Addressing House Committee Regarding HB19-1312

Lori Chenoweth
4/14/19

Madame Chair Lontine and Members of the Committee, thank you for giving me your time and attention today,

I am Lori Chenoweth, a teacher and mother. I have thoroughly researched my children's health options, and find this bill to disrespect my role to choose what is best for my children. I urge you to vote NO on HB19-1312.

As with any medical procedure such as surgery or chemotherapy, there needs to be INFORMED CONSENT. Parents need to know and be able to choose without obstruction the level of risk they are willing to accept. HB19-1312 (Page 5, Lines 6 & 7) requires educational materials to be made available regarding the benefits of vaccines. No where does it mention also providing knowledge to parents of the risks of vaccines of which my children and many others are victims.

When my oldest daughter was born I chose to vaccinate. Our family has faced the consequences of life- altering vaccine injury. My daughters have been tested positive for heterozygous mthfr. Having MTHFR

hinders methylation in the body. Toxins known to be found in vaccines are not detoxified.

Page 8, line 11-13 would make it impossible for my children to receive a medical exemption in spite of their MTHFR gene and the fact that a study has been done proving higher vulnerability to vaccine injury to those who have these gene mutations. This bill also undermines the physician/ patient relationship by forcing the doctor to only give medical exemptions from ACIP's list of contraindications. (Advisory Committee on Immunization Practices) *Provide Handout.*

If my already vaccine injured daughter is subjected to more vaccines it means additional injury and possible death. This law imposes a high level of obstruction for me to make the best health choices for my children. I urge you to value your roles as legislators to listen to your constituents, and vote against this bill. It will have huge and far reaching consequences on the health, and well being of my MTHFR positive daughters as well as any children with genetic abnormalities.

Patient Information	Specimen Information	Client Information
FREYGANG, KATELYN **DOB: 04/25/2015 AGE: 6M** Gender: F Phone: 954.822.7501 Patient ID: 12046	Specimen: EN579673H Requisition: 7433593 Lab Ref #: 121635 Collected: 11/19/2015 / 17:13 PST Received: 11/20/2015 / 02:13 PST Reported: 11/23/2015 / 16:40 PST	Client #: 76000969 MAIL0000 KAY, JAMES L JAMES L. KAY, DO, P.C., Attn: DBA SANTIAGO PEDIATRICS 24432 MUIRLANDS BLVD STE 111 LAKE FOREST, CA 92630-3939

Test Name	In Range	Out Of Range	Reference Range	Lab
BORDETELLA PERTUSSIS/ PARAPERTUSSIS SMEAR,DFA				TXC
SOURCE:	Nasopharyngeal			
B. PERTUSSIS, DFA		DETECTED		
B. PARAPERTUSSIS, DFA	NOT DETECTED			
REFERENCE RANGE: NOT DETECTED				

PERFORMING SITE:

TXC FOCUS DIAGNOSTICS, 33608 ORTEGA HIGHWAY BLD B-WEST WING, SAN JUAN CAPISTRANO, CA 92675-2042 Laboratory Director: HOLLIS BATTERMAN,MD, CLIA: 05D0644251

State of California—Health and Human Services Agency Printed on 11/24/2015 2:00:19 PM Department of Public Health

Routine Childhood Immunization Record and History

PATIENT NAME (Last Name, First Name, Middle Initial): **KATELYN AURORA FREYGANG**

CAIR ID # : 6307976

BIRTH DATE: **4/25/2015**

☐ Male ☒ Female

KNOWN REACTIONS TO VACCINES/ALLERGIES: Risks : Waviers :

PRACTICE NAME/ADDRESS
SANTIAGO PEDIATRICS
24432 MUIRLANDS BLVD
STE 111
LAKE FOREST, CA 92630

MR# :

VACCINES FOR CHILDREN (VFC) ELIGIBILITY (check one)

☒ CHDP/Medi-Cal eligible ☐ No health insurance ☐ American Indian/ Alaskan Native ☐ (Only Federally qualified and rural health centers) Health insurance does not cover IZs ☐ Not eligible

If a combination vaccine (e.g., DTap+IPV+HepB or HepB+Hib) is used, record dose in each section

VACCINE *Underline*	DATE GIVEN*	MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** / VIS I.D.+	VACCINE	DATE GIVEN*	MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** / VIS I.D.+
HepB 1 HBV	04/25/2015		TRANSCRIBED	*IM*	Pneumo Conj 1 PCV13	09/02/2015	PFI L04913-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM LT PCV13 10/22/2014*
HepB 2 HBV	09/02/2015	GSK BC35Z-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM LT 10/22/2014*	Pneumo Conj 2 PCV13	11/03/2015	PFI L99259-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM LT PCV13 10/22/2014*
HepB 3				*IM*	Pneumo Conj 3				*IM*
HepB 4				*IM*	Pneumo Conj 4				*IM*
Rotavirus 1				*oral*	IPV 1 + DTaPIPHi	06/30/2015	AVP C4877AC-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM or SC RT 10/22/2014 4/2/2015 10/22/2014*
Rotavirus 2				*oral*	IPV 2 + DTaPIPHi	09/02/2015	AVP C4747AA-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM or SC RT 10/22/2014 4/2/2015 10/22/2014*
Rotavirus 3				*oral*	IPV 3 + DTaPIPHi	11/03/2015	AVP C4813AB-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM or SC RT 10/22/2014 4/2/2015 10/22/2014*
DTaP/DT/Td/ Tdap 1 + DTaPIPHi	06/30/2015	AVP C4877AC-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM RT 10/22/2014 4/2/2015 10/22/2014*	IPV 4				*IM or SC*
DTaP/DT/Td/ Tdap 2 + DTaPIPHi	09/02/2015	AVP C4747AA-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM RT 10/22/2014 4/2/2015 10/22/2014*	MMR 1				*SC*
DTaP/DT/Td/ Tdap 3 + DTaPIPHi	11/03/2015	AVP C4813AB-VFC.	SANTIAGO PEDIATRICS - JULIA ALFAHOUM, MA	*IM RT 10/22/2014 4/2/2015 10/22/2014*	MMR 2				*SC*
DTaP/DT/Td/ Tdap 4				*IM*	History of Chickenpox Disease: No				

"Madame Chair and committee, thank you for your time.

My name is Andrea Freygang. I am from Colorado Springs and a vaccine refugee from California. I wear hearing aids, I am 50% deaf and missing a rib due to rubella (German measles), so I FULLY understand the impacts of not being vaccinated.

My teenage son is fully vaccinated, however, on 11/3/2015, at six months of age, my daughter got her DTAP shot and within a week she started coughing. I finally realized it was whooping cough due to the unmistakeable whooping cough but, the doctor refused to test until 11/19, I forced him to swab as I refused to leave his office until he did. My daughter tested positive for pertussis (lab test provided for you) and we began antibiotics. My daughter also started having seizures. But because I refused to do any more vaccines, I was constantly denied medical care and actually kicked out of doctors offices. I wasn't even anti-vaccine. I was anti-putting anything in my child till I knew the cause of the seizures. Finally, at 19 months of age I took my daughter to the hospital after a seizure and began getting answers. It took fleeing to Colorado to actually get medical care and a diagnosis. We later found out my daughter has a genetic seizure disorder but she did not have a single seizure or any delays until dTAP. DTAP is well known to be dangerous neurologically and even the U.K. warns about that. (flu, Hep B and chicken pox are optional in the UK). https://www.nhs.uk/conditions/vaccinations/childhood-vaccines-timeline/

The recent outbreak in California of Whooping cough also highlights the vaccine as a vector of disease. 100% of the students in the recent 2019 outbreak were vaccinated and none of the unvaccinated students fell ill. NONE yet we are to be required to take them all without any options or choice even with a family history of reactions or potential immune or neurological issues.

This bill gives away too much local control and decision making and does not specifically outline what will be codified as law since it leaves vague details to agencies than the legislature. It also will make it much more difficult for medical exemptions once the specifics are better outlined since this section on page 8, lines 9-15 leave it wide open for changes outside your purview as the state legislative body.

This is very concerning as it can potentially remove exemptions for children like my daughter. Seizures can be deadly and are extremely frightening and holding a child for hours while she seizes is incredibly scary. In Japan, many vaccine programs have been halted or made voluntary due to risks and reactions like my daughter Japan found 1 in 900 children were neurologically injured by MMR trio vaccine). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4300546/ and this article.
https://www.dailymail.co.uk/health/article-17509/Why-Japan-banned-MMR-vaccine.html

Medical choices always have risk and while there is a need to ensure people are not spreading disease, it is equally important to make sure that we are offering the safest possible product. Instead of mandating further vaccines people feel are dangerous, the better approach is to improve the product (create a vaccine that addresses the concerns). Education can go much further than mandates.

I ask that you reject the bill until you have more time to review the vague aspects of what will be expected by all parties involved instead of leaving it open-ended and decided by whoever runs the CDPHE or AICP.

I ask that you reject this bill because it is vague in implementation, vague in the actual cost expense to implement, will be expensive for Coloradans to defend in court with guaranteed lawsuits to arise and it already duplicates a well working vaccine bill already in place.

Thank you.

frontiers in Endocrinology

Front Endocrinol (Lausanne). 2016; 7: 150.
Published online 2017 Jan 24. doi: 10.3389/fendo.2016.00150

PMCID: PMC5256113
PMID: 28167927

Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Thyroid Autoimmunity

Abdulla Watad,[1,2,3] Paula David,[2,4] Stav Brown,[3] and Yehuda Shoenfeld[2,3,5,*]

[1]Department of Medicine "B", Sheba Medical Center, Tel-Aviv, Israel
[2]Zabludowicz Center for Autoimmune Diseases, Sheba Medical Center, Tel-Aviv, Israel
[3]Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel
[4]Faculdade de Ciências Médicas, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil
[5]Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases, Tel-Aviv University, Tel-Aviv, Israel

Edited by: Alessandro Antonelli, University of Pisa, Italy
Reviewed by: Silvia Martina Ferrari, University of Pisa, Italy; Ilaria Ruffilli, University of Pisa, Italy; Carlo Perricone, Sapienza University, Italy
*Correspondence: Yehuda Shoenfeld, shoenfel@post.tau.ac.il
Specialty section: This article was submitted to Thyroid Endocrinology, a section of the journal Frontiers in Endocrinology

Received 2016 Oct 12; Accepted 2016 Nov 21.

Abstract

The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin in 2011, is an entity that incorporates diverse autoimmune conditions induced by the exposure to various adjuvants. Adjuvants are agents that entail the capability to induce immune reactions. Adjuvants are found in many vaccines and used mainly to increase the response to vaccination in the general population. Silicone has also been reported to be able to induce diverse immune reactions. Clinical cases and series of heterogeneous autoimmune conditions including systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis have been reported to be induced by several adjuvants. However, only a small number of cases of autoimmune thyroid disorder have been included under the umbrella of ASIA syndrome. Indeed, clinical cases of Hashimoto's thyroiditis and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. In our review, we aimed to summarize the current knowledge on ASIA syndrome presented as endocrinopathies, focusing on autoimmune thyroid disorders associated with the various adjuvants.

Keywords: autoimmune/inflammatory syndrome induced by adjuvants, thyroid, endocrinopathy, adjuvants, vaccines, silicone, Hashimoto's thyroiditis, Graves disease

Introduction

Adjuvants are substances that are able to trigger autoimmunity *via* a variety of mechanisms, such as alteration of the host's immune system, polyclonal activation of B cells, effects on cellular immunity, immunoregulatory cells, viral-induced antibodies, and acceleration of molecular mimicry (1). Exposure to adjuvants can occur in a variety of methods due to their wide range of uses in vaccines, mineral oils, silicone implants, and many other products and devices. The association between adjuvant exposure and autoimmunity manifests itself in five autoimmune conditions sharing similar autoimmunity manifestations (2, 3), such as the postvaccination phenomena, the macrophagic myofasciitis syndrome (MMF), the Gulf war syndrome (GWS), siliconosis, and the sick building syndrome (SBS) (4, 5). The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin (6) in 2011, is a single entity that incorporates all five conditions. Extensive research has identified the genetic background, contributing to the development of ASIA syndrome in predisposed individuals following adjuvant exposure. A large number of autoimmune diseases share several alleles of the HLA class II such as DRB1 locus. The development of specific autoantibodies is determined by DRB1 alleles leading to an abnormal response and development of full-blown autoimmune diseases (7, 8).

When used in vaccines, adjuvants are purposely used as immunogenicity enhancing agents that are essential for directing the adaptive immunoresponse (9). However, they might also trigger undesired autoimmune reactions that question the use of adjuvants and their safety in the context of DRB1*01 genetic background (10).

A systematic review by Jara et al. (4) reported that 4479 ASIA cases have been identified since its presentation in 2011. Among them, 305 were considered severe, with the majority of these cases being developed following vaccines mainly directed to HPV, HBV, and seasonal influenza. Despite vaccines' proven record of safety and efficiency, aluminum hydroxide was used in these vaccines along with the viral antigens as an adjuvant. Due to aluminum's capability to enhance the immunoresponse, it enables the usage of smaller amount of antigens. However, enhanced immunogenicity might lead to enhanced reactogenicity in a process not always benign involving pathological stimulation (11).

The other adjuvants containing products yielding severe clinical manifestations are silicone implants and mineral oil fillers (4, 12).

Silicone has been considered as an inert material, which is unable to induce immune reactions in the human body. Therefore, it has been used in many medical devices for the last 60 years, including both silicone and saline breast implants. However, a possible association between silicone exposure and autoimmune diseases has been reported in many studies demonstrating the development of autoimmune diseases and autoantibodies in patients following exposure to silicone implants (13, 14). Improved clinical manifestations after the extraction of implants (15) support the relationship between silicone and autoimmunity.

Mineral oil injections, which are prevalent in Mexico and Latin America for cosmetic uses, have been identified as a leading cause of ASIA syndrome as well *via* the proposed mechanism of chronic inflammation induction leading to granuloma formation and thickening of the dermis (4, 10).

The risk for autoimmune diseases, determined by the patient's genetic background, is increased in patients with autoimmune diseases history such as type 1 diabetes mellitus (T1DM). Thyroid antibodies can be identified in approximately 20–25% of patients with type 1 diabetes, and up to 50% of them progress to clinical autoimmune thyroid disease (AITD) (16). Thyroid autoimmune diseases have been described in many case reports and case series, presenting thyroid autoimmune manifestations along with other autoimmune conditions.

In genetically predisposed individuals, under particular conditions, molecular mimicry between microbial and human antigens has been shown to be able to turn a defensive immunoresponse into autoimmune response. This mechanism has yet to be explored in the field of thyroid autoimmune diseases (17). In our review, we aimed to summarize the current knowledge about ASIA syndrome and the relationship between adjuvants and autoimmune diseases, focusing on its association with autoimmune endocrinopathies and thyroid autoimmunity.

Endocrinopathy and ASIA Syndrome

Pathological processes of the endocrine glands result in abnormal levels of circulating hormones, which lead to endocrinopathies. Some endocrine disorders are immune mediated, such as Hashimoto's thyroiditis (HT), Graves' disease, and T1DM (18–20). Thus, it is possible that endocrine autoimmune diseases can be triggered by adjuvants, configuring cases of ASIA syndrome. Case reports, cohort and case–control studies on ASIA syndrome, and the majority of the endocrinopathies are still scarce. Lately, primary ovarian failure (POF) has been linked to ASIA, especially after vaccination (21–25).

Primary ovarian failure or premature ovarian insufficiency is defined as a combination of amenorrhea, for a minimum of 4 months, decline in sex steroids, and follicle-stimulating hormone (FSH) above 40 IU/l at two measurements with an interval of at least 1 month in women younger than 40 years (26). POF is a disorder with multiple etiologic mechanisms. The presence of lymphocytic invasion in the oophorus and the identification of autoantibodies against ovarium antigens on the theca, granulose, corpus luteum, and zona pellucida (27–29) support the idea that part of its etiology, estimated in 20–30% (30), is immune mediated. Furthermore, POF is commonly associated with other autoimmune diseases, including Addison's disease, thyroiditis, autoimmune polyglandular syndrome, systemic lupus erythematosus (SLE), hemolytic anemia, idiopathic thrombocytopenic purpura (ITP), and Sjogren's syndrome (31). The pathogenesis of POF also involves genetic mutations, metabolic disorders, and environmental factors, such as virus infection, chemo and radiotherapy, and surgeries (30).

HPV vaccine has been reported as an important issue in ASIA syndrome, already being related, for instance, to Guillain-Barré syndrome and other neuropathies, such as SLE, vasculitis, ITP, and autoimmune hepatitis (32–36). Developing autoimmune diseases as an adverse effect of the vaccine can be both due to its HPV virus-like particles, which have potent immuno-stimulatory properties (and can induce autoimmunity by molecular mimicry, epitope spreading, bystander activation, and polyclonal activation) (37), and due to the presence of aluminum as an adjuvant in the vaccine (38). Adjuvants are capable of increasing, intensifying, and prolonging antigen-specific immunoresponse of the vaccines without holding its own specific antigenic effect (38). Autoimmune well-defined diseases, as well as the non-specific immune disorders, following vaccination can present as a subacute vaccination side effect or appear months or years after the boosters (39–43). Genetically predisposed patients are more likely to exhibit late manifestations and are in a higher risk of developing ASIA syndrome (36, 44).

Colafrancesco et al. (21) recently reported three cases of POF following immunization with HPV vaccine. The three patients fulfilled the criteria for ASIA syndrome suggested by Shoenfeld and Agmon-Levin (6). They described three young women, previously healthy and with normal sexual development, who received three administrations of the quadrivalent HPV vaccine. The patients experienced general symptoms, including nausea, stomachaches, heavy and burning sensations in the injected arm, headaches, insomnia, arthralgia, depression, anxiety, and difficulty in concentrating, and then presented amenorrhea within approximately 10 months, 2 years, and 10 years after the first dose. Two of them were positive for previously negative antibodies (anti-TPO and antiovarian). Hormonal screening was performed, showing increased FSH and luteinizing hormone (LH) plus

extremely low levels of estradiol. Pregnancy was excluded, as well as no abnormalities were revealed in the transvaginal and pelvic ultrasound. After a karyotype evaluation and search for Fragile X syndrome with no aberrations, they were diagnosed with POF. Moreover, two of the three patients were siblings leading to the hypothesis that may exist as a rare risk factor for this adverse effect.

Little and Ward (22) also reported a case of POF succeeding HPV vaccination, in a 16-year-old patient, who presented irregular menses after taking the quadrivalent vaccine, followed by oligomenorrhea and amenorrhea. Her hormone profile also showed high levels of FSH and LH and low levels of estradiol and anti-mullerian hormone (AMH), and after excluding pregnancy and genetic, endocrinal, and other causes, she was diagnosed with POF.

Problems of quadrivalent HPV vaccine introduction in the market were wisely pointed by Little and Ward (25). They reported three other cases of young women who develop POF after having quadrivalent HPV vaccine and questioned some issues about its safety. First, despite the fact that the vaccine protocol suggests three doses, in the preclinical studies for toxicity, only two boosters were given to the rats. Still, the animals' reproductive system was not analyzed in a long-term period. Moreover, the phase II and III clinical studies on safety of the vaccine regarding the fertility were not complete: half of the subjects studied were lost to follow-up at 1 year; some of the subjects were on hormone contraception methods, which could mask the ovarian insufficiency; they have not considered medical conditions that flourished more than 7 months after the vaccination as associated with the vaccine; and adverse effects were only reported 2 weeks after the boosters. Furthermore, the placebo used as control in the phase III safety studies of the quadrivalent HPV vaccine was aluminum, also present in the vaccine solution, which was already shown to play as an adjuvant in ASIA syndrome.

Thus, HPV vaccine is likely to be an important trigger in ASIA syndrome, including immuno-mediated endocrine disorders, such as POF. Due to long periods of intervals between the vaccine injections and the development of the ovarian insufficiency, it is questionable if there is indeed a causal relationship between them. However, as previously mentioned, the safety preclinical and clinical studies of HPV vaccine are lacking some information regarding fertility safety, and the side effects were shown to be able to appear even after months or years.

Other vaccines and adjuvants may also trigger POF, as well as other immuno-mediated endocrinopathies, like for instance, type 1-diabetes may be induced by the same adjuvants. Indeed, in a cohort study with 211 young female patients with autoimmune diseases and 857 matched controls, they showed that patients exposed to quadrivalent HPV vaccine were in a higher risk of developing type 1-diabetes mellitus (OR = 1.2) (45). Additionally, it was shown in a prospective cohort study (46) that some vaccines are related to increased levels of diabetes autoantibodies, such as antibody against glutamic acid decarboxylase (GADA) and tyrosine phosphatase (IA-2A). These autoantibodies, which are considered reliable markers for the disease process (47, 48), were more frequently found in the subjects who received hemophilus influenza B (HIB) vaccination (OR = 5.9 and 3.4 in IA-2A and GADA, respectively). Especially, the IA-2A serum concentrations were significantly higher in patients exposed to HIB. Also, BCG was correlated to an enhanced prevalence of IA-2A ($p < 0.01$). The previously mentioned studies suggest that ASIA syndrome, particularly post vaccination, and endocrinopathies might be linked.

Autoimmune Thyroid Disease and ASIA Syndrome

During the last years, abundant case reports and series were published supporting that various autoimmune disorders may be induced by adjuvants and be enclosed under ASIA syndrome (4, 12). Despite the fact of being the most common autoimmune disorder, unexpectedly, we have revealed very few articles and case reports in the literature describing the induction of AITD by various adjuvants. In this section, we report that the relevant case descriptions of AITD were reported to be correlated to immunization and silicone implants.

Hernàn Martinez et al. (49) described a case of a 55-year-old man with a family history of autoimmune diseases and medical history of diabetes and psoriasis, who developed subacute thyroiditis shortly after the administration of an influenza vaccine. Subacute thyroiditis is a very rare disease, and the authors of the mentioned case concluded that the induction of the disease was a result of an interaction between the genetic predisposition and vaccination. Another similar case of subacute thyroiditis was reported in a 25-year-old female (50). The patient was admitted due to fever, swelling, and tender mass in the neck. Two days before her presentation, she received influenza vaccine (Vaxigrip). Biopsy of the thyroid has revealed multinuclear giant cell granulomas.

A previously healthy 36-year-old female presented with clinical symptoms of thyrotoxicosis including tachycardia, anxiety, and tenderness in her neck (51). One month before her presentation, she received H1N1 vaccine. Thyroid function tests confirmed remarkable thyrotoxicosis. Thyroid scintigraphy was performed and showed significant diffuse reduction in the technetium uptake. Therefore, a diagnosis of subacute thyroiditis was made. Moving to another type of adjuvant, cases of granulomatous inflammation of the thyroid have been reported with silicone breast implants (52). Vayssairat et al. (53) described two cases of HT after receiving a silicone gel-filled breast implants. Both cases were induced after a long period of incubation, the first case is a 45-year-old women who had bilateral silicone implant of the breast in 1976 and developed HT in 1991. In addition, the patient complained of other non-specific symptoms including fatigue, morning stiffness, and sicca syndrome. Thyroid ultrasonography showed an enlarged thyroid gland with a diffusely hypoechogenic pattern. The implants were painful and removed, showing extremely dense connective tissue with fibrosis. The second case of HT presented with hyperthyroidism clinical manifestation, 10 years after the silicon implantation, reporting positive anti-TPO. The implants were again painful, and the patient developed positive antinuclear

antibodies (ANA). An animal experiment aimed to evaluate the immunological adjuvancy potential of silicone gel taken from breast implants (54). The study has found that silicone gel is able to stimulate the production of autoantibodies to rat thyroglobulin and bovine collagen II. However, this immune reaction was not associated with any histological evidence of thyroiditis or arthritis.

A cohort study was performed to assess the risk of new onset autoimmune disease in young women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom (55). The study reported an incidence rate ratio (95% CI) of 3.75 (1.25–11.31) for autoimmune thyroiditis among females.

An animal study has reported that immunization of BALB/c mice with the extracellular domain of the human TSH receptor led to the production of TSH binding-inhibiting and thyroid-blocking antibodies accompanied by lymphocytic infiltration of the thyroid (56).

In summary, ASIA syndrome is being more recognized by physicians, and therefore, more studies and cases have reported the correlation of the exposure to various adjuvants with diverse autoimmune diseases. Still, very few clinical reports and animal models studies were published to show the relationship between endocrinopathies in general and AITD in particular with adjuvants. However, the clinical cases of HT and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. Therefore, we believe that the minority of cases is not owing to rarity of association between adjuvants and AITD rather than the lack of awareness among physicians of such association. Consequently, physicians must be mindful that thyroiditis and other thyroid disorders can be induced by diverse adjuvants and therefore to reconsider non-essential vaccination in genetically predisposed individuals for autoimmune diseases.

Author Contributions

AW, PD, SB, and YS designed the study and reviewed the literature on ASIA syndrome and thyroid autoimmunity. AW, PD, and SB wrote the manuscript. AW and YS edited the manuscript. All the authors have revised the paper and approved the final edition.

Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The reviewers IR and SF and handling Editor declared their shared affiliation, and the handling Editor states that the process nevertheless met the standards of a fair and objective review.

