty regarding their mechanism of action and burgeoning evidence of their toxicity in potentially susceptible individuals."

17. ISRAELI, ITALIAN, AND CANADIAN RESEARCHERS TIE HPV VACCINE TO PRIMARY OVARIAN FAILURE

Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants
American Journal of Reproductive Immunology, 2013, Selena Colafrancesco, Carlo Perricone, Lucija Tomljenovic, Yehuda Shoenfeld

Summary: "We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry."

18. INFANTS WHO RECEIVED MORE VACCINES HAD MUCH HIGHER HOSPITALIZATION AND DEATH RATES THAN INFANTS WHO RECEIVED FEWER VACCINES

Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990-2010
Human and Experimental Toxicology, 2012, GS Goldman, NZ Miller

Summary: "The hospitalization rate increased linearly from 11.0% (107 of 969) for 2 doses to 23.5% (661 of 2817) for 8 doses and decreased linearly from 20.1% (154 of 765) for children aged < 0.1 year to 10.7% (86 of 801) for children aged 0.9 year. Our findings show a positive correlation between the number of vaccine doses administered and the percentage of hospitalizations and deaths. Since vaccines are given to millions of infants annually, it is imperative that health authorities have scientific data from synergistic toxicity studies on all combinations of vaccines that infants might receive. Finding ways to increase vaccine safety should be the highest priority."

19. ISRAELI SCIENTISTS EXPLAIN ROLE VACCINE ADJUVANTS (ALUMINUM) ARE PLAYING IN AUTOIMMUNE DISEASES

The spectrum of ASIA: 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants'
Lupus, 2012, N Agmon-Levin, GRV Hughes, Y Shoenfeld

Summary: "It seems that the role of adjuvants [aluminum in vaccines] in the pathogenesis of immune-mediated diseases can no longer be ignored, and the medical community must look towards producing safer adjuvants. Another cornerstone of ASIA is the complex interaction between autoimmunity and adjuvanted vaccines. On the one hand vaccines are beneficial for the vast majority of subjects including those who suffer from autoimmune-rheumatic diseases as delineated in this issue by van Assen and Bijl.16 On the other hand in a small minority of individuals vaccine can trigger the appearance of autoantibodies as documented by Vista et al.17 and Perdan-Pirkmajer et al.18 Moreover, a link between immunization and defined autoimmune diseases has been reported elsewhere and herein."

20. POLISH SCIENTISTS PROPOSE NEW VACCINE SCHEDULE, EXPRESS CONCERN AT HIGH RATE OF VACCINE ADVERSE EVENTS

Neurologic adverse events following vaccination
Prog Health Sci, 2012, Sienkiewicz D., Ku?ak W., Okurowska-Zawada B., Paszko-Patej G.

Summary: "Thus, it is not reasonable to assume that manipulation of the immune system through an increasing number of vaccinations during critical periods of brain development will not result in adverse neurodevelopmental outcomes. European countries have different models of vaccination that have been modified in recent decades. In Scandinavian countries, which have the lowest infant mortality, vaccinations are voluntary and infants receive their first vaccination at 3 months of age. In the first year of life, they receive 9 recommended vaccinations, and at 18 months - MMR. The acellular pertussis vaccine (DTaP) is used, as well as IPV. BCG and Hepatitis B vaccines are administered to children from high risk groups. Similar vaccination schedules exist in other European countries, where the vaccination of neonates was abandoned and a ban on the use of thimerosal in vaccines was introduced. Note also that Scandinavian countries have the lowest rates of autism compared to other developed countries in which children are vaccinated much earlier and with greater number of vaccines."

21. CANADIAN RESEARCHERS REVIEW LITERATURE ON AUTOIMMUNITY AND NEUROLOGICAL RISKS FROM VACCINE ADJUVANT ALUMINUM, EXPRESS DOUBTS REGARDING SAFETY TESTING

Mechanisms of aluminum adjuvant toxicity and autoimmunity in pediatric populations,
Lupus, 2012, L Tomljenovic, CA Shaw

Summary: "Immune challenges during early development, including those vaccine-induced, can lead to permanent detrimental alterations of the brain and immune function. Experimental evidence also shows that simultaneous administration of as little as two to three immune adjuvants can overcome genetic resistance to autoimmunity. In spite of the widespread agreement that vaccines are largely safe and serious adverse complications are extremely rare, a close scrutiny of the scientific literature does not support this view. For example, to date, the clinical trials that could adequately address vaccine safety issues have not been con- ducted (i.e., comparing health outcomes in vaccinated versus non-vaccinated children). Infants and young children should not be viewed as "small adults." Their unique physiology makes them much more vulnerable to noxious environ- mental insults in comparison with the adult population. In spite of this, children are routinely exposed to much higher levels of Al vaccine adjuvants than adults, even though adequate safety data on these compounds are lacking. That Al vaccine adjuvants can induce significant autoimmune conditions in humans can hardly be disputed, although still debatable is how common such side effects are. However, the existing data (or lack thereof) raise questions on whether the current vaccines aimed at pediatric populations can be accepted as having adequate safety profiles. Because infants and children represent those who may be most at risk for complications following vaccination, a more rigorous evaluation of potential vaccine-related adverse health impacts in pediatric populations than what has been provided to date is urgently needed."

22. DANISH RESEARCHERS FOUND CHILDREN 8-TIMES MORE LIKELY TO HAVE A FEBRILE SEIZURE ON THE DAY OF VACCINATION OF DTAP-IPV-HIB VACCINE

Risk of Febrile Seizures and Epilepsy After Vaccination With Diphtheria, Tetanus, Acellular Pertussis, Inactivated Poliovirus, and *Haemophilus Influenzae* Type b
JAMA 2012, Yuelian Sun, Jakob Christensen, Anders Hviid, Jiong Li

Summary: "DTaP-IPV-Hib vaccination was associated with an increased risk of febrile seizures on the day of the first 2 vaccinations given at 3 and 5 months."

23. HARVARD RESEARCHERS FIND VACCINE MERCURY IMPACTS NEURODEVELOPMENT IN RATS

Maternal Thimerosal Exposure Results in Aberrant Cerebellar Oxidative Stress, Thyroid Hormone Metabolism, and Motor Behavior in Rat Pups; Sex- and Strain-Dependent Effects
Cerebellum, 2012, Z. L. Sulkowski & T. Chen & S. Midha & A. M. Zavacki & Elizabeth M. Sajdel-Sulkowska

Summary: "Our data indicate that maternal TM exposure results in a delayed auditory maturation and impaired motor learning in rat pups. Factors that may contribute to these abnormalities include increased cerebellar oxidative stress and decreased D2 activity resulting local intracerebellar T3 deficiency and altered TH-dependent gene expression. Indeed, provided here is the first evidence of altered TH-dependent gene expression following TM exposure. Our data thus demonstrate a negative neurodevelopmental impact of perinatal TM exposure, which appears to be both strain- and sex-dependent. Although, additional studies are needed, data derived from TM exposure in rats may provide clues relevant to understanding neurodevelopmental consequences of TM exposure in humans.

24. SUNY-STONY BROOK SCIENTISTS FIND BOYS RECEIVING THE HEPATITIS B VACCINE SERIES WERE THREE TIMES MORE LIKELY TO HAVE AUTISM

Hepatitis B Vaccination of Male Neonates and Autism Diagnosis, NHIS 1997-2002
Journal of Toxicology and Environmental Health, April 2010, Carolyn Gallagher and Melody Goodman

Summary: "Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vac- cine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period."

25. BRITISH AND SWEDISH SCIENTISTS RAISE CONCERNS ABOUT LIMITED UNDERSTANDING OF VACCINE ALUMINUM'S IMPACT ON THE HUMAN BODY, RAISE RISK OF AUTOIMMUNE RESPONSE

The immunobiology of aluminium adjuvants: how do they really work?
Trends in Immunology 2010, Christopher Exley, Peter Siesjo, Hakan Eriksson

Summary: "Aluminium adjuvants potentiate the immune response, thereby ensuring the potency and efficacy of typically sparingly available antigen. Their concomitant critical importance in mass vaccination programmes may have prompted recent intense interest in understanding how they work and their safety. Progress in these areas is stymied, however, by a lack of accessible knowledge pertaining to the bioinorganic chemistry of aluminium adjuvants, and, consequently, the inappropriate application and interpretation of experimental models of their mode of action.. In relation to this possible 'indirect adjuvanticity' there are burgeoning examples in the scientific literature of aluminium salts inducing sen- sitization to substances that might not normally be considered as antigens. For example, such effects may contribute towards allergies to foods"

26. BABY MONKEYS GIVEN U.S. VACCINE SCHEDULE HAD BRAIN ABNORMALITIES IN REGION RESPONSIBLE FOR SOCIAL AND EMOTIONAL DEVELOPMENT

Influence of pediatric vaccines on amygdala growth and opioid ligand binding in rhesus macaque infants: A pilot study
Acta Neurobiol Exp, 2010, Laura Hewitson, Brian J. Lopresti, Carol Stott

Summary: "The data suggest that vaccine exposure may be associated with significant disturbances in central opioidergic pathways in this model... Volumetric analyses identified significantly greater total brain volume in exposed compared with unexposed animals at both measured time points. These results raise the possibility that multiple vaccine exposures during the previous 3-4 months may have had a significant impact on brain growth and development."

27. SCIENTISTS RAISE CONCERNS ABOUT DENIAL OF ENVIRONMENTAL TOXIN LINK TO AUTISM, REVIEW LIETRATURE

Sorting out the spinning of autism: heavy metals and the question of incidence
Acta Neurobiol, 2010 Mary Catherine DeSoto and Robert T. Hitlan

Summary: "In this paper, we argue that increasingly over the past decade, positions that deny a link to environmental toxins and autism are based on relatively weak science and are disregarding the bulk of scientific literature. The question about toxic exposure and autism is open, with the weight of evidence favoring a connection that is not well understood. Although it is not possible to say with certainty, it seems likely that the connection would be mediated by genetic susceptibility and ability to detoxify. That is, some people have genotypes that confer higher susceptibility to toxic exposures. If so, then 50 years ago few people would have had enough toxic exposure to have the neurological changes that result in autism."

28. RESEARCHERS WARN OF SIZABLE DIFFERENCE IN INDIVIDUAL REACTION TO VACCINES, STRESS NEED TO AVOID INCREASING SIDE EFFECTS OF VACCINES

Interindividual variations in the efficacy and toxicity of vaccines
Toxicology 2010, Thomas C, Moridani M

Summary: "A number of currently available vaccines have shown significant differences in the magnitude of immune responses and toxicity in individuals undergoing vaccination. A number of factors may be involved in the variations in immune responses, which include age, gender, race, amount and quality of the antigen, the dose administered and to some extent the route of administration, and genetics of immune system. Hence, it becomes imperative that researchers have tools such as genomics and proteomics at their disposal to predict which set of population is more likely to be non-responsive or develop toxicity to vaccines. With the increasing number of side effects associated with a number of vaccines reported over the years, it has become imperative to develop new technologies that can effectively assist in the development and evaluation of vaccines for efficacy and toxicity."

29. VACCINE ALUMINUM INJECTED INTO MICE CREATED SIGNIFICANT MOTOR DEFICITS AND MOTOR NEURON DEGENERATION

Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration
Journal of Inorg Biochem, February 2010, Christopher A. Shaw

Summary: "Aluminum-treated mice showed significantly increased apoptosis of motor neurons and increases in reactive astrocytes and microglial proliferation within the spinal cord and cortex. Morin stain detected the presence of aluminum in the cytoplasm of motor neurons with some neurons also testing positive for the presence of hyper-phosphorylated tau protein, a pathological hallmark of various neurological diseases, including Alzheimer's disease and frontotemporal dementia. A second series of experiments was conducted on mice injected with six doses of aluminum hydroxide. Behavioral analyses in these mice revealed significant impairments in a number of motor functions as well as diminished spatial memory capacity. The demonstrated neurotoxicity of aluminum hydroxide and its relative ubiquity as an adjuvant suggest that greater scrutiny by the scientific community is warranted. Overall, the results reported here mirror previous work that has clearly demonstrated that aluminum, in both oral and injected forms, can be neurotoxic."

30. NEWBORN MONKEYS GIVEN A MERCURY-CONTAINING HEPATITIS B VACCINE HAD SIGNIFICANT DELAYS IN NEONATAL REFLEXES AND NEUROLOGICAL DEVELOPMENT

Delayed acquisition of neonatal reflexes in newborn primates receiving a thimerosal-containing Hepatitis B vaccine: Influence of gestational age and birth weight
Neurotoxicology, Sep 2009 Laura Hewitson et. al.

Summary: "In summary, this study provides preliminary evidence of abnormal early neurodevelopmental responses in male infant rhesus macaques receiving a single dose of Th-containing HB vaccine at birth and indicates that further investigation is merited."

31. FRENCH SCIENTISTS REPORT ALUMINUM FROM VACCINES CAUSES CHRONIC COGNITIVE DYSFUNCTION

Long-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction
Journal of Inorganic Biochemistry, 2009, Couette M1, Boisse MF, Maison P, Brugieres P, Cesaro P, Chevalier X, Gherardi RK, Bachoud-Levi AC, Authier FJ.

Summary: "In conclusion, long-term persistence of vaccine-derived aluminum hydroxide within the body assessed by MMF is associated with cognitive dysfunction, not solely due to chronic pain, fatigue and depression. In conclusion, this work is the first firm demonstration that cognitive dysfunction is a central feature in MMF, this dysfunction being much more frequent and severe than suspected by routine neurological evaluation. Instead of being a non-specific bystander effect of pain, fatigue or depression, MACD seems to reflect an underlying organic, inflammatory or toxic, brain involvement."

32. SWEDISH RESEARCHERS FOUND THAT CHILDREN WHO HAD NATURAL MEASLES INFECTION HAD MUCH LOWER RATES OF ALLERGY THAN CHILDREN VACCINATED AGAINST MEASLES

Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection
Pediatrics 2009 Rosenlund H1, Bergstrom A, Alm JS, Swartz J, Scheynius A, van Hage M, Johansen K, Brunekreef B, von Mutius E, Ege MJ, Riedler J, Braun-Fahrlander C, Waser M, Pershagen G; PARSIFAL Study Group.

Summary: "However, in these analyses, measles infection [natural measles] was inversely associated with any allergic symptom or physician's diagnosis of allergy."

33. BOYS RECEIVING THE HEPATITIS B VACCINE SERIES WERE NINE TIMES FOR LIKELY TO NEED SPECIAL EDUCATION AND BE DEVELOPMENTALLY DISABLED

Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years
Toxicological and Environmental Chemistry, September 2008,?Carolyn Gallagher and Melody Goodman

Summary: "This study investigated the association between vaccination with the Hepatitis B triple series vaccine. The odds of receiving Special Education were approximately nine times as great for vaccinated boys (n 1/4 46) as for unvaccinated boys (n 1/4 7), after adjustment for confounders. This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, were more susceptible to developmental disability than were unvaccinated boys."

34. CHILDREN WHO DELAYED THE TIMING OF THE DPT VACCINE HAD LOWER RATES OF ASTHMA

Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma?
Journal of Allergy and Clinical Immunology, 2008, Kara L. McDonald, MS, Shamima I. Huq, BS

Summary: "Early childhood immunizations have been viewed as promoters of asthma development by stimulating a T(H)2-type immune response or decreasing microbial pressure, which shifts the balance between T(H)1 and T(H)2 immunity. Among 11, 531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months."

35. A CDC-SPONSORED DATABASE SHOWED MUCH HIGHER RATES OF NEURODEVELOPMENTAL DISABILITIES FROM MERCURY-CONTAINING VACCINES

Thimerosal exposure in infants and neurodevelopmental disorders: An assessment of computerized medical records in the Vaccine Safety Datalink
Journal of the Neurological Sciences, March 2008, Heather A. Young, David A. Geier, Mark R. Geier

Summary: "Consistent significantly increased rate ratios were observed for autism, autism spectrum disorders, tics, attention deficit disorder, and emotional disturbances with Hg exposure from TCVs. By contrast, none of the control outcomes had significantly increased rate ratios with Hg exposure from TCVs."

36. AUSTRALIAN SCIENTISTS DESCRIBE THE ROLE OF VACCINES IN TRIGGERING ACUTE DISSEMINATED ENCEPHALOMYELITIS ("ADEM")

Post-vaccination encephalomyelitis: Literature review and illustrative case
Journal of Clinical Neuroscience, 2008, Huynh W1, Cordato DJ, Kehdi E, Masters LT, Dedousis C.

Summary: "Post-infectious and post-immunisation encephalomyelitis make up about three-quarters of cases, where the timing of a febrile event is associated with the onset of neurological disease..Post-vaccination Acute disseminated encephalomyelitis has been associated with several vaccines such as rabies, diphtheria-tetanus-polio, smallpox, measles, mumps, rubella, Japanese B encephalitis, pertussis, influenza, hepatitis B, and the Hog vaccine. We review ADEM with particular emphasis on vaccination as the precipitating factor."

37. THE MERCURY USED AS A VACCINE PRESERVATIVE IS FAR MORE NEUROTOXIC THAN THE MERCURY FOUND IN FISH

Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal
Environmental Health Perspectives, August 2005, Thomas M. Burbacher, Danny D. Shen, Noelle Liberato, Kimberly S. Grant, Elsa Cernichiari, and Thomas Clarkson

Summary: The mercury used in vaccines (and still in the flu vaccine given to pregnant women) is far more toxic than the mercury found in fish, because it stays in the brain at much higher levels. "Data from the present study support the prediction that, although little accumulation of Hg in the blood occurs over time with repeated vaccinations, accumulation of Hg in the brain of infants will occur. Thus, conclusion regarding the safety of thimerosal drawn from blood Hg clearance data in human infants receiving vaccines may not be valid, given the significantly slower half-life of Hg in the brain as observed in the infant macaques. There was a much higher proportion of inorganic Hg in the brain of thimerosal monkeys than in the brains of MeHg monkeys (up to 71% vs. 10%). Absolute inorganic Hg concentrations in the brains of the thimerosal-exposed monkeys were approximately twice that of the MeHg monkeys."

38. VACCINE MERCURY DEPLETES A VITAL ANTIOXIDANT, GLUTATHIONE

Thimerosal Neurotoxicity is Associated with Glutathione Depletion: Protection with Glutathione Precursors
Neurotoxicology, Jan 2005, S. Jill James, PhD

Summary: "Thimerosal is an antiseptic containing 49.5% ethyl mercury that has been used for years as a preservative in many infant vaccines and in flu vaccines. Environmental methyl mercury has been shown to be highly neurotoxic, especially to the developing brain. Because mercury has a high affinity for thiol (sulfhydryl (-SH)) groups, the thiol-containing antioxidant, glutathione (GSH), provides the major intracellular defense against mercury-induced neurotoxicity. Cultured neuroblastoma cells were found to have lower levels of GSH and increased sensitivity to thimerosal toxicity compared to glioblastoma cells that have higher basal levels of intracellular GSH. Thimerosal-induced cytotoxicity was associated with depletion of intracellular GSH in both cell lines. Although Thimerosal has been recently removed from most children's vaccines, it is still present in flu vaccines given to pregnant women, the elderly, and to children in developing countries."

39. SCIENTISTS IDENTIFY VACCINE MERCURY'S ROLE IN BLOCKING CRUCIAL NEURODEVELOPMENTAL PATHWAYS

Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal
Molecular Psychiatry, 2004, M Waly, H Oltaneu, R Banerjee, S-W Choi, JB Mason, BS Parker, S Sukumar, S Shim, A Sharma

Summary: "The ethylmercury-containing preservative thimerosal inhibited both IGF-1- and dopamine-stimulated methylation with an IC50 of 1nM and eliminated MS activity. Our findings outline a novel growth factor signaling pathway that regulates MS activity and thereby modulates methylation reactions, including DNA methylation. The potent inhibition of this pathway by ethanol, lead, mercury, aluminum and thimerosal suggest that it may be an important target of neurodevelopmental toxins."

40. UTAH STATE SCIENTISTS FIND AUTOIMMUNE REACTION TO MMR IN CHILDREN WITH AUTISM, INCLUDING AUTOIMMUNITY TO MYELIN BASIC PROTEIN, A BRAIN BUILDING-BLOCK

Abnormal Measles-Mumps-Rubella Antibodies and CNS Autoimmunity in Children with Autism

J Biomed Sci, 2002, Vijendra K. Singh Sheren X. Lin Elizabeth Newell Courtney Nelson

Abstract
Autoimmunity to the central nervous system (CNS), especially to myelin basic protein (MBP), may play a causal role in autism, a neurodevelopmental disorder. Because many autistic children harbor elevated levels of measles antibodies, we conducted a serological study of measles-mumps-rubella (MMR) and MBP autoantibodies. Using serum samples of 125 autistic children and 92 control children, antibodies were assayed by ELISA or immunoblotting methods. ELISA analysis showed a significant increase in the level of MMR antibodies in autistic children. Immunoblotting analysis revealed the presence of an unusual MMR antibody in 75 of 125 (60%) autistic sera but not in control sera. This antibody specifically detected a protein of 73-75 kD of MMR. This protein band, as analyzed with monoclonal antibodies, was immunopositive for measles hemagglutinin (HA) protein but not for measles nucleoprotein and rubella or mumps viral proteins. Thus the MMR antibody in autistic sera detected measles HA protein, which is unique to the measles subunit of the vaccine. Furthermore, over 90% of MMR antibody-positive autistic sera were also positive for MBP autoantibodies, suggesting a strong association between MMR and CNS autoimmunity in autism. Stemming from this evidence, we suggest that an inappropriate antibody response to MMR, specifically the measles component thereof, might be related to pathogenesis of autism.

41. FRENCH SCIENTISTS TIE ALUMINUM ADJUVANT IN VACCINE TO MACROPHAGIC MYOFASCIITIS

Macrophagic myofasciitis lesions assess long-term persistence of vaccine derived aluminum hydroxide in muscle

Brain, 2001 R.K. Gherardi, M. Coquet, P. Cherin, L. Belec, P. Moretto, P.A. Dreyfus

Summary: "Macrophagic myofasciitis (MMF) is an emerging condition of unknown cause, detected in patients with diffuse arthromyalgias and fatigue, and characterized by muscle infiltration by granular periodic acid-Schiff's reagent-positive macrophages and lymphocytes. Intracytoplasmic inclusions have been observed in macrophages of some patients. To assess their significance, electron microscopy was performed in 40 consecutive cases and chemical analysis was done by microanalysis and atomic absorption spectrometry. Inclusions were constantly detected and corresponded to aluminium hydroxide, an immunostimulatory compound frequently used as a vaccine adjuvant."

42. JAPANESE SCIENTISTS FIND VACCINE-STRAIN OF MEASLES IN THE GUTS OF CHILDREN WITH AUTISM

Detection and Sequencing of Measles Virus from Peripheral Mononuclear Cells from Patients with Inflammatory Bowel Disease and Autism
Digestive Diseases and Sciences, 2000, Hisashi Kawashima, Takayuki Mori, Yasuyo Kashiwagi, Kouji Takekuma

Summary: "Additionally, a new syndrome has been reported in children with autism who exhibited developmental regression and gastrointestinal symptoms (autistic enterocolitis), in some cases soon after MMR vaccine. The sequences obtained from the patients with ulcerative colitis and children with autism were consistent with being vaccine strains. The results were concordant with the exposure history of the patients. Persistence of measles virus was confirmed in PBMC in some patients with chronic intestinal inflammation."

43. CDC SCIENTISTS ADMIT THAT 90% OF INFECTIOUS DISEASE MORTALITY DECREASE IN THE UNITED STATES HAPPENED BEFORE VACCINES WERE AVAILABLE

Annual Summary of Vital Statistics: Trends in the Health of Americans During the 20th Century,
Pediatrics, December 2000, Bernard Guyer, MD, Mary Anne Freeman, MA, Donna M. Strobino, PhD, Edward J. Sondik, PhD

Summary: "Thus vaccination does not account for the impressive declines in mortality seen in the first half of the century...nearly 90% of the decline in infectious disease mortality among US children occurred before 1940, when few antibiotics or vaccine were available."

44. VACCINES WITH MERCURY SIGNIFICANTLY RAISED THE BODY LEVELS OF MERCURY IN INFANTS

Iatrogenic exposure to mercury after hepatitis B vaccination in preterm infants
The Journal of Pediatrics, May 2000, Gregory V. Stajich, PharmD, Gaylord P. Lopez, PharmD, ABAT, Sokei W. Harry, MBBS, MPH, William R. Sexson, MD

Summary: "Thimerosal, a derivative of mercury, is used as a preservative in hepatitis B vaccines. We measured total mercury levels before and after the administration of this vaccine in 15 preterm and 5 term infants. Comparison of pre- and post-vaccination mercury levels showed a significant increase in both preterm and term infants after vaccination. Additionally, post-vaccination mercury levels were significantly higher in preterm infants as compared with term infants. Because mercury is known to be a potential neurotoxin to infants, further study of its pharmacodynamics is warranted."

45. UCLA RESEARCHERS FIND THE DTP VACCINE IS CAUSING ASTHMA

Effects of Diphtheria-Tetanus-Pertussis or Tetanus Vaccination on Allergies and Allergy-Related Respiratory Symptoms Among Children and Adolescents in the United States
Journal of Manipulative and Physiological Therapeutics, 2000, Eric Hurwitz and Hal Morgenstern

Summary: "Asthma and other allergic hypersensitivity reactions and related symptoms may be caused, in part, by the delayed effects of DTP or tetanus vaccination. Because the proportion of US children who have received at least 1 dose of DTP vaccine approaches 100%, the number of allergies and allergy-related conditions attributable to DTP or tetanus vaccination in the United States may be very high. For example, assuming that the estimated vaccination effect is unbiased, 50% of diagnosed asthma cases (2.93 million) in US children and adolescents would be prevented if the DTP or tetanus vaccination was not administered."

46. INFANTS RECEIVING MERCURY-CONTAINING VACCINES DEVELOPED SPEECH DISORDERS, SLEEP DISORDERS, AND AUTISM, ACCORDING TO CDC SCIENTISTS

Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.
Proceedings of the Epidemic Intelligence Service Annual Conference, April 2000, Verstraeten T, Davis RL, Gu D, DeStefano F.

Summary: "This analysis suggests that high exposure to ethylmercury from thimerosal-containing vaccines in the first month of life increases the risk of subsequent development of neurologic development impairment."

47. INFECTIOUS DISEASE RATES DECLINED PRECIPITOUSLY IN THE UNITED STATES IN THE 20TH CENTURY BEFORE THE IMPLEMENTATION OF A NATIONAL VACCINE PROGRAM

Trends in Infectious Disease Mortality in the United States During the 20th Century
JAMA, January 6, 1999, Gregory L. Armstrong, MD, Laura A. Conn, MPH, Robert W. Pinner, MD

Summary: "During the first 8 decades of the 20th century, the infectious disease mortality rate in the United States declined substantially...Improvements in living conditions, sanitation, and medical care probably accounted for this trend."

48. CDC SCIENTISTS FIND CHILDREN GIVEN THE MMR VACCINE SHED THE MEASLES VIRUS FOR AT LEAST 2 WEEKS AFTER GETTING THE VACCINE, MAKING THEM VECTORS TO SPREAD MEASLES

Detection of Measles Virus RNA in Urine Specimens from Vaccine Recipients,
Journal of Clinical Microbiology, Sept 1995, Paul A. Rota, Ali S. Khan, Edison Durigon, Thomas Yuron, and William Bellini

Summary: "For the study, daily urine samples were obtained from either 15-month-old children or young adults following measles immunization. Overall, measles virus RNA was detected in 10 of 12 children during the 2-week sampling period. In some cases, measles virus RNA was detected as early as 1 day or as late as 14 days after vaccination. Measles virus RNA was also detected in the urine samples from all four of the young adults between 1 and 13 days after vaccination. This assay will enable continued studies of the shedding and transmission of measles virus and, it is hoped, will provide a rapid means to identify measles infection, especially in mild or asymptomatic cases."