References

1. Perricone C, Colafrancesco S, Mazor RD, Soriano A, Agmon-Levin N, Shoenfeld Y. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) 2013: unveiling the pathogenic, clinical and diagnostic aspects. J Autoimmun (2013) 47:1–16.10.1016/j.jaut.2013.10.004 [PubMed] [CrossRef] [Google Scholar]

2. Vera-Lastra O, Medina G, Cruz-Dominguez MDP, Ramirez P, Gayosso-Rivera JA, Anduaga-Dominguez H, et al. Human adjuvant disease induced by foreign substances: a new model of ASIA (Shoenfeld's syndrome). Lupus (2012) 21:128–35.10.1177/0961203311429317 [PubMed] [CrossRef] [Google Scholar]

3. Meroni PL. Autoimmune or auto-inflammatory syndrome induced by adjuvants (ASIA): old truths and a new syndrome? J Autoimmun (2011) 36:1–3.10.1016/j.jaut.2010.10.004 [PubMed] [CrossRef] [Google Scholar]

4. Jara LJ, García-Collinot G, Medina G, Cruz-Dominguez MD, Vera-Lastra O, Carranza-Muleiro RA, et al. Severe manifestations of autoimmune syndrome induced by adjuvants (Shoenfeld's syndrome). Immunol Res (2016).10.1007/s12026-016-8811-0 [PubMed] [CrossRef] [Google Scholar]

5. Israeli E, Pardo A. The sick building syndrome as a part of the autoimmune (auto-inflammatory) syndrome induced by adjuvants. Mod Rheumatol (2011) 21:235–9.10.1007/s10165-010-0380-9 [PubMed] [CrossRef] [Google Scholar]

6. Shoenfeld Y, Agmon-Levin N. "ASIA" – autoimmune/inflammatory syndrome induced by adjuvants. J Autoimmun (2011) 36:4–8.10.1016/j.jaut.2010.07.003 [PubMed] [CrossRef] [Google Scholar]

7. Israeli E, Agmon-Levin N, Blank M, Shoenfeld Y. Macrophagic myofaciitis a vaccine (alum) autoimmune-related disease. Clin Rev Allergy Immunol (2011) 41:163–8.10.1007/s12016-010-8212-4 [PubMed] [CrossRef] [Google Scholar]

8. Arango M-T, Perricone C, Kivity S, Cipriano E, Ceccarelli F, Valesini G, et al. HLA-DRB1 the notorious gene in the mosaic of autoimmunity. Immunol Res (2016):1–17.10.1007/s12026-016-8817-7 [PubMed] [CrossRef] [Google Scholar]

9. Agmon-Levin N, Hughes GR, Shoenfeld Y. The spectrum of ASIA: "autoimmune (auto-inflammatory) Syndrome induced by adjuvants". Lupus (2012) 21:118–20.10.1177/0961203311429316 [PubMed] [CrossRef] [Google Scholar]

10. Vera-Lastra O, Medina G, Cruz-Dominguez MDP, Jara LJ, Shoenfeld Y. Autoimmune/inflammatory syndrome induced by adjuvants (Shoenfeld's syndrome): clinical and immunological spectrum. Expert Rev Clin Immunol (2013) 9:361–73.10.1586/eci.13.2 [PubMed] [CrossRef] [Google Scholar]

11. Inbar R, Weiss R, Tomljenovic L, Arango MT, Deri Y, Shaw CA, et al. Behavioral abnormalities in young female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil. Vaccine (2016) pii:S0264-410X(16)00016-5.10.1016/j.vaccine.2015.12.067 [PubMed] [CrossRef] [Google Scholar]

12. Colaris MJL, de Boer M, van der Hulst RR, Cohen Tervaert JW. Two hundreds cases of ASIA syndrome following silicone implants: a comparative study of 30 years and a review of current literature. Immunol Res (2016).10.1007/s12026-016-8821-y [PubMed] [CrossRef] [Google Scholar]

13. Muzaffar AR, Rohrich RJ. The silicone gel-filled breast implant controversy: an update. Plast Reconstr Surg (2002) 109:742–7; quiz 748.10.1097/00006534-200202000-00049 [PubMed] [CrossRef] [Google Scholar]

14. Bar-Meir E, Teuber SS, Lin HC, Alosacie I, Goddard G, Terybery J, et al. Multiple autoantibodies in patients with silicone breast implants. J Autoimmun (1995) 8:267–77.10.1006/jaut.1995.0020 [PubMed] [CrossRef] [Google Scholar]

15. Maijers MC, de Blok CJM, Niessen FB, van der Veldt AAM, Ritt MJPF, Winters HAH, et al. Women with silicone breast implants and unexplained systemic symptoms: a descriptive cohort study. Neth J Med (2013) 71:534–40. [PubMed] [Google Scholar]

16. Kahaly GJ, Hansen MP. Type 1 diabetes associated autoimmunity. Autoimmun Rev (2016) 15:644–8.10.1016/j.autrev.2016.02.017 [PubMed] [CrossRef] [Google Scholar]

17. Oldstone MBA. Molecular mimicry and autoimmune disease. Cell (1987) 50:819–20.10.1016/0092-8674(87)90507-1 [PubMed] [CrossRef] [Google Scholar]

18. Prabhakar BS, Bahn RS, Smith TJ. Current perspective on the pathogenesis of Graves' disease and ophthalmopathy. Endocr Rev (2003) 24:802–35.10.1210/er.2002-0020 [PubMed] [CrossRef] [Google Scholar]

19. Hollowell JG, Staehling NW, Flanders WD, Hannon WH, Gunter EW, Spencer CA, et al. Serum TSH, T(4), and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). J Clin Endocrinol Metab (2002) 87:489–99.10.1210/jcem.87.2.8182 [PubMed] [CrossRef] [Google Scholar]

20. Atkinson MA, Maclaren NK. The pathogenesis of insulin-dependent diabetes mellitus. N Engl J Med (1994) 331:1428–36.10.1056/NEJM199411243312107 [PubMed] [CrossRef] [Google Scholar]

21. Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y. Human papilloma virus vaccine and primary ovarian failure: another facet of the autoimmune/inflammatory syndrome induced by adjuvants. Am J Reprod Immunol (2013) 70:309–16.10.1111/aji.12151 [PubMed] [CrossRef] [Google Scholar]

22. Little DT, Ward HRG. Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination. BMJ Case Rep (2012) 2012:2–4.10.1136/bcr-2012-006879 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

23. Gruber N, Shoenfeld Y. A link between human papilloma virus vaccination and primary ovarian insufficiency: current analysis. Curr Opin Obstet Gynecol (2015) 27:265–70.10.1097/GCO.0000000000000183 [PubMed] [CrossRef] [Google Scholar]

24. Hawkes D, Buttery JP. Human papillomavirus vaccination and primary ovarian insufficiency: an association based on ideology rather than evidence. Curr Opin Obstet Gynecol (2016) 28:70–2.10.1097/GCO.0000000000000240 [PubMed] [CrossRef] [Google Scholar]

25. Little DT, Ward HRG. Adolescent premature ovarian insufficiency following human papillomavirus vaccination: a case series seen in general practice. J Investig Med High Impact Case Rep (2014) 2:2324709614556129.10.1177/2324709614556129 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

26. Nelson LM. Clinical practice. Primary ovarian insufficiency. N Engl J Med (2009) 360:606–14.10.1056/NEJMcp0808697 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

27. Kelkar RL, Meherji PK, Kadam SS, Gupta SK, Nandedkar TD. Circulating auto-antibodies against the zona pellucida and thyroid microsomal antigen in women with premature ovarian failure. J Reprod Immunol (2005) 66:53–67.10.1016/j.jri.2005.02.003 [PubMed] [CrossRef] [Google Scholar]

28. Chattopadhyay D, Sen MR, Katiyar P, Pandey LK. Antiovarian antibody in premature ovarian failure. Indian J Med Sci (1999) 53:254–8. [PubMed] [Google Scholar]

29. Mande PV, Parikh FR, Hinduja I, Zaveri K, Vaidya R, Gajbhiye R, et al. Identification and validation of candidate biomarkers involved in human ovarian autoimmunity. Reprod Biomed Online (2011) 23:471–83.10.1016/j.rbmo.2011.06.013 [PubMed] [CrossRef] [Google Scholar]

30. Petrikova J, Lazurova I. Ovarian failure and polycystic ovary syndrome. Autoimmun Rev (2012) 11:A471–8.10.1016/j.autrev.2011.11.010 [PubMed] [CrossRef] [Google Scholar]

31. Hoek A, Schoemaker J, Drexhage HA. Premature ovarian failure and ovarian autoimmunity. Endocr Rev (1997) 18:107–34.10.1210/er.18.1.107 [PubMed] [CrossRef] [Google Scholar]

32. Pugnet G, Ysebaert L, Bagheri H, Montastruc J-L, Laurent G. Immune thrombocytopenic purpura following human papillomavirus vaccination. Vaccine (2009) 27:3690.10.1016/j.vaccine.2009.04.004 [PubMed] [CrossRef] [Google Scholar]

33. Souayah N, Michas-Martin PA, Nasar A, Krivitskaya N, Yacoub HA, Khan H, et al. Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009. Vaccine (2011) 29:886–9.10.1016/j.vaccine.2010.09.020 [PubMed] [CrossRef] [Google Scholar]

34. Alvarez-Soria MJ, Hernandez-Gonzalez A, Carrasco-Garcia de Leon S, del Real-Francia MA, Gallardo-Alcaniz MJ, Lopez-Gomez JL. [Demyelinating disease and vaccination of the human papillomavirus]. Rev Neurol (2011) 52:472–6. [PubMed] [Google Scholar]

35. Gomes SM, Glover M, Malone M, Brogan P. Vasculitis following HPV immunization. Rheumatology (Oxford) (2013) 52:581–2.10.1093/rheumatology/kes168 [PubMed] [CrossRef] [Google Scholar]

36. Gatto M, Agmon-Levin N, Soriano A, Manna R, Maoz-Segal R, Kivity S, et al. Human papillomavirus vaccine and systemic lupus erythematosus. Clin Rheumatol (2013) 32:1301–7.10.1007/s10067-013-2266-7 [PubMed] [CrossRef] [Google Scholar]

37. Sutton I, Lahoria R, Tan I, Clouston P, Barnett M. CNS demyelination and quadrivalent HPV vaccination. Mult Scler (2009) 15:116–9.10.1177/1352458508096868 [PubMed] [CrossRef] [Google Scholar]

38. Israeli E, Agmon-Levin N, Blank M, Shoenfeld Y. Adjuvants and autoimmunity. Lupus (2009) 18:1217–25.10.1177/0961203309345724 [PubMed] [CrossRef] [Google Scholar]

39. Couette M, Boisse MF, Maison P, Brugieres P, Cesaro P, Chevalier X, et al. Long-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction. J Inorg Biochem (2009) 103:1571–8.10.1016/j.jinorgbio.2009.08.005 [PubMed] [CrossRef] [Google Scholar]

40. Mikaeloff Y, Caridade G, Suissa S, Tardieu M. Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood. Neurology (2009) 72:873–80.10.1212/01.wnl.0000335762.42177.07 [PubMed] [CrossRef] [Google Scholar]

41. Shivane A, Hilton DA, Moate RM, Bond PR, Endean A. Macrophagic myofasciitis: a report of second case from UK. Neuropathol Appl Neurobiol (2012) 38:734–6.10.1111/j.1365-2990.2012.01293.x [PubMed] [CrossRef] [Google Scholar]

42. Poser CM, Behan PO. Late onset of Guillain-Barré syndrome. J Neuroimmunol (1982) 3:27–41.10.1016/0165-5728(82)90016-9 [PubMed] [CrossRef] [Google Scholar]

43. Gherardi RK, Authier F-J. Macrophagic myofasciitis: characterization and pathophysiology. Lupus (2012) 21:184–9.10.1177/0961203311429557 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

44. Zafrir Y, Agmon-Levin N, Paz Z, Shilton T, Shoenfeld Y. Autoimmunity following hepatitis B vaccine as part of the spectrum of "autoimmune (auto-inflammatory) syndrome induced by adjuvants" (ASIA): analysis of 93 cases. Lupus (2012) 21:146–52.10.1177/0961203311429318 [PubMed] [CrossRef] [Google Scholar]

45. Grimaldi-Bensouda L, Guillemot D, Godeau B, Bénichou J, Lebrun-Frenay C, Papeix C, et al. Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects. J Intern Med (2014) 275:398–408.10.1111/joim.12155 [PubMed] [CrossRef] [Google Scholar]

46. Wahlberg J, Fredriksson J, Vaarala O, Ludvigsson J, Abis Study Group . Vaccinations may induce diabetes-related autoantibodies in one-year-old children. Ann N Y Acad Sci (2003) 1005:404–8.10.1196/annals.1288.068 [PubMed] [CrossRef] [Google Scholar]

47. Bingley PJ, Bonifacio E, Williams AJK, Genovese S, Bottazzo GF, Gale EA. Prediction of IDDM in the general population: strategies based on combinations of autoantibody markers. Diabetes (1997) 46:1701–10.10.2337/diab.46.11.1701 [PubMed] [CrossRef] [Google Scholar]

48. Samuelsson UU, Sundkvist GG, Borg HH, Fernlund PP, Ludvigsson JJ. Islet autoantibodies in the prediction of diabetes in school children. Diabetes Res Clin Pract (2001) 51:51–7.10.1016/S0168-8227(00)00199-6 [PubMed] [CrossRef] [Google Scholar]

49. Hernán Martinez J, Corder E, Uzcategui M, Garcia M, Sostre S, Garcia A. Subacute thyroiditis and dyserythropoesis after influenza vaccination suggesting immune dysregulation. Bol Asoc Med P R (2011) 103:48–52. [PubMed] [Google Scholar]

50. Hsiao J-Y, Hsin S-C, Hsieh M-C, Hsia P-J, Shin S-J. Subacute thyroiditis following influenza vaccine (Vaxigrip) in a young female. Kaohsiung J Med Sci (2006) 22:297–300.10.1016/S1607-551X(09)70315-8 [PubMed] [CrossRef] [Google Scholar]

51. Girgis CM, Russo RR, Benson K. Subacute thyroiditis following the H1N1 vaccine. J Endocrinol Invest (2010) 33:506.10.1007/BF03346633 [PubMed] [CrossRef] [Google Scholar]

52. Prebtani APH, Asa SL, Ezzat S. Is granulomatous thyroiditis a complication of breast implants? Endocr Pathol (2002) 13:239–44.10.1385/EP:13:3:239 [PubMed] [CrossRef] [Google Scholar]

53. Vayssairat M, Mimoun M, Houot B, Abuaf N, Rouquette AM, Chaouat M. [Hashimoto's thyroiditis and silicone breast implants: 2 cases]. J Mal Vasc (1997) 22:198–9. [PubMed] [Google Scholar]

54. Naim JO, Lanzafame RJ, van Oss CJ. The effect of silicone-gel on the immune response. J Biomater Sci Polym Ed (1995) 7:123–32.10.1163/156856295X00643 [PubMed] [CrossRef] [Google Scholar]

55. Willame C, Rosillon D, Zima J, Angelo M-G, Stuurman AL, Vroling H, et al. Risk of new onset autoimmune disease in 9- to 25-year-old women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom. Hum Vaccin Immunother (2016) 18:1–10.10.1080/21645515.2016.1199308 [PMC free article] [PubMed] [CrossRef] [Google Scholar]

56. Costagliola S, Alcalde L, Tonacchera M, Ruf J, Vassart G, Ludgate M. Induction of thyrotropin receptor (TSH-R) autoantibodies and thyroiditis in mice immunised with the recombinant TSH-R. Biochem Biophys Res Commun (1994) 199:1027–34.10.1006/bbrc.1994.1332 [PubMed] [CrossRef] [Google Scholar]

Hello,

My name is Joyce Regier. I developed Irritable Bowel Disease from my childhood shots and suffered a major flare-up for many years after my pre-college shots. My family has a history of autoimmune disease. Because of my family history, I intend to use one of the exemptions to protect my children from auto-immune disorders often caused by the adjuvants. (Schoenfeld)

This bill will cause exemption rates to rise because it will add HPV and the flu shot to the required school schedule in addition to several others. These 2 shots are the ones most avoided by the general public because of their side effects. Please do not promulgate the CDC schedule. (Pg 9, Line 16)

Governor Polis has stated in news reports that he does not want to encourage mis-trust of the government through this type of legislation. This bill will encourage mistrust of government by tracking a fraction of the population who choose to protect their children in alternative ways. By the wording in this bill, there is no way to fully opt out of the Dept of Health tracking system. This is very concerning to me, as a government database was the foundation for corralling all American-Japanese into the internment camps during WWII. Please provide a way to completely opt partially or non vaccinated children out of the database if we so choose. (Pg8, Lines1-8)

If you really want to lower exemption rates, then look at the bill just introduced in Texas. It places a moratorium on vaccines until they are proven to be safe, including:

- "True saline placebo testing
- studies to identify potential of causing autoimmune, neurological or chronic health conditions up to a year after administration
- evaluated for ability to
    - cause cancer
    - mutate genes
    - affect fertility or cause infertility
    - cause autism spectrum disorder"

If vaccines are truly proven to be safe by those guidelines, then force and pressure would not need to be used to improve exemption rates and we would be more than willing to consider them a viable option.

We all have the same goal, healthy kids and a healthy community.

86R13084 JG-F

By: Hall S.B. No. 2350

A BILL TO BE ENTITLED
AN ACT

relating to the prohibited administration of certain vaccinations.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0045 to read as follows:

Sec. 161.0045. ADMINISTRATION OF CERTAIN VACCINES PROHIBITED. A health care provider may administer a vaccine only if:

(1) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine against a control group that received:

(A) a placebo; or

(B) another vaccine or other substance approved by the United States Food and Drug Administration based on a study that evaluated the safety of that vaccine or substance against a control group that received a placebo for that study;

(2) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine for a sufficient time to identify potential autoimmune, neurological, or chronic health conditions that may arise on or after the first anniversary of the date the vaccine is administered;

(3) the vaccine has been evaluated for the vaccine's potential to:

(A) cause cancer;

(B) mutate genes;

(C) affect fertility or cause infertility; and

(D) cause autism spectrum disorder;

(4) the department has posted on the department's Internet website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

(5) the chemical, pharmacological, therapeutic, and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

SECTION 2. This Act takes effect September 1, 2019.

Journal of Autoimmunity 36 (2011) 4–8

Contents lists available at ScienceDirect

Journal of Autoimmunity

journal homepage: www.elsevier.com/locate/jautimm

Review

'ASIA' – Autoimmune/inflammatory syndrome induced by adjuvants

Yehuda Shoenfeld [a,b,*], Nancy Agmon-Levin [a]

[a] The Zabludowicz Center for Autoimmune Diseases, Department of Medicine B' Sheba Medical Center, Tel-Hashomer, Israel
[b] Incumbent of the Laura Schwarz-kipp Chair for Research of Autoimmune Diseases, Sackler Faculty of Medicine, Tel-Aviv University, Israel

ARTICLE INFO

Article history:
Received 16 June 2010
Received in revised form
15 July 2010
Accepted 20 July 2010

Keywords:
Autoimmunity
Adjuvant
Vaccine
Gulf war syndrome (GWS)
Macrophagic myofasciitis syndrome (MMF)
Silicone

ABSTRACT

The role of various environmental factors in the pathogenesis of immune mediated diseases is well established. Of which, factors entailing an immune adjuvant activity such as infectious agents, silicone, aluminium salts and others were associated with defined and non-defined immune mediated diseases both in animal models and in humans. In recent years, four conditions: siliconosis, the Gulf war syndrome (GWS), the macrophagic myofasciitis syndrome (MMF) and post-vaccination phenomena were linked with previous exposure to an adjuvant. Furthermore, these four diseases share a similar complex of signs and symptoms which further support a common denominator.Thus, we review herein the current data regarding the role of adjuvants in the pathogenesis of immune mediated diseases as well as the amassed data regarding each of these four conditions. Relating to the current knowledge we would like to suggest to include these comparable conditions under a common syndrome entitled **ASIA**, "Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants".

1. Introduction

In recent years four enigmatic medical conditions, defined by hyperactive immune responses were described. These conditions, namely siliconosis, the Gulf war syndrome (GWS), the macrophagic myofasciitis syndrome (MMF) and post-vaccination phenomena share a similar complex of signs and symptoms which suggest a common denominator to each one. Immune mediated conditions (i.e. autoimmune and auto-inflammatory diseases) are a leading cause of morbidity and mortality worldwide and their prevalence is rising in different geographical areas [1–3]. These geo-epidemiological changes can be explained by a complex of genetic and environmental factors [4,5]. Thus, a genetically susceptible subject may develop an autoimmune or auto-inflammatory disease (AI/AIFD) following exposure to a certain environmental factor [5–8]. Noteworthy, infections, toxins, and drugs were linked not only with the occurrence of immune mediated conditions but also with their clinical manifestations [7,8]. Environmental factors that comprise an immune **adjuvant** effect have been recognized for several decades. These adjuvants (i.e. silicone, alum, pristane, infectious components) were found to induce autoimmunity by themselves in different animal models and may possibly provoke AI/AIFD in humans [9–13]. Exposure to these substances were documented in the four medical conditions conversed herein, suggesting that the common denominator to these syndromes is a trigger entailing adjuvant activity. Therefore, in this review we suggest to include these conditions under a common syndrome entitled ASIA, "Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants".

1.1. Adjuvancy – the mechanisms

The term "adjuvant" derives from the Latin word adjuvare, meaning to aid. An immunologic adjuvant is a substance that enhances antigen-specific immune response preferably without triggering one on its own [13]. Adjuvants are commonly used in medicine to boost an immune response to treatments such as vaccination. The adjuvant effect is accomplished *via* several mechanisms that impinge on both the innate and adaptive immune systems [13–15]. Adjuvants increase innate immune responses by mimicking evolutionarily conserved molecules (e.g. bacterial cell walls, LPS, unmethylated CpG-DNA) and binding to Toll-like receptors (TLRs). Additionally, they augment the activities of dendritic cells (DCs), lymphocytes, macrophages and activate the intracellular Nalp3 inflammasome system [13]. Thus, adjuvants increase the local reaction to antigens (e.g. at the site of infection) and subsequently the release of chemokines and cytokines from T-helper and mast cells [13,16–18]. Currently the most widely used adjuvant in medicine is aluminium. Following an injection of aluminium salts (i.e. vaccination) danger-associated molecular patterns such as uric acid are released. High concentrations of uric acid form monosodium ureate crystals

* Corresponding author at: Department of Medicine 'B' and Center for Autoimmune Diseases, Chaim Sheba Medical Center, Tel-Hashomer 52621, Israel. Tel.: +972 3 5302652; fax: +972 3 5352855.
E-mail address: shoenfel@post.tau.ac.il (Y. Shoenfeld).

0896-8411/$ – see front matter © 2010 Elsevier Ltd. All rights reserved.
doi:10.1016/j.jaut.2010.07.003

that are phagocytosed by resident cells and disrupt lysosomes functions. This results in the release of cathepsin B that can directly or indirectly activate the intracellular Nalp3 inflammasome system, and caspase-1. In doing so, aluminium stimulates the production and secretion of cytokines such as IL-1β; IL-18 and IL-33 [14].

Adjuvants also provide physical protection to antigens and aid in antigen translocation to the regional lymph nodes. This will ultimately enable a longer exposure of the immune system to the antigen, enhanced production and activation of both B and T cells and a more robust response. The adjuvant effect on the adaptive immune response is also mediated through activation of the Nalp3 inflammasome, which contribute to the induction of an adaptive T-helper 2(TH2)-type responses, such as interleukin-4 (IL-4) and IgE production (13, 14,6–18).

Formerly, adjuvants were thought to pose little or no independent threat. Alas, studies of animal models and humans demonstrated the ability of some of them to inflict autoimmunity and autoimmune diseases by themselves [13]. Perhaps the most studied adjuvant in this context is Tetramethylpentadecane (TMPD) known as pristane, which is capable of inducing a lupus-like disease in a murine model of systemic lupus erythematosus (SLE) [19,20]. In this model, similarly to the human disease, autoantibodies production and end-organ damage (i.e renal disease) depend on interferon (IFN)-I receptor signaling pathway. Immunization of animals with pristane accelerated the production of IFN-I by monocytes *via* signaling through TLR-7 and the adapter protein MyD88 [19,20]. Immunization with another adjuvant, squalene, induce arthritis in rats and the production of SLE- associated autoantibodies in mice [19,21]. The adjuvant aluminium may be contained in immune complexes produced following vaccination [13,21].

1.2. The adjuvant role of infections

The multi facet associations between infectious agents and autoimmunity or auto-inflammatory conditions have been established and a number of mechanisms by which infectious agents can bring about such responses have been identified (i.e. molecular mimicry, epitope spreading, polyclonal activation and others) [8]. Yet, several questions regarding the interaction between infections and autoimmunity remain to be elucidated. For instance, unlike the classical example of a one-to-one alliance between streptococcal infection and rheumatic fever, the association of several infectious agents with a single autoimmune disease has recently been described [8]. On the other hand the same infectious agent (i.e. EBV) may relate to different systemic and organ specific autoimmune diseases [22]. Another misconception disclosed is the gap in time between exposure to infection and the diagnosis of autoimmune disease. Epidemiological evidence suggests that infectious exposure early in childhood may set the stage for the appearance of an autoimmune disease later in life [23,24]. This notion stands in agreement with the observation that autoimmunity (i.e. autoantibodies) appears years before a full blown autoimmune disease is diagnosed [25]. Recently, Noel Rose[26] suggested another mechanism, the adjuvant effect, by which infections may relate to autoimmunity in a broader sense.

Almost a century ago Jules Freund developed the complete Freund's adjuvant (CFA) that is a water and oil emulsion including killed mycobacteria. The importance of CFA in inducing diseases has been documented in many experimental models. For example, immunization of animals with thyroid antigen (thyroglobulin) and incomplete Freund's adjuvant, lacking the mycobacterial component, induced only the production of anti-thyroid antibody, whereas, immunization with the same antigen joined to CFA resulted in antibody production and inflammatory lesions in the thyroid [26]. Moreover, the addition of another microbial component (i.e. microbial cell wall) to incomplete Freund's adjuvant resulted again in inducing a full blown experimental thyroiditis, supporting the idea of an adjuvant role to these microbial components. In another model of experimental autoimmune myocarditis the addition of the microbial component lypopoplysaccharide to coxsackievirus B3 overcame a genetic barrier and induce autoimmune myocarditis in a strain genetically resistance to infection with coxsackievirus alone [26].

In other words, the activation of autoimmune mechanisms by infectious agents is common, yet the appearance of an autoimmune disease is not as widespread and apparently not always agent-specific. The adjuvant effect of microbial particles, namely the non-antigenic activation of the innate and regulatory immunity as well as the expression of various regulatory cytokines, may determine if an autoimmune response remains limited and harmless or evolve into a full blown disease.

1.3. Vaccines, post-vaccination phenomena and the adjuvant effect

Vaccines are one of the greatest achievements of modern medicine and are commonly and safely inoculated to human and animals worldwide. However, in rare occasions, similarly to infectious agents, vaccines can induce the appearances of autoantibodies, enigmatic inflammatory condition and overt autoimmune disease [9]. Of which, non-specific manifestations such as arthritis, neuronal damage, fatigue, encephalitis and vasculitis were frequently described [9,27]. These rare events were documented in case-reports, case series, studies as well as *via* the CDC vaccines adverse events reporting system, weeks and even months or years following vaccination [27,28]. As such, it was difficult if not impossible to delineate a causal relationship between vaccination and the diagnosis of defined and non-defined AI/AIFD.Nevertheless, for some vaccines such a causal link was noted. In 1976 an outbreak of Guillain-Barré syndrome (GBS) followed immunization with the "swine flu" vaccine [29,30]. Causal relationships have also been accepted for transverse myelitis following oral polio vaccine, arthritis following diphtheria-tetanus-pertussis (DTP) and measles-mumps-rubella (MMR) vaccine combinations and autoimmune thrombocytopenia after MMR [9]. In addition, a number of animal models enabled scientists a better way of studying the cause and effect link between vaccines and autoimmunity. Immunization of young dogs resulted in production of 9 different autoantibodies including lupus-associated ones [31]. In another study, specific vaccination protocols of diabetic prone newborn animals (i.e. NOD mice and BB rats) were associated with an increased incidence of diabetes [32]. Recently intra-peritoneal immunization of Salmon fish with oil-adjuvanted vaccines resulted in the production of autoantibodies (i.e. anti-nuclear, anti-β2GPI, anti-ferritin and anti-salmon blood extracts antibodies) as well as autoimmune diseases documented by granulomatous diseases of the liver and peritoneum, thrombo-embolic disease and immune mediated glomerlulonephritis [33].

The efficacy of most vaccines currently used either for humans or for animal immunization, depends on the presence of an adjuvant in conjunction with the infectious antigen [14]. Adjuvants increase the protective and lasting immune response to the infectious antigen and enable the decrement of antigen amount and thereby the production of a larger amounts of vaccines [13,34]. Alas, as was previously detailed adjuvants can also provoke an autoimmune response. Thus, in addition to the traditional adjuvants, newer more effective and perhaps safer adjuvants have been lately developed, such as the virosome, new oil based adjuvants (i.e.AS03 and MF59) and adjuvants that utilize Toll-like receptor signaling pathways (i.e. IC31 and AS04) [34].

Taking it all together, although the independent role of each vaccine ingredients as well as host risk factors are yet to be defined,

the accumulated data suggest the possibility of accelerated autoimmunity/inflammation following vaccination.

1.4. The macrophagic myofasciitis syndrome and the adjuvant alum

Perhaps the most evaluated post-vaccination condition is the macrophagic myofasciitis syndrome (MMF), in which a causal link was clearly delineated. MMF is a rare immune mediated condition first reported in France by Gherardi et al. [35]. It is caused by deposition of aluminium, used to adjuvant different vaccines, which bring about an immune mediated muscles disease. MMF characterizes by systemic signs and symptoms as well as local active lesion at the site of inoculation [36,37]. Systemic manifestations include myalgias, arthralgia, marked asthenia, muscle weakness, chronic fatigue, fever and in some cases the appearance of a demyelinating disorder. Additionally, elevated creatine kinase (CK) and erythrocyte sedimentation rate as well as the appearance of autoantiboides, and myopathic EMG changes have also been documented [35–38]. The local lesion of MMF was found to result from persistence of aluminium adjuvant at the site of inoculation months and even 8–10 years following immunization [39]. Muscle biopsy reveal infiltration of large PAS-positive, MHC-1- positive macrophages and CD8 T-cells, in the absence of muscle fiber damage. At electron microscopy, these macrophages enclose cytoplasmic crystal material representing aluminium hydroxide [13,36]. Intriguingly, a discrepancy exists between the wide application of aluminium hydroxide and the rarity of MMF. This inconsistency was resolved by the observations that MMF might appear mainly in genetically susceptible subjects carrying the HLA–DRB1*01. This connection was first described in identical twin sisters diagnosed with MMF. In addition it was detected in 66% of 9 patients with MMF compared with 17% of 230 controls suggesting an odds ratio of 9.8 (95% confidence interval 2.0–62.2) [40]. Thus, lending support to the idea that in a minority of genetically prone patients aluminium may induce this syndrome.

1.5. The Gulf war syndrome

Another syndrome implicated to the adjuvant effect is the Gulf war syndrome (GWS). It is portrayed by chronic fatigue and other clinical manifestations that share many similarities with MMF. Multiple vaccinations performed over a short period of time were suggested to be the cause of this syndrome. Of note, during the Gulf war, the veterans' vaccination protocol included the anthrax vaccine, which was administered in a six-shot regimen and was adjuvanted by aluminium hydroxide and squalene [13]. Previously both infectious agents and vaccines have been reported to precede the development of chronic fatigue syndrome (CFS) and fibromyalgia, and a role for Th-2 mediated immune response was suggested [12,41,42]. Therefore, it was postulated that the GWS is the result of the adjuvant effect that induced a chronic Th-2 immune response [12]. Furthermore, Asa et al. [43] sought to find if the presence of antibodies to the adjuvant squalene correlated with the diagnosis of GWS.In a relatively large study of 144 Gulf war-era veterans 95% of overtly ill deployed GWS patients had antibodies to squalene and **100%** of GWS patients immunized for service in Desert Shield who did not deploy, but had the same signs and symptoms as those who did deploy, had antibodies to squalene. In contrast, none of the control groups that incorporated patients with autoimmune diseases, healthy controls and Persian Gulf veteran's not showing signs and symptoms of GWS had antibodies to squalene. Thus, although the pathogenesis of GWS is under scrutiny, the data assembled at this time highlight the possible role of adjuvants in this syndrome.