1-48 Source: http://vaccinesafetycommission.org/

49. ” ‘ASIA’ – AUTOIMMUNE/INFLAMMATORY SYNDROME INDUCED BY ADJUVANTS “

In 2011 a groundbreaking scientific study directly linked the effect of vaccine adjuvants to a range of autoimmune diseases for the first time ever. Defining a new disease syndrome directly connected to the use of vaccine adjuvants encouraged further research by other scientist who have examined and confirmed the correlations in multiple cases.

http://www.sciencedirect.com/science/article/pii/S0896841110000788

50. ALUMINUM’S ROLE IN CNS-IMMUNE SYSTEM INTERACTIONS LEADING TO NEUROLOGICAL DISORDERS

Another study, carried out by scientist from University of British Columbia in 2013, presents a large framework of information and data that links aluminum vaccine adjuvants to various neurological disorders. The scientists have linked aluminum’s potential to induce damage at different levels in the Central Nervous System leading to neuronal death, circuit malfunction and ultimately system failure.

http://people.csail.mit.edu/seneff/Shaw_et_al_Immunome_Res_2013.pdf

51. ALUMINUM AS AN ADJUVANT IN CROHN'S DISEASE INDUCTION

As the title of this study suggest, this study highlights the potential role of aluminum adjuvant to the induction of Crohn's disease. Crohn's disease is a type of inflammatory bowel disease (IBD), which seems to be on an almost epidemic rise in our society today.

https://www.ncbi.nlm.nih.gov/pubmed/22235058

52. ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH VACCINES CONTAINING ADJUVANTS

In a cross-sectional study carried at the Rheumatology and Immunology Department in a hospital associated with the University of Guadalajara in Mexico, 120 immunized patients were closely monitored to identify the frequencies of post-vaccination clinical syndromes such as autoimmune/inflammatory adverse events that may be induced by adjuvants. The result of the study show data on how vaccines containing adjuvants indeed can bring an increased risk of autoimmune/inflammatory adverse effects.

https://www.ncbi.nlm.nih.gov/pubmed/23576057

53. ALUMINUM HYDROXIDE INJECTIONS LEAD TO MOTOR DEFICITS AND MOTOR NEURON DEGENERATION

In this study scientists show that aluminum hydroxide injections lead to neuron degeneration causing various motor deficits just as the title of the study concludes.

http://www.sciencedirect.com/science/article/pii/S0162013409001809

54. ALUMINUM VACCINE ADJUVANTS: ARE THEY SAFE?

In yet another study carried out by Neural Dynamics Research Group at the Department of Ophthalmology and Visual Sciences in the University of British Columbia, scientists strongly question the widely accepted notion that aluminum in vaccines are safe. They present experimental research that clearly shows how aluminum adjuvants have a potential to induce serious immunological disorders in humans such as autoimmunity, long-term brain inflammation and further severe neurological complications.
https://www.ncbi.nlm.nih.gov/pubmed/21568886

55. BIOPERSISTENCE AND SYSTEMIC DISTRIBUTION OF INTRAMUSCULARLY INJECTED PARTICLES: WHAT IMPACT ON LONG-TERM TOLERABILITY OF ALUM ADJUVANTS?

Research carried out by french scientists link the use of aluminum adjuvants to; diffuse myalgia, chronic exhaustion and cognitive dysfunction. Unfortunately though, the full text article is still only available in French.

https://www.ncbi.nlm.nih.gov/pubmed/26259285

56. HUMAN PAPILLOMA VIRUS VACCINE AND PRIMARY OVARIAN FAILURE: ANOTHER FACET OF THE AUTOIMMUNE/INFLAMMATORY SYNDROME INDUCED BY ADJUVANTS.

In a study published in American Journal of Reproductive Immunology, evidence is presented that the HPV vaccine has the potential to trigger a life-disabling autoimmune conditions such as ovarian failure.

https://www.ncbi.nlm.nih.gov/pubmed/23902317

57. ALUMINUM IN THE CENTRAL NERVOUS SYSTEM (CNS): TOXICITY IN HUMANS AND ANIMALS, VACCINE ADJUVANTS, AND AUTOIMMUNITY

This study examines the neurotoxicity of aluminum in humans and animals under various conditions. The study highlights that aluminum exposure in adults can lead to to age-related neurological deficits resembling Alzheimer's disease. And in young children, a highly significant correlation seems to exists between the number of aluminum-adjuvanted vaccines and the rate of autism spectrum disorders (ASD's).

https://www.ncbi.nlm.nih.gov/pubmed/23609067

58. MERCURY NEUROTOXICITY: MECHANISMS OF BLOOD-BRAIN BARRIER TRANSPORT

A scientific study published in a peer reviewed journal named Neuroscience & Biobehavioral, shows how methylmercury (MeHg) is capable of inducing damage in the Central Nervous System (CNS) through migration into the brain by crossing the blood brain barrier. MeHg is the same form of mercury that occurs in the preservative Thiomersal.

https://www.ncbi.nlm.nih.gov/pubmed/2190116

59. DO ALUMINUM VACCINE ADJUVANTS CONTRIBUTE TO THE RISING PREVALENCE OF AUTISM?

As the title of this scientific study suggests, it is exploring if vaccine adjuvants may have a direct role in the increasing occurrence of Autism Spectrum Disorders (ASD's) among the general public. The results show that children from countries with the highest ASD prevalence appear to have the highest exposure to aluminum from vaccines. The increase in exposure to aluminum adjuvants significantly correlates with the increase in ASD prevalence in the United States observed over the last two decades. Also a significant correlation exists between the amounts of aluminum administered to preschool children and the current prevalence of ASD in seven western countries, particularly at 3-4 months of age. The results show that there may be a correlation between aluminum in vaccines and rise of ASD.

https://www.ncbi.nlm.nih.gov/pubmed/22099159

60. ARE THERE NEGATIVE CNS IMPACTS OF ALUMINUM ADJUVANTS USED IN VACCINES AND IMMUNOTHERAPY

This study reviews existing literature on aluminum neurotoxicity and questions the use of aluminum salts as vaccine adjuvants because it concludes that aluminum not only has a direct toxic effect on the nervous system, but also a potential ability to impact & trigger autoimmunity. The scientists raise concerns about the increasing use of aluminum salts as vaccine adjuvants because of its ability to trigger autoimmune & inflammatory responses, change gene expression and affect the Central Nervous System (CNS) at every level.

https://www.ncbi.nlm.nih.gov/pubmed/25428645

49-60 Source: http://iterated-reality.com/en/2017/03/11/13-alarming-scientific-studies-about-vaccine-adjuvants-and-preservatives/

61. Unanswered Questions: A Review of Compensated Cases of Vaccine-Induced Brain Injury

Pace Environmental Law Review, vol. 28, no. 2, 2011
Mary Holland, Louis Conte, Robert Krakow and Lisa Colin

Executive Summary

In 1986, Congress created the Vaccine Injury Compensation Program (VICP) under the National Childhood Vaccine Injury Act (1986 Law). This Program has original jurisdiction for children's claims of vaccine injury. Because almost all children receive multiple vaccinations for daycare and school, it is critically important that the Program provides fundamental fairness, due process and transparency.

This empirical investigation, published in a peer-reviewed law journal, examines claims that the VICP compensated for vaccine-induced encephalopathy and seizure disorder. The VICP has compensated approximately 2,500 claims of vaccine injury since the inception of the program. **This study found 83 cases of acknowledged vaccine-induced brain damage that include autism**, a disorder that affects speech, social communication and behavior. In 21 published cases of the Court of Federal Claims, which administers the VICP, the Court stated that the petitioners had autism or described autism unambiguously. In 62 remaining cases, the authors identified settlement agreements where Health and Human Services (HHS) compensated children with vaccine-induced brain damage, who also have autism or an autism spectrum disorder.

Parents reported the existence of autism in telephone interviews and supplied supplemental materials including medical diagnoses, school records, and completed, standard autism screening questionnaires to verify their reports. In 39 of the 83 cases, or 47% of the cases of vaccine injury reviewed, there is confirmation of autism or autism spectrum disorder beyond parental report. This finding of autism in compensated cases of vaccine injury is significant. U.S. government spokespeople have been asserting no vaccine-autism link for more than a decade. This finding calls into question the decisions of the Court of Federal Claims in the Omnibus Autism Proceeding in 2009 and 2010 and the statement of Health and Human Services on its website that "HHS has never concluded in any case that autism was caused by vaccination."

http://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pelr

62. Infection, vaccines and other environmental triggers of autoimmunity.

Autoimmunity. 2005 May;38(3):235-45.

Abstract

The etiology of autoimmune diseases is still not clear but genetic, immunological, hormonal and environmental factors are considered to be important triggers. Most often autoimmunity is not followed by clinical symptoms unless an additional event such as an environmental factor favors an overt expression. Many environmental factors are known to affect the immune system and may play a role as triggers of the autoimmune mosaic. Infections: bacterial, viral and parasitic infections are known to induce and exacerbate autoimmune diseases, mainly by the mechanism of molecular mimicry. This was studied for some syndromes as for the association between SLE and EBV infection, pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection and more. Vaccines, in several reports were found to be temporally followed by a new onset of autoimmune diseases. The same mechanisms that act in infectious invasion of the host, apply equally to the host response to vaccination. It has been accepted for diphtheria and tetanus toxoid, polio and measles vaccines and GBS. Also this theory has been accepted for MMR vaccination and development of autoimmune thrombocytopenia, MS has been associated with HBV vaccination. Occupational and other chemical exposures are considered as triggers for autoimmunity. A debate still exists about the role of silicone implants in induction of scleroderma like disease. Not only foreign chemicals and agents have been associated with induction of autoimmunity, but also an intrinsic hormonal exposure, such as estrogens. This might explain the sexual dimorphism in autoimmunity. Better understanding of these environmental risk factors will likely lead to explanation of the mechanisms of onset and progression of autoimmune diseases and may lead to effective preventive involvement in specific high-risk groups. So by diagnosing a new patient with autoimmune disease a wide anamnes is work should be done.
https://www.ncbi.nlm.nih.gov/pubmed/16126512

63. Aluminum-Induced Entropy in Biological Systems: Implications for Neurological Disease

Journal of Toxicology, Volume 2014 (2014), Article ID 491316, 27 pages

Aluminum (Al) is invariably toxic to living systems and has no known beneficial role in any biological systems. Humans are increasingly exposed to Al from food, water, medicinals, vaccines, and cosmetics, as well as from industrial occupational exposure. Al disrupts biological self-ordering, energy transduction, and signaling systems, thus increasing biosemiotic entropy. Beginning with the biophysics of water, disruption progresses through the macromolecules that are crucial to living processes (DNAs, RNAs, proteoglycans, and proteins). It injures cells, circuits, and subsystems and can cause catastrophic failures ending in death. Al forms toxic complexes with other elements, such as fluorine, and interacts negatively with mercury, lead, and glyphosate. Al negatively impacts the central nervous system in all species that have been studied, including humans. Because of the global impacts of Al on water dynamics and biosemiotic systems, CNS disorders in humans are sensitive indicators of the Al toxicants to which we are being exposed.

Exerpts: "Animal models of neurological disease plainly suggest that the ubiquitous presence of Al in human beings implicates Al toxicants as causally involved in Lou Gehrig’s disease (ALS), Alzheimer’s disease and autism spectrum disorders.""All these findings plausibly implicate Al adjuvants in pediatric vaccines as causal factors contributing to increased rates of autism spectrum disorders in countries where multiple doses are almost universally administered."

https://www.hindawi.com/journals/jt/2014/491316/

64. Hepatitis B vaccination of male neonates and autism diagnosis, NHIS 1997-2002

J Toxicol Environ Health A. 2010;73(24):1665-77. doi: 10.1080/15287394.2010.519317.

Abstract
Universal hepatitis B vaccination was recommended for U.S. newborns in 1991; however, safety findings are mixed. The association between hepatitis B vaccination of male neonates and parental report of autism diagnosis was determined. This cross-sectional study used weighted probability samples obtained from National Health Interview Survey 1997-2002 data sets. Vaccination status was determined from the vaccination record. Logistic regression was used to estimate the odds for autism diagnosis associated with neonatal hepatitis B vaccination among boys age 3-17 years, born before 1999, adjusted for race, maternal education, and two-parent household.**Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life.** Non-Hispanic white boys were 64% less likely to have autism diagnosis relative to nonwhite boys. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk.

http://www.ncbi.nlm.nih.gov/m/pubmed/21058170/

65. Associations of prenatal and early childhood mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's Environmental Health (MOCEH) study

Science of The Total Environment
Volumes 605–606, 15 December 2017, Pages 251-257

We found that blood mercury levels at late pregnancy and early childhood were associated with more autistic behaviors in children at 5 years of age**.** Further study on the long-term effects of mercury exposure is recommended.
http://www.sciencedirect.com/science/article/pii/S0048969717316479

66. Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum Disorder.

Biol Trace Elem Res. 2017 May 8. doi: 10.1007/s12011-017-1002-6.

Abstract
Environmental factors have been implicated in the etiology of autism spectrum disorder (ASD); however, the role of heavy metals has not been fully defined. This study investigated whether blood levels of mercury, arsenic, cadmium, and lead of children with ASD significantly differ from those of age- and sex-matched controls. One hundred eighty unrelated children with ASD and 184 healthy controls were recruited. **Data showed that the children with ASD had significantly ($p < 0.001$) higher levels of mercury and arsenic** and a lower level of cadmium. The levels of lead did not differ significantly between the groups. **The results of this study are consistent with numerous previous studies, supporting an important role for heavy metal exposure, particularly mercury, in the etiology of ASD.**It is desirable to continue future research into the relationship between ASD and heavy metal exposure.

https://www.ncbi.nlm.nih.gov/pubmed/28480499

67. Slow CCL2-dependent translocation of biopersistent particles from muscle to brain

BMC Medicine 2013, 11:99 doi:10.1186/1741-7015-11-99, 4 April 2013

Abstract

Background: Long-term biodistribution of nanomaterials used in medicine is largely unknown. This is the case for alum, the most widely used vaccine adjuvant, which is a nanocrystalline compound spontaneously forming micron/submicron-sized agglomerates. Although generally well tolerated, alum is occasionally detected within monocyte-lineage cells long after immunization in presumably susceptible individuals with systemic/neurologic manifestations or autoimmune (inflammatory) syndrome induced by adjuvants (ASIA).

Results: Intramuscular injection of alum-containing vaccine was associated with the appearance of aluminum deposits in distant organs, such as spleen and brain where they were still detected one year after injection. Both fluorescent materials injected into muscle translocated to draining lymph nodes (DLNs) and thereafter were detected associated with phagocytes in blood and spleen. Particles linearly accumulated in the brain up to the six-month endpoint; they were first found in perivascular CD11b+ cells and then in microglia and other neural cells. DLN ablation dramatically reduced the biodistribution. Cerebral translocation was not observed after direct intravenous injection, but significantly increased in mice with chronically altered blood-brain-barrier. Loss/gain-of-function experiments consistently implicated CCL2 in systemic diffusion of Al-Rho particles captured by monocyte-lineage cells and in their subsequent neurodelivery. Stereotactic particle injection pointed out brain retention as a factor of progressive particle accumulation.

Conclusion: Nanomaterials can be transported by monocyte-lineage cells to DLNs, blood and spleen, and, similarly to HIV, may use CCL2-dependent mechanisms to penetrate the brain. This occurs at a very low rate in normal conditions explaining good overall tolerance of alum despite its strong neurotoxic potential. However, continuously escalating doses of this poorly biodegradable adjuvant in the population may become insidiously unsafe, especially in the case of overimmunization or immature/altered blood brain barrier or high constitutive CCL-2 production.

http://www.biomedcentral.com/1741-7015/11/99

68. Autism: a form of lead and mercury toxicity

Environ Toxicol Pharmacol. 2014 Nov;38(3):1016-24. doi: 10.1016/j.etap.2014.10.005. Epub 2014 Nov 6.

Abstract

AIM: Autism is a developmental disability characterized by severe deficits in social interaction and communication. The definite cause of autism is still unknown. The aim of this study is to find out the relation between exposure to Lead and/or mercury as heavy metals and autistic symptoms, dealing with the heavy metals with chelating agents can improve the autistic symptoms.

METHOD: Blood and hair samples were obtained from 45 children from Upper Egypt with autism between the ages of 2 and 10 years and 45 children served as controls in the same age range, after taken an informed consent and fill a questionnaire to assess the risk factors. The samples were analyzed blindly for lead and mercury by using atomic absorption and ICP-MS. Data from the two groups were compared, then follow up of the autistic children after treatment with chelating agents were done.

RESULTS: The results obtained showed significant difference among the two groups, there was high level of mercury and lead among those kids with autism. Significant decline in the blood level of lead and mercury with the use of DMSA as a chelating agent. In addition, there was decline in the autistic symptoms with the decrease in the lead and mercury level in blood.

CONCLUSION: Lead and mercury considered as one of the main causes of autism. Environmental exposure as well as defect in heavy metal metabolism is responsible for the high level of heavy metals. Detoxification by chelating agents had great role in improvement of those kids.

http://www.sciencedirect.com/science/article/pii/S1382668914002415

69. Administration of aluminium to neonatal mice in vaccine-relevant amounts is associated with adverse long term neurological outcomes.

J Inorg Biochem. 2013 Nov;128:237-44. doi: 10.1016/j.jinorgbio.2013.07.022. Epub 2013 Jul 19.

Our previous ecological studies of autism spectrum disorder (ASD) has demonstrated a correlation between increasing ASD rates and aluminium (Al) adjuvants in common use in paediatric vaccines in several Western countries. The correlation between ASD rate and Al adjuvant amounts appears to be dose-dependent and satisfies 8 of 9 Hill criteria for causality. We have now sought to provide an animal model to explore potential behavioural phenotypes and central nervous system (CNS) alterations using s.c. injections of Al hydroxide in early postnatal CD-1 mice of both sexes. Injections of a "high" and "low" Al adjuvant levels were designed to correlate to either the U.S. or Scandinavian paediatric vaccine schedules vs. control saline-injected mice. Both male and female mice in the "high Al" group showed significant weight gains following treatment up to sacrifice at 6 months of age. Male mice in the "high Al" group showed significant changes in light-dark box tests and in various measures of behaviour in an open field. Female mice showed significant changes in the light-dark box at both doses, but no significant changes in open field behaviours. These current data implicate Al injected in early postnatal life in some CNS alterations that may be relevant for a better understanding of the aetiology of ASD.

Repetitive administration of aluminium to neonatal mice in amounts comparable to those to children receive via routine vaccinations significantly increases anxiety and reduces exploratory behaviour and locomotor activities. The neurodisruptive effects of aluminium are long-lasting and persist for 6 months following injection.

http://www.sciencedirect.com/science/article/pii/S0162013413001773

70. A comparison of temporal trends in United States autism prevalence to trends in suspected environmental factors

Environ Health. 2014; 13: 73.

Results: The CDDS and IDEA data sets are qualitatively consistent in suggesting a strong increase in autism prevalence over recent decades. The quantitative comparison of IDEA snapshot and constant-age tracking trend slopes suggests that ~75-80% of the tracked increase in autism since 1988 is due to an actual increase in the disorder rather than to changing diagnostic criteria. Most of the suspected environmental toxins examined have flat or decreasing temporal trends that correlate poorly to the rise in autism. Some, including lead, organochlorine pesticides and vehicular emissions, have strongly decreasing trends. Among the suspected toxins surveyed, polybrominated diphenyl ethers, aluminum adjuvants, and the herbicide glyphosate have increasing trends that correlate positively to the rise in autism**.**

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4177682/

71. Toxic Metals and Essential Elements in Hair and Severity of Symptoms among Children with Autism

Maedica (Buchar). 2012 Jan; 7(1): 38–48.

Conclusion: Our data supports the historic evidence that heavy metals play a role in the development of ASD. In combination with an inadequate nutritional status the toxic effect of metals increase along with the severity of symptoms.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3484795/

72. Abnormal measles-mumps-rubella antibodies and CNS autoimmunity in children with autism.

J Biomed Sci. 2002 Jul-Aug;9(4):359-64.

Abstract

Autoimmunity to the central nervous system (CNS), especially to myelin basic protein (MBP), may play a causal role in autism, a neurodevelopmental disorder. Because many autistic children harbor elevated levels of measles antibodies, we conducted a serological study of measles-mumps-rubella (MMR) and MBP autoantibodies. Using serum samples of 125 autistic children and 92 control children, antibodies were assayed by ELISA or immunoblotting methods. ELISA analysis showed a significant increase in the level of MMR antibodies in autistic children. Immunoblotting analysis revealed the presence of an unusual MMR antibody in 75 of 125 (60%) autistic sera but not in control sera. This antibody specifically detected a protein of 73-75 kD of MMR. This protein band, as analyzed with monoclonal antibodies, was immunopositive for measles hemagglutinin (HA) protein but not for measles nucleoprotein and rubella or mumps viral proteins. Thus the MMR antibody in autistic sera detected measles HA protein, which is unique to the measles subunit of the vaccine. Furthermore, over 90% of MMR antibody-positive autistic sera were also positive for MBP autoantibodies, suggesting a strong association between MMR and CNS autoimmunity in autism. Stemming from this evidence, we suggest that an inappropriate antibody response to MMR, specifically the measles component thereof, might be related to pathogenesis of autism.

https://www.ncbi.nlm.nih.gov/pubmed/12145534

73. Impact of environmental factors on the prevalence of autistic disorder after 1979

Journal of Public Health and Epidemiology, Vol.6(9), pp. 271-284, September 2014. Theresa A. Deisher, Ngoc V. Doan, Angelica Omaiye, Kumiko Koyama, Sarah Bwabye

Abstract

The aim of this study was to investigate a previously overlooked, universally introduced environmental factor, fetal and retroviral contaminants in childhood vaccines, absent prior to change points (CPs) in autistic disorder (AD) prevalence with subsequent dose-effect evidence and known pathologic mechanisms of action. Worldwide population based cohort study was used for the design of this study. The United States, Western Australia, United Kingdom and Denmark settings were used. All live born infants who later developed autistic disorder delivered after 1 January 1970, whose redacted vaccination and autistic disorder diagnosis information is publicly available in databases maintained by the US Federal Government, Western Australia, UK, and Denmark. The live births, grouped by father's age, were from the US and Australia. The children vaccinated with MMRII, Varicella and Hepatitis A vaccines varied from 19 to 35 months of age at the time of vaccination. Autistic disorder birth year change points were identified as 1980.9, 1988.4 and 1996 for the US, 1987 for UK, 1990.4 for Western Australia, and 1987.5 for Denmark. Change points in these countries corresponded to introduction of or increased doses of human fetal cell line-manufactured vaccines, while no relationship was found between paternal age or Diagnostic and Statistical Manual (DSM) revisions and autistic disorder diagnosis. Further, linear regression revealed that Varicella and Hepatitis A immunization coverage was significantly correlated to autistic disorder cases. R software was used to calculate change points. Autistic disorder change points years are coincident with introduction of vaccines manufactured using human fetal cell lines, containing fetal and retroviral contaminants, into childhood vaccine regimens. This pattern was repeated in the US, UK, Western Australia and Denmark. Thus, rising autistic disorder prevalence is directly related to vaccines manufactured utilizing human fetal cells. Increased paternal age and DSM revisions were not related to rising autistic disorder prevalence.

http://www.academicjournals.org/journal/JPHE/article-abstract/C98151247042

74. A Positive Association found between Autism Prevalence and Childhood Vaccination uptake across the U.S. Population

Journal of Toxicology and Environmental Health, Part A: Current Issues Volume 74, Issue 14, 2011, Pages 903 - 916

Abstract
The reason for the rapid rise of autism in the United States that began in the 1990s is a mystery. Although individuals probably have a genetic predisposition to develop autism, researchers suspect that one or more environmental triggers are also needed. One of those triggers might be the battery of vaccinations that young children receive. Using regression analysis and controlling for family income and ethnicity, the relationship between the proportion of children who received the recommended vaccines by age 2 years and the prevalence of autism (AUT) or speech or language impairment (SLI) in each U.S. state from 2001 and 2007 was determined. A positive and statistically significant relationship was found: The higher the proportion of children receiving recommended vaccinations, the higher was the prevalence of AUT or SLI. A 1% increase in vaccination was associated with an additional 680 children having AUT or SLI. Neither parental behavior nor access to care affected the results, since vaccination proportions were not significantly related (statistically) to any other disability or to the number of pediatricians in a U.S. state. The results suggest that although mercury has been removed from many vaccines, other culprits may link vaccines to autism. Further study into the relationship between vaccines and autism is warranted.
http://www.ncbi.nlm.nih.gov/pubmed/21623535

75. Effect of thimerosal on the neurodevelopment of premature rats.

World J Pediatr. 2013 Nov;9(4):356-60. doi: 10.1007/s12519-013-0443-z. Epub 2013 Nov 14.

CONCLUSIONS:
The negative adverse consequences on neurodevelopment observed in the present study are consistent with previous studies; this study raised serious concerns about adverse neurodevelopmental disorder such as autism in humans following the ongoing worldwide routine administration of thimerosal containing vaccines to infants.

https://www.ncbi.nlm.nih.gov/pubmed/24235069

76. Lasting neuropathological changes in rat brain after intermittent neonatal administration of thimerosal.

Folia Neuropathol. 2010;48(4):258-69. Olczak M, Duszczyk M, Mierzejewski P, Wierzba-Bobrowicz T, Majewska MD.
Department of Pharmacology and Physiology of the Nervous System, Institute of Psychiatry and Neurology, ul. Sobieskiego 9, Warsaw, Poland.

Abstract
Thimerosal, an organomercurial added as a preservative to some vaccines, is a suspected iatrogenic factor, possibly contributing to paediatric neurodevelopmental disorders including autism. We examined the effects of early postnatal administration of thimerosal (four i.m. injections, 12 or 240 μg THIM-Hg/kg, on postnatal days 7, 9, 11 and 15) on brain pathology in Wistar rats. Numerous neuropathological changes were observed in young adult rats which were treated postnatally with thimerosal. They included: ischaemic degeneration of neurons and "dark" neurons in the prefrontal and temporal cortex, the hippocampus and the cerebellum, pathological changes of the blood vessels in the temporal cortex, diminished synaptophysin reaction in the hippocampus, atrophy of astroglia in the hippocampus and cerebellum, and positive caspase-3 reaction in Bergmann astroglia. These findings document neurotoxic effects of thimerosal, at doses equivalent to those used in infant vaccines or higher, in developing rat brain, suggesting likely involvement of this mercurial in neurodevelopmental disorders.
http://www.termedia.pl/Original-paper-Lasting-neuropathological-changes-in-rat-brain-after-intermittent-neonatal-administration-of-thimerosal,20,15811,1,1.html

77. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats.

2011 Sep 30;223(1):107-18. doi: 10.1016/j.bbr.2011.04.026. Epub 2011 Apr 28.

Abstract

The neurotoxic organomercurial thimerosal (THIM), used for decades as vaccine preservative, is a suspected factor in the pathogenesis of some neurodevelopmental disorders. Previously we showed that neonatal administration of THIM at doses equivalent to those used in infant vaccines or higher, causes lasting alterations in the brain opioid system in rats. Here we investigated neonatal treatment with THIM (at doses 12, 240, 1440 and 3000 μg Hg/kg) on behaviors, which are characteristically altered in autism, such as locomotor activity, anxiety, social interactions, spatial learning, and on the brain dopaminergic system in Wistar rats of both sexes. Adult male and female rats, which were exposed to the entire range of THIM doses during the early postnatal life, manifested impairments of locomotor activity and increased anxiety/neophobia in the open field test. In animals of both sexes treated with the highest THIM dose, the frequency of prosocial interactions was reduced, while the frequency of asocial/antisocial interactions was increased in males, but decreased in females. Neonatal THIM treatment did not significantly affect spatial learning and memory. THIM-exposed rats also manifested reduced haloperidol-induced catalepsy, accompanied by a marked decline in the density of striatal D_2 receptors, measured by immunohistochemical staining, suggesting alterations to the brain dopaminergic system. Males were more sensitive than females to some neurodisruptive/neurotoxic actions of THIM. These data document that early postnatal THIM administration causes lasting neurobehavioral impairments and neurochemical alterations in the brain, dependent on dose and sex. If similar changes occur in THIM/mercurial-exposed children, they could contribute do neurodevelopmental disorders.

http://www.ncbi.nlm.nih.gov/pubmed/21549155

78. B-Lymphocytes from a Population of Children with Autism Spectrum Disorder and Their Unaffected Siblings Exhibit Hypersensitivity to Thimerosal

J Toxicol. 2013;2013:801517. Epub 2013 Jun 9.

Abstract
The role of thimerosal containing vaccines in the development of autism spectrum disorder (ASD) has been an area of intense debate, as has the presence of mercury dental amalgams and fish ingestion by pregnant mothers. We studied the effects of thimerosal on cell proliferation and mitochondrial function from B-lymphocytes taken from individuals with autism, their nonautistic twins, and their nontwin siblings. Eleven families were examined and compared to matched controls. B-cells were grown with increasing levels of thimerosal, and various assays (LDH, XTT, DCFH, etc.) were performed to examine the effects on cellular proliferation and mitochondrial function. A subpopulation of eight individuals (4 ASD, 2 twins, and 2 siblings) from four of the families showed thimerosal hypersensitivity, whereas none of the control individuals displayed this response. The thimerosal concentration required to inhibit cell proliferation in these individuals was only 40% of controls. Cells hypersensitive to thimerosal also had higher levels of oxidative stress markers, protein carbonyls, and oxidant generation.

This suggests certain individuals with a mild mitochondrial defect may be highly susceptible to mitochondrial specific toxins like the vaccine preservative thimerosal.

http://www.ncbi.nlm.nih.gov/pubmed/23843785

79. Thimerosal-Derived Ethylmercury Is a Mitochondrial Toxin in Human Astrocytes: Possible Role of Fenton Chemistry in the Oxidation and Breakage of mtDNA

J Toxicol. 2012; 2012: 373678. Published online Jun 28, 2012. doi: 10.1155/2012/373678

Abstract

Thimerosal generates ethylmercury in aqueous solution and is widely used as preservative. We have investigated the toxicology of Thimerosal in normal human astrocytes, paying particular attention to mitochondrial function and the generation of specific oxidants. We find that ethylmercury not only inhibits mitochondrial respiration leading to a drop in the steady state membrane potential, but also concurrent with these phenomena increases the formation of superoxide, hydrogen peroxide, and Fenton/Haber-Weiss generated hydroxyl radical. These oxidants increase the levels of cellular aldehyde/ketones. Additionally, we find a five-fold increase in the levels of oxidant damaged mitochondrial DNA bases and increases in the levels of mtDNA nicks and blunt-ended breaks. Highly damaged mitochondria are characterized by having very low membrane potentials, increased superoxide/hydrogen peroxide production, and extensively damaged mtDNA and proteins. These mitochondria appear to have undergone a permeability transition, an observation supported by the five-fold increase in Caspase-3 activity observed after Thimerosal treatment.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3395253/

80. Altered urinary porphyrins and mercury exposure as biomarkers for autism severity in Egyptian children with autism spectrum disorder

Metabolic Brain Disease
Eman M. KhaledNagwa A. MeguidGeir BjørklundEmail authorAmr GoudaMohamed H. BaharyAdel HashishNermin M. SallamSalvatore ChirumboloMona A. El-Bana

Abstract
Autism spectrum disorder (ASD) is a complex neurodevelopmental disorder that affects social, communication, and behavioral development. Recent evidence supported but also questioned the hypothetical role of compounds containing mercury (Hg) as contributors to the development of ASD. Specific alterations in the urinary excretion of porphyrin-containing ring catabolites have been associated with exposure to Hg in ASD patients. In the present study, the level of urinary porphyrins, as biomarkers of Hg toxicity in children with ASD, was evaluated, and its correlation with severity of the autistic behavior further explored. A total of 100 children was enrolled in the present study. They were classified into three groups: children with ASD (40), healthy controls (40), and healthy siblings of the ASD children (20). Children with ASD were diagnosed using DSM-IV-TR, ADI-R, and CARS tests. Urinary porphyrins were evaluated within the three groups using high-performance liquid chromatography (HPLC), after plasma evaluation of mercury (Hg) and lead (Pb) in the same groups. Results showed that children with ASD had significantly higher levels of Hg, Pb, and the porphyrins pentacarboxyporphyrin, coproporphyrin, precoproporphyrin, uroporphyrins, and hexacarboxyporphyrin compared to healthy controls and healthy siblings of the ASD children. However, there was no significant statistical difference in the level of heptacarboxyporphyrin among the three groups, while a significant positive correlation between the levels of coproporphyrin and precoproporphyrin and autism severity was observed. Mothers of ASD children showed a higher percentage of dental amalgam restorations compared to the mothers of healthy controls suggesting that high Hg levels in children with ASD may relate to the increased exposure to Hg from maternal dental amalgam during pregnancy and lactation**.** The results showed that the ASD children in the present study had increased blood Hg and Pb levels compared with healthy control children indicating that disordered porphyrin metabolism might interfere with the pathology associated with the autistic neurologic phenotype. The present study indicates that coproporphyrin and precoproporhyrin may be utilized as possible biomarkers for heavy metal exposure and autism severity in children with ASD.

http://link.springer.com/article/10.1007/s11011-016-9870-6

81. Uncoupling of ATP-mediated Calcium Signaling and Dysregulated IL-6 Secretion in Dendritic Cells by Nanomolar Thimerosal

Environmental Health Perspectives, July 2006.
Samuel R. Goth, Ruth A. Chu Jeffrey P. Gregg

Dendritic cells are exquisitely sensitive to Thimerosal, with one mechanism involving the uncoupling of positive and negative regulation of Ca2+ signals contributed by RyR1.

Excerpt: "Our findings that DCs primarily express the RyR1 channel complex and that this complex is uncoupled by very low levels of THI with dysregulated IL-6 secretion raise intriguing questions about a molecular basis for immune dyregulation and the possible role of the RyR1 complex in genetic susceptibility of the immune system to mercury."

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1513334/

82. Interplay of glia activation and oxidative stress formation in fluoride and aluminium exposure.

Pathophysiology. 2015 Mar;22(1):39-48. doi: 10.1016/j.pathophys.2014.12.001. Epub 2014 Dec 13.

RESULT AND CONCLUSION:
Aluminium, fluoride and a combination of aluminium-fluoride treatments caused an increase in brain lipid peroxidation products and reactive oxygen species (ROS) formation. Similarly, an increase in glial activation and inflammatory response were seen in these groups versus the control. Oxidative stress induced glial activation (GFAP) and increased the expression of B cells (CD20). This also corresponded to the extent of tissue damage and lipid peroxidation observed. Taken together, the results suggest a close link between oxidative stress neuroinflamation and degeneration in aluminium-fluoride toxicity.

http://www.ncbi.nlm.nih.gov/pubmed/25577494

83. Nanomolar aluminum induces pro-inflammatory and pro-apoptotic gene expression in human brain cells in primary culture.

J Inorg Biochem. 2005 Sep;99(9):1895-8.

Abstract
Aluminum, the most abundant neurotoxic metal in our biosphere, has been implicated in the etiology of several neurodegenerative disorders including Alzheimer's disease (AD). To further understand aluminum's influence on gene expression, we examined total messenger RNA levels in untransformed human neural cells exposed to 100 nanomolar aluminum sulfate using high density DNA microarrays that interrogate the expression of every human gene. Preliminary data indicate that of the most altered gene expression levels, 17/24 (70.8%) of aluminum-affected genes, and 7/8 (87.5%) of aluminum-induced genes exhibit expression patterns similar to those observed in AD. The seven genes found to be significantly up-regulated by aluminum encode pro-inflammatory or pro-apoptotic signaling elements, including NF-kappaB subunits, interleukin-1beta precursor, cytosolic phospholipase A2, cyclooxygenase-2, beta-amyloid precursor protein and DAXX, a regulatory protein known to induce apoptosis and repress transcription. The promoters of genes up-regulated by aluminum are enriched in binding sites for the stress-inducible transcription factors HIF-1 and NF-kappaB, suggesting a role for aluminum, HIF-1 and NF-kappaB in driving atypical, pro-inflammatory and pro-apoptotic gene expression.The effect of aluminum on specific stress-related gene expression patterns in human brain cells clearly warrant further investigation.
http://www.sciencedirect.com/science/article/pii/S0162013405001182

84. Blood Levels of Mercury Are Related to Diagnosis of Autism: A Reanalysis of an Important Data Set

Journal of Child Neurology, Vol. 22, No. 11, 1308-1311 (2007)
M. Catherine DeSoto, PhD, Robert T. Hitlan, PhD -Department of Psychology, University of Northern Iowa, Cedar Falls, Iowa

Abstract
The question of what is leading to the apparent increase in autism is of great importance. Like the link between aspirin and heart attack, even a small effect can have major health implications. If there is any link between autism and mercury, it is absolutely crucial that the first reports of the question are not falsely stating that no link occurs. We have reanalyzed the data set originally reported by Ip et al. in 2004 and have found that the original p value was in error and that a significant relation does exist between the blood levels of mercury and diagnosis of an autism spectrum disorder. Moreover, the hair sample analysis results offer some support for the idea that persons with autism may be less efficient and more variable at eliminating mercury from the blood.
http://jcn.sagepub.com/cgi/content/abstract/22/11/1308

85. Empirical Data Confirm Autism Symptoms Related to Aluminum and Acetaminophen Exposure

Entropy, November 7, 2012
Stephanie Seneff, Robert M. Davidson and Jingjing Liu

Abstract
Autism is a condition characterized by impaired cognitive and social skills, associated with compromised immune function. The incidence is alarmingly on the rise, and environmental factors are increasingly suspected to play a role. This paper investigates word frequency patterns in the U.S. CDC Vaccine Adverse Events Reporting System (VAERS) database. Our results provide strong evidence supporting a link between autism and the aluminum in vaccines. A literature review showing toxicity of aluminum in human physiology offers further support. Mentions of autism in VAERS increased steadily at the end of the last century, during a period when mercury was being phased out, while aluminum adjuvant burden was being increased. Using standard log-likelihood ratio techniques, we identify several signs and symptoms that are significantly more prevalent in vaccine reports after 2000, including cellulitis, seizure, depression, fatigue, pain and death, which are also significantly associated with aluminum-containing vaccines. We propose that children with the autism diagnosis are especially vulnerable to toxic metals such as aluminum and mercury due to insufficient serum sulfate and glutathione. A strong correlation between autism and the MMR (Measles, Mumps, Rubella) vaccine is also observed, which may be partially explained via an increased sensitivity to acetaminophen administered to control fever.

http://www.mdpi.com/1099-4300/14/11/2227

86. Developmental Regression and Mitochondrial Dysfunction in a Child With Autism

J Child Neurol. 2006 Feb;21(2):170-2.

Abstract
Autistic spectrum disorders can be associated with mitochondrial dysfunction. We present a singleton case of developmental regression and oxidative phosphorylation disorder in a 19-month-old girl. Subtle abnormalities in the serum creatine kinase level, aspartate aminotransferase, and serum bicarbonate led us to perform a muscle biopsy, which showed type I myofiber atrophy, increased lipid content, and reduced cytochrome c oxidase activity. There were marked reductions in enzymatic activities for complex I and III. Complex IV (cytochrome c oxidase) activity was near the 5% confidence level. To determine the frequency of routine laboratory abnormalities in similar patients, we performed a retrospective study including 159 patients with autism (Diagnostic and Statistical Manual of Mental Disorders-IV and Childhood Autism Rating Scale) not previously diagnosed with metabolic disorders and 94 age-matched controls with other neurologic disorders. Aspartate aminotransferase was elevated in 38% of patients with autism compared with 15% of controls ($P < .0001$). The serum creatine kinase level also was abnormally elevated in 22 (47%) of 47 patients with autism. These data suggest that further metabolic evaluation is indicated in autistic patients and that defects of oxidative phosphorylation might be prevalent.

Excerpt: "Children who have (mitochondrial-related) dysfunctional cellular energy metabolism might be more prone to undergo autistic regression between 18 and 30 months of age if they also have infections or immunizations at the same time."

http://jcn.sagepub.com/cgi/content/abstract/21/2/170

87. Thimerosal Neurotoxicity is Associated with Glutathione Depletion: Protection with Glutathione Precursors

Neurotoxicology. 2005 Jan;26(1):1-8.
James SJ, Slikker W 3rd, Melnyk S, New E, Pogribna M, Jernigan S.
Department of Pediatrics, University of Arkansas for Medical Sciences and Arkansas Children's Hospital Research Institute, Little Rock, AR

Abstract
Thimerosol is an antiseptic containing 49.5% ethyl mercury that has been used for years as a preservative in many infant vaccines and in flu vaccines. Environmental methyl mercury has been shown to be highly neurotoxic, especially to the developing brain. Because mercury has a high affinity for thiol (sulfhydryl (-SH)) groups, the thiol-containing antioxidant, glutathione (GSH), provides the major intracellular defense against mercury-induced neurotoxicity. Cultured neuroblastoma cells were found to have lower levels of GSH and increased sensitivity to thimerosol toxicity compared to glioblastoma cells that have higher basal levels of intracellular GSH. Thimerosal-induced cytotoxicity was associated with depletion of intracellular GSH in both cell lines**.** Pretreatment with 100 microM glutathione ethyl ester or N-acetylcysteine (NAC), but not methionine, resulted in a significant increase in intracellular GSH in both cell types. Further, pretreatment of the cells with glutathione ethyl ester or NAC prevented cytotoxicity with exposure to 15 microM Thimerosal. Although Thimerosal has been recently removed from most children's vaccines, it is still present in flu vaccines given to pregnant women, the elderly, and to children in developing countries. The potential protective effect of GSH or NAC against mercury toxicity warrants further research as possible adjunct therapy to individuals still receiving Thimerosal-containing vaccinations.
http://www.ncbi.nlm.nih.gov/pubmed/15527868

88. Aluminum adjuvant linked to gulf war illness induces motor neuron death in mice

Neuromolecular Med. 2007;9(1):83-100.

Abstract
Gulf War illness (GWI) affects a significant percentage of veterans of the 1991 conflict, but its origin remains unknown. Associated with some cases of GWI are increased incidences of amyotrophic lateral sclerosis and other neurological disorders. Whereas many environmental factors have been linked to GWI, the role of the anthrax vaccine has come under increasing scrutiny. Among the vaccine's potentially toxic components are the adjuvants aluminum hydroxide and squalene. To examine whether these compounds might contribute to neuronal deficits associated with GWI, an animal model for examining the potential neurological impact of aluminum hydroxide, squalene, or aluminum hydroxide combined with squalene was developed. Young, male colony CD-1 mice were injected with the adjuvants at doses equivalent to those given to US military service personnel. All mice were subjected to a battery of motor and cognitive-behavioral tests over a 6-mo period postinjections. Following sacrifice, central nervous system tissues were examined using immunohistochemistry for evidence of inflammation and cell death. Behavioral testing showed motor deficits in the aluminum treatment group that expressed as a progressive decrease in strength measured by the wire-mesh hang test (final deficit at 24 wk; about 50%). Significant cognitive deficits in water-maze learning were observed in the combined aluminum and squalene group (4.3 errors per trial) compared with the controls (0.2 errors per trial) after 20 wk. Apoptotic neurons were identified in aluminum-injected animals that showed significantly increased activated caspase-3 labeling in lumbar spinal cord (255%) and primary motor cortex (192%) compared with the controls. Aluminum-treated groups also showed significant motor neuron loss (35%) and increased numbers of astrocytes (350%) in the lumbar spinal cord. The findings suggest a possible role for the aluminum adjuvant in some neurological features associated with GWI and possibly an additional role for the combination of adjuvants.
http://www.ncbi.nlm.nih.gov/pubmed/17114826

89. A Case Series of Children with Apparent Mercury Toxic Encephalopathies Manifesting with Clinical Symptoms of Regressive Autistic Disorder

J Toxicol Environ Health A. 2007 May 15;70(10):837-51.

Abstract
Impairments in social relatedness and communication, repetitive behaviors, and stereotypic abnormal movement patterns characterize autism spectrum disorders (ASDs). It is clear that while genetic factors are important to the pathogenesis of ASDs, mercury exposure can induce immune, sensory, neurological, motor, and behavioral dysfunctions similar to traits defining or associated with ASDs. The Institutional Review Board of the Institute for Chronic Illnesses (Office for Human Research Protections, U.S. Department of Health and Human Services, IRB number IRB00005375) approved the present study. A case series of nine patients who presented to the Genetic Centers of America for a genetic/developmental evaluation are discussed. Eight of nine patients (one patient was found to have an ASD due to Rett's syndrome) (a) had regressive ASDs; (b) had elevated levels of androgens; (c) excreted significant amounts of mercury post chelation challenge; (d) had biochemical evidence of decreased function in their glutathione pathways; (e) had no known significant mercury exposure except from Thimerosal-containing vaccines/Rho(D)-immune globulin preparations; and (f) had alternate causes for their regressive ASDs ruled out. There was a significant dose-response relationship between the severity of the regressive ASDs observed and the total mercury dose children received from Thimerosal-containing vaccines/Rho (D)-immune globulin preparations. Based upon differential diagnoses, 8 of 9 patients examined were exposed to significant mercury from Thimerosal-containing biologic/vaccine preparations during their fetal/infant developmental periods, and subsequently, between 12 and 24 mo of age, these previously normally developing children suffered mercury toxic encephalopathies that manifested with clinical symptoms consistent with regressive ASDs. Evidence for mercury intoxication should be considered in the differential diagnosis as contributing to some regressive ASDs.¨

http://www.ncbi.nlm.nih.gov/pubmed/17454560

90. Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria.

International Journal of Molecular Medicine, 2006

There is a worldwide increasing concern over the neurological risks of thimerosal (ethylmercury thiosalicylate) which is an organic mercury compound that is commonly used as an antimicrobial preservative. In this study, we show that thimerosal, at nanomolar concentrations, induces neuronal cell death through the mitochondrial pathway. Thimerosal, in a concentration- and time-dependent manner, decreased cell viability as assessed by calcein-ethidium staining and caused apoptosis detected by Hoechst 33258 dye. Thimerosal-induced apoptosis was associated with depolarization of mitochondrial membrane, generation of reactive oxygen species, and release of cytochrome c and apoptosis-inducing factor (AIF) from mitochondria to cytosol. Although thimerosal did not affect cellular expression of Bax at the protein level, we observed translocation of Bax from cytosol to mitochondria. Finally, caspase-9 and caspase-3 were activated in the absence of caspase-8 activation. Our data suggest that thimerosal causes apoptosis in neuroblastoma cells by changing the mitochondrial microenvironment.

http://thescipub.com/html/10.3844/ajbbsp.2008.198.207

91. Possible Immunological Disorders in Autism: Concomitant Autoimmunity and Immune Tolerancekk

The Egyptian Journal of Immunology, 2006

Abstract
Autism is a pervasive developmental disorder that affect children early in their life. Immunological disorders is one of several contributing factors that have been suggested to cause autism. Thirty autistic children aged 3-6 years and thirty non-autistic psychologically-free siblings were studied. Circulating IgA and IgG autoantibodies to casein and gluten dietary proteins were detected by enzyme-immunoassays (EIA). Circulating IgG antibodies to measles, mumps and rubella vaccine (M.M.R) and cytomeglovirus were investigated by EIA. Results revealed high seropositivity for autoantibodies to casein and gluten: 83.3% and 50% respectively in autistic children as compared to 10% and 6.7% positivity in the control group. Surprisingly, circulating anti-measles, anti-mumps and anti-rubella IgG were positive in only 50%, 73.3% and 53.3% respectively as compared to 100% positivity in the control group. Anti-CMV IgG was positive in 43.3% of the autistic children as compared to 7% in the control group. It is concluded that, autoimmune response to dietary proteins and deficient immune response to measles, mumps and rubella vaccine antigens might be associated with autism, as a leading cause or a resulting event. Further research is needed to confirm these findings.

http://app.egyptlearn.com/eji/pdf/HQ2007-03680.pdf

92. Mitochondrial Energy-Deficient Endophenotype in Autism

American Journal of Biochemistry and Biotechnology 4 (2): 198-207, 2008

Abstract
While evidence points to a multigenic etiology of most autism, the pathophysiology of the disorder has yet to be defined and the underlying genes and biochemical pathways they subserve remain unknown. Autism is considered to be influenced by a combination of various genetic, environmental and immunological factors; more recently, evidence has suggested that increased vulnerability to oxidative stress may be involved in the etiology of this multifactorial disorder.

Furthermore, recent studies have pointed to a subset of autism associated with the biochemical endophenotype of mitochondrial energy deficiency, identified as a subtle impairment in fat and carbohydrate oxidation. This phenotype is similar, but more subtle than those seen in classic mitochondrial defects. In some cases the beginnings of the genetic underpinnings of these mitochondrial defects are emerging, such as mild mitochondrial dysfunction and secondary carnitine deficiency observed in the subset of autistic patients with an inverted duplication of chromosome 15q11-q13. In addition, rare cases of familial autism associated with sudden infant death syndrome (SIDS) or associated with abnormalities in cellular calcium homeostasis, such as malignant hyperthermia or cardiac arrhythmia, are beginning to emerge. Such special cases suggest that the pathophysiology of autism may comprise pathways that are directly or indirectly involved in mitochondrial energy production and to further probe this connection three new avenues seem worthy of exploration: 1) metabolomic clinical studies provoking controlled aerobic exercise stress to expand the biochemical phenotype, 2) high-throughput expression arrays to directly survey activity of the genes underlying these biochemical pathways and 3) model systems, either based upon neuronal stem cells or model genetic organisms, to discover novel genetic and environmental inputs into these pathways.

http://thescipub.com/html/10.3844/ajbbsp.2008.198.207

93. Pediatric Vaccines Influence Primate Behavior, and Amygdala Growth and Opioid Ligand Binding

Friday, May 16, 2008: IMFAR

Abstract

Background: Macaques are commonly used in pre-clinical vaccine safety testing, but the combined childhood vaccine regimen, rather than individual vaccines, has not been studied. Childhood vaccines are a possible causal factor in autism, and abnormal behaviors and anomalous amygdala growth are potentially inter-related features of this condition.

Objectives: The objective of this study was to compare early infant cognition and behavior with amygdala size and opioid binding in rhesus macaques receiving the recommended childhood vaccines (1994-1999), the majority of which contained the bactericidal preservative ethylmercurithiosalicylic acid (thimerosal).

Methods: Macaques were administered the recommended infant vaccines, adjusted for age and thimerosal dose (exposed; N=13), or saline (unexposed; N=3). Primate development, cognition and social behavior were assessed for both vaccinated and unvaccinated infants using standardized tests developed at the Washington National Primate Research Center. Amygdala growth and binding were measured serially by MRI and by the binding of the non-selective opioid antagonist [11C]diprenorphine, measured by PET, respectively, before (T1) and after (T2) the administration of the measles-mumps-rubella vaccine (MMR).

Results: Compared with unexposed animals, significant neurodevelopmental deficits were evident for exposed animals in survival reflexes, tests of color discrimination and reversal, and learning sets. Differences in behaviors were observed between exposed and unexposed animals and within the exposed group before and after MMR vaccination. Compared with unexposed animals, exposed animals showed attenuation of amygdala growth and differences in the amygdala binding of [11C]diprenorphine. Interaction models identified significant associations between specific aberrant social and non-social behaviors, isotope binding, and vaccine exposure.

Conclusions: This animal model, which examines for the first time, behavioral, functional, and neuromorphometric consequences of the childhood vaccine regimen, mimics certain neurological abnormalities of autism. The findings raise important safety issues while providing a potential model for examining aspects of causation and disease pathogenesis in acquired disorders of behavior and development.

https://www.ncbi.nlm.nih.gov/pubmed/20628439

94. Thimerosal exposure in infants and neurodevelopmental disorders: An assessment of computerized medical records in the Vaccine Safety Datalink.

Young HA, Geier DA, Geier MR.
The George Washington University School of Public Health and Health Services, Department of Epidemiology and Biostatistics, United States.

Abstract
The study evaluated possible associations between neurodevelopmental disorders (NDs) and exposure to mercury (Hg) from Thimerosal-containing vaccines (TCVs) by examining the automated Vaccine Safety Datalink (VSD). A total of 278,624 subjects were identified in birth cohorts from 1990-1996 that had received their first oral polio vaccination by 3 months of age in the VSD. The birth cohort prevalence rate of medically diagnosed International Classification of Disease, 9th revision (ICD-9) specific NDs and control outcomes were calculated. Exposures to Hg from TCVs were calculated by birth cohort for specific exposure windows from birth-7 months and birth-13 months of age. Poisson regression analysis was used to model the association between the prevalence of outcomes and Hg doses from TCVs. Consistent significantly increased rate ratios were observed for autism, autism spectrum disorders, tics, attention deficit disorder, and emotional disturbances with Hg exposure from TCVs**.** By contrast, none of the control outcomes had significantly increased rate ratios with Hg exposure from TCVs. Routine childhood vaccination should be continued to help reduce the morbidity and mortality associated with infectious diseases, but efforts should be undertaken to remove Hg from vaccines. Additional studies should be conducted to further evaluate the relationship between Hg exposure and NDs.

http://www.ncbi.nlm.nih.gov/pubmed/18482737

95. Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years

Journal Toxicological & Environmental Chemistry, Volume 90, Issue 5 September 2008 , pages 997 - 1008

Abstract
This study investigated the association between vaccination with the Hepatitis B triple series vaccine prior to 2000 and developmental disability in children aged 1–9 years (n = 1824), proxied by parental report that their child receives early intervention or special education services (EIS). National Health and Nutrition Examination Survey 1999–2000 data were analyzed and adjusted for survey design by Taylor Linearization using SAS version 9.1 software, with SAS callable SUDAAN version 9.0.1. The odds of receiving EIS were approximately nine times as great for vaccinated boys (n = 46) as for unvaccinated boys (n = 7), after adjustment for confounders. This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys.

http://www.tandfonline.com/doi/abs/10.1080/02772240701806501#.Ue8MEY1wqSo

96. Induction of metallothionein in mouse cerebellum and cerebrum with low-dose thimerosal injection.

Cell Biology and Toxicology. 2009 Apr 9. [Epub ahead of print]

It is thought that the cerebellum is a sensitive organ against thimerosal. As a result of the present findings, in combination with the brain pathology observed in patients diagnosed with autism, the present study helps to support the possible biological plausibility for how low-dose exposure to mercury from thimerosal-containing vaccines may be associated with autism.

http://www.ncbi.nlm.nih.gov/pubmed/19357975

97. Influence of pediatric vaccines on amygdala growth and opioid ligand binding in rhesus macaque infants: A pilot study

Acta Neurobiol Exp 2010, 70: 147–164 Polish Neuroscience Society - PTBUN, Nencki Institute of Experimental Biology

Abstract
This longitudinal, case-control pilot study examined amygdala growth in rhesus macaque infants receiving the complete US childhood vaccine schedule (1994-1999). Longitudinal structural and functional neuroimaging was undertaken to examine central effects of the vaccine regimen on the developing brain. Vaccine-exposed and saline-injected control infants underwent MRI and PET imaging at approximately 4 and 6 months of age, representing two specific timeframes within the vaccination schedule. Volumetric analyses showed that exposed animals did not undergo the maturational changes over time in amygdala volume that was observed in unexposed animals. After controlling for left amygdala volume, the binding of the opioid antagonist [11C]diprenorphine (DPN) in exposed animals remained relatively constant over time, compared with unexposed animals, in which a significant decrease in [11C]DPN binding occurred. These results suggest that maturational changes in amygdala volume and the binding capacity of [11C]DPN in the amygdala was significantly altered in infant macaques receiving the vaccine schedule. The macaque infant is a relevant animal model in which to investigate specific environmental exposures and structural/functional neuroimaging during neurodevelopment.

http://adventuresinautism.com/Hewitsonetal2010.pdf

98. Cultured lymphocytes from autistic children and non-autistic siblings up-regulate heat shock protein RNA in response to thimerosal challenge.