1.6. Siliconosis and the adjuvant disease

Last but not least, immune mediated phenomena and autoimmune diseases following exposure to silicone (i.e. breast implant), had been an issue of debate for many years. Silicone was previously considered to be an inert material, but apparently, alike other adjuvants, it is capable of inducing autoimmune-like phenomena termed in the early 1990s "the adjuvant disease" [44]. At that time various cases of defined connective tissue diseases were described in patients with silicone implants. Moreover, in a large cohort study, based on self-reported symptoms of approximately 11800 implanted women a relative risk of 1.25 (95% CI: 1.08–1.41) for all defined connective tissue diseases was suggested [45]. However, in 2000, a meta-analysis published by Janowsky *et al* [46] that did not include the former study, concluded that the risk of defined connective tissue diseases following silicone breast implantation was only 0.80 (95% CI: 0.62–1.04).

Unlike the controversy regarding defined autoimmune diseases, a relationship between silicone implants and a collection of symptoms that do not fulfill any diagnostic criteria for a defined connective tissue disease was reported by several groups suggesting that indeed a non-defined syndrome may appear following exposure to silicone. Vasey et al. [47] concluded that statistically significant increases in many signs and symptoms such as body ache, joints pain, myalgia, fatigue, impaired cognition and others, were associated with silicone breast implants. In another large study Fryzek et al. [48] found a statistically significant increase in 16 of 28 investigated symptoms in a group of 1546 patients with silicone breast implants compared to a group of 2496 women who underwent reduction mammoplasties. Again, these manifestations bear a resemblance to MMF and GWS and satisfied several criteria for fibromyalgia and chronic fatigue syndrome. The latter are severely disabling conditions that have a number of prominent symptoms in common and coincide in many individuals. While a little is known of their etiology, both conditions are characterized by an aberrant immune response. Recently we and others suggested a role for an adjuvant mechanism in the pathogenesis of these conditions namely, silicone [12] and/or aluminium-containing adjuvants in vaccines [12,37]. This stands in agreement with the FDA's finding that there is a statistically significant link between fibromyalgia and ruptured silicone gel implants [49]. The analysis of this specific set of manifestations led to the definition of

Table 1
The prevalence of clinical manifestations: MMF, Silicone related disease; GWS and post-vaccination events.

Symptoms	MMF $N = 250$	Silicone $N = 100$	GWS $N = 4600$	Post Vaccines $N = 30000$
Myalgias/myopathy/muscle weakness	+++	+++	+	+
Arthralgias/arthritis	+++	+++	++	+
Chronic fatigue/sleep disturbances	+++	+++	+++	+
Neurological/cognitive impairments	+	++	++	+
Fever	+	NR	NR	+
Gastrointestinal	+	NR	+	+
Respiratory	NR	NR	+	+
Skin		+	+	+
Diagnosis of defined autoimmune disease	+ 33% MS	+	NR	+/−
Antibodies	NR	+	+	NR
Increased ESR	++	NR	NR	+
References	8, 21	22	11, 23	24

The prevalence of signs and symptoms was definedas (+) if reported in <30% of subjects, (++) in 30–60% and (+++) if present in more than >60% of subjects. MS – mulple sclerosis; NR – not reported.

Table 2
Suggested criteria for the diagnosis of 'ASIA'.

Major Criteria:

- Exposure to an external stimuli (Infection, vaccine, silicone, adjuvant) prior to clinical manifestations.
- The appearance of 'typical' clinical manifestations:
  - Myalgia, Myositis or muscle weakness
  - Arthralgia and/or arthritis
  - Chronic fatigue, un-refreshing sleep or sleep disturbances
  - Neurological manifestations (especially associated with demyelination)
  - Cognitive impairment, memory loss
  - Pyrexia, dry mouth
- Removal of inciting agent induces improvement
- Typical biopsy of involved organs

Minor Criteria:

- The appearance of autoantibodies or antibodies directed at the suspected adjuvant
- Other clinical manifestations (i.e. irritable bowel syn.)
- Specific HLA (i.e. HLA DRB1, HLA DQB1)
- Evolvement of an autoimmune disease (i.e. MS, SSc)

a new entity termed "siliconosis" which include the presence of body ache, abnormal fatigue, impaired cognition, depression, dry eyes, dry mouth, skin abnormalities, paresthesia, swollen and tender axillary glands, unexplained fever, hair loss, headache and morning stiffness [47–50]. Hence, it seems that the link between silicone and autoimmunity should not be limited by the constraints of defined diseases, but rather relate to the relatively prevalent non-defined symptoms.

1.7. *ASIA – autoimmune/auto-inflammatory syndrome induced by adjuvant: a new syndrome to be defined*

These enigmatic, nevertheless prominent clinical signs and symptoms are common to the four conditions discussed in this review, and coincide in many individuals diagnosed with either 'siliconosis' MMF, GWS or post-vaccination events (Table 1). Additionally, in up to 35% of patients' autoimmunity (i.e. autoantibodies) or an overt autoimmune disease was described.

Furthermore, a common denominator to these four conditions is presently suggested that is the exposure to a component that comprises an adjuvant effect. One might suggest that similarly to animal models, and the genetic link observed in MMF, the adjuvant effect persuade the appearance of these conditions only in subjects who are genetically susceptible. Another possible explanation, that may overcome genetic barriers, is the co-exposure to more that one trigger such as the exposure to another deleterious environmental factor (i.e. infectious agent) or co-exposure to more than one adjuvant [12,51].

Taking it all together, we suggest that these four somehow enigmatic conditions: siliconosis, MMF, GWS and post-vaccination phenomena that share clinical and pathogenic resemblances will be included under a common syndrome entitled the "Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants" (ASIA). We further propose several major and minor criteria, that although require further validation may aid in the diagnosis of this newly defined syndrome (Table 2).

The amassed data regarding each condition may enable us a spacious view of the immune responses to environmental adjuvants, as well as better definition and diagnosis of these conditions. Moreover unraveling the pathogenesis of this newly defined syndrome may facilitate the search for preventive and therapeutic interventions.

Disclosure

Yehuda Shoenfeld appeared in court on the issue of vaccine induced autoimmune conditions.

References

[1] Shoenfeld Y, Selmi C, Zimlichman E, Gershwin ME. The autoimmunologist: geoepidemiology, a new center of gravity, and prime time for autoimmunity. J Autoimmun 2008 Dec;31(4):325–30.
[2] Youinou P, Pers JO, Gershwin ME, Shoenfeld Y. Geo-epidemiology and autoimmunity. J Autoimmun 2010 May;34(3):J163–7.
[3] Shapira Y, Agmon-Levin N, Shoenfeld Y. Defining and analyzing geoepidemiology and human autoimmunity. J Autoimmun 2010 May;34 (3):J168–77.
[4] Borchers AT, Naguwa SM, Shoenfeld Y, Gershwin ME. The geoepidemiology of systemic lupus erythematosus. Autoimmun Rev 2010 Mar;9(5):A277–87.
[5] Shoenfeld Y, Gilburd B, Abu-Shakra M, Amital H, Barzilai O, Berkun Y, et al. The mosaic of autoimmunity: genetic factors involved in autoimmune diseases – 2008. Isr Med Assoc J 2008 Jan;10(1):3–7.
[6] Shoenfeld Y, Zandman-Goddard G, Stojanovich L, Cutolo M, Amital H, Levy Y, et al. The mosaic of autoimmunity: hormonal and environmental factors involved in autoimmune diseases – 2008. Isr Med Assoc J 2008 Jan;10 (1):8–12.
[7] Zifman E, Amital H, Gilburd B, Shoenfeld Y. Antioxidants and smoking in autoimmune disease – opposing sides of the seesaw? Autoimmun Rev 2008 Dec;8(2):165–9.
[8] Kivity S, Agmon-Levin N, Blank M, Shoenfeld Y. Infections and autoimmunity. Trends in Immunology 2009;30(8):409–14.
[9] Agmon-Levin N, Paz Z, Israeli E, Shoenfeld Y. Vaccines and autoimmunity. Nat Rev Rheumatol 2009;5(11):648–52.
[10] Zandman-Goddard G, Blank M, Ehrenfeld M, Gilburd B, Peter J, Shoenfeld Y. A comparison of autoantibody production in asymptomatic and symptomatic women with silicone breast implants. J Rheumatol 1999 Jan;26(1):73–7.
[11] Bar-Meir E, Eherenfeld M, Shoenfeld Y. Silicone gel breast implants and connective tissue disease – a comprehensive review. Autoimmunity 2003 Jun;36(4):193–7.
[12] Agmon-Levin N, Shoenfeld Y. Chronic fatigue syndrome with autoantibodies – the result of an augmented adjuvant effect of Hepatitis B vaccine and silicone implant. Autoimmun Rev 2008;8(1):52–5.
[13] Israeli Eitan, Agmon-Levin Nancy, Blank Miri, Shoenfeld Yehuda. Adjuvants and autoimmunity. Lupus 2009;18(13):1217–25.
[14] Marrack P, McKee AS, Munks MW. Towards an understanding of the adjuvant action of aluminium. Nat Rev Immunol 2009 Apr;9(4):287–93.
[15] McKee AS, Munks MW, MacLeod MK, Fleenor CJ, Van Rooijen N, Kappler JW, et al. Alum induces innate immune responses through macrophage and mast cell sensors, but these sensors are not required for alum to act as an adjuvant for specific immunity. J Immunol 2009 Oct 1;183(7):4403–14.
[16] Kool M, Soullié T, van Nimwegen M, Willart MA, Muskens F, Jung S, et al. Alum adjuvant boosts adaptive immunity by inducing uric acid and activating inflammatory dendritic cells. J Exp Med 2008 Apr 14;205(4):869–82.
[17] Eisenbarth SC, Colegio OR, O'Connor W, Sutterwala FS, Flavell RA. Crucial role for the Nalp3 inflammasome in the immunostimulatory properties of aluminium adjuvants. Nature 2008;453:1122–6.
[18] Hornung V, Bauernfeind F, Halle A, Samstad EO, Kono H, Rock KL, et al. Silica crystals and aluminum salts activate the NALP3 inflammasome through phagosomal destabilization. Nat Immunol 2008 Aug;9(8):847–56.
[19] Satoh M, Reeves WH. Induction of lupus-associated autoantibodies in BALB/c mice by intraperitoneal injection of pristane. J Exp Med 1994;180:2341–6.
[20] Reeves WH, Lee PY, Weinstein JS, Satoh M, Lu L. Induction of autoimmunity by pristane and other naturally occurring hydrocarbons. Trends Immunol 2009 Sep;30(9):455–64.
[21] Santoro D, Stella M, Montalto G, Castellin S. Lupus nephritis after Hepatitis B vaccination: an uncommon complication. Clin Nephrol 2007;67:61–3.
[22] Barzilai O, Sherer Y, Ram M, Izhaky D, Anaya JM, Shoenfeld Y. Epstein-Barr virus and cytomegalovirus in autoimmune diseases: are they truly notorious? A preliminary report. Ann N Y Acad Sci 2007 Jun;1108:567–77.
[23] Edwards CJ, Syddall H, Jameson K, Williams EL, Polosa R, Goswami R, et al. Hertfordshire Cohort Study Group.The presence of anticardiolipin antibodies in adults may be influenced by infections in infancy. QJM 2008 Jan;101 (1):41–7.
[24] Classen JB, Classen DC. Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM. Autoimmunity 2002 Jul;35(4):247–53.
[25] Arbuckle MR, McClain MT, Rubertone MV, Scofield RH, Dennis GJ, James JA, et al. Development of autoantibodies before the clinical onset of systemic lupus erythematosus. N Engl J Med 2003;349:1526–33.
[26] Rose NR. Autoimmunity, infection and adjuvants. Lupus 2010;19(4):354–8.
[27] Mikaeloff Y, Caridade G, Suissa S, Tardieu M. Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood. Neurology 2009 Mar 10;72 (10):873–80.
[28] Vaccines adverse events reporting system (CDC). http://vaers.hhs.gov/index.

[29] Evans D, Cauchemez S, Hayden FG. "Prepandemic" immunization for novel influenza viruses, "swine flu" vaccine, Guillain-Barré syndrome, and the detection of rare severe adverse events. J Infect Dis 2009 Aug 1;200(3):321–8.
[30] Lasky T, Terracciano GJ, Magder L, Koski CL, Ballesteros M, Nash D, et al. The Guillain-Barre syndrome and the 1992-1993 and 1993-1994 influenza vaccines. N Engl J Med 1998;339:1797–802.
[31] Hogenesch H, Azcona-Olivera J, Scott-Moncrieff C, Snyder PW, Glickman LT. Vaccines induced autoimmunity in dogs. Adv Vet Med 1999;41:733–47.
[32] Classen JB. The timing of immunization affects the development of diabetes in rodents. Autoimmunity 1996;24(137-45).
[33] Koppang EO, Bjerkås I, Haugarvoll E, Chan EK, Szabo NJ, Ono N, et al. Vaccination-induced systemic autoimmunity in farmed Atlantic salmon. J Immunol 2008;181:4807–14.
[34] Balofsky A, Agmon-Levin N, Shoenfeld Y. The new H1N1 and HPV vaccines and old fears. Curr Opin Rheumatol; 2010 May 18.
[35] Gherardi RK, Coquet M, Cherin P, Authier FJ, Laforet P, Belec L, et al. Macrophagic myofasciitis: an emerging entity. Groupe d'Etudes et Recherche sur les Maladies Musculaires Acquises et Dysimmunitaires (GERMMAD) de l'Association Francaise contre les Myopathies (AFM). Lancet 1998;352:347–52.
[36] Gherardi RK, Coquet M, Cherin P, Belec L, Moretto P, Dreyfus PA, et al. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. Brain 2001 Sep;124(Pt 9):1821–31.
[37] Exley C, Swarbrick L, Gherardi RK, Authier FJ. A role for the body burden of aluminium in vaccine-associated macrophagic myofasciitis and chronic fatigue syndrome. Med Hypotheses 2009 Feb;72(2):135–9.
[38] Authier FJ, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, et al. Central nervous system disease in patients with macrophagic myofasciitis. Brain 2001 May;124(Pt 5):974–83.
[39] Israeli E, Agmon-Levin N, Blank M and Shoenfeld Y. Macrophagic myofaciitis a vaccine (alum) autoimmune related disease. CRAI 2011.
[40] Guis S, Pellissier JF, Nicoli F, Reviron D, Mattei JP, Gherardi RK, et al. HLA-DRB1*01 and macrophagic myofasciitis. Arthritis Rheum 2002 Sep;46(9):2535–7.
[41] Ablin JN, Shoenfeld Y, Buskila D. Fibromyalgia, infection and vaccination: two more parts in the etiological puzzle. J Autoimmun 2006 Nov;27(3):145–52.
[42] Ortega-Hernandez OD, Shoenfeld Y. Infection, vaccination, and autoantibodies in chronic fatigue syndrome, cause or coincidence? Ann N Y Acad Sci 2009 Sep;1173:600–9.
[43] Asa PB, Cao Y, Garry RF. Antibodies to squalene in Gulf War syndrome. Exp Mol Pathol 2000;68:55–64.
[44] Shoaib BO, Patten BM. Human adjuvant disease: presentation as a 414 multiple sclerosis-like syndrome. South Med J 1996;89:179–88.
[45] Hennekens CH, Lee IM, Cook NR, Hebert PR, Karlson EW, LaMotte F, et al. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. JAMA 1996;275(8):616–21.
[46] Janowsky EC, Kupper LL, Hulka BS. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. N Engl J Med 2000;342(11):781–90.
[47] Vasey FB, Zarabadi SA, Seleznick M, Ricca L. Where there's smoke there's fire: the silicone breast implant controversy continues to flicker: a new disease that needs to be defined. J Rheumatol 2003;30(10):2092–4.
[48] Fryzek JP, Signorello LB, Hakelius L, Feltelius N, Ringberg A, Blot WJ, et al. Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery. Plast Reconstr Surg 2001;107(1):206–13.
[49] Brown SL, Parmentier CM, Woo EK, Vishnuvajjala RL, Headrick ML, et al. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol 2001;28(5):996–1003.
[50] Vermeulen RC, Scholte HR. Rupture of silicone gel breast implants and symptoms of pain and fatigue. J Rheumatol 2003 Oct;30(10):2263–7.
[51] Burek CL, Talor MV. Environmental triggers of autoimmune thyroiditis. J Autoimmun 2009 Nov-Dec;33(3–4):183–9.

Transcription of a Press Conference by Robert F. Kennedy Jr., in response to HB 1312 Wednesday April 10. In the House Health an Insurance committee.

He is chairman of the board and prosecuting attorney for Children's Health Defence.

https://childrenshealthdefense.org

https://www.globalresearch.ca/cdc-medical-deep-state/5672873

Robert F. Kennedy, Jr Discusses Vaccines at The Autism Education Summit

https://www.youtube.com/watch?v=CUjrKBxdI9o

Aluminum adjuvants as mercury adjuvants are neuro toxic.

People have auto immune reactions. Parents should have informed consent. If there are auto immune reactions, doctors should have protocols for what the after effects could be and how to address them. Just telling the parents to give them an aspirin is not good enough for conditions that can last a lifetime.

Press: There is a lot of confusion about what is the scientific consensus. How does the average person sort it out.

Robert F. Kennedy, Jr. responded:

There is a huge difference between the scientific establishment and established science. Established science is not what the CDC says or what Merck says, it's what is published on Pub Med in peer reviewed publication, and what the institute of Medicine says, which is the congressionally appointed arbiter of what is science and what isn't science is.

CDC is a vaccine company. 50% of CDC's budged goes to selling and promoting vaccines. CDC owns 57 vaccine patents. It collects money on them. FDA gets 75% of its budget from the industry. FDA owns part of the Gardisil patent. Every time someone buys a $420 shot of Gardisil, FDA makes money. Individuals who worked on the patent get $150 thousand dollars a year in royalties. These are the division chairs, powerful people in these agencies. I learned from my dad, "Don't trust people in authority." People in authority lie.

You have an industry that is minting and creating phony studies, like the tobacco industry. But the pharmaceutical companies have much more power with the press than the oil or tobacco companies, because they are the biggest advertisers. Of 22 ads on an evening news show, 17 are paid for by Pharma. If I put this issue on one of the news shows, they would get a call from the sponsor immediately. The news only gives Pharma talking points.

Robert F. Kennedy and Robert DeNero said, they would pay $100 K to any member of the press that could cite a study that indicated it is safe to inject mercury into a baby. I can show you 100's of studies that show its not. You can't trust the CDC. You have to go to what IOM actually says.

There are 141 active vaccine bills in the US right now in 35 states. Can you comment on the censorship across all the media?

I grew up with axiom you can't have democracy if you don't have free debate, no matter how controversial the issue. People say the CDC wouldn't lie to us about the health of children. Look at the Catholic church and the pedophile scandal. Look how the press collaborated with them. There was a movie that won an academy award about the Boston Globe who believed the institution was more important than the children that were getting hurt. People in the press have to guard themselves about the belief that the CDD and the vaccine program are so important that we can't entertain criticism about it. That's the mistake people made about the pedophile scandal. We can't talk about it or people will lose faith in this important institution.

What are the Democrats owing to these powerful, powerful multi-national titans? Mark Zukerbuerg and Jeff Besos are saying you have to stop criticism of a pharmaceutical product. Mainstream press is letting them get away with that—demanding censorship about corruption of public agencies.

Raise your hand if you have a child or family member that was injured by a vaccine? (off camera a lot must raise their hands) This isn't people's imagination; it's happening. You would have to ignore, or say these women are all hysterics. It's a time in history that both the press and the Democratic party start listing to women. And its time to remind the Democratic party of its central plank over the last 2 decades, "My Body, My Choice"! What ever happened to that?

Press: About Gardisil, several countries have barred Gardisil. Its my understanding that you have some information on why it is being pushed so heavily in this country, when there are risks.

Why Gardisil are on the market--we got it from Merck and public agencies. My concern about Gardisil is huge injury rate. I represent one girl who was top HS athletic star who got the Gardisil shot at age 15, and now she is in a wheel chair with seizures every 90 seconds. This is typical. I have letters, videos every week of children with "Gardisil syndrome". I believe every girl that gets a Gardisil shot is injured. You cannot inject those levels of aluminum into human

beings and not damage them. It goes into your brain and you may get dementia or Alzheimer's 20 years from now, but it will come out. Yale Medical School published a story in 2017 showed that women who were suffering OCD, anxiety, anorexia, or depression were much more likely to be vaccinated than those that weren't. I believe we are seeing much more recorded injury reported to the HMO's. There is a huge spike of teenagers that are having depression. It was on CBS. Teenage suicide rates going up. CDC can't explain why all these teens are suicidal, depressed, and loosing executive function, and can't deal with social situations. That's exactly what happens in dozens of animal models with animals injected with aluminum. You see these strange behaviors, and inability to function. What studies? Why can't they look t Gardisil. It's a huge human experiment society wide without any safely testing. They suddenly inject a whole generation with one of the most potent neurotoxins in the universe with huge levels of poison, much larger than EPA considers safe.

I'm not a doctor, but all I'm asking is that vaccines undergo the same safety testing that we require of other drugs. Is this radical? And not allowed to print? That vaccines aught to be safety tested like other drugs, against placebos. Its not radical, its something I think most American's would support. I know too much, I read this stuff, and I can't un-think it.

Press: Can you tell where you got the numbers?

All my numbers come from the manufacturer's insert. All manufacturers are required by Congress to include an insert to include a typical example of the studies. Anyone can look them up, but nobody does it, and if you did, nobody would take it. Those odds--2.3 %, showed auto immune disease, and 1 in 40 showed major injury within 6 months, nobody would make that bet. The death rate was double the background rate. The miscarriage rate was 5 times the background rate. The reproductive injury rate was about 5 times the background rate in this country. If you look at the manufactures insert, you can look it up, but doctors don't look it up. They believe what CDC and AAP tells them.

AAP is getting 80% of its income from these companies, its an industry that makes a lot of money from vaccines. Merck lied about this vaccine. It deceived the regulators and the public. There is no proof that the vaccine has any effect on cervical cancer. And there is proof that it actually gives you cancer. I know what I am talking about, its not on "belief". Let Merck sue me if I am saying anything wrong, but they won't.

Press: Bayer paid 4 million dollars in damages, but it doesn't matter that they paid, it doesn't prove anything about injury in this country.

HHS says fewer than 1% of vaccine adverse events are reported. Multiply that 4 billion by 100. (Harvard Health Sciences).

Press: I am African American. We have a lot of auto immune diseases that we can't explain.

There are many studies. You can go to Childrens Health Defence, and there is an article there called "The New Tuskeegee Experimant". (Actually titled CDC's Latest Tuskegee Experiment:

African American Autism and Vaccines (https://www.wnd.com/2011/06/313393/) Africans with pure African blood are more likely to suffer vaccine injury than African Americans. The CDC's most important study, called The Stephano 2004 Study, published in Pediactrics. The 5 researchers studied the MMR vaccine in Georgia. They thought it would be safe to study the MMR, because they thought the autism was caused by mercury. When they got the data back what they showed is black boys had a 205% chance of getting autism if they took the MMR vaccine on time at 36 months of age, compared to waiting. The superiors at CDC were ordered to bring all their data into a conference room and ordered to destroy their data, and then they published their data to Stephano, and said there is no added influence on blacks. We know that is a lie. Particularly mercury vaccines affect boys 4 to one over girls. The reason for that is because testosterone amplifies the neuro toxicity of the mercury molecule. Estrogen tends to affect the mercury molecule to protect the female brain. That is why you see such sexual dimorphism in neuro-developmental disorders. They tend to affect boys at a 4 to 1. There is a study where they gave Thymerisol (the mercury adjuvant) to rats. All 11 male rats died, no female rat even showed any illness. African Americans have as a rule higher testosterone rates than other Americans, so those vaccines, like flu vaccines, with much more mercury in them would affect African Americans much more by logic.

Those vaccines are given more in African American neighborhoods. They are the multidose, cheapest, and there are adverse effects.

In 2016, VAERS (Vaccine Adverse Effects Reporting) has these statistics. If only 1% are reported here are the numbers:

432 deaths → 43,200 deaths

1,091 permanent disabilities -> 109,100

4,132 hospitalization -> 413,200

10,254 emergency room visits -> 1,028,400

This is not science, its suggestive.

They only get post licensing stats of only 1%, because pre-licensing there are no studies, there are no stats. They came under a lot of criticism for that, so they decide to machine capture the numbers. The HMOs have all your vaccine records down to batch. And they have all your medical records.

They could do a cluster analysis to associate certain batches with certain injuries and could capture 100% of the injuries. They hired an agency, Health Care Research Quality. They gave 1 million dollars to a 3 year study on one HMO, Harvard Pilgrim HMO.

They found 10% having possible reactions, and CDC got freaked out and stopped responding to questions for testing and evaluation. One in 10 is a lot different than 1 in 100. As soon as the CDC found out the system worked it fired the people and refused to answer the phone.

In the statute of Congress, in 1986, IOM (Institute of Medicine) was ultimately responsible for the quality of vaccine science coming out of CDC. 1991. They determined 22 illnesses coming out of DTP vaccine. In the literature, 6 are shown to the related to the vaccine, in 4 showed not being related to the vaccine. But in 12 diseases, there is 0 literature. CDC was supposed to produce that literature for all these chronic childhood diseases: anemia, juvenile diabetes, chronic neurological damage, learning disabilities, attention deficit, all part of the chronic epidemic.

IOM thinks these are caused by vaccines, so it rebukes CDC and says if the research capacity is not improved, future reviews of vaccine safety will be similarly handicapped. They come back 3 years later, but now there are 54 conditions—12 shown to be correlated, 5 not correlated, and 38 we have no idea.

And in the 38 is SIDS. SIDS started appearing then, and it is the biggest killer of kids. We never heard of it before '89. CDC says, "We regret the uncertainty, and urge that more definitive research should be done."

15 years later, 2011. IOM's data: 155 diseases possibly related to vaccination, but they never studied autism—CDC has never studied whether autism is caused by vaccines—long after they decided no further studies should be done. IOM says, We think its an epidemic, and you say no studies should be done.

IOM has a book 750 pages long each section is a vaccine, with all the studies and analysis of all the studies. For example, Autism and the DTap Vaccine. There is only 1 study in '04 that said autism was caused by the vaccine. However CDC is not going to count this study, because it was a passive surveillance study and lacked a comparative unvaccinated population—that's their own system—it's so bad that any study based on it we won't count.

CDC's web site says that vaccines don't cause autism. You can't just say that you have to cite something. It cites the 2011 IOM report. That is not what it says. It says we have no clue. CDC has faith that every reporter is just going to look at that and never look at the IOM report.

We cannot have a democracy if we don't have a free and inquisitive press that is skeptical about broad pronouncements by government agencies that are interested in the outcome.

IOM says here are all the vaccines required, and there are the only 2 that have ever been studied for autism. This is a short list of the ingredients, and this is the only ingredient ever studied—Thimerisol. That isn't to say they are good studies, since Bill Thompson from CDC is saying, "We lied about it." At least they are studies—they are crap, but they are studies. None of the others have ever been studied.

IOM is saying we have an epidemic of autism, allergy, asthma, neuro-developmental diseases, epilepsy. No studies have ever looked at this. Here is the graph line for the increase in chronic diseases (goes way up as the increase in vaccinations)

Studies show flu vaccinated kids have 30% more rhinitis, due to the aluminum to give an allergic response to the antigen. It turns out the aluminum also gives an allergic response to anything else in the ambient environment at the time. If you get that shot as a little kid when there is a Timothy weed outbreak, you now have a lifetime allergy to Timothy weed. If there is a peanut oil excipient in that vaccine, you now have a lifetime allergy to peanuts.

There was a randomized study on flu shots, both placebo and flu vaccinated kids got the flu the same, but the vaccinated kids had 4.4 times more non-flu infections because it wrecks your immune system.

The CDC did a study that no independent scientist can ever get into, it is a locked box, looking at the vaccine records of 440,000 kids. CDC looked at it 2001 and looked at kids who got Thimerisol containing HepB vaccine in their 1st 60 days, and compared to kids who did not. And they never published the study. We got it thru the FOIA. You will see why. 1100% greater chance of getting an autism diagnosis. They knew right then what was causing the autism epidemic. The relative risk of smoking a pack of cigarettes a day for 20 years and getting lung cancer is 10—causation/proof. This is 11.35, beyond proof.