Neurotoxicology. 2006 Sep;27(5):685-92. Epub 2006 Jun 16.
Walker SJ, Segal J, Aschner M.
Department of Physiology and Pharmacology, Wake Forest University School of Medicine, Winston-Salem, NC 27156, USA. swalker@wfubmc.edu

Abstract
There are reports suggesting that some autistic children are unable to mount an adequate response following exposure to environmental toxins. This potential deficit, coupled with the similarity in clinical presentations of autism and some heavy metal toxicities, has led to the suggestion that heavy metal poisoning might play a role in the etiology of autism in uniquely susceptible individuals. Thimerosal, an anti-microbial preservative previously added routinely to childhood multi-dose vaccines, is composed of 49.6% ethyl mercury. Based on the levels of this toxin that children receive through routine immunization schedules in the first years of life, it has been postulated that thimerosal may be a potential triggering mechanism contributing to autism in susceptible individuals. One potential risk factor in these individuals may be an inability to adequately up-regulate metallothionein (MT) biosynthesis in response to presentation of a heavy metal challenge. To investigate this hypothesis, cultured lymphocytes (obtained from the Autism Genetic Resource Exchange, AGRE) from autistic children and non-autistic siblings were challenged with either 10 microM ethyl mercury, 150 microM zinc, or fresh media (control). Following the challenge, total RNA was extracted and used to query "whole genome" DNA microarrays. Cultured lymphocytes challenged with zinc responded with an impressive up-regulation of MT transcripts (at least nine different MTs were over-expressed) while cells challenged with thimerosal responded by up-regulating numerous heat shock protein transcripts, but not MTs. Although there were no apparent differences between autistic and non-autistic sibling responses in this very small sampling group, the differences in expression profiles between those cells treated with zinc versus thimerosal were dramatic. Determining cellular response, at the level of gene expression, has important implications for the understanding and treatment of conditions that result from exposure to neurotoxic compounds.

http://www.genome-explorations.com/images/pdfs_publications/10-Cultured%20lymphocytes%20from%20autistic%20children%20and%20non-autis.pdf

99. Sensitization effect of thimerosal is mediated in vitro via reactive oxygen species and calcium signaling.

Toxicology. 2010 July - August;274(1-3):1-9. Epub 2010 May 10.
Migdal C, Foggia L, Tailhardat M, Courtellemont P, Haftek M, Serres M.

Thimerosal, a mercury derivative composed of ethyl mercury chloride (EtHgCl) and thiosalicylic acid (TSA), is widely used as a preservative in vaccines and cosmetic products and causes cutaneous reactions. Since dendritic cells (DCs) play an essential role in the immune response, the sensitization potency of chemicals was studied in vitro using U937, a human promyelomonocytic cell line that is used as a surrogate of monocytic differentiation and activation. Currently, this cell line is under ECVAM (European Center for the Validation of Alternative Methods) validation as an alternative method for discriminating chemicals. Thimerosal and mercury derivatives induced in U937 an overexpression of CD86 and interleukin (IL)-8 secretion similarly to 1-chloro-2,4-dinitrobenzene (DNCB), a sensitizer used as a positive control for DC activation. Non-sensitizers, dichloronitrobenzene (DCNB), TSA and sodium dodecyl sulfate (SDS), an irritant, had no effect. U937 activation was prevented by cell pretreatment with N-acetyl-l-cysteine (NAC) but not with thiol-independent antioxidants except vitamin E which affected CD86 expression by preventing lipid peroxidation of cell membranes. Thimerosal, EtHgCl and DNCB induced glutathione (GSH) depletion and reactive oxygen species (ROS) within 15min; another peak was detected after 2h for mercury compounds only. MitoSOX, a specific mitochondrial fluorescent probe, confirmed that ROS were essentially produced by mitochondria in correlation with its membrane depolarization. Changes in mitochondrial membrane permeability induced by mercury were reversed by NAC but not by thiol-independent antioxidants. Thimerosal and EtHgCl also induced a calcium (Ca(2+)) influx with a peak at 3h, suggesting that Ca(2+) influx is a secondary event following ROS induction as Ca(2+) influx was suppressed after pretreatment with NAC but not with thiol-independent antioxidants. Ca(2+) influx was also suppressed when culture medium was deprived of Ca(2+) confirming the specificity of the measure. In conclusion, these data suggest that thimerosal induced U937 activation via oxidative stress from mitochondrial stores and mitochondrial membrane depolarization with a primordial effect of thiol groups. A cross-talk between ROS and Ca(2+) influx was demonstrated.

http://www.sciencedirect.com/science/article/pii/S0300483X10002040

100. Theoretical aspects of autism: Causes—A review

Journal of Immunotoxicology, January-March 2011, Vol. 8, No. 1 , Pages 68-79

Autism, a member of the pervasive developmental disorders (PDDs), has been increasing dramatically since its description by Leo Kanner in 1943. First estimated to occur in 4 to 5 per 10,000 children, the incidence of autism is now 1 per 110 in the United States, and 1 per 64 in the United Kingdom, with similar incidences throughout the world. Searching information from 1943 to the present in PubMed and Ovid Medline databases, this review summarizes results that correlate the timing of changes in incidence with environmental changes. Autism could result from more than one cause, with different manifestations in different individuals that share common symptoms. Documented causes of autism include genetic mutations and/or deletions, viral infections, and encephalitis following vaccination. Therefore, autism is the result of genetic defects and/or inflammation of the brain. The inflammation could be caused by a defective placenta, immature blood-brain barrier, the immune response of the mother to infection while pregnant, a premature birth, encephalitis in the child after birth, or a toxic environment.

http://informahealthcare.com/doi/abs/10.3109/1547691X.2010.545086

101. Iatrogenic exposure to mercury after hepatitis B vaccination in preterm infants

The Journal of Pediatrics, Volume 136, Issue 5, May 2000, Pages 679–681

Thimerosal, a derivative of mercury, is used as a preservative in hepatitis B vaccines. We measured total mercury levels before and after the administration of this vaccine in 15 preterm and 5 term infants. Comparison of pre- and post-vaccination mercury levels showed a significant increase in both preterm and term infants after vaccination. Additionally, post-vaccination mercury levels were significantly higher in preterm infants as compared with term infants. Because mercury is known to be a potential neurotoxin to infants, further study of its pharmacodynamics is warranted.

http://www.sciencedirect.com/science/article/pii/S0022347600896560

102. Administration of thimerosal to infant rats increases overflow of glutamate and aspartate in the prefrontal cortex: protective role of dehydroepiandrosterone sulfate.

Neurochem Res. 2012 Feb;37(2):436-47. Epub 2011 Oct 21.

Abstract
Thimerosal, a mercury-containing vaccine preservative, is a suspected factor in the etiology of neurodevelopmental disorders. We previously showed that its administration to infant rats causes behavioral, neurochemical and neuropathological abnormalities similar to those present in autism. Here we examined, using microdialysis, the effect of thimerosal on extracellular levels of neuroactive amino acids in the rat prefrontal cortex (PFC). Thimerosal administration (4 injections, i.m., 240 μg Hg/kg on postnatal days 7, 9, 11, 15) induced lasting changes in amino acid overflow: an increase of glutamate and aspartate accompanied by a decrease of glycine and alanine; measured 10-14 weeks after the injections. Four injections of thimerosal at a dose of 12.5 μg Hg/kg did not alter glutamate and aspartate concentrations at microdialysis time (but based on thimerosal pharmacokinetics, could have been effective soon after its injection). Application of thimerosal to the PFC in perfusion fluid evoked a rapid increase of glutamate overflow. Coadministration of the neurosteroid, dehydroepiandrosterone sulfate (DHEAS; 80 mg/kg; i.p.) prevented the thimerosal effect on glutamate and aspartate; the steroid alone had no influence on these amino acids. Coapplication of DHEAS with thimerosal in perfusion fluid also blocked the acute action of thimerosal on glutamate. In contrast, DHEAS alone reduced overflow of glycine and alanine, somewhat potentiating the thimerosal effect on these amino acids. Since excessive accumulation of extracellular glutamate is linked with excitotoxicity, our data imply that neonatal exposure to thimerosal-containing vaccines might induce excitotoxic brain injuries, leading to neurodevelopmental disorders. DHEAS may partially protect against mercurials-induced neurotoxicity.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3264864/?tool=pubmed

103. Hepatitis B vaccine induces apoptotic death in Hepa1-6 cells

Apoptosis. 2012 Jan 17. Hamza H, Cao J, Li X, Li C, Zhu M, Zhao S.
Key Lab of Agricultural Animal Genetics, Breeding, and Reproduction of Ministry of Education, College of Animal Science and Technology, Huazhong Agricultural University, Wuhan, 430070, People's Republic of China,

Abstract
Vaccines can have adverse side-effects, and these are predominantly associated with the inclusion of chemical additives such as aluminum hydroxide adjuvant. The objective of this study was to establish an in vitro model system amenable to mechanistic investigations of cytotoxicity induced by hepatitis B vaccine, and to investigate the mechanisms of vaccine-induced cell death. The mouse liver hepatoma cell line Hepa1-6 was treated with two doses of adjuvanted (aluminium hydroxide) hepatitis B vaccine (0.5 and 1 μg protein per ml) and cell integrity was measured after 24, 48 and 72 h. Hepatitis B vaccine exposure increased cell apoptosis as detected by flow cytometry and TUNEL assay. Vaccine exposure was accompanied by significant increases in the levels of activated caspase 3, a key effector caspase in the apoptosis cascade. Early transcriptional events were detected by qRT-PCR. We report that hepatitis B vaccine exposure resulted in significant upregulation of the key genes encoding caspase 7, caspase 9, Inhibitor caspase-activated DNase (ICAD), Rho-associated coiled-coil containing protein kinase 1 (ROCK-1), and Apoptotic protease activating factor 1 (Apaf-1). Upregulation of cleaved caspase 3,7 were detected by western blot in addition to Apaf-1 and caspase 9 expressions argues that cell death takes place via the intrinsic apoptotic pathway in which release of cytochrome c from the mitochondria triggers the assembly of a caspase activation complex.We conclude that exposure of Hepa1-6 cells to a low dose of adjuvanted hepatitis B vaccine leads to loss of mitochondrial integrity, apoptosis induction, and cell death, apoptosis effect was observed also in C2C12 mouse myoblast cell line after treated with low dose of vaccine (0.3, 0.1, 0.05 μg/ml). In addition In vivo apoptotic effect of hepatitis B vaccine was observed in mouse liver.

http://www.ncbi.nlm.nih.gov/pubmed/22249285

104. Inflammatory Responses to Trivalent Influenza Virus Vaccine Among Pregnant Women

Vaccine. 2011 Nov 8;29(48):8982-7. doi: 10.1016/j.vaccine.2011.09.039. Epub 2011 Sep 22.

Abstract
In the U.S., seasonal trivalent influenza vaccination (TIV) is currently universally recommended for all pregnant women. However, data on the maternal inflammatory response to vaccination is lacking and would better delineate the safety and clinical utility of immunization. In addition, for research purposes, vaccination has been used as a mild immune trigger to examine in vivo inflammatory responses in nonpregnant adults. The utility of such a model in pregnancy is unknown. Given the clinical and empirical justifications, the current study examined the magnitude, time course, and variance in inflammatory responses following seasonal influenza virus vaccination among pregnant women.

Conclusions
Trivalent influenza virus vaccination elicits a measurable inflammatory response among pregnant women. There is sufficient variability in response for testing associations with clinical outcomes. As adverse perinatal health outcomes including preeclampsia and preterm birth have an inflammatory component, a tendency toward greater inflammatory responding to immune triggers may predict risk of adverse outcomes, providing insight into biological mechanisms underlying risk. The inflammatory response elicited by vaccination is substantially milder and more transient than seen in infectious illness, arguing for the clinical value of vaccination. However, further research is needed to confirm that the mild inflammatory response elicited by vaccination is benign in pregnancy

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3204610/#!po=5.55556

105. Elevated maternal C-reactive protein and autism in a national birth cohort.

Mol Psychiatry. 2013 Jan 22. doi: 10.1038/mp.2012.197.
Brown AS, Sourander A, Hinkka-Yli-Salomäki S, McKeague IW, Sundvall J, Surcel HM.

Department of Psychiatry, Columbia University College of Physicians and Surgeons, New York State Psychiatric Institute, New York, NY, USA, Department of Epidemiology, Columbia University Mailman School of Public Health, New York, NY, USA.

Abstract
Autism is a complex neuropsychiatric syndrome with a largely unknown etiology. Inflammation during pregnancy may represent a common pathway by which infections and other insults increase risk for the disorder. Hence, we investigated the association between early gestational C-reactive protein (CRP), an established inflammatory biomarker, prospectively assayed in maternal sera, and childhood autism in a large national birth cohort with an extensive serum biobank. Other strengths of the cohort included nearly complete ascertainment of pregnancies in Finland (N=1.2 million) over the study period and national psychiatric registries consisting of virtually all treated autism cases in the population. Increasing maternal CRP levels, classified as a continuous variable, were significantly associated with autism in offspring. For maternal CRP levels in the highest quintile, compared with the lowest quintile, there was a significant, 43% elevated risk. This finding suggests that maternal inflammation may have a significant role in autism, with possible implications for identifying preventive strategies and pathogenic mechanisms in autism and other neurodevelopmental disorders.Molecular Psychiatry advance online publication, 22 January 2013; doi:10.1038/mp.2012.197.

http://www.ncbi.nlm.nih.gov/pubmed/23337946

106. Neurologic adverse events following vaccination

Prog Health Sci 2012, Vol 2 , No1

Abstract
The present review summarizes data on neurological adverse events following vaccination in the relation to intensity, time of onset, taking into account the immunological and non-immunological mechanisms. The authors described the physiological development of the immune system and the possible immune system responses following vaccination. Toxic property of thimerosal - a mercury-containing preservative used in some vaccines was presented. The neurological complications after vaccination were described. The role of vaccination in the natural course of infectious diseases and the current immunizations schedule in Poland was discussed.
Discussion by Sienkiewicz et. al:"Among the "major" neurological complications, usually manifesting more than 48 hours after vaccination and which might be the cause of permanent damage to the central nervous system (CNS), the following are listed: seizures - especially if there is no increase in body temperature, hypotonic-hyporesponsive episodes, postvaccinal encephalitis, postvaccinal encephalopathy [6, 8-11] and autism [10, 12-14]."

http://progress.umb.edu.pl/sites/progress.umb.edu.pl/files/129-141.pdf

107. Detection and sequencing of measles virus from peripheral mononuclear cells from patients with inflammatory bowel disease and autism.

Dig Dis Sci. 2000 Apr;45(4):723-9.

Abstract
It has been reported that measles virus may be present in the intestine of patients with Crohn's disease. Additionally, a new syndrome has been reported in children with autism who exhibited developmental regression and gastrointestinal symptoms (autistic enterocolitis), in some cases soon after MMR vaccine. It is not known whether the virus, if confirmed to be present in these patients, derives from either wild strains or vaccine strains. In order to characterize the strains that may be present, we have carried out the detection of measles genomic RNA in peripheral mononuclear cells (PBMC) in eight patients with Crohn's disease, three patients with ulcerative colitis, and nine children with autistic enterocolitis. As controls, we examined healthy children and patients with SSPE, SLE, HIV-1 (a total of eight cases). RNA was purified from PBMC by Ficoll-paque, followed by reverse transcription using AMV; cDNAs were subjected to nested PCR for detection of specific regions of the hemagglutinin (H) and fusion (F) gene regions. Positive samples were sequenced directly, in nucleotides 8393-8676 (H region) or 5325-5465 (from noncoding F to coding F region). One of eight patients with Crohn disease, one of three patients with ulcerative colitis, and three of nine children with autism, were positive. Controls were all negative. The sequences obtained from the patients with Crohn's disease shared the characteristics with wild-strain virus. The sequences obtained from the patients with ulcerative colitis and children with autism were consistent with being vaccine strains**.** The results were concordant with the exposure history of the patients. Persistence of measles virus was confirmed in PBMC in some patients with chronic intestinal inflammation.

http://www.ncbi.nlm.nih.gov/pubmed/10759242

61-107 Source: Ginger Taylor MS

Studies: Vaccines linked to deafness

Parents have to act in their children´s best interest and protect their children from getting disabilities like deafness.

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Studies and articles: Vaccines linked to Diabetes

Parents have to act in their children´s best interest and protect their children from getting disabilities like diabetes.

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Studies: Vaccines linked to Demyelination (seizures and brain injury)

Parents have to act in their children´s best interest and protect their children from getting disabilities like brain injury

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Studies: Vaccines linked to Sudden Death Syndrome (SIDS)

Parents have to act in their children´s best interest and protect their children from death.

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Parents have to act in their children´s best interest and protect their children from getting disabilities like seizures.

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Studies: Vaccines linked to Encephalopathy (Brain inflammation/injury):

Parents have to act in their children´s best interest and protect their children from getting disabilities like brain inflammation

1. Iwasa, S et al, "Swelling of the Brain in Mice Caused by Pertussis ... Quantitative Determination and the Responsibility of the Vaccine", Jpn J Med Sci Biol, 1985 , 38(2):53-65.

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Studies: Vaccines linked to Kidney Disease:

Parents have to act in their children´s best interest and protect their children from getting disabilities like kidney disease.

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Studies: Vaccines linked to Lymphadenitis

Parents have to act in their children´s best interest and protect their children from getting disabilities like lymfhadenitis.

1. Bichel, "Post-vaccinial Lymphadenitis Developing into Hodgkin's Disease", Acta Med Scand, 1976, Vol 199, p523-525.

2. Stewart, AM, et al, "Aetiology of Childhood Leukaemia", Lancet, 16 Oct, 1965, 2:789-790. [Listed under Vaccine Adverse Reactions.]

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Pages 112-120 Source: Mary Tocco, Director of Vaccine Research for Michigan

Studies showing that Herd Immunity doesn´t work

Measles outbreak in a fully immunized secondary-school population. "We conclude that outbreaks of measles can occur in secondary schools, even when more than 99 percent of the students have been vaccinated and more than 95 percent are immune", the scientists wrote.

https://www.ncbi.nlm.nih.gov/pubmed/3821823

An outbreak of measles in a highly immunised population: immunisation status and vaccine efficacy.

https://www.ncbi.nlm.nih.gov/pubmed/7841251

Major measles epidemic in the region of Quebec despite a 99% vaccine coverage

https://www.ncbi.nlm.nih.gov/pubmed/1884314

A persistent outbreak of measles despite appropriate prevention and control measures

https://www.ncbi.nlm.nih.gov/pubmed/3618578

An outbreak of measles occurred in a high school with a documented vaccination level of 98 per cent

https://www.ncbi.nlm.nih.gov/pubmed/3826461

The reported coverage of the measles-rubella (MR) or measles-mumps-rubella (MMR) vaccine is greater than 99.0% in Zhejiang province. However, the incidence of measles, mumps, and rubella remains high

https://www.ncbi.nlm.nih.gov/pubmed/24586717

707 measles outbreaks were recorded between 2009 and 2012 in China. China and WHO claim vaccine coverage among children is 95-98%.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4007128/
https://www.economist.com/news/china/21608799-world-health-organisation-gives-china-glowing-report-its-lowering-infant-and-maternal

History is full of proof that the herd immunity does not work

In 1871-2, England, with 98% of the population aged between 2 and 50 vaccinated against smallpox, it experienced its worst ever smallpox outbreak with 45,000 deaths. During the same period in Germany, with a vaccination rate of 96%, there were over 125,000 deaths from smallpox. (The Hadwen Documents http://www.soilandhealth.org/02/0201hyglibcat/020119hadwin/020119hadwin.toc.html)

In Germany, compulsory mass vaccination against diphtheria commenced in 1940 and by 1945 diphtheria cases were up from 40,000 to 250,000. (Don`t Get Stuck, Hannah Allen)
Deaths from diphtheria raise from 200/100 000 to 340/100 000 the same period. https://www.researchgate.net/publication/8251550_Autarchy_market_disintegration_and_health_The_mortality_and_nutritional_crisis_in_Nazi_Germany_1933-1937

In the USA in 1960, two virologists discovered that both polio vaccines were contaminated with the SV 40 virus which causes cancer in animals as well as changes in human cell tissue cultures. Millions of children had been injected with these vaccines. (Med Jnl of Australia 17/3/1973 p555)

In 1967, Ghana was declared measles free by the World Health Organisation after 96% of its population was vaccinated. In 1972, Ghana experienced one of its worst measles outbreaks with its highest ever mortality rate. (Dr H Albonico, MMR Vaccine Campaign in Switzerland, March 1990)

In the UK between 1970 and 1990, over 200,000 cases of whooping cough occurred in fully vaccinated children. (Community Disease Surveillance Centre, UK)

In the 1970`s a tuberculosis vaccine trial in India involving 260,000 people revealed that more cases of TB occurred in the vaccinated than the unvaccinated. (The Lancet 12/1/80 p73)

In 1977, Dr Jonas Salk who developed the first polio vaccine, testified along with other scientists, that mass inoculation against polio was the cause of most polio cases throughout the USA since 1961. (Science 4/4/77 "Abstracts")

In 1978, a survey of 30 States in the US revealed that more than half of the children who contracted measles had been adequately vaccinated. (The People`s Doctor, Dr R Mendelsohn)

In 1979, Sweden abandoned the whooping cough vaccine due to its ineffectiveness. Out of 5,140 cases in 1978, it was found that 84% had been vaccinated three times! (BMJ 283:696-697, 1981)

The February 1981 issue of the Journal of the American Medical Association found that 90% of obstetricians and 66% of pediatricians refused to take the rubella vaccine.

In the USA, the cost of a single DPT shot had risen from 11 cents in 1982 to $11.40 in 1987. The manufacturers of the vaccine were putting aside $8 per shot to cover legal costs and damages they were paying out to parents of brain damaged children and children who died after vaccination. (The Vine, Issue 7, January 1994, Nambour, Qld)

In Oman between 1988 and 1989, a polio outbreak occurred amongst thousands of fully vaccinated children. The region with the highest attack rate had the highest vaccine coverage. The region with the lowest attack rate had the lowest vaccine coverage. (The Lancet, 21/9/91)

In 1990, a UK survey involving 598 doctors revealed that over 50% of them refused to have the Hepatitis B vaccine despite belonging to the high risk group urged to be vaccinated. (British Med Jnl, 27/1/1990)

In 1990, the Journal of the American Medical Association had an article on measles which stated *" Although more than 95% of school-aged children in the US are vaccinated against measles, large measles outbreaks continue to occur in schools and most cases in this setting occur among previously vaccinated children."* (JAMA, 21/11/90)

In the USA, from July 1990 to November 1993, the US Food and Drug Administration counted a total of 54,072 adverse reactions following vaccination. The FDA admitted that this number represented only 10% of the real total, because most doctors were refusing to report vaccine injuries. In other words, adverse reactions for this period exceeded half a million! (National Vaccine Information Centre, March 2, 1994)

In the New England Journal of Medicine July 1994 issue a study found that over 80% of children under 5 years of age who had contracted whooping cough had been fully vaccinated.

On November 2nd, 2000, the Association of American Physicians and Surgeons (AAPS) announced that its members voted at their 57th annual meeting in St Louis to pass a resolution calling for an end to mandatory childhood vaccines. The resolution passed without a single "no" vote. (Report by Michael Devitt)

More studies

http://cdn.greenmedinfo.com/sites/default/files/gmipub_58635_anti_therapeutic_action_vaccination_all.pdf

M-M-R® II
(MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE)

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps, and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live), the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.{1,2}

The growth medium for measles and mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and recombinant human albumin) as stabilizer and neomycin.

The growth medium for rubella is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum] containing recombinant human albumin and neomycin. Sorbitol and hydrolyzed gelatin stabilizer are added to the individual virus harvests.

The cells, virus pools, and fetal bovine serum are all screened for the absence of adventitious agents.

The reconstituted vaccine is for subcutaneous administration. Each 0.5 mL dose contains not less than 1,000 $TCID_{50}$ (tissue culture infectious doses) of measles virus; 12,500 $TCID_{50}$ of mumps virus; and 1,000 $TCID_{50}$ of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

The impact of measles, mumps, and rubella vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of measles, mumps, and rubella cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For measles, 894,134 cases reported in 1941 compared to 288 cases reported in 1995 resulted in a 99.97% decrease in reported cases; for mumps, 152,209 cases reported in 1968 compared to 840 cases reported in 1995 resulted in a 99.45% decrease in reported cases; and for rubella, 57,686 cases reported in 1969 compared to 200 cases reported in 1995 resulted in a 99.65% decrease.{3}

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose (see also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

A study{4} of 6-month-old and 15-month-old infants born to vaccine-immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6-month-old infants developed detectable neutralizing antibody (NT) titers while 100% of the 15-month-old infants developed NT. This rate of seroconversion is higher than that previously reported for 6-month-old infants born to naturally immune mothers tested by HI assay. When the 6-month-old infants of immunized mothers were revaccinated at 15

months, they developed antibody titers equivalent to the 15-month-old vaccinees. The lower seroconversion rate in 6-month-olds has two possible explanations: 1) Due to the limit of the detection level of the assays (NT and enzyme immunoassay [EIA]), the presence of trace amounts of undetectable maternal antibody might interfere with the seroconversion of infants; or 2) The immune system of 6-month-olds is not always capable of mounting a response to measles vaccine as measured by the two antibody assays.

There is some evidence to suggest that infants who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization.{5,6}

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components.{7-12} These studies also established that seroconversion in response to vaccination against measles, mumps, and rubella paralleled protection from these diseases.{13-15}

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.{16-18} See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing.

The RA 27/3 rubella strain in M-M-R II elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine{19-25} and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.{26,27} The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.{27-29} The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,{27,29-31} and provide greater confidence for lasting immunity.

INDICATIONS AND USAGE

Recommended Vaccination Schedule

M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

Individuals first vaccinated at 12 months of age or older should be revaccinated prior to elementary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose. The Advisory Committee on Immunization Practices (ACIP) recommends administration of the first dose of M-M-R II at 12 to 15 months of age and administration of the second dose of M-M-R II at 4 to 6 years of age.{32} In addition, some public health jurisdictions mandate the age for revaccination. Consult the complete text of applicable guidelines regarding routine revaccination including that of high-risk adult populations.

Measles Outbreak Schedule

Infants Between 6 to 12 Months of Age

Local health authorities may recommend measles vaccination of infants between 6 to 12 months of age in outbreak situations. This population may fail to respond to the components of the vaccine. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established. The younger the infant, the lower the likelihood of seroconversion (see CLINICAL PHARMACOLOGY). Such infants should receive a second dose of M-M-R II between 12 to 15 months of age followed by revaccination at elementary school entry.{32}

Unnecessary doses of a vaccine are best avoided by ensuring that written documentation of vaccination is preserved and a copy given to each vaccinee's parent or guardian.

Other Vaccination Considerations

Non-Pregnant Adolescent and Adult Females

Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see below and PRECAUTIONS). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury.{33}

Women of childbearing age should be advised not to become pregnant for 3 months after vaccination and should be informed of the reasons for this precaution.

The ACIP has stated "If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary — one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing — and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured."{33}

Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination (see ADVERSE REACTIONS).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (see PRECAUTIONS, *Nursing Mothers*).

Other Populations

Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel outside the United States, if not immune, can acquire measles, mumps, or rubella and import these diseases into the United States. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can either receive the indicated monovalent vaccine (measles, mumps, or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travelers should receive M-M-R II regardless of their immune status to mumps or rubella.{34-36}

Vaccination is recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.{33,34,37}

According to ACIP recommendations, most persons born in 1956 or earlier are likely to have been infected with measles naturally and generally need not be considered susceptible. All children, adolescents, and adults born after 1956 are considered susceptible and should be vaccinated, if there are no contraindications. This includes persons who may be immune to measles but who lack adequate documentation of immunity such as: (1) physician-diagnosed measles, (2) laboratory evidence of measles immunity, or (3) adequate immunization with live measles vaccine on or after the first birthday.{34}

The ACIP recommends that "Persons vaccinated with inactivated vaccine followed within 3 months by live vaccine should be revaccinated with two doses of live vaccine. Revaccination is particularly important when the risk of exposure to wild-type measles virus is increased, as may occur during international travel."{34}

Post-Exposure Vaccination

Vaccination of individuals exposed to wild-type measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded.{34,38,39} There is no conclusive evidence that vaccination of individuals recently exposed to wild-type mumps or wild-type rubella will provide protection.{33,37}

Use With Other Vaccines

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including gelatin.{40}

Do not give M-M-R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and PRECAUTIONS, *Pregnancy*).

Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).

Febrile respiratory illness or other active febrile infection. However, the ACIP has recommended that all vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper respiratory infection with or without low-grade fever, or other low-grade febrile illness.{41}

Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.

Primary and acquired immunodeficiency states, including patients who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency viruses;{41-43} cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Measles inclusion body encephalitis{44} (MIBE), pneumonitis{45} and death as a direct consequence of disseminated measles vaccine virus infection have been reported in immunocompromised individuals inadvertently vaccinated with measles-containing vaccine.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

WARNINGS

Due caution should be employed in administration of M-M-R II to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination (see ADVERSE REACTIONS).

Hypersensitivity to Eggs

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution, having adequate treatment on hand should a reaction occur (see PRECAUTIONS).{46}

However, the AAP has stated, "Most children with a history of anaphylactic reactions to eggs have no untoward reactions to measles or MMR vaccine. Persons are not at increased risk if they have egg allergies that are not anaphylactic, and they should be vaccinated in the usual manner. In addition, skin testing of egg-allergic children with vaccine has not been predictive of which children will have an immediate hypersensitivity reaction...Persons with allergies to chickens or chicken feathers are not at increased risk of reaction to the vaccine."{47}

Hypersensitivity to Neomycin

The AAP states, "Persons who have experienced anaphylactic reactions to topically or systemically administered neomycin should not receive measles vaccine. Most often, however, neomycin allergy manifests as a contact dermatitis, which is a delayed-type (cell-mediated) immune response rather than anaphylaxis. In such persons, an adverse reaction to neomycin in the vaccine would be an erythematous, pruritic nodule or papule, 48 to 96 hours after vaccination. A history of contact dermatitis to neomycin is not a contraindication to receiving measles vaccine."{47}

Thrombocytopenia

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia with the first dose of M-M-R II (or its component vaccines) may develop thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see ADVERSE REACTIONS).

PRECAUTIONS

General

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Special care should be taken to ensure that the injection does not enter a blood vessel.

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, vaccinees who are infected with HIV should be monitored closely for vaccine-preventable diseases because immunization may be less effective than for uninfected persons (see CONTRAINDICATIONS).{42,43}

Vaccination should be deferred for 3 months or longer following blood or plasma transfusions, or administration of immune globulin (human).{47}

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk.{33} However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see *Nursing Mothers*).

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either before or simultaneously with M-M-R II.

Children under treatment for tuberculosis have not experienced exacerbation of the disease when immunized with live measles virus vaccine;{48} no studies have been reported to date of the effect of measles virus vaccines on untreated tuberculous children. However, individuals with active untreated tuberculosis should not be vaccinated.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

The health-care provider should determine the current health status and previous vaccination history of the vaccinee.

The health-care provider should question the patient, parent, or guardian about reactions to a previous dose of M-M-R II or other measles-, mumps-, or rubella-containing vaccines.

Information for Patients

The health-care provider should provide the vaccine information required to be given with each vaccination to the patient, parent, or guardian.

The health-care provider should inform the patient, parent, or guardian of the benefits and risks associated with vaccination. For risks associated with vaccination see WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Patients, parents, or guardians should be instructed to report any serious adverse reactions to their health-care provider who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.{49}

Pregnancy should be avoided for 3 months following vaccination, and patients should be informed of the reasons for this precaution (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, CONTRAINDICATIONS, and PRECAUTIONS, *Pregnancy*).

Laboratory Tests

See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing, and CLINICAL PHARMACOLOGY.

Drug Interactions

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

Immunosuppressive Therapy

The immune status of patients about to undergo immunosuppressive therapy should be evaluated so that the physician can consider whether vaccination prior to the initiation of treatment is indicated (see CONTRAINDICATIONS and PRECAUTIONS).

The ACIP has stated that "patients with leukemia in remission who have not received chemotherapy for at least 3 months may receive live virus vaccines. Short-term (<2 weeks), low- to moderate-dose systemic corticosteroid therapy, topical steroid therapy (e.g. nasal, skin), long-term alternate-day treatment with low to moderate doses of short-acting systemic steroid, and intra-articular, bursal, or tendon injection of corticosteroids are not immunosuppressive in their usual doses and do not contraindicate the administration of [measles, mumps, or rubella vaccine]."{33,34,37}

Immune Globulin

Administration of immune globulins concurrently with M-M-R II may interfere with the expected immune response.{33,34,47}

See also PRECAUTIONS, *General*.

Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: (1) In a 10-year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome;{50} (2) Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and fetus, there is no evidence that it causes congenital malformations in humans;{37} and (3) Reports have indicated that contracting wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy.{51,52} There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse fetal effects.

Nursing Mothers

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunized with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants.{53} In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.{54,55} Caution should be exercised when M-M-R II is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established (see also CLINICAL PHARMACOLOGY). Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

Geriatric Use

Clinical studies of M-M-R II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of monovalent or bivalent vaccine containing measles, mumps, or rubella:

Body as a Whole

Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Arthralgia and/or arthritis (usually transient and rarely chronic), and polyneuritis are features of infection with wild-type rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children. This type of involvement as well as myalgia and paresthesia, have also been reported following administration of MERUVAX II.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms.

Following vaccination in children, reactions in joints are uncommon and generally of brief duration. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-26%),{17,56,57} and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in women older than 35 years, these reactions are generally well tolerated and rarely interfere with normal activities.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS); subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; paresthesia.

Encephalitis and encephalopathy have been reported approximately once for every 3 million doses of M-M-R II or measles-, mumps-, and rubella-containing vaccine administered since licensure of these vaccines.

The risk of serious neurological disorders following live measles virus vaccine administration remains less than the risk of encephalitis and encephalopathy following infection with wild-type measles (1 per 1000 reported cases).{58,59}

In severely immunocompromised individuals who have been inadvertently vaccinated with measles-containing vaccine; measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported (see CONTRAINDICATIONS). In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of infection with wild-type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with infection with wild-type measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Centers for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.{60}

Cases of aseptic meningitis have been reported to VAERS following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Respiratory System

Pneumonia; pneumonitis (see CONTRAINDICATIONS); sore throat; cough; rhinitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; urticaria; rash; measles-like rash; pruritis.

Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); swelling; induration; tenderness; vesiculation at injection site; Henoch-Schönlein purpura; acute hemorrhagic edema of infancy.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

Urogenital System

Epididymitis; orchitis.

Other

Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see CONTRAINDICATIONS). No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982 to 1993.{61}

Under the National Childhood Vaccine Injury Act of 1986, health-care providers and manufacturers are required to record and report certain suspected adverse events occurring within specific time periods after vaccination. However, the U.S. Department of Health and Human Services (DHHS) has established a Vaccine Adverse Event Reporting System (VAERS) which will accept all reports of suspected events.{49} A VAERS report form as well as information regarding reporting requirements can be obtained by calling VAERS 1-800-822-7967.

DOSAGE AND ADMINISTRATION

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravascularly.

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

The recommended age for primary vaccination is 12 to 15 months.

Revaccination with M-M-R II is recommended prior to elementary school entry. See also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*.

Children first vaccinated when younger than 12 months of age should receive another dose between 12 to 15 months of age followed by revaccination prior to elementary school entry.{32} See also INDICATIONS AND USAGE, *Measles Outbreak Schedule*.

Immune Globulin (IG) is not to be given concurrently with M-M-R II (see PRECAUTIONS, *General* and PRECAUTIONS, *Drug Interactions*).

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Single Dose Vial — First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of restored vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. M-M-R II, when reconstituted, is clear yellow.

Use With Other Vaccines

M-M-R II should be given one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)], and PedvaxHIB® [*Haemophilus b* Conjugate Vaccine (Meningococcal Protein Conjugate)] using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone.

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens.

However, other schedules have been used. The ACIP has stated "Although data are limited concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTaP [or DTwP], IPV [or OPV], Hib with or without Hepatitis B vaccine, and varicella vaccine), data from numerous studies have

indicated no interference between routinely recommended childhood vaccines (either live, attenuated, or killed). These findings support the simultaneous use of all vaccines as recommended."{62}

HOW SUPPLIED

No. 4681 — M-M-R II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), **NDC** 0006-4681-00; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Storage

To maintain potency, M-M-R II must be stored between -58°F and +46°F (-50°C to +8°C). Use of dry ice may subject M-M-R II to temperatures colder than -58°F (-50°C).

Protect the vaccine from light at all times, since such exposure may inactivate the viruses.

Before reconstitution, store the lyophilized vaccine at 36°F to 46°F (2°C to 8°C). The diluent may be stored in the refrigerator with the lyophilized vaccine or separately at room temperature. **Do not freeze the diluent.**

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 36°F to 46°F (2°C to 8°C) and discard if not used within 8 hours.

For information regarding stability under conditions other than those recommended, call 1-800-MERCK-90.

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Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

For patent information: www.merck.com/product/patent/home.html

Revised: 05/2017

uspi-v205c-i-1705r007

Side-effects of MMR vaccine when a cohort of 100,000 children are vaccinated

Have you ever been studying a side-effect list for vaccines? We will give you an example. Every year around 115,000 children are born in Sweden and 98% of them are vaccinated. We round it to 100,000 children for the sake of simplicity.

Below are the side-effects and frequency of the GlaxoSmithKlines MMR vaccine Priorix (against measles, mumps and rubella) according to the package leaflet from the Swedish Medical Products Agency: http://www.fass.se/LIF/product?userType=0&nplId=19980717000112
(In parentheses we have given information about the correlating number of children affected per year):

Very common	≥1/10 (10 000 – or more children/year)
Common:	≥1/100, <1/10 (1 000 – 10,000 children/year)
Uncommon:	≥1/1,000, <1/100 (100 – 1,000 children/year)
Rare:	≥1/10,000, <1/1,000 (10 – 100 children/year)

Adverse effects of MMR vaccine when the yearly cohort of 100,000 children are vaccinated

Infections and infestations:
Common: **upper respiratory tract infections** (≥1 / 100, <1/10) (1,000 – 10,000 children / year)
Uncommon: **otitis media** (middle ear inflammation) (≥1 / 1,000, <1/100) (100 – 1,000 children / year)

Blood and lymphatic system:
Uncommon: **lymphadenopathy** (≥1 / 1,000, <1/100) (100 – 1,000 children / year)

Immune system:
Rare: **allergic reactions** ≥1 / 10,000, <1/1,000) (10 – 100 children / year)

Metabolism and Nutrition:
Uncommon: **anorexia** (≥1 / 1,000, <1/100) (100 – 1000 children / year)

Mental disorders:
Uncommon: **anxiety, persistent crying, insomnia** (≥1 / 1,000, <1/100) (100 – 1000 children / year)

Central, peripheral nervous system:
Rare: **fever cramps** ≥1 / 10,000, <1/1,000) (10 – 100 children / year)

Eye:
Uncommon: **conjunctivitis** (≥1 / 1,000, <1/100**)** (100 – 1000 children / year)

Respiratory, thoracic and mediastinal disorders:
Uncommon: **bronchitis, cough** (≥1 / 1,000, <1/100) (100 – 1000 children / year)

Gastrointestinal tract:
Uncommon: **enlarged parotid glands, diarrhea, vomiting** (≥1 / 1,000, <1/100) (100 – 1000 children / year)

Skin and subcutaneous tissue:
Common: **rash** (≥1 / 100, <1/10) (1,000 – 10,000 children / year)

General disorders and administration site conditions:
Very common: redness at the injection site, **fever ≥38 ° C** (rectally) or ≥37.5 ° C (axillary / oral) (≥10) (10,000 children / year)
Common: pain and swelling at the injection site, **fever> 39.5 ° C** (rectally) or > 39 ° C (axillary / oral) (≥1 / 100, <1/10) (1,000 – 10,000 children / year)

In general, the frequency of adverse events was equivalent to the first and second vaccine dose. An exception to this is injection site pain, which was "common" after the first dose (≥1 / 100, <1/10) (1,000 – 10,000 children / year) and "very common" after the second dose of the vaccine. (≥10) (10,000 children / year)

Data after launching

During post-marketing follow-up of GlaxoSmithKlines MMR vaccine Priorix, the following adverse reactions have been identified. Since they have been reported voluntarily from a population of unknown size, the frequency cannot be reliably estimated:

Infections and infestations:
Meningitis, measles-like syndrome, esophagus syndrome (including **orchitis, epididymitis and parotitis**)

Blood and lymphatic system:
Thrombocytopenia, thrombocytopenic purpura

Immune system:
Anaphylactic reactions

Nervous system:
Encephalitis*, cerebellitis, **cerebellitis-like symptoms** (including **transient myocardial and transient ataxia**), **Guillain-Barré syndrome, transverse myelitis, peripheral neuritis**

Blood vessels:
Vasculitis (vascular inflammation)

Skin and subcutaneous tissue:
Erythema multiforme

Musculoskeletal system and connective tissue:
Arthralgia, arthritis (muscle and joint pain)

* Encephalitis has been reported at a rate of less than 1 of 10 million doses. The risk of encephalitis after vaccination is much lower than the risk of encephalitis caused by natural diseases (measles: 1 in 1,000 to 2,000 cases; mumps: 2-4 in 1,000 cases; rubella: approximately 1 in 6,000 cases).

Our own statistical calculation model

If we use mean values we have the following data per cohort of 100,000 children:

Upper respiratory tract infection	**5,000 children / year**
Ear inflammation	**500 children / year**
Lymphadenopathy	**500 children / year**
Allergic reactions	**50 children / year**
Anorexia:	**500 children / year**
Anxiety, persistent cry, can´t sleep:	**500 children / year**
Fever cramps:	**50 children / year**
Eye inflammation:	**500 children / year**
Bronchitis, cough:	**500 children / year**
Enlargened parotid glands, diarrhea, vomiting:	**500 children / year**
Rash	**5,000 children / year**
Fever 38 degrees centigrade	**10,000 children / year**
Fever 39.5	**5,000 children / year**
A total of	**28,600 cases / year**

If 100,000 children are vaccinated it brings along more than 28,600 side-effects, which means that there is a 28% risk of getting a side-effect from the vaccine. Even if the fever cases, depending on how the study is conducted, should be meant to be contracted with 5,000, still 23,600 children will have adverse effects.

This brings along that around every fourth child may be affected and that in 10,000 - 15,000 cases the parents will stay at home with their feverish children. In Sweden two cohorts are vaccinated and that would mean 20,000 to 30 000 feverish children. Before we started to vaccinate, in average 10,000 individuals got the measles in Sweden. Most cases healed without complications. Honestly, has the child, the parents or the society then gained anything at all from the vaccination?

According to the list above, an unknown number of children will get the following complications. If we presume that the complications are very rare and only occurs in 1/100,000 cases still mean that two children each year (since there are two cohorts receiving the MPR vaccine) will get each of the listed complications from the vaccine, there will be two children who will get meningitis, two who will get thrombocytopenia (they can bleed to death), two who will get Gullian-Barré's syndrome and so on. However, this does not apply to encephalitis, which is said to occur in less than 1/1,000,000 vaccine doses. We also know from studies that only 1-17% of the adverse effects are spontaneously reported.

- Meningitis
- Measles alike syndrome
- Mumps alike syndrome
- Thrombocytopenia, thrombocytopenic purpura
- Anaphylactic reactions
- Encephalitis*
- Cerebellitis, cerebellitis-like symptoms (including transient disturbances and transient ataxia)
- Guillain-Barré Syndrome,
- Transversal myelitis
- Peripheral neurite
- Vasculitis (vascular inflammation)
- Erythema multiforme
- Arthralgia, arthritis (muscle and joint pain)

The parents should be happy as their child at least didn´t contract natural measles!?...

Administracinė byla Nr. I-6-662/2016
Teisminio proceso Nr. 3-66-3-00057-2015-8
Procesinio sprendimo kategorija 17.1

LIETUVOS VYRIAUSIASIS ADMINISTRACINIS TEISMAS

S P R E N D I M A S
LIETUVOS RESPUBLIKOS VARDU

2016 m. liepos 5 d.
Vilnius

Lietuvos vyriausiojo administracinio teismo išplėstinė teisėjų kolegija, susidedanti iš teisėjų Audriaus Bakavecko (pranešėjas), Arūno Dirvono, Irmanto Jarukaičio (kolegijos pirmininkas), Dainiaus Raižio ir Veslavos Ruskan,

sekretoriaujant Violetai Tamošiūnaitei,

dalyvaujant pareiškėjai Lietuvos Respublikos Seimo narei Dangutei Mikutienei,

pareiškėjų atstovui advokatui Gintarui Kalinauskui,

atsakovo Sveikatos apsaugos ministerijos atstovams Nerijai Kuprevičienei, Vytautui Usoniui ir Aleksandrui Naujūnui,

viešame teismo posėdyje išnagrinėjo norminę administracinę bylą pagal pareiškėjų Lietuvos Respublikos Seimo narių Dangutės Mikutienės, Gintaro Tamošiūno, Vitalijaus Gailiaus ir Aurelijos Stancikienės pareiškimą ištirti, ar Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymu Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ patvirtintos Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ 94 punktas (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) neprieštarauja Lietuvos Respublikos civilinio kodekso 2.25 straipsnio 1 ir 2 dalims, Lietuvos Respublikos žmonių užkrečiamųjų ligų profilaktikos ir kontrolės įstatymo 11 straipsnio 1 ir 5 dalims, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 1 straipsnio 2 dalies 3 punktui, 14 straipsnio 2 daliai, Lietuvos Respublikos viešojo administravimo įstatymo 3 straipsnio 1 punkte įtvirtintam įstatymo viršenybės principui ir 6 straipsnio 2 daliai, Lietuvos Respublikos švietimo įstatymo 5 straipsnyje įtvirtintam lygių galimybių principui, konstituciniam asmenų lygiateisiškumo ir konstituciniam teisinės valstybės principams; taip pat, ar Lietuvos Respublikos sveikatos apsaugos ministro 2004 m. gruodžio 24 d. įsakymu Nr. V-951 „Dėl Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ patvirtinimo“ patvirtintų Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ pildymo taisyklių 9 punkto (2015 m. lapkričio 26 d. įsakymo Nr. V-1336 redakcija) nuostatos neprieštarauja Lietuvos Respublikos asmens duomenų teisinės apsaugos įstatymo 5 straipsnio 2 ir 3 daliai, 10 straipsnio 1 daliai, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 8 straipsnio 1 daliai.

Išplėstinė teisėjų kolegija

n u s t a t ė:

I.

1. Lietuvos Respublikos Seimo nariai Dangutė Mikutienė, Gintaras Tamošiūnas, Vitalijus Gailius ir Aurelija Stancikienė (toliau – ir pareiškėjai, Seimo nariai) 2015 m. gruodžio 30 d.

pareiškimu kreipėsi į Lietuvos vyriausiąjį administracinį teismą prašydami ištirti, ar Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymu Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ patvirtintos Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ 94 punktas (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) neprieštarauja Lietuvos Respublikos civilinio kodekso 2.25 straipsnio 1 ir 2 dalims, Lietuvos Respublikos žmonių užkrečiamųjų ligų profilaktikos ir kontrolės įstatymo 11 straipsnio 1 ir 5 dalims, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 1 straipsnio 2 dalies 3 punktui, 14 straipsnio 2 daliai, Lietuvos Respublikos viešojo administravimo įstatymo 3 straipsnio 1 punkte įtvirtintam įstatymo viršenybės principui ir 6 straipsnio 2 daliai, Lietuvos Respublikos švietimo įstatymo 5 straipsnyje įtvirtintam lygių galimybių principui, konstituciniam asmenų lygiateisiškumo ir konstituciniam teisinės valstybės principams; taip pat ar Lietuvos Respublikos sveikatos apsaugos ministro 2004 m. gruodžio 24 d. įsakymu Nr. V-951 „Dėl Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ patvirtinimo“ patvirtintų Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ pildymo taisyklių 9 punkto (2015 m. lapkričio 26 d. įsakymo Nr. V-1336 redakcija) nuostatos neprieštarauja Lietuvos Respublikos asmens duomenų teisinės apsaugos įstatymo 5 straipsnio 2 ir 3 daliai, 10 straipsnio 1 daliai, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 8 straipsnio 1 daliai.

2. Pareiškime teigiama, kad Lietuvos Respublikos sveikatos apsaugos ministras 2014 m. birželio 12 d. priėmė įsakymą Nr. V-683 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo, kuriuo nustatė kad priimant vaiką į įstaigą ir vėliau kiekvienais metais turi būti pateiktas Vaiko sveikatos pažymėjimas (forma Nr. 027-1/A) [4.5, 4.10]. Jeigu pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito, nesant skiepų kontraindikacijų, į įstaigą toks vaikas nepriimamas. Lietuvos Respublikos sveikatos apsaugos ministras minėtu įsakymu nustatė, kad šis įsakymas įsigalioja nuo 2016 m. sausio 1 d. Iki 2016 m. sausio 1 d. galiojančiame Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos „Ikimokyklinio ir priešmokyklinio ugdymo programų vykdymo bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ (toliau – ir Įsakymas Nr. V-313) 94 punkte buvo nustatyta, kad priimant vaiką į įstaigą ir vėliau kiekvienais metais turi būti pateiktas Vaiko sveikatos pažymėjimas (forma Nr. 027-1/A) [4.5, 4.10], o 95 punkte nustatytas draudimas priimti sergančius ar (ir) turinčius užkrečiamųjų ligų požymių (karščiuoja, skundžiasi skausmu, viduriuoja, vemia, kosti, yra išskyrų iš nosies ir kt.) vaikus, taip pat turinčius utėlių ar glindų. Pareiškėjams kyla klausimas ir abejonė, ar vaiko sveikata, šiuo atveju sirgimas, priklauso nuo fakto, ar vaikas skiepytas, ar neskiepytas, t. y. ar *a priori* galima teigti, kad jeigu vaikas neskiepijamas, tai jo sveikatos būklė skiriasi nuo kitų vaikų ir jis negali būti priimtas į ugdymo įstaigą. Pagal minėtą Įsakymo Nr. V-313 95 punktą, negali būti priimti ar lankyti ugdymo įstaigos vaikai, sergantys arba turintys aiškius ligų požymius.

3. Pareiškėjai vadovaujasi Lietuvos Respublikos viešojo administravimo įstatymo (toliau – ir Viešojo administravimo įstatymas) 3 straipsnio 1 punktu, 6 straipsnio 2 dalimi, 3 straipsnio 1 dalies 4 punktu, 3 straipsnio 1 dalies 1 punktu ir pažymi, kad Lietuvos Respublikos sveikatos apsaugos ministerija (toliau – ir Ministerija) ir ministras, kaip viešojo administravimo subjektai, be specialiųjų teisės nuostatų, savo veikloje privalo laikytis viešojo administravimo srityje taikomų viešojo administravimo principų. Pareiškėjai abejoja, ar sveikatos apsaugos ministras, privalėdamas vadovautis Lietuvos Respublikos Konstitucija (toliau – ir Konstitucija) ir įstatymais, savo iniciatyva gali riboti sveikų vaikų priėmimą į ugdymo įstaigas, taip ne tik pažeisdamas žmogaus teisių ir laisvių ribojimo sąlygas, iš anksto nustatydamas ribojimus pasirinkti sveikatos priežiūros paslaugas,

bet ir kišdamasis į kitos valdymo šakos sritį dėl vaikų ugdymo programų. Įsakyme Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) nėra nurodytas įstatymas, kuriuo vadovaujantis ar kurio pagrindu buvo priimtas įsakymas, ribojantis sveikatos paslaugų suteikimą bei iš anksto nustatantis gydymo sąlygas ir draudimus dėl sveikų vaikų priėmimo į ugdymo įstaigas.

4. Pareiškėjai pažymi, kad 2014 m. sausio 3 d. Lietuvos Respublikos sveikatos apsaugos ministras priėmė įsakymą Nr. V-8 „Dėl Nacionalinės imunoprofilaktikos 2014-2018 metų programos patvirtinimo“, kuriuo buvo patvirtinta Nacionalinė imunoprofilaktikos 2014-2018 metų programa (toliau – ir Programa). Programoje nurodomas nacionalinių skiepijimų kalendorius yra rekomenduojamas, tačiau būtinas tėvų (ar) globėjų sutikimas vaiką skiepyti. Kadangi ši prevencinė priemonė yra rekomendacinio pobūdžio ir jai būtinas tėvų ar globėjų sutikimas, kyla klausimas, ar Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas yra suderintas su Programos 14 punktu ir užtikrina nuoseklų teisinį reguliavimą. Pažangiose ir išsivysčiusiose šalyse – Anglijoje, Danijoje, Suomijoje, Vokietijoje, Islandijoje, Airijoje, Olandijoje, Norvegijoje, Vokietijoje, Estijoje – nėra privalomų vakcinų.

5. Pareiškėjų manymu, Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas prieštarauja Lietuvos Respublikos civilinio kodekso (toliau – ir CK) 2.25 straipsnio 1 ir 2 dalims, kadangi nors ir skiepijimas nėra privalomas ir negali sukurti jokių teisinių pasekmių, tačiau neduodant tėvams sutikimo, jie praranda galimybę ugdyti vaikus ugdymo įstaigose, taip paneigiant CK 2.25 straipsnyje įtvirtintą asmens teisę į kūno neliečiamumą ir vientisumą.

6. Pareiškėjai taip pat abejoja, ar Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas neprieštarauja Lietuvos Respublikos žmonių užkrečiamųjų ligų profilaktikos ir kontrolės įstatymo (toliau – ir Užkrečiamų ligų įstatymas) 11 straipsnio 1 ir 5 dalimis, numatančiomis, kad imunoprofilaktika gali būti taikoma asmenims tik jų sutikimu, išskyrus kituose teisės aktuose numatytus atvejus, bei visuotinė imunoprofilaktika gali būti taikoma tik šio Įstatymo nustatyta tvarka paskelbus teritorijų karantiną. Akivaizdu, kad įstatymas reikalauja tokias priemonės taikyti tik esant asmens sutikimui, ar apibrėžus tokius atvejus, kaip susijusius su grėsme visuomenės sveikatai, tačiau nepaneigiant asmens teisių ir laisvių principo įgyvendinimo. Pareiškėjai kelia klausimą, ar Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas *a priori* numatantis, kad neskiepyti vaikai negali būti priimti į ugdymo įstaigą, yra proporcingas ir reikalingas siekiamiems tikslams įgyvendinti. Imunoprofilaktika yra ne vienintelė priemonė padidinti žmonių atsparumą užkrečiamosioms ligoms. Be to, turi būti aiškios grėsmės, kad būtų vykdoma visuotinė imunoprofilaktika ir ribojama ugdymo įstaigų veikla ir vaikų ugdymo procesas.

7. Kaip jau buvo minėta, pagal Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktą nuo tymų, raudonukės ir poliomielito nepaskiepytas vaikas, nesant skiepų kontraindikacijų, į ugdymo įstaigą nepriimamas. Pareiškėjai teigia, jog vaikas, nepaskiepytas nuo kokliušo, bus priimtas į įstaigą (susirgimų atvejų 2012 m. – 154), o vaikas, nepaskiepytas, pvz., nuo tymų (susirgimų kuriais per 2003-2012 metų laikotarpį nebuvo užfiksuota), nepateks į ugdymo įstaigą. Pažymi, jog yra žymiai grėsmingesnių susirgimų (pvz., kokliušas, hepatitas B), kurie kelia realią grėsmę vaikų sveikatai.