The senior CDC vaccine scientist, Dr William Thompson, wants to testify in front of Congress, but Congress won't subpoena him, because they don't want him to talk. And the press won't cover him. He says he has been cheating on every autism study for the last 20 years. He is the co-author of all these studies. He was in the room when they destroyed the first studies. In a voice recording, he said, "The whole system is paralyzed. We need Congress to come in and analyze the data, with an independent contractor to do it. I have great shame now when I meet families with autism-- I have been part of the problem. CDC put the research 10 years behind. Because the CDC has not been transparent; we have missed 10 years of research, because CDC is so paralyzed right now, by anything related to autism. They are not doing what they should be doing--looking for things associated with autism. I'm completely ashamed, that's what I did. " (what I could hear of the recording.)

It's shocking to me out of all the newspapers in the US, none have investigated this. In the 2000 investigation from the House Government reform Committee, all these are quotations from it, talking about the corruption: The cmmittee at the FDA that licenses all vaccines, they are not part of the FDA, they are brought in from the industry—they license the vaccines, based on this non-existent science. Then it goes to another committee called ASIP(?), and they add it to the schedule. And all of them have financial ties to the industry. This is typical. Look at this: For example, 3 of the 5 FDA advisory committees have voted to approve the Roto virus vaccine in December of '97, had financial ties to pharmaceutical companies that were developing different versions of the vaccine. One of the 5 voting members 's employer had a 9 million dollar contract for the Roto virus vaccine. One of the 5 voting members was a principle investigator for Merck grant to develop the Roto vaccine. One of the 5 voting members received a million dollars from vaccine manufacturers toward vaccine development. Those are the guys that licensed the Roto virus vaccine that your kids have to take. This is ASIP—go to

CDC—it admits it did not adopt evidence based guidelines for 2011. That raises the question, what were they basing it on? Just relationships, that's it. I'll show you the relationships. BTW, all the vaccines like MMR and Gardisil were already done. These 2 Committees brought this industry from 1 billion in '86, to 50 billion today, in 2019, and that's why we are getting all these new vaccines.

Here is a Congressional investigation of the CDC side, that mandates the vaccines. The majority of the ACIP members were conflicted: the chairman, served on Merck's advisory board. Another member shares a patent on a vaccine development for the very same disease that had a $350 thousand dollar grant to develop this vaccine. Its Paul Offen. He owned the patent, he voted it on, and he sold his patent back to Merck for $186 million dollars. And he is the darling of the media in this country. He can publish editorials every 6 months in the NY Times, and people die to get him on their shows. Another member was under contract with the Merck vaccine division to receive funds from various vaccine manufacturers including Pasteur—under contract. Another member received a salary from Merck. Another member was participating in vaccine studies with Merck. Another member received grants from Merck to approve a vaccine that Merck owned the patent for.

In case you think that was an anomaly, this was 11 years later, the HHS inspector general says 97% of committee members failed to make conflict disclosures. At least 58% had an unidentified potential conflict, and 32% had conflicts.

This is CDC's budget. $11.5 billion—5 billion goes to vaccine sales and promotion. CDC's website claims over 130 times, "CDC does not accept commercial support." But only 20 million is spent on safety.

From 2002-2009 Julie Gerberding was CDC director who brought us the MMR monopoly, and she brought us the Gardisil vaccine with all that crappy science. She oversaw numerous vaccine studies, which were recently deemed unreliable by the IOM. 2010, she became president of Merck Vaccines with an estimated $2.5 million annual salary, and lucrative stock options. That was her bribe for giving Gardisil to all our little girls and poisoning them. $38 million dollars to Julie Gerberding.

CDC or NIH employees whose names appear on vaccine patents can receive up to $150K in licensing fees per year in perpetuity.

$4,061,322,557.08 the amount paid out by the vaccine court.

The industry claim that "We erased Measles"—here is the chart of what actually happened. And you can do this for virtually almost all infectious diseases. They were erased by hygiene, chlorine, sewage treatment, and good food. And then the vaccine was introduced, 1963.

MMR was never safety tested. Nothing. They legaly have to say if they were, and they weren't. We know the MMR causes a lot of injuries, its one that causes more injuries than others. It causes 6 times the amount of seizures than actual measles does. But they say "Measles vaccine

saves lives." It was introduced in 1963. In 1962 408 people died of measles. So we can assume 408 people were saved from this vaccine every year. The question we don't know is, are more people dying? That's what we have to answer to have a cost benefit analysis. That's what science should do. Could we do better with a single measles vaccine? Could we improve those odds. Nothing like that is ever done. That is the problem, they don't study it.

This is recent study: if you get measles when you are young, you are much less likely to get certain forms of cancer. This is Non-Hodgekins Lymphoma, Hodgekins lymphohoma—by not having measles, you have a 40% chance of getting Non-Hodgekins Lymphoma. For Hodgekins lymphoma, it's a 230% greater chance. Heart disease was dramatically lessened if you had measles. Cardio vascular disease in a Japanese study. After 22 years, the people that didn't get vaccinated were by far the more long lived. The death rate 22 years later is a 3rd less without being vaccinated. Shouldn't this be studied? Shouldn't we be forcing the industry to study this?

Immunization

Non-Medical Exemption Form (Religious and Personal Belief)

Vaccines are one of the greatest public health achievements of the past century and save an estimated 3 million children's lives every year. The Colorado Department of Public Health and Environment strongly supports vaccination as one of the easiest and most effective tools in preventing diseases that can cause serious illness and even death. For nearly all children, the benefits of preventing disease with a vaccine far outweigh the risks. Declining to follow the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) immunization schedule for number, space and timing of doses, may endanger an unvaccinated child's health and others who come into contact with him/her. Some vaccine-preventable diseases are common in other countries and unvaccinated children could easily get one of these diseases while traveling or from a traveler.

Colorado law C.R.S. § 25-4-902 requires all students attending any school in the state of Colorado to be vaccinated against certain vaccine-preventable diseases as established by Colorado Board of Health rule 6 CCR 1009-2, unless an exemption is filed. This law applies to students attending public, private and parochial kindergarten, elementary and secondary schools through 12th grade, colleges or universities, and child care facilities licensed by the Colorado Department of Human Services including child care centers, school-age child care centers, preschools, day camps, resident camps, day treatment centers, family child care homes, foster care homes, and Head Start programs. Prior to kindergarten, a non-medical exemption must be filed each time a student is due for vaccines according to the schedule developed by the ACIP.[1,2] From kindergarten through 12th grade, a non-medical exemption must be filed every year during the student's school enrollment/registration process.[1] Students with a recorded immunization exemption may be kept out of a child care facility or school during a disease outbreak; the length of time will vary depending on the type of the disease and the circumstances of the outbreak.

Please complete all required fields below; incomplete forms will not be accepted. *All fields are required unless noted optional.*

Type of Non-Medical Exemption Claimed: □ Personal Belief □ Religious

Student Information:

Last Name:	First Name:	(optional) Middle Name:
Gender: □ Female □ Male	Date of Birth:	
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

Parent/Guardian Completing This Form: □ Check if an emancipated student or student over 18 years old

Last Name:	First Name:	(optional) Middle Name:
Relationship to student: □ Mother □ Father □ Guardian		
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

School/Licensed Child Care Facility Information:

School Name/Licensed Child Care Facility:		
School District:		□ Check if Not Applicable
Address:		
City:	State:	Zip Code:
Phone Number:		Grade of Student:

[1] Colorado Board of Health rule 6 CCR 1009-2: https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=7698&fileName=6%20CCR%201009-2.

[2] 2018 Recommended Immunizations from Birth through 6 Years Old: www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf. Based on this schedule, a non-medical exemption would be submitted at 2 months, 4 months, 6 months, 12 months and 18 months of age.

Vaccine Preventable Disease Information

The information provided below is to ensure parents/guardians/students are informed about the risks of not vaccinating.

Diphtheria, tetanus, pertussis (DTaP, Tdap) - Unvaccinated children may be at increased risk of developing diphtheria, tetanus and/or pertussis if exposed to these diseases. Serious symptoms and effects of diphtheria include heart failure, paralysis, breathing problems, coma, and death. Serious symptoms and effects of tetanus include "locking" of the jaw, difficulty swallowing and breathing, seizures, painful tightening of muscles in the head and neck, and death. Serious symptoms and effects of pertussis (whooping cough) include severe coughing fits that can cause vomiting and exhaustion, pneumonia, seizures, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.pdf and http://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.pdf

Haemophilus influenzae type b (Hib) - Unvaccinated children may be at increased risk of developing invasive Hib disease if exposed to this disease. Serious symptoms and effects include bacterial meningitis, pneumonia, severe swelling in the throat, brain damage, deafness, infections of the blood, joints, bones, and covering of the heart, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hib.pdf

Hepatitis B - Unvaccinated children may be at increased risk of developing hepatitis B if exposed to this disease. Serious symptoms and effects include jaundice, life-long liver problems such as liver damage, scarring, liver cancer, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.pdf

Inactivated poliovirus (IPV) - Unvaccinated children may be at increased risk of developing polio if exposed to this disease. Serious symptoms and effects include paralysis of muscles that control breathing, meningitis, permanent disability, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/ipv.pdf

Measles, mumps, rubella (MMR) - Unvaccinated children may be at increased risk of developing measles, mumps, and/or rubella if exposed to these diseases. Serious symptoms and effects of measles include pneumonia, seizures, brain damage, and death. Serious symptoms and effects of mumps include meningitis, painful swelling of the testicles or ovaries, sterility, deafness, and death. Serious symptoms and effects of rubella include rash, arthritis, and muscle or joint pain. If a pregnant woman gets rubella, she could have a miscarriage or her baby could be born with serious birth defects such as deafness, heart problems, and mental retardation. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf

Pneumococcal conjugate (PCV13) - Unvaccinated children may be at increased risk of developing pneumococcal disease if exposed to this disease. Serious symptoms and effects include pneumonia, lung infections, blood infections, meningitis and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.pdf.

Varicella (chickenpox) - Unvaccinated children may be at increased risk of developing varicella if exposed to this disease. Serious symptoms and effects include severe skin infections, pneumonia, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.pdf

Required Vaccines for School Entry - Place an "X" next to each vaccine you are declining.

	Diphtheria, tetanus, pertussis (DTaP)		Inactivated poliovirus (IPV)
	Tetanus, diptheria, pertussis (Tdap)		Measles, mumps, rubella (MMR)
	Haemophilus influenzae type b (Hib)		Pneumococcal conjugate (PCV13)
	Hepatitis B		Varicella (chickenpox)

Statement of Exemption

I am the parent/guardian of the above-named student or am the student himself/herself (emancipated or over 18 years of age) and am declining the vaccine(s) indicated above due to a religious or personal belief that is opposed to vaccines. The information I have provided on this form is complete and accurate.

- I may change my mind at any time and accept vaccination(s) for my child/myself in the future.
- I can review evidence-based vaccine information at www.colorado.gov/cdphe/immunization-education, or www.ImmunizeforGood.com for additional information on the benefits and risks of vaccines and the diseases they prevent.
- I can contact the Colorado Immunization Information System (CIIS) at www.ColoradoIIS.com or my health care provider to locate my child's/my immunization record.[3]

I acknowledge that I have read this document in its entirety.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

(Optional) I authorize my/my student's school to share my/my student's immunization records with state/local public health agencies and the Colorado Immunization Information System, the state's secure, confidential immunization registry.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

[3] Under Colorado law, you have the option to exclude your child's/your information from CIIS at any time. To opt out of CIIS, go to www.colorado.gov/cdphe/ciis-opt-out-procedures. Please be advised you will be responsible for maintaining your child's/your immunization records to ensure school compliance.

Vaccination Quotes from Experts

"The decline in infectious diseases in developed countries had nothing to do with vaccinations, but with the decline in poverty and hunger."
–Dr. Gerhard Buchwald, MD

"Crib death" was so infrequent in the pre-vaccination era that it was not even mentioned in the statistics, but it started to climb in the 1950s with the spread of mass vaccination against diseases of childhood.
–Harris L. Coulter, PhD

"It is pathetic and ludicrous to say we ever vanquished smallpox with vaccines, when only 10% of the population was ever vaccinated."
–Dr. Glen Dettman

"Up to 90% of the total decline in the death rate of children between 1860-1965 because of whooping cough, scarlet fever, diphtheria, and measles occurred before the introduction of immunizations and antibiotics." –Dr. Archie Kalokerinos, MD

"We've got to stop calling chickenpox and measles diseases, because they're not. They're infections, and infections come and go in a week to ten days, and leave behind a lifetime of immunity. A disease is something that comes and stays, and frequently can't be cured. So when you vaccinate to avoid an infection, what you potentially are doing is causing a disease."
–Dr. Sherri J. Tenpenny D.O., Board Certified in Emergency Medicine and Osteopathic Manipulative Medicine

"I think that no person would permit anybody to get close to them with an inoculation if they would really know how they are made, what they carry, what has been lied to them about them and what the real percent of danger is of contracting such a disease which is minimal."
–Dr. Eva Snead

"In the Spring of 1948 measles was running in epidemic proportions in this section of the country. Our first act, then, was to have our own little daughters play with children known to be in the "contagious phase." When the syndrome of fever, redness of the eyes and throat, catarrh [inflammation of a mucous membrane], spasmodic bronchial cough, and Koplik spots [measles skin spots] had developed and the children were obviously sick, vitamin C was started. In this experiment it was found that 1000 mg every four hours, by mouth, would modify the attack . . . When 1000 mg was given every two hours all evidence of the infection cleared in 48 hours . . . the drug (vitamin C) was given 1000 mg every 2 hours around the clock for four days . . . These little girls did not develop the measles rash during the above experiment and although exposed many times since still maintain this "immunity."
–Fred R. Klenner, MD, "The Use of Vitamin C as an Antibiotic," Journal of Applied Nutrition – 1953.

"In a predictable reaction to the recent measles outbreaks, both Republicans and Democrats in Congress filed a "Vaccines Saves Lives" resolution last Friday. Claiming that there is "no credible evidence" that vaccines cause "life-threatening or disabling disease," the resolution interprets the vaccination issue as some kind of national security threat—thereby supposedly trumping your right to make informed decisions about your own and your children's health. If passed, this resolution will bolster the current backlash against vaccine exemptions and pave the way for states' efforts to mandate universal vaccinations."
–Alliance for Natural Health – February, 2015.

"The greatest threat of childhood diseases lies in the dangerous and ineffectual efforts made to prevent them through mass immunization.... There is no convincing scientific evidence that mass inoculations can be credited with eliminating any childhood disease."
–Dr. Robert Mendelsohn, MD

"Official data shows that large-scale vaccination has failed to obtain any significant improvement of the diseases against which they were supposed to provide protection"
–Dr. Sabin, developer of Polio vaccine.

"There is a great deal of evidence to prove that immunization of children does more harm than good."
–Dr. J. Anthony Morris (formerly Chief Vaccine Control Officer at the US Federal Drug Admin.)

"My suspicion, which is shared by others in my profession, is that the nearly 10,000 SIDS deaths that occur in the United States each year are related to one or more of the vaccines that are routinely given children. The pertussis vaccine is the most likely villain, but it could also be one or more of the others."
–Dr. Mendelsohn, MD

"The medical authorities keep lying. Vaccination has been a disaster on the immune system. It actually causes a lot of illnesses. We are changing our genetic code through vaccination."
–Guylaine Lanctot M.D., author of the best-seller 'Medical Mafia'

" You can't vaccinate believing that your children are protected and then feel that your children are not protected because somehow, some non-vaccinated child is carrying some secret organism that no one else is carrying. It just doesn't make any sense."
–Dr. Larry Palevsky, board-certified pediatrician

"My data proves that the studies used to support immunization are so flawed that it is impossible to say if immunization provides a net benefit to anyone or to society in general. This question can only be determined by proper studies which have never been performed. The flaw of previous studies is that there was no long term follow up and chronic toxicity was not looked at. The American Society of Microbiology has promoted my research…and thus acknowledges the need for proper studies."
–John B.Classen, M.D., M.B.A.

"If vaccines were good for us, there would be no reason for dishonesty and deceit."
–Joseph Mercola, DO

"The really sad thing is the amount of doctors who say to me, 'I know that vaccines are causing autism, but I won't say it on camera because the pharmaceutical industry will destroy my career just like they did to Andy Wakefield.'"
–Del Bigtree, Producer, Vaxxed

"No batch of vaccine can be proved safe before it is given to children."
— Surgeon General of the United States, Leonard Scheele, addressing an AMA convention in 1955.

"Congress needs to face the facts about vaccines. They are not 100% safe—nor are they guaranteed to stop diseases. From 2005 to 2014, no child in America died from measles, yet 108 babies died from the MMR (mumps, measles, rubella) vaccine. There is also an abundance of evidence that shows the dangers of exposure to even small amounts of mercury, which can still be found in flu vaccines. Mercury has been linked to severe neurological effects and even autism. Despite the widely touted belief that the link between vaccines and autism has been "debunked," researchers found eighty-three cases of autism among those compensated by the Vaccine Injury Compensation Program for vaccine-induced brain damage."
–Alliance for Natural Health – 2015.

"We predict that after a long disease-free period, the introduction of infection will lead to far larger epidemics than that predicted by standard models. "Large-scale epidemics can arise with the first substantial epidemic not arising until 52 years after the vaccination program has begun." [Guess what year 52 years from first created and licensed measles vaccine? 2015.]
–J.M. Herrernan Ph.D – 2009.

"Everyday millions of children are lined up and injected with toxic putrid substances grown on animal organs, cancer cells, aborted fetuses and other toxic substances. Few people are questioning how those viruses were obtained and how they were grown in a laboratory. If one would ask these sensible questions, one would become very enlightened about vaccine production. I warn you now, discussing vaccine-production will turn your stomach. Vaccines are made from the most vilest and filthiest substances on the earth. Since the definition of abomination is "anything that is filthy", the term describes vaccinations adequately and truthfully. The vaccine "cauldron" is full of putrid junk from bodies

exposed to disease and excreting morbid purulence. Science gathers this junk up in hopes of making vaccines for "preventing" disease; and we are being fooled while vaccinations cause increases in diseases."
–Dr. Joseph Mercola

"The fact is that many countries that call themselves free succumbed to medical dictatorship…people are sicker and less healthy…A country which mandates vaccination is not a free country…It is a country of zombies who do what they are told by vested interests who intimidate them and use them to make money."
–Dr. Viera Scheibner

"Parents are frightened into having their babies and children "immunized" against a whole series of diseases, having them inoculated with vaccines, serums, anti-toxins and toxoids of all kinds. The constant stream of propaganda carried on by the pharmaceutical houses and commercial medicine to keep this profitable business alive is filled with manufactured and "doctored" statistics, lies, distortions and statements designed to frighten parents. The whole purpose of this propaganda is not to secure the health and welfare of children, but to guarantee the steady inflow of profits to the physicians and manufacturing drug houses."
–Dr. Herbert Shelton

"There is no evidence whatsoever of the ability of vaccines to prevent any diseases. To the contrary, there is a great wealth of evidence that they cause serious side effects."
–Dr. Viera Scheibner

"[Vaccines] can have tumorigenic kidney cells of a cocker spaniel in it. It can have human fetal cells with retroviruses. [It can have] aluminum, which is one of the most horrible things to inject into any sort of life form, especially into a muscle… Parents really need to know that their doctors are not informed and therefore they cannot give informed consent, and that they really need to think about it because you cannot unvaccinate. The fear of, "Oh, what if my child gets a disease"—that's where knowing the history is really important because what we're talking about is under which conditions people become susceptible . That's really more important than transmission. Because, yes, measles transmits very rapidly through the population, but it actually has a lot of benefits to the immune system—so much so that they're using it to treat cancer today."
–Suzanne Humphries, MD

"The explanation of an epidemic is simple, we are now seeing: 1 in 6 children with specific learning disabilities; 12-15% children with attention deficit disorder; 1 in 87 with autism spectrum – a 1700% increase over ten years; 1% sudden infant death; 40 deaths and 15,000 substantive adverse Gardasil reactions; 1 in 15 over 65 with dementia; 1 in 8 over 85; Chronic fatigue syndrome; Fibromyalgia; Seizure disorders; "West" syndrome Global developmental delay; 1 in 450 with type 1 diabetes; 1 in 2 men and 1 in 3 women will develop cancer over a lifetime; Gulf war syndrome affecting and disabling 250,000 troops and 42,000 deaths. These vaccinated soldiers show the exact same neurological damages after vaccination as the infants and children are exhibiting after each childhood vaccination. These are strokes – oxygen demand exceeding oxygen supply – conclusively! There is no such thing as an acquired genetic epidemic. The epidemic is an acquired phenomenon, from environmental factors, for which I can now conclusively show, vaccinations are the mass culprit for most of this."
–Dr. Andrew Moulden, PhD

"The 'victory over epidemics' was not won by medical science or by doctors–and certainly not by vaccines…..the decline…has been the result of technical, social and hygienic improvements and especially of improved nutrition. Here the role of the potato…deserves special mention…..Consider carefully whether you want to let yourself or your children undergo the dangerous, controversial, ineffective and no longer necessary procedure called vaccination, because the claim that vaccinations are the cause for the decline of infectious diseases is utter nonsense."–The Vaccination Nonsense (2004 Lectures)
–Dr. Med. G. Buchwald ISBN 3-8334-2508-3 page 108.

"There is no evidence that any influenza vaccine thus far developed is effective in preventing or mitigating any attack of influenza. The producers of these vaccines know that they are worthless, but they go on selling them, anyway."
–Dr. J. Anthony Morris (formerly Chief Vaccine Control Officer at the US Federal Drug Administration).

"But already before Salk developed his vaccine, polio had been constantly regressing; the 39 cases out of every 100,000 inhabitants registered in 1942 had gradually diminished from year to year until they were reduced to only 15 cases in 1952."
–M. Beddow Baylay, English surgeon and medical historian. Slaughter of the Innocent, Hans Reusch, Civitas Publishers, Switzerland, and Swain, New York, 1983.

"Operating on the false notion that universal vaccination will somehow arrest the advance of common disease (a reality readily proven false based on several examples, including the current flu vaccine which authorities admit will shield less than 18% of the vaccinated population from the flu), the new authoritarians demand that laws be passed to effectuate that objective, to compel against their will every man, woman, and child to be injected with vaccine…We must defend the rights of others to dissent against deprivations of right so that we may enjoy a like defense when we find ourselves out of step with the will of the majority."
–Jonathan Emord, Constitutional Attorney – 2015.

"If you want the truth on vaccination you must go to those who are not making anything out of it. If doctors shot at the moon every time it was full as a preventive of measles and got a shilling for it, they would bring statistics to prove it was a most efficient practice, and that the population would be decimated if it were stopped."
–Dr Allinson

"People ask why the 'real professionals' are not coming forth with the facts about vaccinations. The truth is that we are being given facts by the 'real professionals' – professionals that have absolutely nothing to profit from by telling the truth. Many doctors and practitioners, risking their professional status, are coming forth with research which is never told to the public. The safety concerns and protective ability of vaccinations have always been many. But, first and foremost, we should be very concerned about the current push to take away the personal freedom of choice which has many serious implications both for the present and future health of children and adults."
–Loretta Lanphier, NP, CN, CH – 2015.

"It's a socialist idea – herd mentality. You are at risk if you have evidence that is sufficient to show you are at risk. They say if you are not vaccinated you post a risk. But they are not proving it. They know scientifically that even if everyone is vaccinated, some will still contract the disease. It is impossible to ensure 100% vaccination. That would evoke the most gruesome police-state imaginable."
–Jonathan Emord, Constitutional Attorney – 2015.

"Industry has become FDA's client. People at FDA know that they have to be careful about upsetting industry" and that "even if a product doesn't work, . . . there is pressure on managers that gets transmitted down to reviewers to find some way of approving it."
–Dr. David B. Ross, Former FDA medical reviewer.

"Majorities are never the proof of truth."
–Dr. Walter R. Hadwen – 1896.

"Public health does not trump individual liberty."
–Lee Hieb, MD – 2015.

"I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless."
–David J. Graham, MD – Associate Director of the Food and Drug Administration's (FDA) Office of Drug Safety – 2004.

"FDA is inherently biased in favor of the pharmaceutical industry. It views industry as its client, whose interests it must represent and advance. It views its primary mission as approving as many drugs it can, regardless of whether the drugs are safe or needed."
–David J. Graham, MD – Associate Director of the Food and Drug Administrations's (FDA) Office of Drug Safety – 2005.

"When it comes to vaccinations, I just say NO. There are too many other options.

–Patrick Price, DC – 2015.

"There are 2 analogies I want to leave you with to illustrate the unreasonableness of CDER's (Center for Drug Evaluation and Research) standard of evidence as applied to safety, both pre- and post-approval. The second analogy is more graphic, but I think it brings home the point more clearly. Imagine for a moment that you have a pistol with a barrel having 100 chambers. Now, randomly place 95 bullets into those chambers. The gun represents a drug and the bullets represent a serious safety problem. Using CDER's standard, only when you have 95 bullets or more in the gun will you agree that the gun is loaded and a safety problem exists. Let's remove 5 bullets at random. We now have 90 bullets distributed across 100 chambers. Because there is only a 90% chance that a bullet will fire when I pull the trigger, CDER would conclude that the gun is not loaded and that the drug is safe."
–David J. Graham, MD – Associate Director of the Food and Drug Administrations' (FDA) Office of Drug Safety. Testimony before the U.S. Senate Committee on Finance – 2004.

"Jurist Oliver Wendelle Holmes Jr. decided that compulsory vaccination was constitutional under the 14th Amendment. His decision was a deviation from constitutional jurisprudence. Certainly some vaccines may be helpful and beneficial; however, individuals should not be compelled to vaccinate by the power of the state, particularly when well-known serious adverse reactions can occur. Rather than pushing mandatory vaccination, the government and medical establishment should devote resources to eliminating safety risks associated with vaccines."
–Jonathan Emord, Constitutional Attorney – 2015.

"Our children have the right to get infections. We have immune systems for that purpose… These are typically benign childhood conditions. We cannot sterilize the body [with vaccines]. We cannot sterilize our society. We need to be affected by these viruses… and we can treat it all naturally."
–Jack Wolfson, DO, cardiologist at Wolfson Integrative Cardiology, in a Jan. 29, 2015 CNN interview, "Watch Doctors Have Heated Debate over Vaccination."

"Medical and scientific research, as well as overwhelming clinical reports, have clearly demonstrated the potential for risk posed by many commonly administered vaccines. These same reports have indicated that the effectiveness of many of these vaccines has not been adequately proven. Based on such evidence, doctors of chiropractic have been joined by progressive medical doctors and public health administrators in questioning public policy regarding mandatory vaccines…It is the position of The World Chiropractic Alliance that… No person should be forced by government regulation or societal pressure to receive any medication or treatment, including vaccines, against his or her will. This includes mandated vaccines as a requirement for public school admission or for employment eligibility."
–The World Chiropractic Alliance – "Vaccinations and Freedom of Choice in Health Care" (accessed Aug. 21, 2014).

"AAPS does not oppose vaccines. AAPS has never taken an anti-vaccine position, although opponents have tried to paint that picture. AAPS has only attempted to halt government or school districts from blanket vaccine mandates that violate parental informed consent… The Centers for Disease Control admits that the reported number of adverse effects of vaccines is probably only 10% of actual adverse effects…Rampant conflicts of interest in the approval process has been the subject of several Congressional hearings, and a recent Congressional report concluded that the pharmaceutical industry has indeed exerted undue influence on mandatory vaccine legislation toward its own financial interests. The vaccine approval process has also been contaminated by flawed or incomplete clinical trials, and government officials have chosen to ignore negative results. For example, the CDC was forced to withdraw its recommendation of the rotavirus vaccine within one year of approval. Yet public documents obtained by AAPS show that the CDC was aware of alarmingly high intussuception rates months before the vaccine was approved and recommended. Mandatory vaccines violate the medical ethic of informed consent. A case could also be made that mandates for vaccines by school districts and legislatures is the de facto practice of medicine without a license."
–The Association of American Physicians and Surgeons (AAPS) – "Fact Sheet on Mandatory Vaccinations" Apr. 9, 2009.

"[W]e are standing publicly for the legal right to follow our conscience when making educated vaccine decisions for our families. Among us are parents with healthy children and those with children who have been hurt by one-size-fits-all vaccine mandates that ignore the genetic and biological differences which make some people more vulnerable than others for having severe reactions to prescription drugs and vaccines. No American should be legally forced to play vaccine roulette with a child's life…If we cannot be free to make informed, voluntary decisions about which pharmaceutical products we are willing to risk our lives for, then we are not free in any sense of the word. Because if

the State can tag, track down and force individuals against their will to be injected with biological products of unknown toxicity today, then there will be no limit on which individual freedoms the State can take away in the name of the greater good tomorrow."
–Barbara Loe Fisher, Co-founder and President of the National Vaccine Information Center – "Rally for Conscientious Exemption to Vaccination" Oct. 16, 2008.

"Prior to the universal varicella vaccination program, 95% of adults experienced natural chickenpox (usually as school aged children)—these cases were usually benign and resulted in long term immunity. This high percentage of individuals having long term immunity has been compromised by mass vaccination of children which provides at best 70 to 90% immunity that is temporary and of unknown duration—shifting chickenpox to a more vulnerable adult population where chickenpox carries 20 times more risk of death and 15 times more risk of hospitalization compared to children. Add to this the adverse effects of both the chickenpox and shingles vaccines as well as the potential for increased risk of shingles for an estimated 30 to 50 years among adults. The Universal Varicella (Chickenpox) Vaccination Program now requires booster vaccines; however, these are less effective than the natural immunity that existed in communities prior to licensure of the varicella vaccine."
–Gary S. Goldman, Ph.D.

"The original idea that vaccination could strengthen the herd's immunity, assumed that there was only one clinical event, and that one natural exposure equated life-long immunity. But this was not the case back when the diseases circulated freely. Vaccinators miss the point that the body defends most efficiently as a result of ongoing re-exposure. They try to mimic this with boosters. But the vaccination plan leaves the elderly(due to vaccine-induced immunity being short-lived and antigens taken out of circulation) and the very young(due to lack of transferable maternal immunity) more vulnerable to several diseases that were not a threat to them before vaccination. In the case of chicken pox, vaccination renders the elderly more apt to shingles infections, because the herd has now lost the continued and benign re-exposures to children with chicken pox."
–Suzanne Humphries, MD

"The formal demonstration that both maternal antibodies and early exposure to infection are required for long-term protection illustrated that constant re-infection cycles have an essential role in building a stable herd immunity. In a population that is not constantly exposed to the infection during early infancy under the immunologic umbrella of maternal antibodies or vaccinated thoroughly a serious risk of re-emerging infections may arise."
–Navarini AA et al. 2010. Long-lasting immunity by early infection of maternal-antibody-protected infants. Eur J Immunol. Jan;40(1):113-6. PMID: 19877011.

"I believe that when diseases disappear from sight, the disappearance is never solely by virtue of the vaccine. Yet the vaccine always gets the credit, because the blind faith in vaccines is prioritized over the scientific evidence. Evidence to the contrary of the value of vaccination is consistently snuffed out and kept away from the mainstream media, so that the herd never hears a peep of the truth. Instead, they get the "herd immunity" sound bite, which gives undeserved credit to the risk-benefit ratio of vaccination. Inside the web of half-truths and misinformation, the vaccine religion somehow justifies the public display of resentment and fear of the unvaccinated. "
–Suzanne Humphries, MD

"Vaccines are the most poisonous and dangerous health threat ever developed for children. They are designed to corrupt a pure mind, body and soul. We should have the natural right to choose what we put into our bodies. Nature is God's medicine!"
–Edward F. Group, III, DC, NP, DACBN, DCBCN, DABFM – 2015.

"Smallpox vaccination ended in the 1980s because smallpox had declined and because there was so much trouble with the old unsafe vaccine. That same trouble with the newer supposedly more safe smallpox vaccines is why smallpox vaccination ended after the 2003 first responder effort. Which makes you wonder just how much more trouble there was with the old smallpox vaccine which had a very long list of known bacterial and other "contaminants" because of its method of production. After the 2003 vaccines, reports of generalized vaccinia, autoinoculation, erythema multiforme, myopericarditis, ocular vaccinia, and postvaccinial encephalitis were reported. Smallpox was declared eradicated before clear distinctions between different poxviruses were made using DNA analysis. Symptoms alone are what were counted for smallpox during smallpox epidemics. Vaccination was a major source of smallpox

outbreaks, and only a small portion of the earth's entire herd was ever even vaccinated. Considering all of this, how can anyone believe that smallpox was eradicated with a vaccine?"
–Suzanne Humphries, MD

"I assert that it is beyond the functions of law to dictate a medical procedure, or enforce any scientific theory."
–Emeritus Professor F. W. Newman of University College, London – 1874.

"MLI (Measles-Like Illness) is common, particularly in younger age groups, and can be caused by a variety of pathogens that are difficult to differentiate clinically without laboratory guidance. In order of frequency, other common viral causes of rash-like illness – parvovirus B19, rubella, cytomegalovirus, and Epstein–Barr virus – were identified in our study."
–Wang, et al., "Evaluating measles surveillance using laboratory-discarded notifications of measles-like illness during elimination," Epidemiol. Infect. 2007, p. 1366.

"There is a terrible dichotomy between the information we as parents should expect from all the above-named sources, and what they give us – especially when you consider that there's not a doctor, nurse, pharmaceutical researcher or CVS pharmacist who can tell you, on a per-vaccination basis, whether your child will be susceptible to dire injury from the next administered vaccine, regardless of a history of ostensible non-reaction, because they don't know. Given the severity of the illnesses that can result from vaccines?"
–Shawn Siegel – Host of weekly radio/internet show, The Vaccine Myth: An Issue of Trust, on the Logos Radio Network.

"Most people in the U.S. do not even realize that U.S. law prevents anyone damaged by vaccines from suing the manufacturer. In 1986, Congress passed a law preventing legal liability to vaccine damages, because the drug companies manufacturing vaccines blackmailed them, by threatening to stop manufacturing vaccines without legal protection. There were so many lawsuits resulting from vaccine injuries and deaths prior to this time, that it was no longer profitable for them to continue marketing vaccines without legal protection. So instead of Congress requiring that drug companies manufacture safer vaccines, they complied with the drug companies' requests and passed legislation protecting the drug companies. In 2011 this law was upheld by the U.S. Supreme Court."
–Health Impact News – 2015.

"Any system of public health policy (vaccination policy in particular) requires the cooperation and trust of the public in the policy makers. If you have a situation to where you have to mandate vaccines, with very few exemptions, where in order to get social security benefits or to get your children into school, they have to be vaccinated according to the recommend schedule, this is not a measure of the success of the program, but a measure of its failure. The system in this country is failing very, very badly. The regulators have had a choice 1) to be honest and transparent with the public or 2) to lie and deceive the public and to increase the stringency of the mandates that they have enforced. That is the erroneous cost they have chosen to take and they have done so largely, I believe, in the interest of the pharmaceutical industry who are desperate to protect their profits. And also to cover up the extent to which the diseases they are vaccinating against are nowhere near as severe as they say…If we do not win this battle right now, we and our children's children will be owned by the pharmaceutical industry."
–Dr. Andrew Wakefield, leading expert in gut health – 2015.

"One of the 5 studies used to dismiss the vaccine-autism link was co-authored by Dr. Poul Thorsen, who has collaborated with the CDC from 1998 to the present time. Dr. Thorsen is featured on the Department of Health and Human Services Office of Inspector General's Most Wanted Fugitive List as he was indicted on April 14, 2011 by a Federal grand jury on 22 counts of fraud and embezzlement. Dr. Thorsen was installed as the lead investigator for a cohort of scientists from Denmark to investigate the vaccine autism link using Danish databases. Thorsen's work was funded by a CDC grant of over $10 million dollars. Most of the funds were disbursed after he coauthored the aforementioned thimerosal-autism paper, which was reviewed prior to publication by Dr. Diana Schendel. While compiling the results for this publication, Denmark researchers deliberately withheld critical data that would have revealed a decline in autism rates in Denmark after mercury-containing vaccines were removed from the Danish childhood vaccine schedule in 1992. The manuscript was initially rejected by the Journal of the American Medical Association and the Lancet, leading medical journals. Dr. Coleen Boyle of the CDC then took the unusual action of advocating for the paper by submitting a letter pushing for expedited review by the journal Pediatrics. The letter was signed by Dr. Jose Cordero, then Director of the CDC National Center for Birth Defects and Developmental

Disabilities. Dr. Thorsen has coauthored 36 peer-reviewed publications in collaboration with the CDC. Since his indictment by a Federal Grand Jury for fraud, he has coauthored four papers in collaboration with Dr. Schendel. Why is the branch of the CDC charged with responsibility for autism research collaborating with a fugitive charged with defrauding the very agency, the CDC, engaging in this critically important research? Why haven't any of his studies been retracted or been subjected to review?"
–Brian Hooker, Ph.D. Written testimony submitted to Congress – Autism Hearing – November, 2012.

"Let's be honest. The falling vaccination rate is hurting Big Pharma a heck of a lot more than it's hurting us. And that's what this is REALLY about — drug companies manipulating our government because they're worried they won't recoup the BILLIONS they spent developing vaccines we don't want. Well, the next time CDC gets an urge to write a report, maybe it should read the Declaration of Independence first. Because there's a little clause in there promising each of us life, liberty and the pursuit of happiness. As in it's your life, and you have the liberty to choose what you put into your body. And I don't give a damn whether our government is happy about it or not."
–Dr. William Campbell Douglass II – The Douglass Report – 2014.

"As a concerned, compassionate and considerate paediatrician, I can only arrive at one conclusion. Unvaccinated children have by far the best chance of enjoying marvelous health. Any vaccination at all works to cripple the chances of this end."
–Françoise Berthoud, MD [paediatrician] – 2010.

The U.S. vaccine market will grow at a CAGR of 5.3% between 2012 and 2018. The market, which valued US$12.8 billion in 2012, will reach US$17.4 billion by 2018. Pediatric vaccines were the leading sub-segment of the human vaccine segment in 2012. The segment of pediatric vaccines currently has an impressive share of the market and holds good future prospects owing to government compulsion for immunizing children in the U.S."
–Transparency Market Research, Mar. 19 2015.

The Theory of 'Herd Immunity. "As we see with the continual [measles] outbreaks, even at 95%, we still do not have full immunity. In China, the vaccination rates are even higher – 99%. But there are also still measles outbreaks there. So is the answer 100%? And what if at 100% you still get outbreaks? We've gone from herd immunity supposedly achieved at 55% to herd immunity that is clearly not achieved even at 95%. At what point will public health officials have to confront the possibility that herd immunity may not be the best theory on which to base vaccination policy?
–Marco Cacere, Author

"During the National Vaccine Advisory Committee's (NVAC) February 2015 meeting, American adults were put on notice by Big Brother that non-compliance with federal vaccine recommendations will not be tolerated. Make no mistake about this plan's [Healthy People 2020 Goals – adult immunization plan] intent, if "awareness" efforts and "incentivization" of vaccine policy do not increase adult vaccine uptake, the partnering with your employer and other community groups is meant to lower the hammer and force you to comply. The electronic tracking systems that are enthusiastically being embraced by not only the federal government but also state governments and employers, without regard for your privacy, will be used to identify noncompliers."
–Theresa Wrangham – NVIC Executive Director – 2015.

"Vaccination Is Not Immunization. When vaccines are effective, they do not confer complete or "natural" immunity. This is well-known, but hardly ever explained to parents and others. In fact, vaccines only confer an artificial, partial or temporary immunity. The only way to obtain full immunity from an infectious illness is if one actually goes through the illness and recovers fully. Vaccine-based "immunity", by way of contrast, diminishes in its protective effect after one or more years, assuming it was effective at all. As stated in an earlier section of this article, one does not know if one's vaccination was or is ever effective or not. There is no easy way to tell."
–Lawrence Wilson, MD – 2015.

"Researchers are now realizing that B. pertussis bacteria have evolved and become vaccine resistant. It is reminiscent of the way that bacteria have become resistant to antibiotics, thanks to the massive overuse of antibiotics in food production…A lowered risk [from a vaccine] might sound like a good thing, but if bacteria and viruses are evolving and becoming vaccine resistant, mirroring what we're seeing with growing resistance against antibiotics, the entire vaccine program would need a serious review. What if we're misusing vaccines like we've misused antibiotics, creating far worse diseases and reduced immune function in the process?"

–Joseph Mercola, DO – 2015.

"40 years ago when I started my practice, only 1 in 10,000 children had autism. Today it's 1 in 100. What is the only difference we have seen? The inordinate number of vaccines that are being given to children today. My partners and I have over 35,000 patients who have never been vaccinated. You know how many cases of autism we have seen? ZERO, ZERO. I have made this statement for over 40 years: 'NO VACCINES, NO AUTISM'."
–Dr. Mayer Eisenstein, MD

"I predict that Gardasil will become the greatest medical scandal of all time because at some point in time, the evidence will add up to prove that this vaccine, technical and scientific feat that it may be, has absolutely no effect on cervical cancer and that all the very many adverse effects which destroy lives and even kill, serve no other purpose than to generate profit for the manufacturers. Gardasil is useless and costs a fortune! In addition, decision-makers at all levels are aware of it! Cases of Guillain-Barré syndrome, paralysis of the lower limbs, vaccine-induced MS, and vaccine-induced encephalitis can be found, whatever the vaccine."
–Dr. Bernard Dalbergue, former Merck physician

from https://oawhealth.com/2015/04/01/vaccination-quotes-from-experts/

List of Vaccines and Inserts;

http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Adenovirus Type 4 and 7; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM247515.pdf

Anthrax; http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM074923.pdf

BCG Tuberculosis; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM202934.pdf

Cholera Oral; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM506235.pdf

Diphtheria & Tetanus Toxoids Absorbed; http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142732.pdf

DTaP;

Infanrix; http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm101568.htm

DAPTACEL; http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm101572.htm

Pediarix; Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus Vaccine Combined http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm136517.htm

KINRIX; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf

Quadracel; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf

Pentacel; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf

PedvaxHIB; Haemophilus B Conjugate Vaccine (Meningococcal Protein Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf

ActHIB; Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf

HIBERIX; Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf

Comvax; Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109869.pdf

Havrix; Hepatitis A Vaccine, Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf

VAQTA; Hepatitis A Vaccine, Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf

Twinrix; Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110079.pdf

Recombivax HB; Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf

Engerix-B; Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

Gardasil; Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111266.pdf

Cervarix; Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM186981.pdf

Gardasil 9; Human Papillomavirus 9-valent Vaccine, Recombinant
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426460.pdf

Influenza Vaccines; NO name Influenza A (H1N1) 2009 Monovalent Vaccine (CSL Limited)
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182401.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf

Influenza Virus Vaccine, H5N1 FOR NATIONAL STOCKPILE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112836.pdf

Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted; http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM376464.pdf

FLUAD; FOR 65+ Influenza Vaccine, Adjuvanted http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM474387.pdf

AFLURIA QUADRIVALENT; 18+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM518295.pdf

Flucelvax Quadrivalent; 4+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM502899.pdf

AFLURIA; 5+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf

FluLaval; 3+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112904.pdf

FluMist; 2-49 Influenza Vaccine Live, Intranasal http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm

Fluarix; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM335392.pdf

Fluvirin; 4+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123694.pdf

Agriflu; 18+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM371815.pdf

FLUCELVAX; 4+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM329134.pdf

Flublok; 18+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM336020.pdf

FluMist® Quadrivalent; 2-49 http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM294307.pdf

Fluarix Quadrivalent; 3+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf

FluLaval®; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM404086.pdf

Fluzone Quadrivalent; 2 Types- http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426679.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM513242.pdf

FluLaval®; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM404086.pdf

IXIARO; Japanese Encephalitis Vaccine, Inactivated, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142569.pdf

JE-Vax; 1+; Japanese Encephalitis Virus Vaccine Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123761.pdf

M-M-R II; 1+ Measles, Mumps, and Rubella Virus Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM375080.pdf

PROQUAD; 1-12 Measles, Mumps, Rubella and Varicella Virus Vaccine LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123793.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123796.pdf

Menveo; 2-55 Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf

MenHibrix; 6 weeks-18 months Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM308577.pdf

Menactra; 9 months-55 years Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf

BEXSERO; 10-55 Neisseria meningitidis serogroup B http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf

TRUMENBA; 10-25 *Neisseria meningitidis* serogroup B. http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM421139.pdf

Menomune-A/C/Y/W-135; 2+ Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM308370.pdf

Pneumovax 23; 2+ Pneumococcal Vaccine, Polyvalent http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM257088.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM277628.pdf

Prevnar; 2, 4, 6 & 12-15 months Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM137038.pdf

Prevnar 13; 6 weeks-5 years Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197}Protein) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf

IPOL; 6 weeks+ Poliovirus Vaccine Inactivated (Monkey Kidney Cell) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

IMOVAX; all ages Rabies Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133484.pdf

RabAvert; Rabies Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM312931.pdf

Rotarix; 6-24 weeks Rotavirus Vaccine LIVE Oral http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133539.pdf

RotaTeq; 6-32 weeks Rotavirus Vaccine LIVE Oral, Pentavalent http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142290.pdf

ACAM2000; Smallpox (Vaccinia) Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142572.pdf

No Trade Name; 7+ Tetanus and Diphtheria Toxoids, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM164127.pdf

TENIVAC; 7+ Tetanus and Diphtheria Toxoids Adsorbed For Adult Use http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152826.pdf

No Trade Name; 6 weeks until 7 ys Diphtheria and Tetanus Toxoid Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142732.pdf

Adacel; 10-64 Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM243729.pdf

Boostrix; 10+ Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf

Vivotif; 6+ Typhoid Vaccine Live Oral Ty21a http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142807.pdf

Typhin Vi; 2+ Typhoid Vi Polysaccharide Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142811.pdf

Varivax; Varicella Virus Vaccine LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM165651.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM165647.pdf

YF-Vax; 9 months+ Yellow Fever Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142831.pdf

Zostavax; 50+ Shingles Zoster Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM132831.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM285015.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM176340.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM285016.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM249230.pdf

Journal of Translational Science

oat open access text

Research Article ISSN: 2059-268X

Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

Anthony R Mawson[1]*, Brian D Ray[2], Azad R Bhuiyan[3] and Binu Jacob[4]

[1]Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[2]President, National Home Education Research Institute, PO Box 13939, Salem, OR 97309, USA

[3]Associate Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[4]Former graduate student, Department of Epidemiology and Biostatistics School of Public Health, Jackson State University, Jackson, MS 39213, USA

Abstract

Vaccinations have prevented millions of infectious illnesses, hospitalizations and deaths among U.S. children, yet the long-term health outcomes of the vaccination schedule remain uncertain. Studies have been recommended by the U.S. Institute of Medicine to address this question. This study aimed 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, and 2) to determine whether an association found between vaccination and neurodevelopmental disorders (NDD), if any, remained significant after adjustment for other measured factors. A cross-sectional study of mothers of children educated at home was carried out in collaboration with homeschool organizations in four U.S. states: Florida, Louisiana, Mississippi and Oregon. Mothers were asked to complete an anonymous online questionnaire on their 6- to 12-year-old biological children with respect to pregnancy-related factors, birth history, vaccinations, physician-diagnosed illnesses, medications used, and health services. NDD, a derived diagnostic measure, was defined as having one or more of the following three closely-related diagnoses: a learning disability, Attention Deficient Hyperactivity Disorder, and Autism Spectrum Disorder. A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated. The vaccinated were less likely than the unvaccinated to have been diagnosed with chickenpox and pertussis, but more likely to have been diagnosed with pneumonia, otitis media, allergies and NDD. After adjustment, vaccination, male gender, and preterm birth remained significantly associated with NDD. However, in a final adjusted model with interaction, vaccination but not preterm birth remained associated with NDD, while the interaction of preterm birth and vaccination was associated with a 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5). In conclusion, vaccinated homeschool children were found to have a higher rate of allergies and NDD than unvaccinated homeschool children. While vaccination remained significantly associated with NDD after controlling for other factors, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD. Further research involving larger, independent samples and stronger research designs is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health.

Abbreviations: ADHD: Attention Deficit Hyperactivity Disorder; ASD: Autism Spectrum Disorder; AOM: Acute Otitis Media; CDC: Centers for Disease Control and Prevention; CI: Confidence Interval; NDD: Neurodevelopmental Disorders; NHERI: National Home Education Research Institute; OR: Odds Ratio; PCV-7: Pneumococcal Conjugate Vaccine-7; VAERS: Vaccine Adverse Events Reporting System.

Introduction

Vaccines are among the greatest achievements of biomedical science and one of the most effective public health interventions of the 20th century [1]. Among U.S. children born between 1995 and 2013, vaccination is estimated to have prevented 322 million illnesses, 21 million hospitalizations and 732,000 premature deaths, with overall cost savings of $1.38 trillion [2]. About 95% of U.S. children of kindergarten age receive all of the recommended vaccines as a requirement for school and daycare attendance [3,4], aimed at preventing the occurrence and spread of targeted infectious diseases [5]. Advances in biotechnology are contributing to the development of new vaccines for widespread use [6].

Under the currently recommended pediatric vaccination schedule [7], U.S. children receive up to 48 doses of vaccines for 14 diseases from birth to age six years, a figure that has steadily increased since the 1950s, most notably since the Vaccines for Children program was created in 1994. The Vaccines for Children program began with vaccines targeting nine diseases: diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b disease, hepatitis B, measles, mumps, and rubella. Between 1995 and 2013, new vaccines against five other diseases were added for children age 6 and under: varicella, hepatitis A, pneumococcal disease, influenza, and rotavirus vaccine.

Although short-term immunologic and safety testing is performed on vaccines prior to their approval by the U.S. Food and Drug Administration, the long-term effects of individual vaccines and of the vaccination program itself remain unknown [8]. Vaccines are acknowledged to carry risks of severe acute and chronic adverse effects, such as neurological complications and even death [9], but such risks are considered so rare that the vaccination program is believed to be safe and effective for virtually all children [10].

There are very few randomized trials on any existing vaccine recommended for children in terms of morbidity and mortality, in

Correspondence to: Anthony R Mawson, Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA, E-mail: Anthony.r.mawson@jsums.edu

Key words: *acute diseases, chronic diseases, epidemiology, evaluation, health policy, immunization, neurodevelopmental disorders, vaccination*

Received: March 22, 2017; **Accepted:** April 21, 2017; **Published:** April 24, 2017

part because of ethical concerns involving withholding vaccines from children assigned to a control group. One exception, the high-titer measles vaccine, was withdrawn after several randomized trials in west Africa showed that it interacted with the diphtheria-tetanus-pertussis vaccine, resulting in a significant 33% increase in child mortality [11]. Evidence of safety from observational studies includes a limited number of vaccines, e.g., the measles, mumps and rubella vaccine, and hepatitis B vaccine, but none on the childhood vaccination program itself. Knowledge is limited even for vaccines with a long record of safety and protection against contagious diseases [12]. The safe levels and long-term effects of vaccine ingredients such as adjuvants and preservatives are also unknown [13]. Other concerns include the safety and cost-effectiveness of newer vaccines against diseases that are potentially lethal for individuals but have a lesser impact on population health, such as the group B meningococcus vaccine [14].

Knowledge of adverse events following vaccinations is largely based on voluntary reports to the Vaccine Adverse Events Reporting System (VAERS) by physicians and parents. However, the rate of reporting of serious vaccine injuries is estimated to be <1% [15]. These considerations led the former Institute of Medicine (now the National Academy of Medicine) in 2005 to recommend the development of a five-year plan for vaccine safety research by the Centers for Disease Control and Prevention (CDC) [16,17]. In its 2011 and 2013 reviews of the adverse effects of vaccines, the Institute of Medicine concluded that few health problems are caused by or associated with vaccines, and found no evidence that the vaccination schedule was unsafe [18,19]. Another systematic review, commissioned by the US Agency for Healthcare Research and Quality to identify gaps in evidence on the safety of the childhood vaccination program, concluded that severe adverse events following vaccinations are extremely rare [20]. The Institute of Medicine, however, noted that studies were needed: to compare the health outcomes of vaccinated and unvaccinated children; to examine the long-term cumulative effects of vaccines; the timing of vaccination in relation to the age and condition of the child; the total load or number of vaccines given at one time; the effect of other vaccine ingredients in relation to health outcomes; and the mechanisms of vaccine-associated injury [19].

A complicating factor in evaluating the vaccination program is that vaccines against infectious diseases have complex nonspecific effects on morbidity and mortality that extend beyond prevention of the targeted disease. The existence of such effects poses a challenge to the assumption that individual vaccines affect the immune system independently of each other and have no physiological effect other than protection against the targeted pathogen [21]. The nonspecific effects of some vaccines appear to be beneficial, while in others they appear to increase morbidity and mortality [22,23]. For instance, both the measles and Bacillus Calmette–Guérin vaccine reportedly reduce overall morbidity and mortality [24], whereas the diphtheria-tetanus-pertussis [25] and hepatitis B vaccines [26] have the opposite effect. The mechanisms responsible for these nonspecific effects are unknown but may involve *inter alia*: interactions between vaccines and their ingredients, e.g., whether the vaccines are live or inactivated; the most recently administered vaccine; micronutrient supplements such as vitamin A; the sequence in which vaccines are given; and their possible combined and cumulative effects [21].

A major current controversy is the question of whether vaccination plays a role in neurodevelopmental disorders (NDDs), which broadly include learning disabilities, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD). The controversy has been fueled by the fact that the U.S. is experiencing what has been described as a "silent pandemic" of mostly subclinical developmental neurotoxicity, in which about 15% of children suffer from a learning disability, sensory deficits, and developmental delays [27,28]. In 1996 the estimated prevalence of ASD was 0.42%. By 2010 it had risen to 1.47% (1 in 68), with 1 in 42 boys and 1 in 189 girls affected [29]. More recently, based on a CDC survey of parents in 2011–2014, 2.24% of children (1 in 45) were estimated to have ASD. Rates of other developmental disabilities, however, such as intellectual disability, cerebral palsy, hearing loss, and vision impairments, have declined or remained unchanged [30]. Prevalence rates of Attention Deficit Hyperactivity Disorder (ADHD) have also risen markedly in recent decades [31]. Earlier increases in the prevalence of learning disability have been followed by declining rates in most states, possibly due to changes in diagnostic criteria [32].

It is believed that much of the increase in NDD diagnoses in recent decades has been due to growing awareness of autism and more sensitive screening tools, and hence to greater numbers of children with milder symptoms of autism. But these factors do not account for all of the increase [33]. The geographically widespread increase in ASD and ADHD suggests a role for an environmental factor to which virtually all children are exposed. Agricultural chemicals are a current focus of research [34-37].

A possible contributory role for vaccines in the rise in NDD diagnoses remains unknown because data on the health outcomes of vaccinated and unvaccinated children are lacking. The need for such studies is suggested by the fact that the Vaccine Injury Compensation Program has paid $3.2 billion in compensation for vaccine injury since its creation in 1986 [38]. A study of claims compensated by the Vaccine Injury Compensation Program for vaccine-induced encephalopathy and seizure disorder found 83 claims that were acknowledged as being due to brain damage. In all cases it was noted by the Court of Federal Claims, or indicated in settlement agreements, that the children had autism or ASD [39]. On the other hand, numerous epidemiological studies have found no association between receipt of selected vaccines (in particular the combined measles, mumps, and rubella vaccine) and autism [10,40-45], and there is no accepted mechanism by which vaccines could induce autism [46].

A major challenge in comparing vaccinated and unvaccinated children has been to identify an accessible pool of unvaccinated children, since the vast majority of children in the U.S. are vaccinated. Children educated at home ("homeschool children") are suitable for such studies as a higher proportion are unvaccinated compared to public school children [47]. Homeschool families have an approximately equal median income to that of married-couple families nationwide, somewhat more years of formal education, and a higher average family size (just over three children) compared to the national average of just over two children [48-50]. Homeschooling families are slightly overrepresented in the south, about 23% are nonwhite, and the age distribution of homeschool children in grades K-12 is similar to that of children nationwide [51]. About 3% of the school-age population was homeschooled in the 2011-2012 school year [52].

The aims of this study were 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, including acute and chronic conditions, medication and health service utilization, and 2) to determine whether an association found between vaccination and NDDs, if any, remained significant after adjustment for other measured factors.

Methods

Study planning

To implement the study, a partnership was formed with the National Home Education Research Institute (NHERI), an organization that has been involved in educational research on homeschooling for many years and has strong and extensive contacts with the homeschool community throughout the country (www.nheri.org). The study protocol was approved by the Institutional Review Board of Jackson State University.

Study design

The study was designed as a cross-sectional survey of homeschooling mothers on their vaccinated and unvaccinated biological children ages 6 to 12. As contact information on homeschool families was unavailable, there was no defined population or sampling frame from which a randomized study could be carried out, and from which response rates could be determined. However, the object of our pilot study was not to obtain a representative sample of homeschool children but a convenience sample of unvaccinated children of sufficient size to test for significant differences in outcomes between the groups.

We proceeded by selecting 4 states (Florida, Louisiana, Mississippi, and Oregon) for the survey (Stage 1). NHERI compiled a list of statewide and local homeschool organizations, totaling 84 in Florida, 18 in Louisiana, 12 in Mississippi and 17 in Oregon. Initial contacts were made in June 2012. NHERI contacted the leaders of each statewide organization by email to request their support. A second email was then sent, explaining the study purpose and background, which the leaders were asked to forward to their members (Stage 2). A link was provided to an online questionnaire in which no personally identifying information was requested. With funding limited to 12 months, we sought to obtain as many responses as possible, contacting families only indirectly through homeschool organizations. Biological mothers of children ages 6-12 years were asked to serve as respondents in order to standardize data collection and to include data on pregnancy-related factors and birth history that might relate to the children's current health. The age-range of 6 to 12 years was selected because most recommended vaccinations would have been received by then.