8. Pareiškėjai mano, kad Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatos prieštarauja Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo (toliau – ir Pacientų įstatymas) 1 straipsnio 2 dalies 3 punkto, 14 straipsnio 2 dalies nuostatoms bei negarantuoja paciento teisės į privataus gyvenimo neliečiamumą. Būtent Konstitucijos ir įstatymų saugomos vertybės, tokios kaip teisė į privatų gyvenimą, teisė į asmens neliečiamumą, teisė į švietimą, sveikatos apsaugos ministro įsakymu yra iškreipiamos, nes tėvai savo sveikų vaikų negali leisti į ugdymo įstaigas arba turi priverstinai skiepyti savo vaikus, t. y. ribojant jų valdžią ir galimybę laisvai pasirinkti sveikatos paslaugas ar jų nesirinkti, įpareigojant rinktis tik vieną imuniteto didinimui skirtą priemonę. Konstitucinių vertybių ir teisių ribojimas negalimas poįstatyminiu aktu.

9. Pareiškėjai nurodo, kad Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ pildymo taisyklių, patvirtintų Lietuvos Respublikos sveikatos apsaugos ministro 2015 m. lapkričio 26 d. įsakymu Nr. V-1336 (toliau – ir Vaiko sveikatos pažymėjimo pildymo taisyklės), kurios įsigalios 2016 m. sausio 1 d., 9 punkte numatyta, kad vadovaujantis Lietuvos Respublikos sveikatos apsaugos ministro 2014 m. birželio 12 d. įsakymo Nr. V-683 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo“ 94 punktu, pildant ikimokyklines ir (ar) priešmokyklines įstaigas lankančių vaikų pažymėjimus, laukelyje „Diagnozė“ įrašoma, ar vaikas yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas) (pavyzdys: paskiepytas visais reikalingais skiepais, norint lankyti ikimokyklinę ugdymo įstaigą; paskiepytas tik nuo tymų ir raudonukės; nepaskiepytas nė vienu iš reikalingų skiepų, norint lankyti ikimokyklinę ugdymo įstaigą). Jei vaikas nepaskiepytas esant skiepų kontraindikacijoms, tai privaloma nurodyti (pavyzdys: neskiepytas nuo tymų esant kontraindikacijoms).

10. Pareiškėjai vadovaujasi Lietuvos Respublikos asmens duomenų teisinės apsaugos įstatymo (toliau – ir ADTAĮ) 2 straipsnio 8 dalimi ir teigia, jog informacija apie asmens pasiskiepijimą nuo atitinkamų ligų yra laikytina ypatingais asmens duomenimis. Ypatingų asmens duomenų tvarkymas laikomas teisėtu tik tuo atveju, jeigu jis atitinka ADTAĮ 3, 5 ir 10 straipsnių reikalavimus. Pripažinus Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatas prieštaraujančias įstatymams, nėra jokio teisėto tikslo rinkti duomenis ir teikti duomenis apie skiepus ugdymo įstaigoms, kaip tai numato Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punktas. Be to, pareiškėjų manymu, minėtame punkte įtvirtintas reglamentavimas prieštarauja Pacientų įstatymo 8 straipsnio 1 daliai, numatančiai, kad paciento privatus gyvenimas yra neliečiamas, bei ADTAĮ 5 straipsnio 2 ir 3 dalims, 10 straipsnio 1 daliai, kadangi informacija apie paciento gyvenimo faktus gali būti renkama tik su paciento sutikimu ir tuo atveju, jei tai yra būtina ligai diagnozuoti, gydyti ar pacientui slaugyti.

11. Pareiškėjai atkreipia dėmesį, kad Lietuvos Respublikos Seimas 2015 gruodžio 22 d. priėmė Lietuvos Respublikos švietimo įstatymo (toliau – ir Švietimo įstatymas) Nr. I-1489 2, 7, 8, 9, 24, 27, 36, 37, 43, 46 ir 47 straipsnių pakeitimo įstatymo projektą Nr. XIIP-3375(2), kuris numato, kad privalomu tampa ir priešmokyklinis ugdymas. Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas, draudžiantis priimti vaikus į ugdymo įstaigą, neleidžia priimti neskiepytų vaikų į priešmokyklinio ugdymo įstaigas, o tai prieštarauja Švietimo įstatymui. Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatos numato papildomas sąlygas dėl privalomo vaiko ugdymo ir prieštarauja Švietimo įstatymo nuostatomis dėl priešmokyklinio ugdymo sąlygų. Tokiu atveju skiepijimas tampa lemiama sąlyga dėl galimybės lankyti ugdymo įstaigas. Sveikatos apsaugos ministras įsiterpia į kitą valstybės valdymo šakos sritį, šiuo atveju į švietimo ir vaikų ugdymo, nes vaikas nebus priimtas į neformalųjį ugdymą, priešmokyklinę ugdymo programą, nors pagal Švietimo įstatymą nuo 2016 m. rugsėjo 1 d. tai tampa privaloma. Seimo nariai kelia klausimą, ar sveikatos apsaugos ministras, priimdamas minėtą įsakymą, neviršijo įgaliojimų, įsiterpdamas į kitos valdymo šakos sritį, t. y. į švietimo ir ugdymo, reguliuodamas sveikų vaikų priėmimą ir sąlygas į ugdymo įstaigas ir vykdant ugdymo programas. Mano, kad Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatos prieštarauja Švietimo įstatymo 5 straipsnyje įvirtintam lygių galimybių principui, numatančiam, kad švietimo sistema yra socialiai teisinga, ji užtikrina asmens teisių įgyvendinimą, kiekvienam asmeniui ji laiduoja švietimo prieinamumą, bendrojo išsilavinimo bei pirmosios kvalifikacijos įgijimą ir sudaro sąlygas tobulinti turimą kvalifikaciją ar įgyti naują. Pagal sveikatos apsaugos ministro įsakymą, neatsižvelgiant į tai, kad vaikas sveikas, nepaskiepytas, jis negali būti priimtas į ugdymo įstaigą. Nuo 2016 m. rugsėjo 1 d. priešmokykliniam ugdymui tapus privalomuoju, nesant įstatyminio reguliavimo ar reikalavimų, poįstatyminiu aktu ribojamas priėmimas į ugdymo įstaigą priešmokyklinėje grupėje. Susidaro situacija, kai sveikas vaikas negali būti priimtas į ugdymo įstaigas, nors Švietimo įstatymas pripažįsta švietimą prioritetine valstybės

remiama visuomenės raidos sritimi. Taip pat toks teisinis reguliavimas sukuria sąlygas, kad vaikai, jau pradėję lankyti ugdymo įstaigas iki įsakymo įsigaliojimo, jas lankys, o kiti nebus priimami.

12. Pareiškėjai mano, kad Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatos riboja tėvų valdžios turinį ir, net nesant įstatyminio reguliavimo, riboja tėvų galimybes laisvai rinktis ugdymo įstaigas ir būti atsakingiems už savo vaikų sveikatą bei laisvai rinktis sveikatos priežiūros paslaugas ar jų pobūdį. Toks reguliavimas prieštarauja CK 3.165 straipsnio nuostatai, jog tėvai turi pirmumo teisę prieš kitus asmenis būti atsakingais už savo vaikų sveikatą bei auklėjimą. Toks reguliavimas taip pat iškreipia CK 3.155 straipsnio 1 ir 2 dalių nuostatų įgyvendinimą ir riboja tėvų asmenines teises ir pareigas laisvai ir neribotai rinktis sveikatos priežiūros paslaugas. Jeigu manoma, kad reikalingos papildomos sąlygos ar ribojimai tėvų priežiūrai vaikų sveikatos srityje, tai turi būti reguliuojama įstatymais arba turi būti įstatyminis pagrindas tokiam reguliavimui.

13. Pareiškėjai remiasi Konstitucijos 28 straipsniu, 29 straipsniu ir 38 straipsnio 1 dalimi, vadovaujasi Lietuvos Respublikos Konstitucinio Teismo (toliau – ir Konstitucinis Teismas) išaiškinimais dėl asmens teisių apribojimo (žr., pvz., 1997 m. vasario 13 d. nutarimą, 2004 m. gruodžio 13 d. nutarimą), dėl teisės aktų hierarchijos (žr., pvz., 2005 m. sausio 19 d. nutarimą, 2007 m. gegužės 5 d. nutarimą ir kt.). Pažymi, kad Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto nuostatos akivaizdžiai konkuruoja su Švietimo įstatymo saugomomis vertybėmis bei iškreipia ne tik ugdymo procesą, bet ir sveikatos paslaugų teikimą, sąlygas bei laisvą tėvų pasirinkimą dėl vaikų sveikatos priežiūros sąlygų ir būdų.

14. Pareiškėjai taip pat vadovaujasi Konstitucijos 22 straipsnio 3 dalimi, Konstitucinio Teismo išaiškinimais dėl žmogaus teisės į privatumą (žr., pvz., 2002 m. spalio 23 d. nutarimą, 2003 m. kovo 24 d. nutarimą), Lietuvos vyriausiojo administracinio teismo praktika dėl viešojo administravimo subjektų pareigos veikti aukštesnės galios teisės aktais suteiktos kompetencijos ribose (žr., pvz., 2006 m. liepos 28 d. sprendimą administracinėje byloje Nr. I^{444}-4/2006, 2007 m. lapkričio 23 d. sprendimą administracinėje byloje Nr. I^{438}-15/2007 ir kt.), Europos Žmogaus Teisių Teismo 2012 m. birželio 26 d. sprendimu *Kurič ir kiti* prieš *Slovėniją* (pareiškimo Nr. 26828/06) dėl nediskriminavimo principo ir kt.

II.

15. Rengiantis nagrinėti norminę bylą teismo posėdyje, buvo gautas atsakovo Lietuvos Respublikos sveikatos apsaugos ministerijos (toliau – ir atsakovas) atsiliepimas, kuriame prašoma pareiškėjų pareiškimą atmesti kaip nepagrįstą.

16. Atsakovas dėl Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto atitikties Viešojo administravimo įstatymo 3 straipsnio 1 punkte įtvirtintam įstatymo viršenybės principui ir 6 straipsnio 2 daliai nurodo, kad Ministerija neviršijo savo, kaip viešojo administravimo subjekto, įgaliojimų, nustatydama ginčijamą teisinį reglamentavimą. Ministerija, kaip viešojo administravimo subjektas, turi įstatymų leidėjo jai suteiktą kompetenciją priimti sprendimus – teisės aktus, nustatančius privalomojo pobūdžio teisės normas visuomenės sveikatos priežiūros srityje, nagrinėjamu atveju – pagrindinius įstaigų, įmonių ar grupių, kurios vykdo ikimokyklinio ir (ar) priešmokyklinio ugdymo programas, ugdymo proceso organizavimo sveikatos saugos reikalavimus. Atkreipia dėmesį, kad Įsakymas Nr. V-313 priimtas remiantis Lietuvos Respublikos visuomenės sveikatos priežiūros įstatymo (toliau – ir Visuomenės sveikatos priežiūros įstatymas) 36 straipsnio 1 dalimi. Pareiškėjų teiginiai dėl viršytų Ministerijos įgaliojimų atmestini kaip nepagrįsti. Vadovaujasi Lietuvos Aukščiausiojo Teismo 2004 m. sausio 13 d. nutartimi civilinėje byloje Nr. 3K-7-24/2004. Pagal Lietuvos Respublikos Vyriausybės įstatymo 26 straipsnio 3 dalį, Ministerijai vadovauja ministras, kuris sprendžia ministerijos kompetencijai priklausančius klausimus, užtikrina Lietuvos Respublikos įstatymų įgyvendinimą, priima ir pasirašo įsakymus bei užtikrina jų vykdymo kontrolę. Valdymo sritys, už kurias yra atsakingas sveikatos apsaugos ministras, yra nustatytos Lietuvos Respublikos Vyriausybės 2010 m. kovo 24 d. nutarime Nr. 330. Vadovaujantis Sveikatos apsaugos ministerijos nuostatų, patvirtintų Lietuvos Respublikos

Vyriausybės 1998 m. liepos 24 d. nutarimu Nr. 926, 9.2 papunkčiu, vienas svarbiausių Ministerijos veiklos tikslų – formuoti valstybės politiką visuomenės sveikatos priežiūros srityje, organizuoti, koordinuoti ir kontroliuoti jos įgyvendinimą. Paneigtina pareiškėjų keliama abejonė dėl įstatyminio pagrindo buvimo Ministerijai nustatyti ginčijamą teisinį reguliavimą. Ministerijos nuomone, pareiškime ydingai, nepagrįstai ir nelogiškai formuluojami teiginiai, kuriuose pasisakoma apie žmogaus teisių ir laisvių ribojimų nustatymus. Ministerija atkreipia dėmesį, kad nustatytuoju teisiniu reguliavimu nėra ribojamos paciento teisės pasirinkti sveikatos priežiūros įstaigą ar specialistą. Pareiškėjų teiginiai dėl sveikatos apsaugos ministro kišimosi į kitą valdymo sritį – vaikų ugdymo programas – visiškai nepagrįsi, kadangi Įsakymas Nr. V-313 nustato pagrindinius įstaigų, įmonių ar grupių, kurios vykdo ikimokyklinio ir (ar) priešmokyklinio ugdymo programas, ugdymo proceso organizavimo sveikatos saugos reikalavimus.

17. Dėl Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto atitikties Programai atsakovas nurodo, jog pareiškimo 5 punkte yra cituojamos Programos 14 punkto nuostatos, tačiau visiškai nėra aišku, kokias aplinkybes pareiškėjai siekia pagrįsti šia citata. Programos 5 punkte pateikta situacijos analizė, konstatuojama esama būklė, tačiau nenustatomi reikalavimai. Pagrindiniai Programos tikslai yra valdyti, mažinti sergamumą, protrūkių tikimybę, pašalinti ir išnaikinti vakcinomis valdomas užkrečiamąsias ligas (tymai, raudonukė) ir užtikrinti skiepijimo saugumą, efektyvumą ir prieinamumą. Įsakymo Nr. V-313 teisiniu reguliavimu siekiama sukurti saugią aplinką vaikų ugdymo įstaigose ir užkirsti kelią užkrečiamųjų ligų plitimui. Tokia praktika taikoma ir kitose šalyse, o kai kuriose Europos Sąjungos šalyse visi ar kai kurie skiepijimai pagal šalies vaikų skiepijimų kalendorių yra privalomi. Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktu yra siekiama įgyvendinti Programos tikslus ir uždavinius.

18. Dėl Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto atitikties Užkrečiamų ligų įstatymo 11 straipsnio 1 ir 5 dalims ir CK 2.25 straipsnio 1 ir 2 dalims atsakovas išdėsto, jog pareiškėjai nepateikė jokių argumentų, kuriais remiantis galima būtų suabejoti dėl Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto atitikties šioms įstatyminėms teisės normoms. Mano, kad pareiškimas neatitinka Lietuvos vyriausiojo administracinio teismo principinių reikalavimų, keltinų pareiškimui ištirti norminio teisės akto atitiktį įstatymams ar Lietuvos Respublikos Vyriausybės nutarimams, kadangi pareiškimas yra deklaratyvaus pobūdžio, o jame išdėstytais teiginiais, Ministerijos manymu, reiškiama subjektyvi, neargumentuota, nepagrįsta aiškiai suformuluotais teisiniais argumentais pareiškėjų pozicija. Tiek Užkrečiamųjų ligų įstatymo 11 straipsnio 1 dalis, tiek Pacientų įstatymo nuostatos nustato draudimą teikti sveikatos priežiūros paslaugas pacientui be jo ar jo atstovų sutikimo, o Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas nereglamentuoja skiepijimų privalomumo ar skiepijimo be tėvų (kitų vaiko atstovų) sutikimo, todėl nėra jokio pagrindo teigti, kad 94 punktas neatitinka įstatyminio reguliavimo. Atkreipia dėmesį, kad Užkrečiamųjų ligų įstatymo 11 straipsnio 5 dalyje reglamentuojamas visuotinės imunoprofilaktikos taikymas, o vaikų skiepijimai pagal Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nėra ir negali būti traktuojami kaip visuotinė imunoprofilaktika. Pagal Užkrečiamųjų ligų įstatymo 11 straipsnio 4 dalį, imunoprofilaktikos tvarką nustato Sveikatos apsaugos ministerija. Atsižvelgiant į tai, darytina išvada, kad Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas neprieštarauja Užkrečiamųjų ligų įstatymo 11 straipsnio 5 daliai. CK 2.25 straipsnio 1 ir 2 dalys nustato draudimą atlikti tam tikrus veiksmus be paciento (jo atstovo) sutikimo, tačiau šio įstatymo nuostatos nenustato reikalavimų ar kitų priemonių, susijusių su vaikų ikimokykliniu ugdymu, todėl mano, jog pareiškimo 6.2, 6.3 papunkčiuose dėstomi teiginiai vertintini kaip nesusiję su nagrinėjamos bylos dalyku. Informuoja, jog Pasaulio sveikatos organizacija numatė, kad iki 2018 metų poliomielitas, tymai ir raudonukė turi būti likviduoti (pašalinti), todėl skiepijimų apimtys kiekvienoje įstaigoje, teritorijoje, šalyje turi būti didelės, siekiant išvengti bet kokių galimybių plisti ligų sukėlėjams.

19. Atsakovo manymu, iš pareiškimo neaišku, kokia apimtimi Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas prieštarauja Pacientų įstatymo 1 straipsnio

2 dalies 3 punktui ar 14 straipsnio 2 daliai. Pažymi, kad sveikatos apsaugos ministro įsakymu patvirtinta nuostata niekaip nepažeidžia paciento privataus gyvenimo neliečiamumo teisės, kadangi Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas nustato ugdymo proceso organizavimo sveikatos saugos reikalavimus. Minėtas punktas nenustato privalomo vaikų skiepijimo, todėl sprendimą turi teisę priimti vaiko tėvai ar kiti atstovai. Pagal Visuomenės sveikatos priežiūros įstatymo 36 straipsnio 1 dalyje nustatytą reguliavimą siekiama užtikrinti, kad ikimokyklinio ugdymo mokyklose ir bendrojo lavinimo mokyklose būtų sudarytos sąlygos vaikų sveikatai išsaugoti ir stiprinti, vaikų sveikatos priežiūrai užtikrinti. To paties straipsnio 2 dalies 2 ir 3 punktuose nurodyta, kad vaikų sveikatos sauga įgyvendinama užtikrinant visiems vaikams tinkamą sveikatos priežiūrą, didinant visų vaikų imunitetą užkrečiamosioms ligoms, nuo kurių skiepijama.

20. Dėl Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punkto atitikties Švietimo įstatymo 5 straipsnyje įtvirtintam lygių galimybių principui, konstituciniam asmenų lygiateisiškumo ir konstituciniam teisinės valstybės principams atsakovas išdėsto, jog Švietimo įstatymo pakeitimo įstatymas, nustatysiantis privalomą priešmokyklinį švietimą, įsigalios tik 2016 m. rugsėjo 1 d., todėl pareiškėjai neturi jokio teisinio pagrindo teigti, kad 94 punktas prieštarauja Švietimo įstatymui, t. y. toms jo nuostatoms, kurios dar neįsigaliojo. Sveikatos apsaugos ministerija dar iki pareiškėjų nurodomo Švietimo įstatymo pakeitimo įstatymo įsigaliojimo pagal kompetenciją atliks sveikatos apsaugos ministro priimtų teisės aktų analizę bei, esant pagrindui, atliks atitinkamų norminių teisės aktų pakeitimus, siekiant, kad sveikatos apsaugos ministro nustatomas reglamentavimas atitiktų aukščiausią juridinę galią turinčius teisės aktus. Vadovaujasi Lietuvos vyriausiojo administracinio teismo 2013 m. birželio 18 d. sprendimu administracinėje byloje Nr. I^{261}-16/2013 ir teigia, jog sveikatos apsaugos ministro įtvirtintu reglamentavimu siekiama itin svarbių tikslų, o būtent – apsaugoti socialiai labiau pažeidžiamas asmenų grupes – užtikrinti vaikų sveikatos išsaugojimą, sudaryti sąlygas vaikams augti ir vystytis saugioje bei sveikoje aplinkoje, nurodytomis priemonėmis užtikrinti ir tų vaikų, kurie negali būti skiepijami dėl kontraindikacijų, sveikatos apsaugą, sukurti specifinį imunitetą užkrečiamosioms ligoms, kuris gali būti įgytas po skiepų arba išsivystyti natūraliai persirgus tam tikra užkrečiama liga. Įsakymo Nr. V-313 (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija) 94 punktas neprieštarauja konstituciniam teisinės valstybės bei konstituciniam asmenų lygiateisiškumo principui, kadangi priemonės nurodytiems tikslams pasiekti yra proporcingos, taip pat šios priemonės nenustato asmenų teisių ir laisvių varžymo labiau, nei reikia siektiniems tikslams.

21. Atsakovas nurodo, kad pareiškėjai nepateikia argumentų, kuriais remiantis būtų daromos išvados, jog Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punktas galimai prieštarauja ADTAĮ 5 straipsnio 2 daliai, todėl Ministerija neturi galimybės pateikti atsikirtimų į nemotyvuotą pareiškėjų teiginį. Be to, atsižvelgiant į tai, kad duomenų apie sveikatą tvarkymas reglamentuotas specialiose ADTAĮ nuostatose, o būtent ADTAĮ 5 straipsnio 3 dalyje bei 10 straipsnyje, mano, jog minėto punkto atitiktis ADTAĮ 5 straipsnio 2 daliai neturėtų būti vertinama. Nuosekliai vertinant Vaiko sveikatos pažymėjimo pildymo taisyklių nuostatas ADTAĮ 5 straipsnio 3 dalies bei 10 straipsnio 1 dalies nustatyto reglamentavimo prasme, darytina išvada, kad šių taisyklių 9 punktas neprieštarauja nurodytoms ADTAĮ normoms. Dėl Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto atitikties Pacientų įstatymo 8 straipsnio 1 daliai pareiškėjai taip pat apsiriboja neargumentuotais, nepagrįstais teiginiais, kurie vertintini kaip subjektyvi pareiškėjų nuomonė. Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punktas neprieštarauja Pacientų įstatymo 8 straipsnio 1 daliai dėl to, kad pacientas (jo atstovas), priimdamas sprendimą dėl jam teiktinų sveikatos priežiūros paslaugų, sutikimą turi išreikšti raštu, kaip tai reglamentuoja pastarojo įstatymo III skyrius. Ministerijos nuomone, paciento (jo atstovo) sutikimas dėl sveikatos priežiūros paslaugų teikimo apima ne tik sutikimą dėl konkrečios paslaugos gavimo asmens sveikatos priežiūros paslaugas teikiančioje įstaigoje, bet kartu tokiu būdu yra išreiškiama ir paciento (jo atstovo) valia dėl informacijos apie paciento gyvenimo faktus, kiek tai susiję su paciento sveikata, rinkimu, tvarkymu. Pacientų įstatymo 8 straipsnio 1 dalyje yra aiškiai nurodyta, kad pirmiau nurodyta informacija renkama tik su paciento sutikimu. Pagrįsta teigti, jog pacientas (jo atstovas),

kreipdamasis į asmens sveikatos priežiūros įstaigą dėl tam tikrų paslaugų suteikimo, savo valią turi išreikšti Pacientų įstatymo nustatyta tvarka. Be to, pareiškėjai visiškai neanalizuoja kitų Pacientų įstatymo normų.

22. Dėl tarptautinių organizacijų rekomendacijų, formuojamos praktikos, nustatytų uždavinių, taip pat Lietuvos Respublikos įsipareigojimų ir siekiamų tikslų bei dėl vakcinų kokybės, saugumo, patekimo į rinką tvarkos atsakovas išdėsto, jog Pasaulio sveikatos organizacijai (toliau – ir PSO) paskelbus apie tymų, raudonukės ir įgimto raudonukės sindromo eliminavimą (pašalinimą) pasaulyje, Lietuva, kaip ir kitos šalys, siekia įgyvendinti PSO numatytus tymų, raudonukės ir įgimto raudonukės sindromo eliminavimo (pašalinimo) uždavinius ir tikslus. Visi į Lietuvos Respublikos rinką tiekiami vaistiniai preparatai, taip pat ir vakcinos, yra saugūs, kokybiški bei efektyvūs, o nustačius, jog vaistinis preparatas yra žalingas, neveiksmingas, jo naudos ar rizikos santykis tapo nepalankus ar atsirado kitų Lietuvos Respublikos farmacijos įstatyme nurodytų pagrindų, yra sustabdomas ar panaikinamas tokio vaistinio preparato registracijos pažymėjimo galiojimas arba tvirtinamas sąlygų keitimas.

23. Atsakovas pateikia informaciją apie Slovėnijos Respublikos Konstitucinio Teismo 2004 m. vasario 12 d. sprendimą ir Jungtinių Amerikos Valstijų Antrosios apygardos Apeliacinio teismo 2015 m. sausio 7 d. sprendimą.

Išplėstinė teisėjų kolegija

k o n s t a t u o j a:

III.

24. Į Lietuvos vyriausiąjį administracinį teismą kreipęsi pareiškėjai kelia klausimą dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymu Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ patvirtintos Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ (toliau – ir Higienos norma 75:2010) 94 punkto (2014 m. birželio 12 d. įsakymo Nr. V-683 redakcija), numatančio, jog „priimant vaiką į įstaigą ir vėliau kiekvienais metais turi būti pateiktas Vaiko sveikatos pažymėjimas (forma Nr. 027-1/a) [4.5, 4.10]. Jeigu pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito, nesant skiepų kontraindikacijų, į įstaigą toks vaikas nepriimamas“, atitikties Lietuvos Respublikos civilinio kodekso 2.25 straipsnio 1 ir 2 dalims, Lietuvos Respublikos žmonių užkrečiamųjų ligų profilaktikos ir kontrolės įstatymo 11 straipsnio 1 ir 5 dalims, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 1 straipsnio 2 dalies 3 punktui, 14 straipsnio 2 daliai, Lietuvos Respublikos viešojo administravimo įstatymo 3 straipsnio 1 punkte įtvirtintam įstatymo viršenybės principui ir 6 straipsnio 2 daliai, Lietuvos Respublikos švietimo įstatymo 5 straipsnyje įtvirtintam lygių galimybių principui, konstituciniam asmenų lygiateisiškumo ir konstituciniam teisinės valstybės principams.

25. Taip pat pareiškėjai kelia klausimą dėl Lietuvos Respublikos sveikatos apsaugos ministro 2004 m. gruodžio 24 d. įsakymu Nr. V-951 „Dėl Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ patvirtinimo“ patvirtintų Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ pildymo taisyklių 9 punkto (2015 m. lapkričio 26 d. įsakymo Nr. V-1336 redakcija), *inter alia* numatančio, jog „vadovaujantis Lietuvos Respublikos sveikatos apsaugos ministro 2014 m. birželio 12 d. įsakymo Nr. V-683 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo“ 94 punktu, pildant ikimokyklines ir (ar) priešmokyklines įstaigas lankančių vaikų pažymėjimus, laukelyje „Diagnozė“ įrašoma, ar vaikas

yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas) (pavyzdys: paskiepytas visais reikalingais skiepais, norint lankyti ikimokyklinę ugdymo įstaigą; paskiepytas tik nuo tymų ir raudonukės; nepaskiepytas nė vienu iš reikalingų skiepų, norint lankyti ikimokyklinę ugdymo įstaigą). Jei vaikas nepaskiepytas esant skiepų kontraindikacijoms, tai privaloma nurodyti (pavyzdys: neskiepytas nuo tymų esant kontraindikacijoms)“ atitikties Lietuvos Respublikos asmens duomenų teisinės apsaugos įstatymo 5 straipsnio 2 ir 3 daliai, 10 straipsnio 1 daliai, Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 8 straipsnio 1 daliai.

26. Pažymėtina, kad Lietuvos Respublikos sveikatos apsaugos ministras 2016 m. sausio 26 d. įsakymu Nr. V-93 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai patvirtinimo“ pakeitė Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymą Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ ir jį išdėstė nauja redakcija (toliau – ir Higienos norma 75:2016). Nauja redakcija išdėstytos Higienos normos 75:2016 79 punktas įtvirtina, jog „priimant vaiką ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą ir vėliau kiekvienais metais vaiko tėvai (globėjai) švietimo teikėjui pateikia vaiko sveikatos pažymėjimą (forma Nr. 027-1/a) [13.9]. Jeigu vaiko sveikatos pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito nesant skiepų kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas“.

27. Atsižvelgdami į ginčijamo teisinio reguliavimo pakeitimus, pareiškėjai 2016 m. gegužės 16 d. pateikė Lietuvos vyriausiajam administraciniam teismui patikslintą pareiškimą, kuriame vietoje Higienos normos 75:2010 94 punkto prašė tirti pakeistojo ir šiuo metu galiojančio – Higienos normos 75:2016 79 punkto – atitiktį aukštesnės galios teisės aktams. Išplėstinės teisėjų kolegijos vertinimu, atsižvelgiant į tai, jog nors šiai norminio administracinių aktų teisėtumo tyrimo bylai aktualus sveikatos apsaugos ministro įsakymas buvo išdėstytas nauja redakcija, byloje prašytosios tirti nuostatos turinys išliko tapatus ir galiojantis, todėl norminio administracinio akto teisėtumo teisena turi būti tęsiama. Atitinkamai byloje toliau, be kita ko, bus tiriama būtent šiuo metu galiojančios poįstatyminio teisės akto nuostatos – Higienos normos 75:2016 79 punkto – atitiktis aukštesnės galios teisės aktams.

28. Pastebėtina ir tai, jog iš Administracinių bylų teisenos įstatymo šešioliktojo skirsnio, nustatančio pareiškimų ištirti norminių administracinių aktų teisėtumą nagrinėjimo tvarką, matyti, kad norminės administracinės bylos nagrinėjimo ribas pirmiausia apibrėžia pareiškėjo pareiškime pateiktas prašymas, jo apimtis, taip pat šį prašymą pagrindžiantys teisiniai argumentai (Lietuvos vyriausiojo administracinio teismo 2013 m. gegužės 21 d. nutartis administracinėje byloje Nr. I^{662}-11/2013, Lietuvos vyriausiojo administracinio teismo 2015 m. vasario 3 d. sprendimas administracinėje byloje Nr. A-213-552/2015). Nors pareiškėjai konkrečioje byloje Lietuvos vyriausiojo administracinio teismo ir prašo tirti viso Higienos normos 75:2016 79 punkto atitiktį aukštesnės galios teisės aktams, iš jų procesinių dokumentų matyti, jog abejonės šios nuostatos teisėtumu kyla ir atitinkamai teisiniai argumentai, pagrindžiantys šias abejones, yra nukreipti į tą nuostatos dalį, kurioje yra formuluojamas draudimas į ugdymo įstaigas priimti nepaskiepytus vaikus. Likusi nuostatos dalis – taisyklė, jog priimant vaiką į įstaigą ir vėliau kiekvienais metais turi būti pateiktas Vaiko sveikatos pažymėjimas (forma Nr. 027-1/a) [4.5, 4.10] – pareiškėjų kvestionuojama nėra. Atsižvelgdama į tai, išplėstinė teisėjų kolegija šioje byloje tirs Higienos normos 75:2016 79 punkto atitiktį aukštesnės galios teisės aktams ta apimtimi, kuria yra įtvirtinama, jog jeigu vaiko sveikatos pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito nesant skiepų

kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas.

IV.

29. Į Lietuvos vyriausiąjį administracinį teismą kreipęsi pareiškėjai abejones kėlė tiek dėl Higienos normos 75:2016 79 punkto, įtvirtinančio, jog nepaskiepijus vaiko nuo tymų, raudonukės ir poliomielito nesant skiepų kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas, turinio, tiek dėl jo formos atitikties aukštesnės galios teisės aktams.

30. Pirmiausia išplėstinė teisėjų kolegija mano esant reikalinga pasisakyti dėl minėtos nuostatos atitikties konstituciniam teisinės valstybės principui. Šio konstitucinio principo turinys yra atskleistas Lietuvos Respublikos Konstitucinio Teismo (toliau – ir Konstitucinis Teismas) jurisprudencijoje.

31. Konstitucinis Teismas, aiškindamas konstitucinį teisinės valstybės principą, ne kartą yra konstatavęs, kad konstitucinis teisinės valstybės principas – universalus principas, kuriuo yra grindžiama visa Lietuvos teisės sistema ir pati Konstitucija, kad konstitucinis teisinės valstybės principas aiškintinas neatsiejamai nuo Konstitucijos preambulėje skelbiamo atviros, teisingos, darnios pilietinės visuomenės ir teisinės valstybės siekio, kad minėto konstitucinio principo turinys atsiskleidžia įvairiose Konstitucijos nuostatose. Šio principo esmė – teisės viešpatavimas. Konstitucinis teisinės valstybės principas – itin talpus, jis apima daug įvairių tarpusavyje susijusių imperatyvų. Juo turi būti vadovaujamasi ir kuriant teisę, ir ją įgyvendinant (Konstitucinio Teismo 2004 m. gruodžio 29 d., 2012 m. vasario 6 d., 2012 m. liepos 3 d. ir kt. nutarimai).

32. Konstitucinis Teismas taip pat yra konstatavęs, jog iš konstitucinio teisinės valstybės principo, kitų konstitucinių imperatyvų kyla reikalavimas įstatymų leidėjui, kitiems teisėkūros subjektams paisyti iš Konstitucijos kylančios teisės aktų hierarchijos. Šis reikalavimas, be kita ko, reiškia, kad draudžiama žemesnės galios teisės aktais reguliuoti tuos visuomeninius santykius, kurie gali būti reguliuojami tik aukštesnės galios teisės aktais, taip pat kad žemesnės galios teisės aktuose draudžiama nustatyti tokį teisinį reguliavimą, kuris konkuruotų su nustatytuoju aukštesnės galios teisės aktuose (Konstitucinio Teismo 2005 m. sausio 19 d., 2005 m. rugsėjo 20 d. nutarimai ir kt.). Poįstatyminiu teisės aktu yra realizuojamos įstatymo normos, todėl poįstatyminiu teisės aktu negalima pakeisti įstatymo ir sukurti naujų bendro pobūdžio teisės normų, kurios konkuruotų su įstatymo normomis, nes taip būtų pažeista Konstitucijoje įtvirtinta įstatymų viršenybė poįstatyminių aktų atžvilgiu (Konstitucinio Teismo 2002 m. rugpjūčio 21 d. nutarimas). Poįstatyminiai teisės aktai negali prieštarauti įstatymams, konstituciniams įstatymams ir Konstitucijai, jie turi būti priimami remiantis įstatymais, nes poįstatyminis teisės aktas yra įstatymo normų taikymo aktas nepriklausomai nuo to, ar tas aktas yra vienkartinio (*ad hoc*) taikymo, ar nuolatinio galiojimo (Konstitucinio Teismo 2003 m. gruodžio 30 d., 2005 m. vasario 7 d. nutarimai). Toks teisės akto formos nesilaikymas, kai Konstitucija reikalauja, kad tam tikri santykiai būtų reguliuojami įstatymu, tačiau jie yra reguliuojami poįstatyminiu aktu (nepriklausomai nuo to, ar šiuos santykius kokiu nors aspektu reguliuoja dar ir įstatymas, su kuriame nustatytu teisiniu reguliavimu konkuruoja poįstatyminiame akte nustatytas teisinis reguliavimas, ar joks įstatymas šių santykių apskritai nereguliuoja), gali būti pakankamu pagrindu tokį poįstatyminį teisės aktą pripažinti prieštaraujančiu Konstitucijai (2004 m. gruodžio 13 d. nutarimas).

33. Pagal Konstituciją su žmogaus teisių ir laisvių turinio apibrėžimu ar jų įgyvendinimo garantijų įtvirtinimu susijusį teisinį reguliavimą galima nustatyti tik įstatymu. Kita vertus, tais atvejais, kai Konstitucija nereikalauja įstatyminio tam tikrų su žmogaus teisėmis, jų įgyvendinimu susijusių santykių reguliavimo, šie santykiai gali būti reguliuojami ir poįstatyminiais aktais – aktais, reglamentuojančiais žmogaus teisių įgyvendinimo procesinius (procedūrinius) santykius, atskirų žmogaus teisių įgyvendinimo tvarką ir pan. (Konstitucinio Teismo 2004 m. gruodžio 13 d. nutarimas, 2007 m. gegužės 5 d. nutarimas). Kai kada poreikį įstatymų nustatytą teisinį reguliavimą detalizuoti ir sukonkretinti poįstatyminiuose teisės aktuose gali lemti būtinumas teisėkūroje remtis

specialiomis žiniomis ar specialia (profesine) kompetencija (Konstitucinio Teismo 2005 m. vasario 7 d. nutarimas). Tačiau (tai savo aktuose taip pat ne kartą yra pabrėžęs Konstitucinis Teismas) jokiomis aplinkybėmis poįstatyminiais teisės aktais negalima nustatyti asmens teisės atsiradimo sąlygų, riboti teisės apimties; poįstatyminiais teisės aktais negalima nustatyti ir tokio su žmogaus teisėmis, jų įgyvendinimu susijusių santykių teisinio reguliavimo, kuris konkuruotų su nustatytuoju įstatyme (Konstitucinio Teismo 2007 m. gegužės 5 d. nutarimas).

V.

34. Konstitucijos 21 straipsnio 1 dalis įtvirtina, jog žmogaus asmuo neliečiamas. Asmens neliečiamumo, kaip teisės saugomos vertybės, turinį sudaro fizinis bei psichinis neliečiamumas (Konstitucinio Teismo 2000 m. gegužės 8 d. nutarimas, 2012 m. birželio 4 d. nutarimas). Ši teisė į asmens neliečiamybę nėra absoliuti, t. y. ji gali būti ribojama. Tačiau tai gali būti daroma tik įstatymuose nustatytais pagrindais bei tvarka (Konstitucinio Teismo 2000 m. gegužės 8 d. nutarimas).

35. Minėtąją konstitucinę nuostatą atkartoja Civilinio kodekso 2.25 straipsnio 1 dalis, *inter alia* įtvirtinanti, jog fizinis asmuo neliečiamas. Fizinio asmens neliečiamumas – tai jo teisė pačiam spręsti dėl intervencijos į jo kūną ir teisė reikalauti, kad be jo sutikimo jo kūnui nebūtų taikoma jokia intervencija (Mikelėnas V.; Bartkus. G.; Mizaras, V.; Keserauskas, Š. Lietuvos Respublikos civilinio kodekso komentaras. Antroji knyga. Vilnius: Justitia, 2002, p. 75).

36. Europos Žmogaus Teisių Teismas (toliau – ir EŽTT) savo ruožtu asmens fizinį ir psichologinį neliečiamumą priskiria privataus gyvenimo sampratai Europos žmogaus teisių ir pagrindinių laisvių apsaugos konvencijos (toliau – ir Konvencija) 8 straipsnio prasme (žr. pvz., EŽTT 2005 m. birželio 16 d. sprendimą byloje *Storck* prieš *Vokietiją*, pareiškimo Nr. 61603/00, 143 paragrafas). Pasak EŽTT, net menkiausias kišimasis į asmens fizinę neliečiamybę prieš šio asmens valią turi būti laikomas Konvencijos 8 straipsnio laiduojamo privataus gyvenimo gerbimo ribojimu (*Ibid.*).

37. EŽTT savo praktikoje taip pat yra akcentavęs, jog fizinė asmens neliečiamybė apima pačius intymiausius asmens privataus gyvenimo aspektus, bei tai, kad net ir pati menkiausia priverstinio pobūdžio medicininė intervencija prilygsta šios teisės ribojimui (žr. EŽTT 2003 m. liepos 22 d. sprendimą byloje *Y.F.* prieš *Turkiją*, pareiškimo Nr. 24209/94, 33 paragrafas, 2012 m. kovo 15 d. sprendimą byloje *Solomakhin* prieš *Ukrainą*, pareiškimo Nr. 24429/03, 33 paragrafas). Laisvė priimti ar atsisakyti konkrečios medicininės procedūros arba pasirinkti alternatyvią gydymo formą yra nepakeičiama laisvo apsisprendimo ir asmens autonomijos principų dalis (žr. EŽTT 2010 m. birželio 10 d. sprendimą byloje *Maskvos Jehovos liudytojai* prieš *Rusiją*, pareiškimo Nr. 302/02, 136 paragrafas). Į laisvo asmens apsisprendimo aprėptį patenka ir galimybė užsiimti veiklomis, kurios gali būti suprantamos kaip fiziškai ar morališkai žalingos ar pavojingos tam asmeniui (žr. EŽTT 2002 m. balandžio 29 d. sprendimą byloje *Pretty* prieš *Jungtinę Karalystę*, pareiškimo Nr. 2346/02, 62 paragrafas). Priverstinis skiepijimas, kaip ne savo noru pasirinkta medicininė procedūra, savo ruožtu prilygsta privataus gyvenimo, apimančio fizinę ir psichologinę asmens neliečiamybę, gerbimo, laiduojamo Konvencijos 8 straipsnio 1 dalies, ribojimui (žr. EŽTT 1999 m. liepos 5 d. sprendimą byloje *Matter* prieš *Slovakiją*, pareiškimo Nr. 31534/96, 64 paragrafas, 2002 m. liepos 9 d. sprendimą byloje *Salvetti* prieš *Italiją*, pareiškimo Nr. 42197/98).

38. Tačiau asmens teisė į fizinę neliečiamybę, kaip jo teisės į privatų gyvenimą dalis, nėra absoliuti. Pagal nusistovėjusią EŽTT praktiką, valstybė turi teisę reglamentuoti individo veiksmus, keliančius pavojų kitų asmenų gyvybei ir saugumui (žr. EŽTT 1997 m. vasario 19 d. sprendimą byloje *Laskey ir kt.* prieš *Jungtinę Karalystę*, pareiškimų Nr. 21627/93, 21628/93 ir 21974/93, 43 paragrafas). Kuo rimtesnį pavojų kelia tokie veiksmai, tuo didesnę reikšmę, sveriant teisinius gėrius, įgyja visuomenės sveikata ir saugumas prieš asmens autonomiją (žr. cituotą *Pretty* bylą, 74 paragrafas). EŽTT taip pat pripažįsta, jog privalomą skiepijimą, kaip asmens fizinės neliečiamybės ribojimą, gali pateisinti tokie teisėti ir demokratinėje visuomenėje reikalingi tikslai kaip visuomenės sveikatos poreikiai ar būtinybė užkardyti užkrečiamųjų ligų plitimą, tačiau bet kokie teisės į

privataus gyvenimą ribojimai pirmiausia turi, kaip tai išplaukia iš Konvencijos 8 straipsnio 2 dalies, būti nustatyti įstatymu.

VI.

39. Išplėstinei teisėjų kolegijai, remiantis tuo, kas nurodyta pirmiau, nekyla abejonių dėl to, jog tiriamąja nuostata – Higienos normos 75:2016 79 punktu, *inter alia* įtvirtinančiu, jog jeigu vaiko sveikatos pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito nesant skiepų kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas – yra ribojama konstitucinė asmens teisė į fizinę asmens neliečiamybę, kuri, be kita ko, yra ir asmens teisės į privatų gyvenimą dalis.

40. Minėta, jog tiek iš pirmiau apžvelgtojo konstitucinio teisinės valstybės principo, apimančio ir teisės aktų hierarchijos principą, tiek iš Konvencijos 8 straipsnio 2 dalies išplaukia, jog teisės į fizinę asmens neliečiamybę, kaip asmens teisės į privatų gyvenimą dalies, apimtis negali būti ribojama poįstatyminiu teisiniu reguliavimu, o siekiant teisėto bei demokratinėje visuomenėje reikalingo tikslo ji gali būti apribota tik įstatymuose nustatytais pagrindais bei tvarka.

VII.

41. Konkrečioje byloje atsakovas, bandydamas pagrįsti Higienos normos 75:2016 79 punkto teisėtumą, teigė, jog turėjo iš įstatymų kylantį pagrindą poįstatyminiame teisės akte įtvirtinti draudimą į ikimokyklinio ir (ar) priešmokyklinio ugdymo įstaigas priimti nuo tymų, raudonukės ir poliomielito nepaskiepytus vaikus. Norminio administracinių aktų teisėtumo tyrimo bylos posėdyje bei savo teismui pateiktame atsiliepime atsakovas, be kita ko, tokiais jo įgaliojimus priimti ginčijamą poįstatyminio teisės akto nuostatą suteikiančiais pagrindais įvardijo Lietuvos Respublikos sveikatos sistemos įstatymo 2 straipsnio 5 ir 6 dalis, 61 straipsnio 1 dalies 7 punktą bei Lietuvos Respublikos visuomenės sveikatos priežiūros įstatymo 12 straipsnio, 16 straipsnio 1 dalis ir 36 straipsnio 1 dalį.

42. Lietuvos Respublikos sveikatos sistemos įstatymo (iki 2016 m. gegužės 1 d. galiojusi redakcija) 2 straipsnio 5 dalis įtvirtina, jog sveikatinimo veikla – asmens sveikatos priežiūra, visuomenės sveikatos priežiūra, farmacinė ir kita sveikatinimo veikla, kurios rūšis ir reikalavimus ją vykdantiems subjektams nustato Sveikatos apsaugos ministerija, o šio straipsnio 6 dalis numato, jog asmens sveikatos priežiūra – valstybės licencijuota fizinių ir juridinių asmenų veikla, kurios tikslas laiku diagnozuoti asmens sveikatos sutrikimus ir užkirsti jiems kelią, padėti atgauti ir sustiprinti sveikatą. Sveikatos sistemos įstatymo 61 straipsnio 1 dalies 7 punktas savo ruožtu įtvirtina, jog Sveikatos apsaugos ministerija rengia ir priima pagal kompetenciją teisės aktus sveikatinimo veiklos rūšių, išvardytų šiame straipsnyje, įgyvendinimo klausimais. Lietuvos Respublikos visuomenės sveikatos priežiūros įstatymo 12 straipsnis *inter alia* numato, jog visuomenės sveikatos priežiūros viešąjį administravimą pagal savo kompetenciją vykdo Sveikatos apsaugos ministerija, o šio įstatymo 16 straipsnio 1 dalis įtvirtina, jog privalomuosius higienos normatyvus bei taisykles, reglamentuojančias fizinių ir juridinių asmenų veiklą, nustato Visuomenės sveikatos saugos reglamentas (higienos norma). Visuomenės sveikatos priežiūros įstatymo 36 straipsnio 1 dalis taip pat numato, jog ikimokyklinio ugdymo mokyklose ir bendrojo lavinimo mokyklose turi būti sudarytos sąlygos vaikų sveikatai išsaugoti ir stiprinti, vaikų sveikatos priežiūrai užtikrinti.

43. Išplėstinės teisėjų kolegijos vertinimu, atsakovo nurodytos įstatyminės normos nesudaro pagrindo tiriamajai poįstatyminio akto nuostatai, kuria yra ribojama pirmiau aptartųjų asmens teisių apimtis, priimti. Pažymėtina, jog teisės normos, kurias cituoja atsakovas yra definicinės (Sveikatos sistemos įstatymo 2 str. 5 ir 6 d.), apibrėžiančios atsakovo funkciją (Sveikatos sistemos įstatymo 61 str. 1 d. 7 p.), suteikiančios jam kompetenciją (Visuomenės sveikatos priežiūros įstatymo 12 str., 16 str. 1 d.) ir programinio pobūdžio (Visuomenės sveikatos priežiūros įstatymo 36 str. 1 d.). Tačiau nė

viena iš šių įstatymo normų nėra nustatomi pirmiau aptartų asmens teisių ribojimo pagrindai ir tvarka, t. y. įstatymu nėra įtvirtintas teisinis reguliavimas, numatantis privalomąjį vaikų skiepijimą, kaip asmens teisės į fizinį kūno neliečiamumą ribojimą, kurį būtų galima realizuoti ar detalizuoti poįstatyminiu teisės aktu. Minėta, jog poįstatyminiu teisės aktu negalima pakeisti įstatymo ir sukurti naujų bendro pobūdžio teisės normų, *inter alia* – ir naujų asmens teisių ribojimų, o įstatymuose įtvirtinta Sveikatos apsaugos ministerijos kompetencija leisti Visuomenės sveikatos saugos reglamentus (higienos normas) ar bendro pobūdžio pareiga ikimokyklinio ugdymo mokyklose sudaryti sąlygas vaikų sveikatai išsaugoti ir stiprinti savaime galimybės nukrypti nuo šio teisės aktų hierarchijos principo turinio elemento nesudaro ir priimti naujas, ribojančio pobūdžio poįstatyminio teisės aktų lygmens nuostatas, Sveikatos apsaugos ministerijos neįgalina.

44. Atsižvelgdama į tai, kad, kaip minėta, asmens teises ribojantis reguliavimas gali būti įtvirtinamas ne žemesnės galios nei įstatymas teisės akte, taip pat įvertinusi tai, jog ginčijama nuostata neturi įstatyminio pagrindo (t. y. nėra grindžiama aiškiu ir vienareikšmių įstatyme įtvirtintu teisiniu reguliavimu), – išplėstinė teisėjų kolegija konstatuoja, jog Higienos normos 75:2016 79 punktas ta apimtimi, kuria įtvirtinama, jog jeigu vaiko sveikatos pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito nesant skiepų kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas, prieštarauja konstituciniam teisinės valstybės principui, suponuojančiam teisės aktų hierarchiją.

45. Pridurtina, jog pareiškėjai šioje norminio administracinio akto teisėtumo tyrimo byloje kėlė klausimą ne tik dėl Higienos normos 75:2016 79 punkto atitikties konstituciniam teisinės valstybės principui, bet ir dėl jo atitikties konstituciniam asmenų lygiateisiškumo principui bei konkrečioms Civilinio kodekso, Žmonių užkrečiamųjų ligų profilaktikos ir kontrolės įstatymo, Pacientų teisių ir žalos sveikatai atlyginimo įstatymo, Viešojo administravimo įstatymo ir Švietimo įstatymo nuostatoms. Lietuvos vyriausiasis administracinis teismas savo praktikoje yra konstatavęs, jog kai yra keliamas norminio administracinio akto atitikties keliems aukštesnės galios teisės aktams (jų dalims) ar kelioms to paties teisės akto nuostatoms klausimas, norminio administracinio akto teisėtumo bylą nagrinėjantis administracinis teismas, konstatavęs norminio administracinio akto prieštaravimą vienai aukštesnės galios teisės akto nuostatai, nebeprivalo tirti norminio administracinio akto teisėtumo kitų aukštesnės galios teisės aktų nuostatų atžvilgiu (žr. LVAT 2006 m. gegužės 11 d. nutartį administracinėje byloje Nr. I^{444}-02/2006, LVAT 2013 m. birželio 18 d. nutartį administracinėje byloje Nr. I^{261}-15/2013, LVAT 2015 m. kovo 23 d. nutartį administracinėje byloje Nr. I-9-662/2015). Atsižvelgiant į tai, Lietuvos vyriausiojo administracinio teismo išplėstinei teisėjų kolegijai šioje byloje konstatavus, kad Higienos normos 75:2016 79 punktas minėta apimtimi prieštarauja konstitucinio teisinės valstybės principo apimamam teisės aktų hierarchijos principui, išnyksta poreikis tirti šios nuostatos atitiktį likusiųjų, pirmiau nurodytų aukštesnės teisinės galios teisės aktų, atžvilgiu.

VIII.

46. Šioje norminio administracinio akto teisėtumo tyrimo byloje į Lietuvos vyriausiąjį administracinį teismą buvo kreiptasi ir prašant ištirti Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto teisėtumą.

47. Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punktas įtvirtina: „Laukelyje „Diagnozė“ įrašomi kiti, gydytojo manymu, svarbūs dėl dalyvavimo ugdymo veikloje vaiko sveikatos sutrikimai (TLK-10-AM kodai), kurie nebuvo priskirti pagal formoje išvardytas organizmo sistemas ir paminėti anksčiau. Vadovaujantis Lietuvos Respublikos sveikatos apsaugos ministro 2014 m. birželio 12 d. įsakymu Nr. V-683 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo 94 punktu, pildant ikimokyklines ir (ar)

priešmokyklines įstaigas lankančių vaikų pažymėjimus, laukelyje „Diagnozė“ įrašoma, ar vaikas yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas) (pavyzdys: paskiepytas visais reikalingais skiepais, norint lankyti ikimokyklinę ugdymo įstaigą; paskiepytas tik nuo tymų ir raudonukės; nepaskiepytas nė vienu iš reikalingų skiepų, norint lankyti ikimokyklinę ugdymo įstaigą). Jei vaikas nepaskiepytas esant skiepų kontraindikacijoms, tai privaloma nurodyti (pavyzdys: neskiepytas nuo tymų esant kontraindikacijoms)“.

48. Kaip ir ankstesnėje bylos dalyje, taip ir šioje – iš pareiškėjų motyvų visumos matyti, jog jie kvestionuoja Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto teisėtumą ne visa apimtimi, bet tik ta, kuria vadovaujantis Higienos normos 75:2010 94 punktu yra nustatyta pareiga pildant ikimokyklines ir (ar) priešmokyklines įstaigas lankančių vaikų pažymėjimus, laukelyje „Diagnozė“ įrašyti, ar vaikas yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas). Pareiškėjų manymu, tai prieštarauja Lietuvos Respublikos asmens duomenų teisinės apsaugos įstatymo 5 straipsnio 2 ir 3 daliai bei Lietuvos Respublikos pacientų teisių ir žalos sveikatai atlyginimo įstatymo 8 straipsnio 1 daliai. Taigi, būtent minėta apimtimi poįstatyminio teisės akto nuostatos teisėtumą byloje tirs ir išplėstinė teisėjų kolegija.

49. Kaip minėta pirmiau, pagal bendrąją taisyklę norminės administracinės bylos nagrinėjimo ribas pirmiausia apibrėžia pareiškėjo pareiškime pateiktas prašymas, jo apimtis, taip pat šį prašymą pagrindžiantys teisiniai argumentai. Lietuvos vyriausiasis administracinis teismas, kuriam yra pavesta norminių administracinių aktų teisėtumo kontrolė, savo ruožtu turi pareigą iš teisės sistemos šalinti poįstatyminės galios aktus, prieštaraujančius Konstitucijai ir įstatymams.

50. Konkrečioje byloje pareiškėjas neprašo ištirti Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto atitikties konstituciniam teisinės valstybės principui, be kita ko, suponuojančiam teisės aktų hierarchijos reikalavimo, tačiau išplėstinė teisėjų kolegija, atsižvelgdama į bylos duomenų visetą ir nevisapusiškai pareiškėjų kreipimesi išdėstytus argumentus, dėl toliau nurodytų priežasčių pasisakys dėl Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto teisėtumo būtent minėtuoju aspektu.

51. Pažymėtina, jog, kaip matyti iš Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto formuluotės, šios teisės normos hipotezė yra grindžiama kita, šioje norminėje byloje ištirtąja nuostata – Higienos normos 75:2010 94 punktu (atitinkamai – Higienos normos 75:2016 79 punktu). Teisės teorijoje normos hipotezė, be kita ko, yra laikoma teisės normoje įtvirtintos dispozicijos (elgesio taisyklės) veikimo sąlygų visuma. Kitais žodžiais tariant, tai yra pagrindas taikyti normoje išreikštą taisyklę. Kadangi Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punkto hipotezė yra grindžiama pirmiau nurodytais motyvais konstituciniam teisinės valstybės principui prieštaraujančia pripažinta nuostata – Higienos normos 75:2010 94 punktu (šiuo metu galiojančio – Higienos normos 75:2016 79 punktu) – išplėstinės teisėjų kolegijos vertinimu, ši nuostata ta apimtimi, kuria nustatyta, jog vadovaujantis Higienos normos 75:2010 94 punktu yra nustatyta pareiga pildant ikimokyklines ir (ar) priešmokyklines įstaigas lankančių vaikų pažymėjimus, laukelyje „Diagnozė“ įrašyti, ar vaikas yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas) prieštarauja konstitucinio teisinės valstybės principo apimamam teisės aktų hierarchijos principui.