Recruitment and informed consent

Homeschool leaders were asked to sign Memoranda of Agreement on behalf of their organizations and to provide the number of member families. Non-responders were sent a second notice but few provided the requested information. However, follow-up calls to the leaders suggested that all had contacted their members about the study. Both the letter to families and the survey questions were stated in a neutral way with respect to vaccines. Our letter to parents began:

"Dear Parent, This study concerns a major current health question: namely, whether vaccination is linked in any way to children's long-term health. Vaccination is one of the greatest discoveries in medicine, yet little is known about its long-term impact. The objective of this study is to evaluate the effects of vaccination by comparing vaccinated and unvaccinated children in terms of a number of major health outcomes ..."

Respondents were asked to indicate their consent to participate, to provide their home state and zip code of residence, and to confirm that they had biological children 6 to 12 years of age. The communications company Qualtrics (http://qualtrics.com) hosted the survey website. The questionnaire included only closed-ended questions requiring yes or no responses, with the aim of improving both response and completion rates.

A number of homeschool mothers volunteered to assist NHERI promote the study to their wide circles of homeschool contacts. A number of nationwide organizations also agreed to promote the study in the designated states. The online survey remained open for three months in the summer of 2012. Financial incentives to complete the survey were neither available nor offered.

Definitions and measures

Vaccination status was classified as unvaccinated (i.e., no previous vaccinations), partially vaccinated (received some but not all recommended vaccinations) and fully vaccinated (received all recommended age-appropriate vaccines), as reported by mothers. These categories were developed on the premise that any long-term effects of vaccines would be more evident in fully-vaccinated than in partially-vaccinated children, and rare or absent in the unvaccinated. Mothers were asked to use their child's vaccination records to indicate the recommended vaccines and doses their child had received. Dates of vaccinations were not requested in order not to overburden respondents and to reduce the likelihood of inaccurate reporting; nor was information requested on adverse events related to vaccines, as this was not our purpose. We also did not ask about dates of diagnoses because chronic illnesses are often gradual in onset and made long after the appearance of symptoms. Since most vaccinations are given before age 6, vaccination would be expected to precede the recognition and diagnosis of most chronic conditions.

Mothers were asked to indicate on a list of more than 40 acute and chronic illnesses all those for which her child or children had received a diagnosis by a physician. Other questions included the use of health services and procedures, dental check-ups, "sick visits" to physicians, medications used, insertion of ventilation ear tubes, number of days in the hospital, the extent of physical activity (number of hours the child engaged in "vigorous" activities on a typical weekday), number of siblings, family structure (mother and father living in the home, divorced or separated), family income and/or highest level of education of mother or father, and social interaction with children outside the home (i.e., amount of time spent in play or other contact with children outside the household). Questions specifically for the mother included pregnancy-related conditions and birth history, use of medications during pregnancy, and exposure to an adverse environment (defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory). NDD, a derived diagnostic category, was defined as having one or more of the following three closely related and overlapping diagnoses: a learning disability, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD) [53].

Statistical methods

Unadjusted bivariate analyses using chi-square tests were performed initially to test the null hypothesis of no association between vaccination status and health outcomes, i.e., physician-diagnosed acute and chronic illnesses, medications, and the use of health services. In most analyses, partially and fully vaccinated children were grouped together as the "vaccinated" group, with unvaccinated children as the control group. The second aim of the study was to determine whether any association found between vaccination and neurodevelopmental disorders remained significant after controlling for other measured factors. Descriptive statistics on all variables were computed to determine frequencies and percentages for categorical variables and means (± SD) for continuous variables. The strength of associations

between vaccination status and health outcomes were tested using odds ratios (OR) and 95% Confidence Intervals (CI). Odds ratios describe the strength of the association between two categorical variables measured simultaneously and are appropriate measures of that relationship in a cross-sectional study [54]. Unadjusted and adjusted logistic regression analyses were carried out using SAS (Version 9.3) to determine the factors associated with NDDs.

Results

Socio-Demographic characteristics of respondents

The information contained in 415 questionnaires provided data on 666 homeschool children. Table 1 shows the characteristics of the survey respondents. Mothers averaged about 40 years of age, were typically white, college graduates, with household incomes between $50,000 to $100,000, Christian, and married. The reasons for homeschooling for the majority of respondents (80-86%) were for a moral environment, better family relationships, or for more contact with their child or children.

The children as a group were similarly mostly white (88%), with a slight preponderance of females (52%), and averaged 9 years of age. With regard to vaccination status, 261 (39%) were unvaccinated, 208 (31%) were partially vaccinated, and 197 (30%) had received all of the recommended vaccinations. All statistical analyses are based on these numbers.

Acute illness

Vaccinated children (N=405), combining the partially and fully vaccinated, were significantly less likely than the unvaccinated to have had chickenpox (7.9% vs. 25.3%, p <0.001; Odds Ratio = 0.26, 95% Confidence Interval: 0.2, 0.4) and whooping cough (pertussis) (2.5% vs. 8.4%, p <0.001; OR 0.3, 95% CI: 0.1, 0.6), and less likely, but not significantly so, to have had rubella (0.3% vs. 1.9%, p = 0.04; OR 0.1, 95% CI: 0.01, 1.1). However, the vaccinated were significantly more likely than the unvaccinated to have been diagnosed with otitis media (19.8% vs. 5.8%, p <0.001; OR 3.8, 95% CI: 2.1, 6.6) and pneumonia (6.4% vs. 1.2%, p = 0.001; OR 5.9, 95% CI: 1.8, 19.7). No significant differences were seen with regard to hepatitis A or B, high fever in the past 6 months, measles, mumps, meningitis (viral or bacterial), influenza, or rotavirus (Table 2).

Chronic illness

Vaccinated children were significantly more likely than the unvaccinated to have been diagnosed with the following: allergic rhinitis (10.4% vs. 0.4%, p <0.001; OR 30.1, 95% CI: 4.1, 219.3), other allergies (22.2% vs. 6.9%, p <0.001; OR 3.9, 95% CI: 2.3, 6.6), eczema/atopic dermatitis (9.5% vs. 3.6%, p = 0.035; OR 2.9, 95% CI: 1.4, 6.1), a learning disability (5.7% vs. 1.2%, p = 0.003; OR 5.2, 95% CI: 1.6, 17.4), ADHD (4.7% vs. 1.0%, p = 0.013; OR 4.2, 95% CI: 1.2, 14.5), ASD (4.7% vs. 1.0%, p = 0.013; OR 4.2, 95% CI: 1.2, 14.5), any neurodevelopmental disorder (i.e., learning disability, ADHD or ASD) (10.5% vs. 3.1%, p <0.001; OR 3.7, 95% CI: 1.7, 7.9) and any chronic illness (44.0% vs. 25.0%, p <0.001; OR 2.4, 95% CI: 1.7, 3.3). No significant differences were observed with regard to cancer, chronic fatigue, conduct disorder, Crohn's disease, depression, Types 1 or 2 diabetes, encephalopathy, epilepsy, hearing loss, high blood pressure, inflammatory bowel disease, juvenile rheumatoid arthritis, obesity, seizures, Tourette's syndrome, or services received under the Individuals with Disabilities Education Act (Table 3).

Partial *versus* full vaccination

Partially vaccinated children had an intermediate position between the fully vaccinated and unvaccinated in regard to several but not all health outcomes. For instance, as shown in Table 4, the partially vaccinated had an intermediate (apparently detrimental) position in terms of allergic rhinitis, ADHD, eczema, and learning disability.

Gender differences in chronic illness

Among the vaccinated (combining partially and fully vaccinated children), boys were more likely than girls to be diagnosed with a chronic condition – significantly so in the case of allergic rhinitis (13.9% vs. 7.2%, p = 0.03; OR 2.1, 95% CI: 1.1, 4.1), ASD (7.7% vs. 1.9%, p = 0.006; OR 4.3, 95% CI: 1.4, 13.2), and any neurodevelopmental disorder (14.4% vs. 6.7%, p = 0.01; OR 2.3, 95% CI: 1.2, 4.6) (Table 5).

Use of medications and health services

The vaccinated (combining the partially and fully vaccinated) were significantly more likely than the unvaccinated to use medication for allergies (20.0% vs. 1.2%, p <0.001; OR 21.5, 95% CI: 6.7, 68.9), to have used antibiotics in the past 12 months (30.8% vs. 15.4%, p <0.001; OR 2.4, 95% CI: 1.6, 3.6), and to have used fever medications at least once (90.7% vs. 67.8%, p <0.001; OR 4.6, 95% CI: 3.0, 7.1). The vaccinated were also more likely to have seen a doctor for a routine checkup in the past 12 months (57.6% vs. 37.2%, p <0.001; OR 2.3, 95% CI: 1.7, 3.2), visited a dentist during the past year (89.4% vs. 80.5%, p <0.001; OR 2.0, 95% CI: 1.3, 3.2), visited a doctor or clinic due to illness in the past year (36.0% vs. 16.0%, p <0.001; OR 3.0, 95% CI: 2.0, 4.4), been fitted with ventilation ear tubes (3.0% vs. 0.4%, p = 0.018; OR 8.0, 95% CI: 1.0, 66.1), and spent one or more nights in a hospital (19.8% vs. 12.3%, p = 0.012; OR 1.8, 95% CI: 1.1, 2.7) (Table 6).

Table 1. Characteristics of the respondents[a]

	Mean (SD)[a]
Age (n=407)	40.59 (6.7)
	Number (%)[a]
Race	
White	382 (92.5%)
Non-White	21 (7.6%)
Total	413
Education	
High School Graduate or Less	35 (8.5%)
Some College	114 (27.5%)
College Graduate	187 (45.2%)
Post-Graduates	78 (18.5%)
Total	414
Total Gross Household Income	
< $49,999	123 (30.8%)
$50,000-100,000	182 (45.5%)
> $100,000	95 (23.8%)
Total	400
Religious Affiliation	
Christianity	375 (91.2%)
Non-Christianity	36 (8.8%)
Total	411
Marital Status	
Married	386 (93.7%)
Not Married	26 (6.3%)
Total	412

[a]Missing observations are excluded.

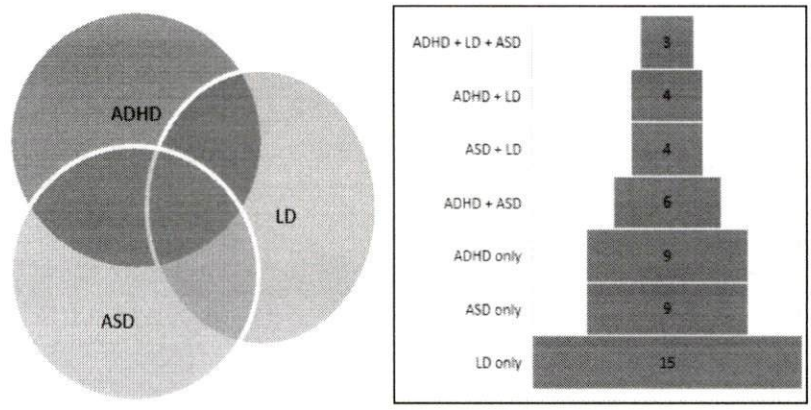


Figure 1. The overlap and distribution of physician-diagnosed neurodevelopmental disorders, based on mothers' reports

Table 2. Vaccination status and health outcomes – Acute Conditions

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Chickenpox						
Yes	32 (7.9%)	66 (25.3%)	98 (14.7%)	38.229	< 0.001	0.26 (0.2 - 0.4)
No	373 (92.1%)	195 (74.7%)	568 (85.3%)			
Otitis media						
Yes	80 (19.8%)	16(5.8%)	96 (14.4%)	26.643	< 0.001	3.8 (2.1 - 6.6)
No	325 (80.2%)	245 (94.2%)	507 (85.6%)			
Pneumonia						
Yes	26 (6.4%)	3 (1.2%)	29 (4.4%)	10.585	< 0.001	5.9 (1.8 - 19.7)
No	379 (93.6%)	258 (98.8%)	637 (95.6%)			
Whooping cough						
Yes	10 (2.5%)	22 (8.4%)	32 (4.8%)	12.326	< 0.001	0.3 (0.1 - 0.6)
No	395 (97.5%)	239 (91.6%)	634 (95.2%)			
Rubella						
Yes	1 (0.3%)	5 (1.9%)	6 (0.9%)	4.951	0.037	0.1 (0.01 - 1.1)
No	404 (99.6%)	256 (98.1%)	660 (99.1%)			

Table 3. Vaccination status and health outcomes – Chronic Conditions

Chronic Disease	Vaccinated (n=405)	Unvaccinated (n=261)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis					
Yes	42 (10.4%)	1 (0.4%)	26.21	< 0.001	30.1 (4.1 - 219.3)
	363 (89.6%)	260 (99.6%)			
Allergies					
Yes	90 (22.2%)	18 (6.9%)	29.44	< 0.001	3.9 (2.3 - 6.6)
No	315 (77.9%)	243 (93.1%)			
ADHD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
ASD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
Eczema (atopic dermatitis)					
Yes	38 (9.5%)	9 (3.6%)	8.522	0.035	2.9 (1.4 - 6.1)
No	367 (90.5%)	252 (96.4%)			
Learning Disability					
Yes	23 (5.7%)	3 (1.2%)	8.6803	0.003	5.2 (1.6 - 17.4)
No	382 (94.3%)	258 (98.9%)			
Neurodevelopment Disorder					
Yes	42 (10.5%)	8 (3.1%)	12.198	< 0.001	3.7 (1.7 - 7.9)
No	313 (89.5%)	253 (96.9%)			
Any Chronic Condition					
Yes	178 (44.0%)	65 (24.9%)	24.8456	< 0.001	2.4 (1.7 - 3.3)
No	227 (56.0%)	196 (75.1%)			

Table 4. Partial versus full vaccination and chronic health conditions

	Unvaccinated (n=261)	Partially Vaccinated (n=208)	Fully Vaccinated (n=197)	Total (n=666)	Chi-Square	P-value
Chronic Conditions						
Allergic rhinitis						
Yes	1 (0.4%)	17 (8.2%)	25 (12.7%)	43 (6.5%)	29.6306	< 0.001
No	260 (99.6%)	191 (91.8%)	172 (87.3%)	623 (93.5%)		
Allergies						
Yes	18 (6.9%)	47 (22.6%)	43 (21.8%)	108 (16.2%)	27.4819	< 0.001
No	243 (93.1%)	161 (77.4%)	154 (78.2%)	558 (83.8%)		
ADHD						
Yes	3 (1.2%)	8 (3.9%)	11 (5.6%)	22 (3.3%)	7.1900	0.075
No	258 (98.8%)	200 (96.1%)	186 (94.4%)	644 (96.7%)		
ASD						
Yes	3 (1.2%)	11 (5.3%)	8 (4.6%)	22 (3.3%)	6.7109	0.034
No	258 (98.8%)	197 (94.7%)	189 (95.4%)	644 (96.7%)		
Eczema (atopic dermatitis)						
Yes	9 (3.5%)	18 (8.7%)	20 (10.2%)	47 (7.1%)	8.8683	0.012
No	252 (96.5%)	190 (91.3%)	177 (89.8%)	619 (92.9%)		
Learning Disability						
Yes	3 (1.2%)	11 (5.3%)	12 (6.1%)	26 (3.9%)	8.8541	0.012
No	258 (98.8%)	197 (94.7%)	185 (93.9%)	640 (96.1%)		
NDD						
Yes	8 (3.1%)	21 (10.1%)	21 (10.7%)	50 (7.5%)	12.2443	0.002
No	253 (96.9%)	187 (89.9%)	176 (89.3%)	616 (92.5%)		
Any Chronic Condition						
Yes	65 (24.9%)	94 (45.2%)	84 (42.6%)	243 (36.5%)	25.1301	< 0.001
No	196 (75.1%)	114 (54.8%)	113 (57.4%)	423 (63.5%)		

Table 5. Chronic conditions and gender among vaccinated children

	Male (n=194)	Female (n=209)	Total (n=403)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis						
Yes	27 (13.9%)	15 (7.2%)	42 (10.4%)	4.8964	0.0269	2.1 (1.1 - 4.1)
No	167 (86.1%)	194 (92.8%)	361 (90.0%)			
Allergies						
Yes	50 (25.8%)	40 (19.1%)	90 (22.3%)	2.5531	0.1101	1.5 (0.91 - 2.4)
No	144 (74.2%)	168 (80. 9%)	313 (77.7%)			
ADHD						
Yes	13 (6.7%)	6 (2.9%)	19 (4.7%)	3.2856	0.0699	2.4 (0.90 - 6.5)
No	181 (93.3%)	203 (97.1%)	384 (95.3%)			
ASD						
Yes	15 (7.7%)	4 (1.9%)	19 (4.7%)	7.5810	0.0059	4.3 (1.4 - 13.2)
No	178 (92.3%)	205 (98.1%)	384 (95.3%)			
Eczema						
Yes	19 (9.89%)	19 (9.1%)	38 (9.4%)	0.0582	0.8094	1.1 (0.6 - 2.1)
No	175 (90.2%)	190 (90.9%)	365 (90.6%)			
Learning Disability						
Yes	14 (7.2%)	9 (4.3%)	23 (5.7%)	1.5835	0.2083	1.7 (0.7 - 4.1)
No	180 (92.8%)	200 (95.7%)	380 (94.3%)			
NDD						
Yes	28 (14.4%)	14 (6.7%)	42 (10.4%)	6.4469	0.0111	2.3 (1.2 - 4.6)
No	166 (85.6%)	195 (93.3%)	361 (89.6%)			
Any Chronic Condition						
Yes	94 (48.5%)	83 (39.7%)	177 (43.9%)	3.1208	0.0773	1.4 (1.0 - 2.1)
No	100 (51.5%)	126 (60.3%)	226 (56.1%)			

Factors associated with neurodevelopmental disorders

The second aim of the study focused on a specific health outcome and was designed to determine whether vaccination was associated with neurodevelopmental disorders (NDD) and, if so, whether the association remained significant after adjustment for other measured factors. As noted, because of the relatively small numbers of children with specific diagnoses, NDD was a derived variable combining children with a diagnosis of one or more of ASD, ADHD and a learning disability. The close association and overlap of these diagnoses in the

Table 6. Vaccination status, medication use and health services utilization

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Medication Use						
Medication for Allergy						
Yes	81 (20.0%)	3 (1.2%)	84 (12.6%)	51.170	< 0.001	21.5 (6.7 - 68.9)
No	324 (80.0%)	258 (98.8%)	582 (87.4%)			
Used antibiotics in the past 12 months						
Yes	124 (30.8%)	40 (15.4%)	164 (24.7%)	20.092	< 0.001	2.4 (1.6 - 3.6)
No	279 (69.2%)	220 (84.6%)	499 (75.3%)			
Used fever medication 1+ times						
Yes	350 (90.7%)	173 (67.8%)	523 (81.6%)	53.288	< 0.001	4.6 (3.0 - 7.1)
No	36 (9.3%)	82 (32.2%)	118 (18.4%)			
Using fitted ear drainage tubes						
Yes	12 (3.0%)	1 (0.4%)	13 (2.0%)	5.592	0.018	8.0 (1.0 - 66.1)
No	389 (97.0%)	260 (99.6%)	649 (98.0%)			
Used medication for ADHD						
Yes	7 (1.7%)	3 (1.2%)	10 (1.5%)	0.346	0.556	-
No	398 (98.3%)	256 (98.8%)	654 (98.5%)			
Used medication for Seizures						
Yes	4 (1.0%)	1 (0.4%)	5 (0.8%)	0.769	0.653	-
No	400 (99.0%)	258 (99.6%)	658 (99.2)			
Health Services Utilization						
Emergency Department visit in the past 12 months						
Yes	38 (9.5%)	23 (9.0%)	61 (9.3%)	0.047	0.828	-
No	364 (90.5%)	234 (91.0%)	598 (90.7%)			
Sick visit to doctor in the past year						
Yes	145 (36.0%)	41 (16.0%)	186 (28.2%)	31.096	< 0.001	3.0 (2.0 - 4.4)
No	258 (64.0%)	216 (84.0%)	474 (71.8%)			
Ever spent one or more nights in the hospital						
Yes	80 (19.8%)	32 (12.3%)	112 (16.8%)	6.267	0.012	1.8 (1.1 - 2.7)
No	325 (80.2%)	228 (87.7%)	553 (83.2%)			
Seen doctor for checkup in past 12 months						
Yes	233 (57.6%)	97 (37.2%)	330 (49.6%)	26.336	< 0.001	2.3 (1.7 - 3.2)
No	172 (42.4%)	164 (62.8%)	336 (50.4%)			
Seen dentist in the past 12 months						
Yes	362 (89.4%)	210 (80.5%)	572 (85.9%)	10.424	< 0.001	2.0 (1.3 - 3.2)
No	43 (10.6%)	51 (19.5%)	94 (14.1%)			

study is shown in the figure above (Figure 1). The figure shows that the single largest group of diagnoses was learning disability (n=15) followed by ASD (n=9), and ADHD (n=9), with smaller numbers comprising combinations of the three diagnoses.

Unadjusted analysis

Table 7 shows that the factors associated with NDD in unadjusted logistic regression analyses were: vaccination (OR 3.7, 95% CI: 1.7, 7.9); male gender (OR 2.1, 95% CI: 1.1, 3.8); adverse environment, defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory (OR 2.9, 95% CI: 1.1, 7.4); maternal use of antibiotics during pregnancy (OR 2.3, 95% CI: 1.1, 4.8); and preterm birth (OR 4.9, 95% CI: 2.4, 10.3). Two factors that almost reached statistical significance were vaccination during pregnancy (OR 2.5, 95% CI: 1.0, 6.3) and three or more fetal ultrasounds (OR 3.2, 95% CI: 0.92, 11.5). Factors that were not associated with NDD in this study included mother's education, household income, and religious affiliation; use of acetaminophen, alcohol, and antacids during pregnancy; gestational diabetes; preeclampsia; Rhogham shot during pregnancy; and breastfeeding (data not shown).

Adjusted analysis

After adjustment for all other significant factors, those that remained significantly associated with NDD were: vaccination (OR 3.1, 95% CI: 1.4, 6.8); male gender (OR 2.3, 95% CI: 1.2, 4.3); and preterm birth (OR 5.0, 95% CI: 2.3, 11.1). The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors.

In a final adjusted model designed to test for this possibility, controlling for the interaction of preterm birth and vaccination, the following factors remained significantly associated with NDD: vaccination (OR 2.5, 95% CI: 1.1, 5.6), nonwhite race (OR 2.4, 95% CI: 1.1, 5.4), and male gender (OR 2.3, 95% CI: 1.2, 4.4). Preterm birth itself, however, was not significantly associated with NDD, whereas the combination (interaction) of preterm birth and vaccination was associated with 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5) (Table 8).

Discussion

Following a recommendation of the Institute of Medicine [19] for studies comparing the health outcomes of vaccinated and unvaccinated

Table 7. Unadjusted analysis of potential risk factors for neurodevelopmental disorders

	NDD					
Vaccination Status	**Yes (N=50)**	**No (N=616)**	**Total* (N=666)**	**Chi-Square**	**P-value**	**OR (95% CI)****
Vaccinated	42	363	405	12.198	<0.001	3.7 (1.7 - 7.9)
Not Vaccinated	8	253	261			Ref
Race						
Non-White	9	71	80	1.8208	0.177	1.7 (0.7 - 3.6)
White	41	544	585			Ref
Child's Gender						
Male	32	283	315	5.9471	0.015	2.1 (1.1 - 3.8)
Female	18	331	349			Ref
Adverse Environment						
Yes	6	27	33	5.8706	0.053	2.9 (1.1 - 7.4)
No	40	523	563			Ref
Do not know	4	66	70			0.8 (0.3 - 2.3)
Medication during Pregnancy - Antibiotics						
Yes	10	61	71	4.950	0.026	2.3 (1.1 - 4.8)
No	40	555	595			Ref
Medication during Pregnancy –Vaccinated						
Yes	6	32	38	3.965	0.057	2.5 (1.0 - 6.3)
No	44	583	627			Ref
Preterm birth						
Yes	12	37	49	22.910	< 0.001	4.9 (2.4 - 10.3)
No	38	578	616			Ref
Ultrasound						
None	3	71	74	5.898	0.052	Ref
1-3 times	30	419	449			1.7 (0.5 - 5.7)
> 3 times	17	124	141			3.2 (0.92 - 11.5)

*Numbers may not add to column totals due to missing or incomplete data.

**Note that Odds Ratios are the cross-product ratios of the entries in the 2-by-2 tables, and are an estimate of the relative incidence (or risk) of the outcome associated with the exposure factor.

Table 8. Adjusted logistic regression analyses of risk factors and NDD*

	Adjusted Model (Model 1)	**Adjusted Model with Interaction (Model 2)**
Vaccination Status		
Vaccinated	3.1 (1.4 - 6.8)	2.5 (1.1 - 5.6)
Not Vaccinated	Ref	Ref
Race		
Non-White	2.3 (1.0 - 5.2)	2.4 (1.1 - 5.4)
White	Ref	Ref
Child's Gender		
Male	2.3 (1.2 - 4.3)	2.3 (1.2 - 4.4)
Female	Ref	Ref
Preterm birth		NS
Yes	5.0 (2.3 - 11.1)	
No	Ref	
Preterm birth and Vaccination interaction		
No interaction	Not in the model	Ref
Preterm and Vaccinated		6.6 (2.8 - 15.5)

*Number of observation read 666, number of observations used 629. NDD=47, Not NDD = 582

children, this study focused on homeschool children ages 6 to 12 years based on mothers' anonymous reports of pregnancy-related conditions, birth histories, physician-diagnosed illnesses, medications and healthcare use. Respondents were mostly white, married, and college-educated, upper income women who had been contacted and invited to participate in the study by the leaders of their homeschool organizations. Data from the survey were also used to determine whether vaccination was associated specifically with NDDs, a derived diagnostic category combining children with the diagnoses of learning disability, ASD and/or ADHD.

With regard to acute and chronic conditions, vaccinated children were significantly less likely than the unvaccinated to have had chickenpox and pertussis but, contrary to expectation, were significantly more likely to have been diagnosed with otitis media, pneumonia, allergic rhinitis, eczema, and NDD. The vaccinated were also more likely to have used antibiotics, allergy and fever medications; to have been fitted with ventilation ear tubes; visited a doctor for a health issue in the previous year, and been hospitalized. The reason for hospitalization and the age of the child at the time were not determined, but the latter finding appears consistent with a study of 38,801 reports to the VAERS of infants who were hospitalized or had died after receiving vaccinations. The study reported a linear relationship between the number of vaccine doses administered at one time and the rate of hospitalization and death; moreover, the younger the infant at the time of vaccination, the higher was the rate of hospitalization and death [55]. The hospitalization rate increased from 11% for 2 vaccine doses to 23.5% for 8 doses ($r^2 = 0.91$), while the case fatality rate increased significantly from 3.6% for those receiving from 1-4 doses to 5.4 % for those receiving from 5-8 doses.

In support of the possibility that the number of vaccinations received could be implicated in risks of associated chronic illness, a

comparison of unvaccinated, partially and fully vaccinated children in the present study showed that the partially vaccinated had increased but intermediate odds of chronic disease, between those of unvaccinated and fully vaccinated children, specifically for allergic rhinitis, ADHD, eczema, a learning disability, and NDD as a whole.

The national rates of ADHD and LD are comparable to those of the study. The U.S. rate of ADHD for ages 4-17 (twice the age range of children than the present study), is 11% [31]. The study rate of ADHD for ages 6 to 12 is 3.3%, and 4.7% when only vaccinated children are included. The national LD rate is 5% [32], and the study data show a rate of LD of 3.9% for all groups, and 5.6% when only vaccinated children are included. However, the ASD prevalence of 2.24% from a CDC parent survey is lower than the study rate of 3.3%. Vaccinated males were significantly more likely than vaccinated females to have been diagnosed with allergic rhinitis, and NDD. The percentage of vaccinated males with an NDD in this study (14.4%) is consistent with national findings based on parental responses to survey questions, indicating that 15% of U.S. children ages 3 to 17 years in the years 2006-2008 had an NDD [28]. Boys are also more likely than girls to be diagnosed with an NDD, and ASD in particular [29].

Vaccination was strongly associated with both otitis media and pneumonia, which are among the most common complications of measles infection [56,57]. The odds of otitis media were almost four-fold higher among the vaccinated (OR 3.8, 95% CI: 2.1, 6.6) and the odds of myringotomy with tube placement were eight-fold higher than those of unvaccinated children (OR 8.0, 95% CI: 1.0, 66.1). Acute otitis media (AOM) is a very frequent childhood infection, accounting for up to 30 million physician visits each year in the U.S., and the most common reason for prescribing antibiotics for children [58,59]. The incidence of AOM peaks at ages 3 to 18 months and 80% of children have experienced at least one episode by 3 years of age. Rates of AOM have increased in recent decades [60]. Worldwide, the incidence of AOM is 10.9%, with 709 million cases each year, 51% occurring in children under 5 years of age [61]. Pediatric AOM is a significant concern in terms of healthcare utilization in the U.S., accounting for $2.88 billion in annual health care costs [62].

Numerous reports of AOM have been filed with VAERS. A search of VAERS for "Cases where age is under 1 and onset interval is 0 or 1 or 2 or 3 or 4 or 5 or 6 or 7 days and Symptom is otitis media" [63] revealed that 438,573 cases were reported between 1990 and 2011, often with fever and other signs and symptoms of inflammation and central nervous system involvement. One study [64] assessed the nasopharyngeal carriage of *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis* during AOM in fully immunized, partly immunized children with 0 or 1 dose of Pneumococcal Conjugate Vaccine-7 (PCV7), and "historical control" children from the pre-PCV-7 era, and found an increased frequency of *M. catarrhalis* colonization in the vaccinated group compared to the partly immunized and control groups (76% vs. 62% and 56%, respectively). A high rate of *Moraxella catarrhalis* colonization is associated with an increased risk of AOM [65].

Successful vaccination against pneumococcal infections can lead to replacement of the latter in the nasopharyngeal niche by nonvaccine pneumococcal serotypes and disease [66]. Vaccination with PCV-7 has a marked effect on the complete microbiota composition of the upper respiratory tract in children, going beyond shifts in the distribution of pneumococcal serotypes and known potential pathogens and resulting in increased anaerobes, gram-positive bacteria and gram-negative bacterial species. PCV-7 administration also correlates highly with the emergence and expansion of oropharyngeal types of species. These observations have suggested that eradication of vaccine serotype pneumococci can be followed by colonization of other bacterial species in the vacant nasopharyngeal niche, leading to disequilibria of bacterial composition (dysbiosis) and increased risks of otitis media. Long-term monitoring has been recommended as essential for understanding the full implications of vaccination-induced changes in microbiota structure [67].

The second aim of the paper focused on a specific health outcome and sought to determine whether vaccination remained associated with neurodevelopmental disorders (NDD) after controlling for other measured factors. After adjustment, the factors that remained significantly associated with NDD were vaccination, nonwhite race, male gender, and preterm birth. The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors. This was shown in a final adjusted model with interaction (controlling for the interaction of preterm birth with vaccination). In this model, vaccination, nonwhite race and male gender remained associated with NDD, whereas preterm birth itself was no longer associated with NDD. However, preterm birth combined with vaccination was associated with a 6.6-fold increased odds of NDD.

In summary, vaccination, nonwhite race, and male gender were significantly associated with NDD after controlling for other factors. Preterm birth, although significantly associated with NDD in unadjusted and adjusted analyses, was no longer associated with NDD in the final model with interaction. However, preterm birth and vaccination combined was strongly associated with NDD in the final adjusted model with interaction, more than doubling the odds of NDD compared to vaccination alone. Preterm birth has long been known as a major factor for NDD [68,69], but since preterm infants are routinely vaccinated, the separate effects of preterm birth and vaccination have not been examined. The present study suggests that vaccination could be a contributing factor in the pathogenesis of NDD but also that preterm birth by itself may have a lesser or much reduced role in NDD (defined here as ASD, ADHD and/or a learning disability) than currently believed. The findings also suggest that vaccination coupled with preterm birth could increase the odds of NDD beyond that of vaccination alone.

Potential limitations

We did not set out to test a specific hypothesis about the association between vaccination and health. The aim of the study was to determine whether the health outcomes of vaccinated children differed from those of unvaccinated homeschool children, given that vaccines have nonspecific effects on morbidity and mortality in addition to protecting against targeted pathogens [11]. Comparisons were based on mothers' reports of pregnancy-related factors, birth histories, vaccinations, physician-diagnosed illnesses, medications, and the use of health services. We tested the null hypothesis of no difference in outcomes using chi-square tests, and then used Odds Ratios and 96% Confidence Intervals to determine the strength and significance of the association.

If the effects of vaccination on health were limited to protection against the targeted pathogens, as is assumed to be the case [21], no difference in outcomes would be expected between the vaccinated and unvaccinated groups except for reduced rates of the targeted infectious diseases. However, in this homogeneous sample of 666 children there were striking differences in diverse health outcomes between the groups. The vaccinated were less likely to have had chickenpox or whooping cough, as expected, but more likely to have been diagnosed with pneumonia and ear infections as well as allergies and NDDs.

What credence can be given to the findings? This study was not intended to be based on a representative sample of homeschool children but on a convenience sample of sufficient size to test for significant differences in outcomes. Homeschoolers were targeted for the study because their vaccination completion rates are lower than those of children in the general population. In this respect our pilot survey was successful, since data were available on 261 unvaccinated children.

To eliminate opportunities for subjectivity or opinion in the data, only factual information was requested and the questions involved memorable events such as physician-diagnosed diseases in a child. With regard to minimizing potential bias in the information provided by mothers, all communications with the latter emphasized neutrality regarding vaccination and vaccine safety. To minimize recall bias, respondents were asked to use their child's vaccination records. To enhance reliability, closed-ended questions were used and each set of questions had to be completed before proceeding to the next. To enhance validity, parents were asked to report only physician-diagnosed illnesses.

Mothers' reports could not be validated by clinical records because the survey was designed to be anonymous. However, self-reports about significant events provide a valid proxy for official records when medical records and administrative data are unavailable [70]. Had mothers been asked to provide copies of their children's medical records it would no longer have been an anonymous study and would have resulted in few completed questionnaires. We were advised by homeschool leaders that recruitment efforts would have been unsuccessful had we insisted on obtaining the children's medical records as a requirement for participating in the study.

A further potential limitation is under-ascertainment of disease in unvaccinated children. Could the unvaccinated have artificially reduced rates of illness because they are seen less often by physicians and would therefore have been less likely to be diagnosed with a disease? The vaccinated were indeed more likely to have seen a doctor for a routine checkup in the past 12 months (57.5% vs. 37.1%, $p < 0.001$; OR 2.3, 95% CI: 1.7, 3.1). Such visits usually involve vaccinations, which non-vaccinating families would be expected to refuse. However, fewer visits to physicians would not necessarily mean that unvaccinated children are less likely to be seen by a physician if their condition warranted it. In fact, since unvaccinated children were more likely to be diagnosed with chickenpox and whooping cough, which would have involved a visit to the pediatrician, differences in health outcomes are unlikely to be due to under-ascertainment.

Strengths of the study include the unique design of the study, involving homeschool mothers as respondents, and the relatively large sample of unvaccinated children, which made it possible to compare health outcomes across the spectrum of vaccination coverage. Recruitment of biological mothers as respondents also allowed us to test hypotheses about the role of pregnancy-related factors and birth history as well as vaccination in NDD and other specific conditions. In addition, this was a within-group study of a demographically homogeneous population of mainly white, higher-income and college-educated homeschooling families in which the children were all 6-12 years of age. Information was provided anonymously by biological mothers, obviously well-informed about their own children's vaccination status and health, which likely increased the validity of the reports.

Conclusions

Assessment of the long-term effects of the vaccination schedule on morbidity and mortality has been limited [71]. In this pilot study of vaccinated and unvaccinated homeschool children, reduced odds of chickenpox and whooping cough were found among the vaccinated, as expected, but unexpectedly increased odds were found for many other physician-diagnosed conditions. Although the cross-sectional design of the study limits causal interpretation, the strength and consistency of the findings, the apparent "dose-response" relationship between vaccination status and several forms of chronic illness, and the significant association between vaccination and NDDs all support the possibility that some aspect of the current vaccination program could be contributing to risks of childhood morbidity. Vaccination also remained significantly associated with NDD after controlling for other factors, whereas preterm birth, long considered a major risk factor for NDD, was not associated with NDD after controlling for the interaction between preterm birth and vaccination. In addition, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD above that of vaccination alone. Nevertheless, the study findings should be interpreted with caution. First, additional research is needed to replicate the findings in studies with larger samples and stronger research designs. Second, subject to replication, potentially detrimental factors associated with the vaccination schedule should be identified and addressed and underlying mechanisms better understood. Such studies are essential in order to optimize the impact of vaccination of children's health.

Competing Interests

The authors declare that they have no financial interests that had any bearing on any aspect of the conduct or conclusions of the study and the submitted manuscript.

Author contributions

AM designed the study, contributed to data analysis and interpretation, and drafted the paper. BR designed the study, contributed to data collection, and edited the paper. AB contributed to data analyses and edited the paper. BJ contributed to data analyses and editing. All authors read and approved the final version of the paper.

Funding sources

This study was supported by grants from Generation Rescue, Inc., and the Children's Medical Safety Research Institute, charitable organizations that support research on children's health and safety. The funders had no role or influence on the design and conduct of the research or the preparation of reports.

Acknowledgments

The authors thank all those who contributed critical comments, suggestions and financial support for the project. We also thank the collaborating homeschool organizations and especially the mothers who participated in the survey.

Disclaimer

This study was approved by the Institutional Review Board of Jackson State University and completed prior to Dr. Mawson's tenure-track appointment at Jackson State University.

References

1. Centers for Disease Control and Prevention (CDC) (1999) Ten great public health achievements--United States, 1900-1999. *MMWR Morb Mortal Wkly Rep* 48: 241-243. [Crossref]

2. Whitney CG, Zhou F, Singleton J, Schuchat A; Centers for Disease Control and Prevention (CDC) (2014) Benefits from immunization during the vaccines for children program era - United States, 1994-2013. *MMWR Morb Mortal Wkly Rep* 63: 352-355. [Crossref]

3. Centers for Disease Control and Prevention (CDC) (2007) Vaccination coverage among children in kindergarten--United States, 2006-07 school year. *MMWR Morb Mortal Wkly Rep* 56: 819-821.[Crossref]

4. Centers for Disease Control and Prevention (CDC) (2013) Vaccination coverage among children in kindergarten - United States, 2012-13 school year. *MMWR Morb Mortal Wkly Rep* 62: 607-612. [Crossref]

5. http://www.cdc.gov/vaccines/vacgen/whatifstop.htm (Accessed 19 June 2016)

6. http://www.hhs.gov/nvpo/vacc_plan/index.html (Accessed 19 June 2015).

7. http://www.cdc.gov/vaccines/schedules/index.html (Accessed 19 June 2016).

8. Ward BJ (2000) Vaccine adverse events in the new millennium: is there reason for concern? *Bull World Health Organ* 78: 205-215.[Crossref]

9. Sienkiewicz D, Kulak W, Okurowska-Zawada B, Paszko-Pateg G (2012) Neurologic adverse events following vaccination. *Prog Health Sci* 2:129-141.

10. Pollard AJ (2007) Childhood immunisation: what is the future? *Arch Dis Child* 92: 426-433. [Crossref]

11. Aaby P, Whittle H, Benn CS (2012) Vaccine programmes must consider their effect on general resistance. *BMJ* 344: e3769. [Crossref]

12. Cunningham AS (2015) Vaccine mandates in the US are doing more harm than good. *BMJ* 351: h4576. [Crossref]

13. Dórea JG. Exposure to mercury and aluminum in early life: developmental vulnerability as a modifying factor in neurologic and immunologic effects. *Int J Environ Res Public Health*(2015) 12(2):1295-313.

14. Crowcroft NS1, Deeks SL2, Upshur RE2 (2015) Do we need a new approach to making vaccine recommendations? *BMJ* 350: h308. [Crossref]

15. Kessler DA1 (1993) Introducing MEDWatch. A new approach to reporting medication and device adverse effects and product problems. *JAMA* 269: 2765-2768. [Crossref]

16. http://www.nap.edu/catalog.php?record_id=11234 (Accessed 19 June 2016).

17. http://www.cdc.gov/vaccinesafety/pdf/iso-finalscientific_agenda-nov- 10.pdf (Accessed 19 June 2016).

18. Institute of Medicine (2012) Adverse Effects of Vaccines: Evidence and Causality. The National Academies Press, Washington, DC.

19. Institute of Medicine (2013) The childhood immunization schedule and safety: Stakeholder concerns, scientific evidence, and future studies.The National Academies Press, Washington, DC.

20. Maglione MA, Das L, Raaen L, Smith A, Chari R, et al. (2014) Safety of vaccines used for routine immunization of US children: a systematic review. *Pediatrics* 134:325-337. [Crossref]

21. Siegrist CA (2008) Vaccine Immunology. Vaccines. (5thEdtn). Saunders Elsevier.

22. Benn CS, Netea MG, Selin LK, Aaby P (2013) A small jab - a big effect: nonspecific immunomodulation by vaccines. *Trends Immunol* 34: 431-439.[Crossref]

23. Jensen KJ, Benn CS, van Crevel R (2016) Unravelling the nature of non-specific effects of vaccines - A challenge for innate immunologists. *Semin Immunol* 28:377-383. [Crossref]

24. Sørup S, Benn CS, Poulsen A, Krause TG, Aaby P, et al. (2014) Live vaccine against measles, mumps, and rubella and the risk of hospital admissions for nontargeted infections. *JAMA* 311: 826-835.[Crossref]

25. Aaby P, Benn C, Nielsen J, Lisse IM, Rodrigues A, et al. (2012)Testing the hypothesis that diphtheria-tetanus-pertussis vaccine has negative non-specific and sex-differential effects on child survival in high-mortality countries. *BMJ Open* 2:e000707. [Crossref]

26. Garly ML1, Jensen H, Martins CL, Balé C, Baldé MA, et al. (2004) Hepatitis B vaccination associated with higher female than male mortality in Guinea-Bissau: an observational study. *Pediatr Infect Dis J* 23:10861092. [Crossref]

27. Grandjean P, Landrigan PJ (2006) Developmental neurotoxicity of industrial chemicals. *Lancet* 368: 2167-2178.[Crossref]

28. Boyle CA, Boulet S, Schieve LA, Cohen RA, Blumberg SJ, , et al. (2011) Trends in the prevalence of developmental disabilities in US Children, 1997-2008. *Pediatrics* 127:10341042. [Crossref]

29. Baio J (2014) Prevalence of Autism Spectrum Disorder among children aged 8 years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2010 Surveillance Summaries. *MMWR* 63:1-21.

30. Zablotsky B, Black LI, Maenner MJ, Schieve LA, Blumberg SJ (2015) Estimated prevalence of autism and other developmental disabilities following questionnaire changes in the 2014 National Health Interview Survey. *Natl Health Stat Report* 13:1-20.

31. Visser SN, Danielson ML, Bitsko RH, Holbrook JR, Kogan MD, et al. (2014) Trends in the parent-report of health care provider-diagnosed and medicated attention-deficit/hyperactivity disorder: United States, 2003-2011. *J Am Acad ChildAdolesc Psychiatry* 53:34-46.e2. [Crossref]

32. Cortiella C, Horowitz SH (2014) The State of Learning Disabilities: Facts, Trends and Emerging Issues. National Center for Learning Disabilities, New York:.

33. Cornwall W (2015) Autism rates are up, but is it really on the rise? *Science Magazine*.

34. Landrigan PJ (2010) What causes autism? Exploring the environmental contribution. *Curr Opin Pediatr* 22: 219-225.[Crossref]

35. Nevison CD (2014) A comparison of temporal trends in United States autism prevalence to trends in suspected environmental factors. *Environ Health* 13: 73.[Crossref]

36. Shaw CA, Seneff S, Kette SD, Tomljenovic L, Oller JW Jr, et al. (2014) Aluminum-induced entropy in biological systems: implications for neurological disease. *J Toxicol* 2014: 491316.[Crossref]

37. Sealey LA, Hughes BW, Sriskanda AN1, Guest JR1, Gibson AD1, et al. (2016) Environmental factors in the development of autism spectrum disorders. *Environ Int* 88: 288-298.[Crossref]

38. http://www.hrsa.gov/vaccinecompensation/data.html (Accessed 20 June 2016).

39. Holland M, Conte L, Krakow R, Colin L (2011)Unanswered questions from the Vaccine Injury Compensation Program: A review of compensated cases of vaccine-induced brain injury. *Pace Envtl L Rev* 28:480.

40. Doja A, Roberts W (2006) Immunizations and autism: a review of the literature. *Can J Neurol Sci*33: 341-346.[Crossref]

41. Price CS, Thompson WW, Goodson B, Weintraub ES, Croen LA, et al. (2010) Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics* 126: 656-664.[Crossref]

42. DeStefano F, Price CS, Weintraub ES (2013) Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. *J Pediatr* 163:561-567. [Crossref]

43. McNeil MM, Gee J, Weintraub ES, Belongia EA, Lee GM, et al. (2014) The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine* 32: 5390-5398. [Crossref]

44. Taylor LE, Swerdfeger AL, Eslick GD (2014) Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. *Vaccine* 32: 3623-3629. [Crossref]

45. Jain A, Marshall J, Buikema A, Bancroft T, Kelly JP, et al. (2015) Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. *JAMA* 313: 1534-1540.[Crossref]

46. Gerber JS, Offit PA (2009) Vaccines and autism: a tale of shifting hypotheses. *Clin Infect Dis* 48: 456-461.[Crossref]

47. Choi BK, Manning ML (2010) The immunization status of home-schooled children in America. *J Pediatr Health Care* 24: 42-47.[Crossref]

48. Ray BD (2010) Academic achievement and demographic traits of homeschool students: a nationwide study. *J Acad Leadership* 8: 1.

49. https://www.census.gov/library/publications/time-series/statistical_abstracts.html (Accessed 19 August 2016).

50. http://files.eric.ed.gov/fulltext/ED505409.pdf (Accessed 22 August 2016).

51. http://nces.ed.gov/pubs2006/2006042.pdf (Accessed 22 August 2016).

52. http://eric.ed.gov/?id=ED544174 (Accessed 22 August 2016).

53. Surén P, Bakken IJ, Aase H, Chin R, Gunnes N, et al. (2012) Autism spectrum disorder, ADHD, epilepsy, and cerebral palsy in Norwegian children. *Pediatrics* 130: e152-158. [Crossref]

54. Zocchetti C, Consonni D, Bertazzi PA (1997) Relationship between prevalence rate ratios and odds ratios in cross-sectional studies. *Int J Epidemiol* 26: 220-223.[Crossref]

55. Goldman GS, Miller NZ (2012) 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. *Hum ExpToxicol* 31:1012-1021. [Crossref]

56. Orenstein WA, Perry RT, Halsey NA (2004)The clinical significance of measles: a review. *J Infect Dis* 189:S4-S16. [Crossref]

57. CDC (2013) Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). Recommendations and Reports. *MMWR* 62:1-34.

58. Dhooge IJ (2003) Risk factors for the development of otitis media. *Curr Allergy Asthma Rep* 3: 321-325. [Crossref]

59. Siegel RM (2010) Acute otitis media guidelines, antibiotic use, and shared medical decision-making. *Pediatrics* 125:384-386. [Crossref]

60. Casselbrant ML, Mandel EM (2003) Epidemiology. Evidence-based otitis media. BC Decker, Hamilton, ON, Canada. Pp. 147–162.

61. Monasta L1, Ronfani L, Marchetti F, Montico M, VecchiBrumatti L, et al. (2012) Burden of disease caused by otitis media: systematic review and global estimates. *PLoS One* 7: e36226.[Crossref]

62. Ahmed S1, Shapiro NL, Bhattacharyya N (2014) Incremental health care utilization and costs for acute otitis media in children. *Laryngoscope* 124: 301-305.[Crossref]

63. http://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&SYMPTOMS[]=Otitis+media+%2810033078%29&NUMDAYS[]=0&NUMDAYS[]=1&NUMDAYS[]=2&NUMDAYS[]=3&NUMDAYS[]=4&NUMDAYS[]=5&NUMDAYS[]=6&NUMDAYS[]=7&WhicAge=range&LOWAGE=0.0&HIGHAGE=1.0) (Accessed 25 August, 2016).

64. Revai K, McCormick DP, Patel J, Grady JJ, Saeed K, et al. (2006) Effect of pneumococcal conjugate vaccine on nasopharyngeal bacterial colonization during acute otitis media. *Pediatrics* 117:1823–1829. [Crossref]

65. Faden H, Harabuchi Y, Hong JJ (1994) Epidemiology of Moraxella catarrhalis in children during the first 2 years of life: relationship to otitis media. *J Infect Dis* 169: 1312-1317. [Crossref]

66. Weinberger DM, Malley R, Lipsitch M (2011) Serotype replacement in disease after pneumococcal vaccination. *Lancet* 378:1962-1973. [Crossref]

67. Biesbroek G, Wang X, Keijser BJ, Eijkemans RM, Trzcinski K, et al. (2014) Seven-valent pneumococcal conjugate vaccine and nasopharyngeal microbiota in healthy children. *Emerg Infect Dis* 20: 201-210.

68. Goldin RL, Matson JL (2016) Premature birth as a risk factor for autism spectrum disorder. *Dev Neurorehabil* 19: 203-206.[Crossref]

69. Padilla N, Eklöf E, Mårtensson GE, Bölte S, Lagercrantz H, et al. (2015) Poor brain growth in extremely preterm neonates long before the onset of autism spectrum disorder symptoms. *Cereb Cortex* 27: 1245-1252. [Crossref]

70. Short ME, Goetzel RZ, Pei X, Tabrizi MJ, Ozminkowski RJ, et al. (2009) How accurate are self-reports? Analysis of self-reported health care utilization and absence when compared with administrative data. *J Occup Environ Med* 51:786-796. [Crossref]

71. Fisker AB, Hornshøj L, Rodrigues A, Balde I, Fernandes M, et al. (2014) Effects of the introduction of new vaccines in Guinea-Bissau on vaccine coverage, vaccine timeliness, and child survival: an observational study. *Lancet Glob Health* 2:e478-e487.

Kubota Y. Association of measles and mumps with cardiovascular disease: the Japan Collaborative Cohort (JACC) study 2015

> "Measles and mumps infections were associated with decreased risks of mortality from cardiovascular disease."

Cramer D. Mumps and ovarian cancer: modern interpretation of an historic association 2010

> "Our study suggests...unanticipated long-term anticancer benefits of a mumps infection."

Morfin F. Detection of measles vaccine in the throat of a vaccinated child 2002

> "...the vaccine virus was isolated in the throat, showing that subcutaneous injection of an attenuated measles strain can result in respiratory excretion of the virus."

Kaic B. Spotlight on measles 2010: excretion of vaccine strain measles virus in urine pharyngeal secretion of a child with vaccine associated febrile rash illness, Croatia, March 2010

Trier H. Duration of immunity and occurrence of secondary vaccine failure following vaccination against measles, mumps, rubella.

> "If wild virus can be spread via individuals with subclinical infections, it is doubtful whether population immunity (herd immunity) ...can be attained in large populations."

Warfel J. Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model 2014

> "Our results suggest that in addition to the potential contribution of reduced efficacy and waning immunity of the acellular pertussis vaccine, its inability to prevent colonization and transmission provides a plausible explanation for pertussis resurgence."

Cost of Vaccine Injuries to the State of Colorado

Cassie Miller

From 1990 to 2019, there were 9,296 events recorded in Colorado in the Vaccine Adverse Event Reporting System (VAERS). 684 of those events were considered serious (death, disability, hospitalization).

Found 684 cases where Location is Colorado and Serious and Vaccination Date from '1990-01-01' to '2019-12-31'

Table

Location	Event Category	Serious	Count	Percent
Colorado	Death	Yes	61	8.92%
	Death	total	61	8.92%
	Permanent Disability	Yes	133	19.44%
	Permanent Disability	total	133	19.44%
	Office Visit	Yes	21	3.07%
	Office Visit	total	21	3.07%
	Emergency Room	Yes	393	57.46%
	Emergency Room	total	393	57.46%
	Emergency Doctor/Room	Yes	22	3.22%
	Emergency Doctor/Room	total	22	3.22%
	Hospitalized	Yes	480	70.18%
	Hospitalized	total	480	70.18%
	Hospitalized, Prolonged	Yes	31	4.53%
	Hospitalized, Prolonged	total	31	4.53%
	Recovered	Yes	337	49.27%
	Recovered	total	337	49.27%
	Life Threatening	Yes	151	22.08%
	Life Threatening	total	151	22.08%
	total		1629	238.16%
TOTAL			† 1629	† 238.16%

Type of Injury	Number	Approximate Cost	Total Cost
Deaths	61	$9,200[1]	$561,000
Permanent Disabilities	133	$1,200,000[2]	$159,600,000
ER Visits	393	$3,000	$1,179,000
Hospitalized	480	$10,000	$4,800,000
			$166,140,000

That is a very rough estimate of $166,140,000 over the course of 30 years or $5,538,000 per year as a result of vaccine injuries.

1. Most deaths were SIDS deaths. Approximation is based off the average costs of an ambulance, ER visit, and autopsy.
2. Approximation is based off a study by David Mandell at the Center for Mental Health Policy and Services Research looking at the lifetime costs of caring for an autistic child. They found the average to be from $1.4 million to $2.4 million and this includes lost wages for parents and child, adult residential care, and costs of special education to the public school system. I divided this by 50 years since that is the average life expectancy of a person with autism and then spread it over 30 years.

Doctors are not taught to look for or recognize vaccine injuries and most do not even know there is a system to report injuries to. As a result there is a serious lack of knowledge about exactly how many people are being injured every year by vaccines. In 2007, the CDC funded a study by Harvard Pilgrim Health Care for three years involving 715,000 patients that found **"fewer than 1% of vaccine adverse events are reported".**

If we extrapolate those numbers, **we are looking at a cost of $16.6 billion over the course of 30 years or $553.8 million dollars per year.**

HEALTH IMPACT NEWS
News that Impacts Your Health that Other Media Sources May Censor!

April 10, 2019

Print This Post

MMR Vaccine Fraud: Why Aren't Government Health Officials Talking About Mumps Outbreaks which Far Exceed Measles Outbreaks?

MMR Vaccine's Poison Pill: Mumps After

Top Stories This Week

Puberty, Reduced Testosterone and Sperm Counts

This article represents Part I of a two-part series on mumps. Part II will delve further into the mumps vaccine's spillover effects on fertility.

By Robert F. Kennedy, Jr., Chairman of the Board
Children's Health Defense

Across the country, frenzied legislators are responding to the pharmaceutical industry's orchestrated fear campaign around measles by seeking to impose further mandating of Merck's measles, mumps and rubella (MMR) vaccine.

Although ongoing mumps outbreaks involving thousands of at-risk adolescents and young adults completely dwarf the number of measles cases, no one is covering the mumps story—because it will expose the fact that Merck has been in court for over eight years due to scientists blowing the whistle on Merck's fabrication and falsification of the effectiveness of the mumps component of its MMR vaccine.

Instead of punishing Merck for its chicanery, legislatures are rewarding the company by making it impossible to refuse Merck's profitable vaccine, subjecting a generation of American children to the risk of serious complications from mumps infection at an age that nature never intended.

When younger children experience mumps, the virus is relatively harmless; infected children often exhibit no symptoms.

When mumps strikes adolescents or adults, on the other hand, the infection can cause far more serious adverse effects, including inflammation of various organs (brain, pancreas, ovaries and testicles)—as well as damage to male fertility.

Inflammation of one or both testicles (a condition called orchitis) occurs in approximately one in three post-pubertal men who get mumps and can contribute to sperm defects and subfertility as well as impairing the function of cells that produce testosterone.

An estimated 30% to 87% of men with bilateral orchitis induced by mumps experience full-blown infertility—a major cause for concern given the significant declines in male fertility observed over the past several decades.

Thus, it appears that Merck's vaccine, instead of protecting children, not only delays onset of disease to later age cohorts but has the potential to cause serious and permanent injury.

Merck and mumps vaccines

Harvard Immunologist to Legislators: Unvaccinated Children Pose ZERO Risk to Anyone

8,913 Views

Medical Doctor: Blood of Every Vaccine Injured or Killed Child on Hands of Murder-by-Vaccine Pediatricians

4,368 Views

100 Percent of Oat Products Tested Positive for Weedkiller Glyphosate

4,053 Views

Children's Hospital Los Angeles Doctor Experimenting on

(FDA) licensed Merck's initial mumps-only vaccine in 1967.

In 1971, Merck introduced its first combination MMR vaccine, followed by the MMR-II vaccine in 1978 (which repurposed the rubella component) and the MMR-plus-varicella (MMRV) ProQuad vaccine in 2005.

Since the initial 1967 vaccine, Merck has enjoyed a unique monopoly position in the U.S. market for mumps and MMR vaccines, with combined sales of MMR-II and ProQuad bringing in over $720 million in 2014 alone.

Merck consistently places in the top five pharmaceutical companies globally, and the market valued its stocks at a seven-year high as of late 2018.

In order to score the lucrative MMR monopoly, Merck needed to satisfy the FDA that all three components of the combination vaccine could achieve 95% efficacy, but the mumps portion was bedeviling.

In fact, as alleged in a lawsuit filed by two senior Merck scientists in 2010 under the False Claims Act, the company has known since the late 1990s that the mumps component of the MMR is "far less" than 95% effective.