52. Išplėstinė teisėjų kolegija taip pat atkreipia dėmesį, jog konstitucinis teisinės valstybės principas implikuoja ir teisės sistemos vidinės darnos reikalavimą. Nagrinėjamu atveju nauja redakcija išdėsčius vieną poįstatyminį teisės aktą – Higienos normą 75:2016 – Vaiko sveikatos pažymėjimo pildymo taisyklės atnaujintos nebuvo, jose paliekant nuorodą į Higienos normą 75:2010, tokiu būdu iš esmės darant nuorodą į nebegaliojantį teisės aktą. Tačiau konkrečiu atveju konstatavus, jog Higienos normą išdėsčius nauja redakcija norminei administracinei bylai aktualus reguliavimas – taisyklė, išreiškianti draudimą į ikimokyklinio ir (ar) priešmokyklinio ugdymo įstaigas priimti nuo tymų, raudonukės ir poliomielito nepaskiepytus vaikus – savo esme bei turiniu nepakito ir ji nebuvo suderinama su konstituciniu teisinės valstybės principu, šios aplinkybės savarankiška analizė nebetenka prasmės.

53. Konstatavus, jog Vaiko sveikatos pažymėjimo pildymo taisyklių 9 punktas pirmiau įvardyta apimtimi prieštarauja konstitucinio teisinės valstybės principo apimamam teisės aktų hierarchijos principui, išnyksta poreikis tirti ir šios nuostatos atitiktį pareiškėjų nurodytų kitų, aukštesnės teisinės galios teisės aktų, nuostatoms.

Vadovaudamasi Lietuvos Respublikos administracinių bylų teisenos įstatymo 115 straipsnio 1 dalies 2 punktu, 117 straipsnio 1 dalimi, Lietuvos vyriausiojo administracinio teismo išplėstinė teisėjų kolegija

n u s p r e n d ž i a:

Pripažinti, kad Lietuvos Respublikos sveikatos apsaugos ministro 2016 m. sausio 26 d. įsakymu Nr. V-93 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo“ patvirtintos Lietuvos higienos normos HN 75:2016 „Ikimokyklinio ir priešmokyklinio ugdymo programų vykdymo bendrieji sveikatos saugos reikalavimai“ 79 punktas ta apimtimi, kuria šiame punkte numatyta, jog jeigu vaiko sveikatos pažymėjime nurodyta, kad vaikas nepaskiepytas pagal Lietuvos Respublikos sveikatos apsaugos ministro patvirtintą Lietuvos Respublikos vaikų profilaktinių skiepijimų kalendorių nuo tymų, raudonukės ir poliomielito nesant skiepų kontraindikacijų, ugdyti pagal ikimokyklinio ir (ar) priešmokyklinio ugdymo programą toks vaikas nepriimamas, prieštarauja konstitucinio teisinės valstybės principo apimamam teisės aktų hierarchijos principui.

Pripažinti, kad Lietuvos Respublikos sveikatos apsaugos ministro 2004 m. gruodžio 24 d. įsakymu Nr. V-951 „Dėl Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ patvirtinimo“ patvirtintų Statistinės apskaitos formos Nr. 027-1/A „Vaiko sveikatos pažymėjimas“ pildymo taisyklių 9 punktas (2015 m. lapkričio 26 d. įsakymo Nr. V-1336 redakcija) ta apimtimi, kuria šiame punkte numatyta, jog vadovaujantis Lietuvos Respublikos sveikatos apsaugos ministro 2014 m. birželio 12 d. įsakymo Nr. V-683 „Dėl Lietuvos Respublikos sveikatos apsaugos ministro 2010 m. balandžio 22 d. įsakymo Nr. V-313 „Dėl Lietuvos higienos normos HN 75:2010 „Įstaiga, vykdanti ikimokyklinio ir (ar) priešmokyklinio ugdymo programą. Bendrieji sveikatos saugos reikalavimai“ patvirtinimo“ pakeitimo“ 94 punktu, pildant ikimokyklines ir (ar) priešmokyklines įstaigas lankančių vaikų Pažymėjimus, laukelyje „Diagnozė“ įrašoma, ar vaikas yra paskiepytas visais skiepais, kurie yra reikalingi, norint lankyti ikimokyklinio ugdymo įstaigas (tymai, raudonukė, poliomielitas) (pavyzdys: paskiepytas visais reikalingais skiepais, norint lankyti ikimokyklinę ugdymo įstaigą; paskiepytas tik nuo tymų ir raudonukės; nepaskiepytas nė vienu iš reikalingų skiepų, norint lankyti ikimokyklinę ugdymo įstaigą). Jei vaikas nepaskiepytas esant skiepų kontraindikacijoms, tai privaloma nurodyti (pavyzdys: nepaskiepytas nuo tymų esant kontraindikacijoms), prieštarauja konstitucinio teisinės valstybės principo apimamam teisės aktų hierarchijos principui.

Sprendimas neskundžiamas.

Sprendimas skelbiamas Teisės aktų registre.

Teisėjai Audrius Bakaveckas

Arūnas Dirvonas

Irmantas Jarukaitis

Dainius Raižys

Veslava Ruskan

KOPIJA TIKRA
Teismo posėdžių sekretorė
Laisvida Versekienė
2016.04.05

Court of Justice of the European Union
PRESS RELEASE No 66/2017
Luxembourg, 21 June 2017

Press and Information

Judgment in Case C-621/15
N. W and Others v Sanofi Pasteur MSD and Others

Where there is a lack of scientific consensus, the proof of the defect of the vaccine and of a causal link between the defect and the damage suffered may be made out by serious, specific and consistent evidence

The temporal proximity between the administering of a vaccine and the occurrence of a disease, the lack of personal and familial history of the person vaccinated and the existence of a significant number of reported cases of the disease occurring following such vaccines being administered may, where applicable, constitute sufficient evidence to make out such proof

Between the end of 1998 and the middle of 1999 Mr J. W was vaccinated against hepatitis B using a vaccine produced by Sanofi Pasteur. In August 1999, Mr W began to present with various troubles, which led to a diagnosis of multiple sclerosis in November 2000. Mr W died in 2011. Earlier, in 2006, he and his family had brought legal proceedings against Sanofi Pasteur to obtain compensation for the damage they claim Mr W suffered due to the vaccine.

The case was sent before the cour d'appel de Paris (Court of Appeal, Paris, France), which observed, inter alia, that there was no scientific consensus supporting a causal relationship between the vaccination against hepatitis B and the occurrence of multiple sclerosis. It held that no such causal link had been demonstrated and dismissed the action.

The French Cour de cassation (Court of Cassation), before which an appeal against the judgment of the Cour d'appel de Paris was brought, asks the Court of Justice whether, despite there being no scientific consensus and given that, under the EU directive on liability for defective products, [1] the injured person is required to prove the damage, the defect and the causal relationship, the court may base itself on serious, specific and consistent evidence enabling it to conclude that there is a causal link between the defect in a vaccine and that there is a causal link between the vaccine and the disease. Reference has been made in particular to Mr W's previous excellent state of health, the lack of family antecedents and the close temporal connection between the vaccination and the appearance of the disease.

In today's judgment, the Court holds that evidentiary rules allowing the court, where there is not certain and irrefutable evidence, to conclude that there is a defect in a vaccine and a causal link between the defect and a disease on the basis of a set of evidence the seriousness, specificity and consistency of which allows it to consider, with a sufficiently high degree of probability, that such a conclusion corresponds to the reality of the situation, are compatible with the Directive. Such evidentiary rules do not bring about a reversal of the burden of proof which it is for the victim to discharge, since that system places the burden on the victim to prove the various elements of his case which, taken together, will provide the court hearing the case with a basis for its conclusion as to the existence of a defect in the vaccine and a causal link between that defect and the damage suffered.

Moreover, excluding any method of proof other than certain proof based on medical research, could make it excessively difficult in many situations or, where it is common ground that medical research neither confirms nor rules out the existence of a causal link, impossible to establish

[1] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985, L 210, p. 29).

producer liability, thereby undermining the effectiveness of the Directive and its objectives, which are to protect consumer health and safety and ensure a fair apportionment between the injured person and the producer of the risks inherent in modern technological production.

The Court nevertheless adds that national courts must ensure that the evidence adduced is sufficiently serious, specific and consistent to warrant the conclusion that, having regard also to the evidence produced and the arguments put forward by the producer, a defect in the product appears to be the most plausible explanation for the occurrence of the damage. National courts must also safeguard their own freedom of assessment in determining whether such proof has been made out to the requisite legal standard, until such time as they consider themselves in a position to draw a definitive conclusion on the matter.

In the present case, the Court considers that the temporal proximity between the administering of a vaccine and the occurrence of a disease, the lack of personal and familial history of that disease, together with the existence of a significant number of reported cases of the disease occurring following such vaccines being administered, appears on the face of it to constitute evidence which, taken together, may lead a national court to consider that a victim has discharged his burden of proof. That could be the case inter alia where that evidence leads the court to consider, first, that the administering of the vaccine is the most plausible explanation for the occurrence of the disease and, second, that the vaccine therefore does not offer the safety that one is entitled to expect.

The Court adds that it is not possible for the national legislature or the national courts to introduce a method of proof under which the existence of a causal link between the defect attributed to a vaccine and the damage suffered by the victim will automatically be established when certain predetermined causation-related factual evidence is presented, as that would have the consequence of the burden of proof provided for in the Directive being undermined.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Press contact: Holly Gallagher ☎ (+352) 4303 3355

REPUBBLICA ITALIANA

IN NOME DEL POPOLO ITALIANO

TRIBUNALE DI MILANO

Sezione Lavoro

Il dott. Nicola Di Leo in funzione di giudice del lavoro ha pronunciato la seguente

SENTENZA

nella causa civile di I Grado iscritta al **N. 14276/2013 R.G.** promossa da:

[redacted], con il patrocinio dell'avv. [redacted] e GENOVESI ALESSANDRA (GNVLSN77D57A662X) VIA TURATI, 6 20121 MILANO; con elezione di domicilio in [redacted]

ATTORE

[redacted], con il patrocinio dell'avv. [redacted] e GENOVESI ALESSANDRA (GNVLSN77D57A662X) VIA TURATI, 6 20121 MILANO; con elezione di domicilio in [redacted]

ATTORE

[redacted] (C.F.), con il patrocinio dell'avv. [redacted] GENOVESI ALESSANDRA (GNVLSN77D57A662X) VIA TURATI, 6 20121 MILANO; con elezione di domicilio [redacted]

ATTORE

contro:

MINISTERO DELLA SALUTE (C.F.), con il patrocinio dell'avv. AVVOCATURA STATO MILANO , con elezione di domicilio in VIA FREGUGLIA, 1 20122 MILANO, presso e nello studio dell'avv. AVVOCATURA STATO MILANO

CONVENUTO

OGGETTO: indennizzo l. 210/92.

SVOLGIMENTO DEL PROCESSO

Con ricorso al Tribunale di Milano, quale giudice del lavoro, depositato in data 9/10/13, [redacted] quali genitori di [redacted] hanno chiamato in giudizio il MINISTERO DELLA SALUTE esponendo che il proprio figlio avrebbe contratto una *sindrome autistica* in seguito alle vaccinazioni descritte nell'atto introduttivo del giudizio, che avrebbero contenuto, in modo pericoloso, alcuni metalli pesanti e inquinanti quali l'alluminio - la cui tossicità aumenterebbe in presenza di altre componenti quali il polisorbato 80 - e il mercurio.

In particolare, successivamente e nell'immediata prossimità rispetto alla iniezione delle tre dosi della vaccinazione esavalente *Infanrix Hexa SK* nel 2006, [redacted] avrebbe manifestato sintomi patologici fino alla *diagnosi di autismo* posta in essere il 12/10/10, con nesso di causalità, solo in tale data, accertato rispetto alla menzionata somministrazione.

Ha, poi, allegato la parte ricorrente che, il 5/4/11, avrebbe presentato rituale domanda di indennizzo al Ministero.

Tuttavia, non avendo trovato accoglimento la propria istanza, ha dato avvio al presente giudizio, chiedendo che fosse accertato il diritto di [redacted] all'indennizzo di cui alla legge n. 210/92 per il danno irreversibile subito (in tutte le componenti previste dall'articolo 2, commi uno e due, di tale legge, ivi compresa l'indennità integrativa speciale e *l'una tantum* di cui al secondo comma), con decorrenza dalla presentazione della domanda amministrativa, oltre agli interessi legali sui ratei arretrati come per legge e con attribuzione del beneficio per il periodo successivo. Con vittoria di spese.

Costituendosi ritualmente in giudizio, con articolata memoria difensiva, il MINISTERO DELLA SALUTE ha contestato la fondatezza delle domande, chiedendone il rigetto. Con vittoria di spese.

La convenuta, unicamente, ha rilevato come non dovrebbe sussistere il nesso causale tra le vaccinazioni e la malattia contratta dal bambino.

All'udienza di discussione, si è nominato un c.t.u..

Poi, la causa è stata oralmente discussa e decisa come da dispositivo pubblicamente letto.

MOTIVI DELLA DECISIONE

Deve essere, preliminarmente, dichiarata la legittimazione passiva del MINISTERO DELLA SALUTE.

Infatti, la Corte di cassazione ha chiarito che

"in tema di controversie relative all'indennizzo previsto dalla legge 25 febbraio 1992, n. 210, in favore di soggetti che hanno riportato danni irreversibili a causa di *vaccinazioni* obbligatorie, trasfusioni e somministrazione di emoderivati, e da questi ultimi proposte per l'accertamento del diritto al beneficio, *sussiste la legittimazione passiva del Ministero della salute, in quanto soggetto pubblico che, analogamente, decide in sede amministrativa pronunciandosi sul ricorso di chi chiede la prestazione assistenziale.*" (cfr. Cass. Ordinanza n. 29311 del 28/12/2011).

Venendo, quindi, al merito, è, innanzitutto, da evidenziare che, dagli atti di causa, risulta *contestata tra le parti unicamente la consequenzialità eziologica* tra la sindrome autistica da cui è affetto [redacted] e le vaccinazioni descritte nel ricorso.

Per tale motivo, per la verifica del nesso causale, è stata espletata una consulenza tecnica d'ufficio.

Il consulente ha confermato che il bambino risulta affetto da sindrome autistica ed è venuto a verificare con serietà e cura il nesso causale tra la somministrazione della *vaccinazione esavalente Infanrix Hexa SK* nel 2006 al bambino e la patologia, potendosi far rinvio alla complessiva relazione peritale.

In particolare, in ogni caso, è possibile evidenziare come il perito del giudice non si sia accontentato del *criterio cronologico*, ossia della *stretta successione temporale* tra la presentazione della malattia e le iniezioni del vaccino, ma altresì è andato ad analizzare, in maniera ponderata e attenta, le diverse prospettazioni delle parti (pag. 10 e 11 CTU).

Sul punto, ha, dapprima, motivato come non vi fossero ragioni per ritenere attendibile la tesi del Ministero, per la quale si dovrebbe accreditare l'autismo sofferto

da [redacted] quale *malattia genetica*, non ritenendo esistente "*alcuna specifica costante alterazione trasmissibile del materiale cromosomico*" (p. 11).

Piuttosto, il perito del giudice è venuto a ritenere plausibile la tesi per cui nel vaccino *Infanrix Hexa SK* vi sarebbero state delle dosi di mercurio, impiegato quale disinfettante, ritenendo attendibile il dato grazie alla stima di cui al *report della GlaxoSmithKline,* motivando, con ciò, le concrete possibilità per cui si potrebbe ritenere, *più probabile che non*, l'incidenza causale della vaccinazione in parola sulla patologia riscontrata dal bambino.

Il consulente, sulla base dell'attenta analisi esposta, è venuto, così, a concludere che

"è probabile, in misura certamente superiore al contrario, che il disturbo autistico del piccolo [redacted] sia stato concausato, sulla base di un polimorfismo che lo ha reso suscettibile alla tossicità di uno o più ingredienti (o inquinanti), dal vaccino *Infanrix Hexa SK* somministrato in tre dosi fra il marzo e l'ottobre 2006. Il presidio, come recentemente risultato da documenti riservati della stessa casa farmaceutica che ne detiene il brevetto, mostra una specifica idoneità lesiva per il disturbo autistico, la cui portata, teoricamente piccola se calcolata sui dati della sperimentazione clinica pre-autorizzazione - spiegherebbe solo il 2-5% dei casi di malattia - è in realtà sottostimata per l'esistenza, recentemente confermata dall'autorità sanitaria australiana, di lotti del vaccino contenenti un disinfettante a base di mercurio, oggi ufficialmente bandito per via della comprovata neurotossicità, in concentrazioni tali da eccedere largamente i livelli massimi raccomandati per lattanti del peso di pochi Kg.

Detti elementi, oltre a smentire in radice le ragioni di parte resistente, ossia la causa genetica della malattia, l'assenza di mercurio nel vaccino o, in ogni caso, la sua innocuità, accreditano attualmente il nominato presidio quale unica causa conosciuta della malattia in oggetto, rendendola perciò di gran lunga più probabile delle eventuali altre, così incerte sotto il profilo dell'efficienza lesiva da risultare oggi relegate all'ambito della mera ipotesi.

Tale premessa - e questa soltanto - consente, a parere di chi scrive, di ritenere finalmente soddisfatto il criterio di riferimento etiologico, noto come "principio di esclusione di altre cause", su cui l'attuale giurisprudenza di merito pare fondare. Questo, sempre a parere di chi scrive, è stato sin'ora travisato e confuso con quello, cronologico, del *post hoc, propter hoc*, ritenuto - erroneamente - che i vaccini, sino a pochi mesi fa ufficialmente estranei alla patogenesi dell'autismo, potessero essere elevati alla dignità di causa probabile per semplice mancanza di valide alternative. In realtà, sino a che GlaxoSmithKline (produttrice del nominato presidio, nda) non ha riconosciuto, sia pure involontariamente, i cinque casi di autismo emersi durante la sperimentazione clinica del *Infanrix Hexa SK*, il nesso fra vaccini e malattia costituiva, alla stregua di qualsiasi altra ipotesi

etiopatogenetica, una semplice possibilità. Questa, evidentemente, rendeva la successione dei due fatti (somministrazioni di vaccino e progressiva regressione autistica) assai più facilmente casuale che non".

Sulla base della relazione tecnica espletata nel presente giudizio, dunque, *è più probabile, in misura certamente superiore al contrario*, che il disturbo autistico di [redacted] sia stato *causato* o almeno *concausato*, sulla base di un polimorfismo che lo ha reso suscettibile alla tossicità di uno o più ingredienti (o inquinanti), dal vaccino Infanrix Hexa SK somministrato in tre dosi fra il marzo e l'ottobre 2006.

In materia di nesso eziologico ha, tra l'altro, chiarito la Corte di cassazione che

"in tema di responsabilità civile, qualora l'evento dannoso si ricolleghi a più azioni o omissioni, il problema del concorso delle cause trova soluzione nell'art. 41 cod. pen. - norma di carattere generale, applicabile nei giudizi civili di responsabilità - in virtù del quale il concorso di cause preesistenti, simultanee o sopravvenute, anche se indipendenti dall'omissione del colpevole, non esclude il rapporto di causalità fra dette cause e l'evento, essendo quest'ultimo riconducibile a tutte" (cfr. Cass. Ordinanza n. 15537 del 14/07/2011).

È possibile, del resto, osservare come l'analisi del consulente del giudice possa essere, a questo punto, *anche ulteriormente asseverata* dalla *stretta successione temporale* tra i disturbi patologici riscontrati e la somministrazione del vaccino, non contestata dal Ministero convenuto.

Acclarata la sussistenza del nesso causale tra tale vaccinazione e la malattia, quanto all'inquadramento della malattia, non risulta in contestazione tra le parti *l'ascrivibilità alla prima categoria della tabella A* allegata d.p.r. 834 del 1981 (cfr. la allegazione di cui a pag. 40 del ricorso, non contestata nella memoria, nella quale è stata formulata solo la tesi della inesistenza di un rapporto eziologico, e, ad ogni modo, il doc. 2, all. 26 ric.).

Riconosciuto tale inquadramento, deve essere, quindi, a tal punto, accolta la domanda dei ricorrenti di ottenere dal Ministero le corresponsione di tutte le spettanze menzionate dall'articolo 2, commi uno e due, della legge n. 210 del 1992, secondo le somme menzionate in dispositivo e anche per gli arretrati dal 1.5.11 (primo giorno del mese successivo alla data di presentazione della domanda amministrativa del 5.4.11: cfr. doc. 4 ric.).

In particolare, occorre condannare, perciò, il Ministero convenuto a versare alla parte ricorrente l'indennizzo di cui all'articolo 2, co. 1, cit., nella misura prevista, oltre che a corrispondere *l'indennità integrativa speciale*.

Si deve, poi, dichiarare il diritto della parte ricorrente *alla rivalutazione* sia dell'indennizzo che dell'indennità integrativa speciale secondo il tasso annuale di inflazione programmata, come previsto dall'art. 2 della legge n. 210 del 1992, avendo chiarito la Corte di cassazione che

"in tema di danni da trasfusione e somministrazione di emoderivati, l'indennità integrativa speciale, prevista dall'art. 2, comma 2, della legge n. 210 del 1992, è soggetta a rivalutazione annuale, in seguito alla sentenza della Corte costituzionale n. 293 del 2011, che ha dichiarato illegittima l'esclusione della rivalutazione per violazione del principio di uguaglianza, rispetto alla disciplina, introdotta con l'art. 2, comma 363, della legge n. 244 del 2007, dei danni da somministrazione di talidomide. Poiché, peraltro, il riferimento a tale normativa è stato individuato dalla Corte costituzionale come mero "tertium comparationis" del giudizio di legittimità, la spettanza della rivalutazione non è ancorata all'entrata in vigore della legge n. 244 del 2007" (cfr. Cass. L, Ordinanza n. 10769 del 27/06/2012; Sentenza n. 22256 del 27/09/2013).

Si devono, poi, ritenere spettanti gli interessi dal 121° giorno dalla presentazione della domanda del 5/4/11, dovendosi reputare che, pure per tale tipo di crediti assistenziali, valga quanto affermato dalla Corte costituzionale nella sentenza n. 156/91, secondo la quale occorre tener conto anche dei tempi per la definizione del procedimento amministrativo.

Infine, considerato come la parte ricorrente abbia dimostrato come il vaccino *esavalente Infanrix Hexa SK* rientri tra quelli "*obbligatori*" per legge (cfr. il documento dell'Asl del 12/1/06 che *elenca le "vaccinazioni obbligatorie"*, tra le quali, per le patologie da prevenirsi - come ivi nominate - si deve ritenere incluso il vaccino in esame: cfr. all. 8 al doc. 2 ric.), è possibile riconoscere alla stessa, ai sensi dell'art. 2, co. 2, della legge n. 210/92 - per il periodo ricompreso tra il manifestarsi dell'evento dannoso in data 12.10.10 (cfr. il verbale di causa e il doc. 2, all. 30 e doc. 4 all. 6 ric.) e l'ottenimento dell'indennizzo, ossia fino alla data della presente sentenza - *un assegno una tantum* nella misura pari, per ciascun anno, al 30 per cento dell'indennizzo dovuto ai sensi del comma 1 dell'art. 2 della stessa legge, con esclusione, per tale voce, di interessi legali e rivalutazione monetaria.

Prevedono, infatti, l'articolo 1, co. 1 e l'art. 2, co. 2 della legge n. 210 del 1992 che

Art. 1, co. 1: "chiunque abbia riportato, *a causa di vaccinazioni obbligatorie* per legge o per ordinanza di una autorità sanitaria italiana, lesioni o infermità, dalle quali sia derivata una menomazione permanente della integrità psico-fisica, ha diritto ad un indennizzo da parte dello Stato, alle condizioni e nei modi stabiliti dalla presente legge";

art. 2, co. 2: "(...) *ai soggetti di cui al comma 1 dell'articolo 1*, anche nel caso in cui l'indennizzo sia stato già concesso, è corrisposto, a domanda, per il periodo ricompreso tra il manifestarsi dell'evento dannoso e l'ottenimento dell'indennizzo previsto dalla presente legge, un *assegno una tantum* nella misura pari, per ciascun anno, al 30 per cento dell'indennizzo dovuto ai sensi del comma 1 e del primo periodo del presente comma, con esclusione di interessi legali e rivalutazione monetaria".

Sicché, per il combinato disposto di tali due norme, trattandosi nell'ipotesi dell'esavalente Infanrix Hexa SK di *"vaccinazione obbligatoria"* che rientra certamente nell'articolo 1, co. 1., cit., si deve riconoscere alla parte attorea l'*una tantum* prevista dall'articolo 2, comma due, menzionato (cfr. Cass. Sentenza n. 8976 del 07/04/2008).

In tal senso, nel dispositivo, si provvede alla condanna del Ministero convenuto.

Infine, in ragione della soccombenza, si deve porre le spese di c.t.u. a carico solidale delle parti e, nei rapporti interni tra le stesse, a carico della parte convenuta, con diritto di rivalsa per la parte ricorrente di quanto eventualmente versato al c.t.u., con liquidazione effettuata come da separata ordinanza.

Ugualmente, le spese di lite sono liquidate, secondo il principio della soccombenza, come da dispositivo, in ragione del valore e della durata della causa.

P.Q.M.

1. accertato il diritto di [redacted] all'indennizzo di cui all'art. 2, co. 1, della legge n. 210/92, condanna il MINISTERO DELLA SALUTE alla corresponsione, in favore della parte attorea, dell'indennizzo nella misura prevista per la I categoria della Tabella A del dpr. 834/81, integrato da una somma corrispondente all'importo dell'indennità integrativa speciale di cui alla legge 27 maggio 1959, n. 324, con condanna ai

relativi versamenti e con decorrenza dal primo giorno del mese successivo alla presentazione della domanda del 5/4/11, oltre ad accessori di legge dal 121° giorno dalla domanda.

2. Condanna, perciò, il Ministero convenuto a versare alla parte ricorrente l'indennizzo nella misura prevista, dichiarando il diritto della parte ricorrente alla rivalutazione sia dell'indennizzo che dell'indennità integrativa speciale secondo il tasso annuale di inflazione programmata, come previsto dall'art. 2, primo comma, della legge n. 210 del 1992.
3. Ai sensi dell'art. 2, co. 2, della legge n. 210/92, per il periodo ricompreso tra il manifestarsi dell'evento dannoso in data 12.10.10 e l'ottenimento dell'indennizzo, ossia fino alla data della presente sentenza, condanna il Ministero convenuto a corrispondere a parte attorea un assegno *una tantum* nella misura pari, per ciascun anno, al 30 per cento dell'indennizzo dovuto ai sensi del comma 1 dell'art. 2 della stessa legge, con esclusione, per tale voce, di interessi legali e rivalutazione monetaria.
4. Condanna l'amministrazione ai relativi versamenti, pone le spese di c.t.u. a carico solidale delle parti e, nei rapporti interni tra le stesse, a carico della parte convenuta, con diritto di rivalsa da parte ricorrente di quanto eventualmente versato alla c.t.u., con liquidazione come da separata ordinanza di pari data. Condanna la parte convenuta a rimborsare alla parte ricorrente le spese di lite, che si liquidano complessivamente in € 3000, oltre IVA, CPA.

Fissa il termine di 60 giorni per il deposito della sentenza.

Sentenza provvisoriamente esecutiva.

Milano, 23/09/2014

il Giudice

Dott. Nicola Di Leo