A 2005 study published in *Vaccine* estimated the effectiveness of mumps vaccination to be closer to 69%, and the authors noted that their results were consistent with other studies.

The two whistleblowers assert in the lawsuit—which is reportedly headed to trial sometime this year—that Merck has "willfully and illegally maintained its monopoly" through "ongoing manipulation" and by "representing to the public and government agencies a falsely inflated efficacy rate for its Mumps Vaccine."

Specifically, the two scientists claim that Merck executives ordered them to use "rigged" methodologies, including taking antibodies from rabbits and adding them to human blood vials, in order to gull regulators into assuming an antibody response robust and durable enough to merit licensing. When those "enhanced" tactics did not achieve Merck's "fabricated [95%] efficacy rate," the whistleblowers allege, the company resorted to simply falsifying the test data and engaging in other fraudulent activities.

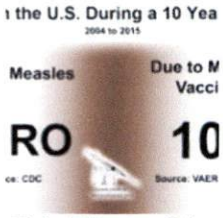
Unprotected adolescents and young adults

The poor performance of the MMR's mumps component and the doubtful "durability" of mumps-specific immunity following vaccination are of concern.

In fact, we are already living with the legacy of this badly flawed vaccine.

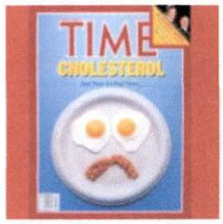
as 8 for Transgender Therapy with Government Funding

3,420 Views



Side Effects of the Measles Vaccine Include Brain Damage and Death

2,325 Views



The Reason Big Pharma and Big Food Want You to Think Eggs are Bad – And Why They Are Not

1,759 Views

Japan has the

Rather than protecting a generation of American children from mumps infection in childhood, the vaccine has merely postponed the onset of the virus to older age groups, putting them at much greater risk.

Researchers confirm an increase in the median age of mumps patients, a surge in the size and number of mumps outbreaks in highly vaccinated populations and higher rates of complications—including orchitis.

Across the country, galloping mumps epidemics have been ravishing an older generation of vaccinated individuals.

The Centers for Disease Control and Prevention (CDC) reported 150 outbreaks (9,200 cases) in the year and a half from January 2016 to June 2017, affecting "schools, universities, athletics teams and facilities, church groups, workplaces, and large parties and events."

Over the past several years, the number of college campuses reporting mumps outbreaks has exploded—at institutions ranging from Harvard and Temple to Syracuse, Louisiana State and Indiana universities.

At the University of Missouri, which in 2016 reported 193 mumps cases on campus, the health center director reported not having seen anything like it "in her 31 years at the school."

Commenting on the fact that all of the afflicted students had had the requisite two doses of MMR, she noted, "The fact that we have mumps showing up in highly immunized populations likely reflects something about the effectiveness of the vaccine."

A naval ship, the USS Fort McHenry, has been unable to come ashore since early January because of a mumps contagion that has devastated its crew—even though the military vaccinates all personnel against the virus and despite the Navy having immediately subjected the crew in question to another MMR booster.

The mumps virus has also made a "comeback" in other settings where younger adults congregate.

Lowest Infant Mortality Rate Following Ban on Mandatory Vaccinations

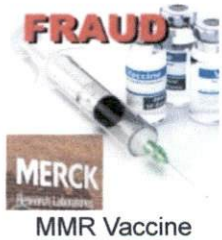
1,719 Views

No, You Don't Have a "Right" to Demand that Others are Vaccinated

1,492 Views

CDC Issues Public Health Warning for Fluoride Toothpaste

1,289 Views



MMR Vaccine Fraud: Why Aren't Government Health Officials Talking About Mumps Outbreaks which Far Exceed Measles Outbreaks?

1,283 Views

For example, a naval ship deployed to the Persian Gulf, the USS Fort McHenry, has been unable to come ashore since early January because of a mumps contagion that has devastated its crew—even though the military vaccinates all personnel against the virus and despite the Navy having immediately subjected the crew in question to another MMR booster.

News accounts have declined to comment on mumps complications but describe the quarantine as "a morale killer" for crew members who are accustomed to having monthly port calls.

Infection control protocols stipulate that the Navy cannot declare the situation "under control" until "50 days after the last affected service member recovers."

Endangering rather than protecting youth

All of these cohorts are part of an age group that should never get mumps. As Children's Health Defense recently noted, whereas "flares of illness in vaccinated groups should prompt some serious questions about *vaccine failure*," legislators and government agencies "are displaying a dangerous indifference to vaccination's unintended consequences."

Dancing to puppet strings manipulated by Merck, legislators across the country are trying to foist even harsher MMR mandates on unwilling Americans, dooming a generation of children to the serious risks of late-onset mumps infections.

Read the full article at ChildrensHealthDefense.org.

Want to learn more from Children's Health Defense? Sign up for free news and updates from Robert F. Kennedy, Jr. and the Children's Health Defense. Your donation will help to support them in their efforts.

Comment on this article at VaccineImpact.com**.**

MERCOLA
Take Control of Your Health

Unvaccinated Americans Barred From Public Spaces?

Written by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE

- March 27, 2019, Rockland County, New York barred any infant, child or teen under the age of 18 who is not vaccinated against measles from entering "public places" until the state of emergency is lifted in 30 days or until they get an MMR shot
- April 5, 2019, a Rockland County judge lifted the state of emergency, saying the number of measles cases did not meet the legal requirement for an emergency order
- There's a growing push for health care providers in the U.S. and Canada to vaccinate minor children without their parents' consent if they feel a child is "mature" enough to make his or her own health risk decisions
- California state Sen. Dr. Richard Pan has introduced a bill to make it even more difficult for children attending day care or school to get a medical vaccine exemption. The bill, SB276, would make the California Department of Public Health the final judge of the validity of all medical exemptions, not the child's physician who has written the exemption
- Since California eliminated the personal belief vaccine exemption in 2015, medical exemptions have risen from 0.2 percent in 2015-16 to 0.7 percent in 2017-18. According to Pan, this tiny rise in medical exemptions among children attending day care and school is putting communities at serious risk for disease outbreaks

The following referenced information contains opinion and perspective on a health topic related to vaccine science, policy, law or ethics that is being discussed in public forums, including in medical, law and other professional journals; newspapers, magazines and other print; broadcast and online media outlets; state legislatures and the U.S. Congress.

Readers are encouraged to go to the websites of the **U.S. Department of Health and Human Services** (DHHS) for the perspective of federal agencies responsible for vaccine research, development, regulation and policymaking, including the **U.S. Centers for Disease Control** (CDC) for information on vaccine policymaking; to the **U.S. Food and Drug Administration** (FDA) for information on regulating vaccines for safety and effectiveness; and to **National Institutes of Health**'s National Institute of Allergy and Infectious Diseases (NIAID) for information on research and the development of new vaccines.

The **World Health Organization** has stated that "vaccine hesitancy" is one of the top 10 global public health threats.

If you had any doubts about growing tyranny in the U.S., several recent news stories should open your eyes to the harsh truth. The U.S. Constitution protects the civil liberties of all Americans, including freedom of thought, speech, conscience, religious belief and the right to dissent and petition the government, as well as the right to assembly.[1,2,3]

Yet these constitutional rights are being infringed upon in remarkably blatant ways these days: Unvaccinated infants, children and teens under the age of 18 are being banned from entering public places in Rockland County, New York; a SWAT team was sent to break down the door of a home in another state where parents were caring for an **unvaccinated child** with a high fever after a doctor reported the child should have been taken to a hospital;

Legislators in several states have introduced bills to suspend the legal right of parents to make medical risk decisions for their minor children and allow doctors instead to get "informed consent" from the young children themselves; a pediatrician politician in California is lobbying for a law that will give state health department officials the power to deny a medical exemption written by a child's physician.

The times we live in are as surreal as they are terrifying, and clearly demonstrate that unless we stand together to protect the rights of ALL, and not just select groups who agree with the status quo, we are all in jeopardy. Even if you are not affected right now by the **forced vaccination** dragnet sweeping across the nation, rest assured, in time you will be caught in its net as well if in the future you decline even one of the dozens of government recommended vaccinations for yourselves or your children.

Unvaccinated Children in New York Suburb Barred From Public Places

Perhaps the most egregious example of the "boiled frog" game currently being played to see how apathetic and compliant Americans are when their constitutional rights are stripped away, was the Rockland County, New York, ban on unvaccinated children. As of March 27, 2019, anyone under the age of 18 who is not vaccinated against measles was barred from entering "public places,"[4,5] defined as:[6]

> *"[A] place where more than 10 persons are intended to congregate for purposes such as civic, governmental, social, or religious functions, or for recreation or shopping, or for food or drink consumption, or awaiting transportation, or for daycare or educational purposes, or for medical treatment.*
>
> *A place of public assembly shall also include public transportation vehicles,*

including but not limited to, publicly or privately owned buses or trains, but does not include taxi or livery vehicles."

Considering "public places" includes just about any space outside the domain of your private home, unvaccinated infants, children and teens were essentially being placed under what closely resembles house arrest. Parents whose unvaccinated child was caught in a public place faced six months in jail or a $500 fine.[7]

Children with state-approved medical exemptions were exempted from the ban, but not those with religious exemptions. Schools were also barred from allowing unvaccinated students from attending, unless they have an approved medical exemption. Within the first four days of the ban, nearly 500 MMR vaccinations were administered.[8]

Fortunately, on April 5, a Rockland County judge lifted the state of emergency, saying the number of measles cases did not meet the legal definition of an epidemic required for an emergency order declaration.[9] Judge Rolf Thorsen also stated that unvaccinated children are "hereby permitted to return to their respective schools forthwith and otherwise to assemble in public places."[10]

Rockland County has a large orthodox and Hasidic Jewish community, a portion of which declines a number of vaccines for religious reasons. (One commonly cited religious objection is that some vaccines use DNA proteins from aborted fetal cells and rubella vaccine in the MMR shot was created using aborted fetal cells.)

County commissioner of health Dr. Patricia Schnabel Ruppert said they've had "excellent cooperation from the [orthodox Jewish] community,"[11] with many rabbis urging their congregations to vaccinate their children.

To learn why the forced vaccination campaign is more about Big Pharma profit-making than protecting public health, see "**Why Herd Immunity Is a Hoax**." You can also find

more information about measles and why the hype about the infection's risks is being overblown in "**Measles Propaganda Can Have Dire Public Health Ramifications**."

The Push to Eliminate Parental Right to Protect the Welfare of Minor Children

In related news, there's a growing push for health care providers in the U.S. and Canada to vaccinate minors without their parents' consent if they feel a child is "mature" enough to make his or her own health risk decisions. Timothy Caulfield, a professor of health law and policy at the University of Alberta, told the Calgary Herald:[12]

> "*From an ethical and legal perspective, if they are a competent teenager, then they are the ones you should be having the conversations with ... I would say there is an obligation to revisit this topic [of vaccination] with a patient who has become competent.*"

Calgary Herald continues:[13]

> "*The mature minor doctrine plays out on a case-by-case basis. So, a minor may be competent to make decisions about vaccines, but maybe not open-heart surgery. Still, given vaccines are considered safe, and given that discussions around vaccinations would be relatively straightforward, 'I think it's entirely possible a 13-, 14- or 15-year old would be competent on their own to consent' to the shots, Caulfield said.*"

A Washington, D.C., lawmaker introduced a bill last month to allow minor children of any age to get vaccines in the city without a parent's knowledge or consent after a doctor says a child is "mature" enough to make the decision.[14]

The problem with this reasoning is that vaccines come with risks that can be greater for

some individuals than others and, unlike a mother or father, minor children are not always aware of their own health or vaccine reaction history. Will a doctor truly inform a child and will the child be able to understand?

Just how long of a list of possible side effects are children going to be given when the topic of vaccination comes up?

Is a 13-year-old really capable of deciding whether the risk of Guillain-Barre syndrome, encephalopathy, chronic inflammatory demyelinating polyradiculoneuropathy, **rheumatoid arthritis** or other serious brain and immune system disorders are risks that he or she is willing to take to obtain temporary artificial immunity to a particular infection, if even temporary vaccine-acquired immunity is obtained?

These are among a long list of vaccine injuries for which patients have received compensation from the federal vaccine injury compensation program. For a more extensive list of potential side effects, see "**How Much Do You Really Know About Vaccine Safety?**"

One could easily argue the decision to vaccinate requires far greater critical thinking skills, maturity and careful consideration than weighing the benefits and risks of open-heart surgery.

New York Bill Aims to Strip Parental Consent for Vaccination of Minors

The same "mature minor" doctrine is being more frequently called for in the U.S. as well. As reported by The Vaccine Reaction:[15]

> *"[S]everal states already use the 'mature minor' doctrine to give minors the right to make vaccines decisions and other decisions about medical*

interventions without parental knowledge or consent. So far, the rights of minors to seek and receive vaccination varies from state to state. For example ... Washington has been using the recent outbreak of measles to invoke the mature minor policy.

Similar laws are in place in Alaska, Arkansas, Alaska, Arkansas, Delaware, Idaho, Illinois, Kansas, Louisiana, Maine, Massachusetts, Montana, Nevada, Oregon, Pennsylvania, South Carolina, Tennessee and West Virginia. Expanding that slippery slope, a new bill has been introduced in New York that would permit minors 14 years of age and older to be vaccinated without parental permission ...

State Senator Liz Krueger and Assemblywoman Patricia Fahy have introduced bill S. 4244/A. 6564 proposing to allow children older than age 13 to ask for and receive any of the vaccines in the Public Health Law, which would include poliomyelitis, mumps, measles, diphtheria, rubella, varicella, Haemophilus influenzae type b (Hib), pertussis, tetanus, pneumococcal disease, meningococcal disease and hepatitis B."

Vaccine Package Inserts Debunk 'Safety Across the Board' Claims

Will the doctor giving a vaccine to a child without the parent's knowledge or consent actually read the vaccine package insert to the child, and explain what it all means? As just one example, the 2005 package insert for Sanofi Pasteur's Tripedia vaccine (diphtheria, tetanus and acellular pertussis or DTaP) states:[16,17]

"A review by the Institute of Medicine (IOM) found evidence for a causal relationship between tetanus toxoid and both brachial neuritis and Guillain-

Barré syndrome.

A few cases of demyelinating diseases of the CNS [central nervous system] have been reported following some tetanus toxoid-containing vaccines or tetanus and diphtheria toxoid-containing vaccines, although the IOM concluded that the evidence was inadequate to accept or reject a causal relationship.

Adverse events reported during post-approval use of Tripedia vaccine include idiopathic thrombocytopenic purpura, SIDS, anaphylactic reaction, cellulitis, autism, convulsion/grand mal convulsion, encephalopathy, hypotonia, neuropathy, somnolence and apnea. Events were included in this list because of the seriousness or frequency of reporting.

Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to components of Tripedia vaccine."

According to this insert, Sanofi Pasteur admits SIDS, autism and brain inflammation are all side effects reported after Tripedia DTaP vaccinations and were reported frequently enough to warrant inclusion, even if a causal relationship cannot be established due to the limitations of prelicensure studies and a lack of vaccine adverse event reporting by vaccine providers that was mandated under the National Childhood Vaccine Injury Act of 1986 but is not enforced.

In 2017, DTaP was one of five vaccines ruled by the federal **Vaccine Injury Compensation Program** (VICP) to have caused the death of a 5-month-old baby boy, who died of SIDS within 24 hours of vaccination.[18]

The Tripedia DTaP vaccine also contains a number of bioactive and potentially

hazardous ingredients, including casein, to which some children are allergic; the excitotoxin MSG; thimerosal (mercury) and **aluminum**, both of which are neurotoxic; formaldehyde and **polysorbate 80**.

To say that all vaccines are so safe that parents don't even need to be involved in the vaccine decision-making process is irresponsible in the extreme. It is mothers and fathers, who are legally responsible for their minor children, and they are the ones who will bear the emotional and financial burden if something goes wrong, not the doctor and certainly not the vaccine manufacturer.

Vaccine administrators and manufacturers were effectively shielded from any financial liability for vaccine injuries and deaths by amendments to the 1986 Act and by the U.S. Supreme Court in 2011.

California Legislator Aims to Make It Even More Difficult to Obtain Medical Exemption

As noted by Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center (NVIC) in "**Don't Let Them Frighten You Into Giving Up This Medical Choice**," the Centers for Disease Control and Prevention (CDC) and medical trade organizations have so narrowed the definition of a medical exemption that almost no previous vaccine reaction or health condition is considered a contraindication to vaccination.

More than 99 percent of Americans do not qualify for a medical exemption under federal vaccine guidelines today.

California state Sen. Dr. Richard Pan, Sacramento, who spearheaded the 2015 campaign to eliminate the personal belief vaccination for children attending day care and school,

has now introduced a bill to make it even more difficult to get a medical vaccine exemption in the state. According to Pan, since the removal of the personal belief exemption in California, medical exemptions to vaccination for children have tripled in the state.[19]

"It is clear that a small number of physicians are monetizing their exemption-granting authority and profiting from the sale of medical exemptions," he told ABC News.[20] The new bill, SB276, would make health officials employed by the California Department of Public Health (CDPH) the final judge of the validity of all medical exemptions written by private physicians. As reported by the news station:[21]

> *"Additionally, under SB 276, CDPH will create and maintain a database of medical exemptions, and CDPH and County Health Officers will have the authority to revoke medical exemptions granted by licensed physicians if they are found to be fraudulent or inconsistent with contraindications to vaccination per CDC guidelines.*
>
> *The lawmaker argues the implementation of Senate Bill 277, which abolished the personal belief exemption in California, generated an overall vaccination rate increase to more than 95 percent statewide.*
>
> *Pan says California has also experienced a dramatic increase in the number of medical exemptions. Since the passage of SB 277, the rate of medical exemptions has more than tripled (from 0.2 percent in 2015-16 to 0.7 percent in 2017-18). Low vaccination rates in certain pockets of the state put children and communities at risk."*

Let me repeat that: 0.7 percent of Californian children have received a medical exemption from vaccination, and they now want you to believe this miniscule ratio of unvaccinated children put communities at serious risk for disease outbreaks? At risk of

what, exactly? If all of these vaccines are so effective at protecting against disease, what's the concern?

1 in 168 Children Require Emergency Care After First Round of Vaccinations

In 2015, immunologist Tetyana Obukhanych, Ph.D., wrote an open letter[22] to legislators explaining why children who have not received certain vaccines (specifically IPV, DTaP, HepB, and Hib) pose no risk to others. She also addressed the frequency of serious adverse events, stressing the importance of personal choice in the face of such risks:

> *"It is often stated that vaccination rarely leads to serious adverse events. Unfortunately, this statement is not supported by science. A recent study done in Ontario, Canada, established that vaccination actually leads to an emergency room visit for 1 in 168 children following their 12-month vaccination appointment and for 1 in 730 children following their 18-month vaccination appointment (see appendix for a scientific study, Item #5).*
>
> *When the risk of an adverse event requiring an ER visit after well-baby vaccinations is demonstrably so high, vaccination must remain a choice for parents, who may understandably be unwilling to assume this immediate risk in order to protect their children from diseases that are generally considered mild or that their children may never be exposed to."*

In the lecture above, Obukhanych, who wrote the book "Vaccine Illusion: How Vaccination Compromises Our Natural Immunity and What We Can Do to Regain Our Health," explains how vaccines damage your immune function, which can result in any number of adverse health effects.

Health and Human Services Has Neglected Critical Vaccine Safety Obligations for Decades

The National Childhood Vaccine Injury Act of 1986 granted partial financial immunity to vaccine makers for injuries and deaths caused by their vaccines and, in 2011, the U.S. Supreme Court declared FDA licensed and CDC recommended vaccines to be "unavoidably unsafe" and effectively removed all remaining liability from the multibillion-dollar vaccine industry.

With that liability risk eliminated, so was any incentive to make sure their products are safe. The responsibility to ensure vaccine safety instead falls on the U.S. Health and Human Services (HHS). As reported by AIM Integrative Medicine:[23]

> *"Hence, since 1986, HHS has had the primary and virtually sole responsibility to make and assure improvements in the licensing, manufacturing, adverse reaction reporting, research, safety and efficacy testing of vaccines in order to reduce the risk of adverse vaccine reactions.*
>
> *In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit biennial reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years."*

August 2017, Del Bigtree, founder of Informed Consent Action Network (ICAN) and Robert F. Kennedy Jr., founder of Children's Health Defense, filed a Freedom of Information Act request to the HHS, requesting access to its safety reports.[24] After being stonewalled for eight months, ICAN and Kennedy sued the HHS, demanding copies of the congressional reports to be released.

As noted by ICAN,[25] "provisions of the (1986 Act) ... legally require the HHS to conduct

science that reduces the risk of vaccine injury. Failure to do so could result in legal action against HHS ... HHS has not acted in its duties regarding vaccine safety, forcing 78 million American children into a vaccine program with no safety provisions."

ICAN also recently sued the FDA after the agency failed to respond to FOIA requests for copies of the clinical trials it relied upon when licensing influenza vaccines for pregnant women.

A February 11, 2019 ICAN update[26] reveals "the FDA has not licensed any **influenza vaccine** as an indicated use for pregnant women, let alone conducted or required any pharmaceutical company to conduct any clinical trial which supports the safety of injecting pregnant women with the influenza vaccine."

Refusal of Medical Treatment Treated as a Violent Crime

The last piece of news I'm going to cover here is the Arizona case where a SWAT team with guns drawn used a battering-ram to break down the door to the home of a family whose 2-year-old son had a fever and a doctor reported them to state authorities for failing to take the child to a hospital. As reported by NBC News:[27]

> *"Sarah Beck brought her 2-year-old son to Southwest College of Naturopathic Medicine on Feb. 25 and was told he had a temperature of more than 105 [degrees Fahrenheit], according to reports by the Chandler Police Department.*
>
> *The doctor believed the child could be suffering from a 'life-threatening' illness that could not be tested for at the clinic, so she told Beck to take the toddler to the hospital ... The mother was reluctant because the boy wasn't vaccinated, and she feared 'possible repercussions,' the report said.*
>
> *When the doctor found out later that day the child had never made it to the*

> *hospital, she called the DCS [Department of Child Services], which contacted the Chandler Police Department because 'there was a present danger to (the child's) health/wellbeing and that he required immediate medical attention,' police said."*

The parents insisted the child did not need medical attention as he was recovering and his fever was rapidly coming down. The doctor suspected the child might have meningitis, but it turned out to be respiratory syncytial virus, and the parents appear to have been correct in their assessment that he was not in severe danger.

One could also argue that tyrannical repercussions against those who choose not to vaccinate their children is at fault here, as the parents would probably not have hesitated to take the boy to the hospital had they not been fearful of repercussions — a fear that is well warranted, I might add. This case is a frightening illustration of medical tyranny, where excessive violence is used against parents who disagree with the medical establishment.

In this case, the couple's three children were all removed from the home, and Arizona state Rep. Kelly Townsend, R-Mesa (who has worked on legislation that requires DCS to obtain a search warrant before removing a child) expressed concern that the baby pregnant Sarah is carrying might be taken from them as well "over a misdiagnosis by the doctor."[28]

"I call on DCS to immediately return the children who are also being traumatized due to this misdiagnosis," Townsend said in a statement. "The parents were correct; the doctor was wrong."

Don't Let Them Shut Down the Vaccine Safety Conversation

Again and again, we find that there are big gaps in vaccine science and the most basic

of safety investigations has been neglected or never was performed in the first place. Yet, we are told over and over again that "There is no debate. The science is settled: Vaccines are safe. End of discussion."

If you missed Loe Fisher's commentary on the effort to **shut down the public conversation about health and vaccination**, while calls for "no exceptions" mandatory vaccinations grow stronger, I urge you to read it or watch her video today. Now, more than ever, it is crucial to push this conversation into the broad light of day, because having the right to make our own decisions about medical risk taking such as vaccination is at the very heart of our freedom as individuals.

When government officials can break down your door because you disagree with your doctor, when doctors can sweet-talk your child into getting vaccinated without your child fully understanding the risks, when politicians can ban your children from entering public spaces simply because they're unvaccinated, then you know the end of freedom is very, very near.

The time to take a stand for the rights of everyone, not just the select few, is running out. And remember, once one small group loses its right to autonomy, everyone's right to autonomy will disappear shortly thereafter. Guaranteed. Because that's how tyranny works.

Don't think for a second that just because you believe in vaccination, and you and all of your children have received all your shots, that you're somehow immune from government overreach and tyranny. Before you know it, you may not have a choice in whether you want to take a certain drug or not.

Or the kind of surgical procedure that government health officials tell you that you must get. Or, you might suddenly find yourself part of a group deemed unfit to reproduce and be required to get sterilized "for the greater good" of society.

Who knows where it might end? In time, you may not have the right to choose your education — the government will decide what kind of worker bee they need, and what profession you're best suited for. Or, you may lose your right to marry someone the government does not approve of — if you're granted marital rights at all, that is.

Who's to say such civil and human rights cannot be taken away by certain individuals in control of an authoritarian government? Eliminating the legal right to exercise informed consent to vaccine risk-taking and to decline a vaccination for health reasons or for personal beliefs is a very slippery slope. One thing is for sure: It will not end there.

THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.]

On a side note:
Almost every Dr. Who's articles I've shared has been labeled negatively by Wikipedia
↳ or they used to & No longer exist
Look up Andrew Wakefield

The Problem with Wikipedia and the Digital Revolution

By Dr. Paul Craig Roberts
Global Research, April 11, 2019

Theme: Media Disinformation

Yesterday (April 10, 2019) a reader alerted me to the fact that I am being smeared on Wikipedia as a "vocal supporter of the current Russian government and its policies." The reader also reports that an article in the Daily Beast calls me a "Putin worshiper." The reader says that he tried to edit the Wikipedia entry without success, and he urged me to give it my attention.

I do not know whether the person who wrote my Wikipedia entry intended to smear me or is merely uninformed. However, dissenting voices do get smeared on Wikipedia. It is an ongoing problem for many of us. For years readers and people who know me would make corrections to my Wikipedia biography, but as soon as the corrections were made, they would be erased and the smears reinstalled.

The problem with Wikipedia is that it is an idealistic approach based on the belief that truth is more likely to emerge when everyone has a voice than when explanations are provided by a select group of experts or peers. This idealistic approach is not without merit. Moreover, it might work very well with subjects and people who do not have ideological opponents or are of no threat to those intent on controlling explanations.

The problem arises when a subject or a person is controversial and is especially the case if the person's arguments disprove or dissent from official explanations. In The Matrix in which we live, truth-tellers are unwelcome to those who control the explanations in order to advance their agendas. Until truth-tellers can be silenced or completely censured, the practice is to discredit them with smears. Thus, I and many others have been described as "conspiracy theorists" for reporting factual information that contradicts the official and unproven explanation of 9/11, anti-semites for criticizing Israel's mistreatment of the Palestinians and influence over U.S. foreign policy, and as "Russian agents" or "Putin stooges" for keeping the record straight about Ukraine, Syria, and Putin's effort to avoid military conflict with the West.

In the pre-Internet age it was difficult to smear people. Newspaper editors would allow letters to the editor to correct factual mistakes or to provide a different interpretation of a collection of facts, but shied away from smears. This doesn't mean that smears never happened, but not with the abandon of the Internet era.

Open works in process like Wikipedia, Internet comment sections and social media are ideally suited for smearing people and broadcasting the smears worldwide prior to any correction of them. Thus, the digital revolution has been a godsend to government agencies such as the CIA, State Department, Mossad, the Israel Lobby, corporations and other private interest groups, ideological movements such as neoconservatism and Identity Politics, and politicians, all of whom have agendas that are furthered by controlling the explanations.

As money is the highest value for many people, **there is an unlimited supply of people who can be**

hired to smear those who challenge official explanations. A smear can start in a comment section, move to social media, and from there to a website and on to Wikipedia.

It is truth tellers who are smeared, people such as Julian Assange, Edward Snowden, Manning, and whistleblowers whose messages are inconvenient for powerful private and government interests.

Smears are effective. There is no shortage of gullible and uninformed or misinformed people. They take a smear at face value and avoid the person or idea smeared. Despite the extreme clarity of Julian Assange's orchestrated persecution, many see him as a "rapist escaping justice," "Russian spy," and "a blackmailer of governments and people."

READ MORE: Bernie Sanders' Jewish Outreach Director Suspended for Blunt and Honest Criticism of Netanyahu Government

In short mud sticks better than facts. That is why I am not optimistic about the future of truth in the digital age. Many see the digital age as the era when truth will flourish. I understand their case. Their belief is not without merit. But the digital age is also an age in which lies can flourish because, unlike the print age, they can be so easily spread.

Consider, for example, the description of me as a "vocal supporter of the current Russian government and its policies" and a "Putin worshiper." I am a well known critic of the Russian government's neoliberal economic policies. Michael Hudson and I have jointly criticized the Russian government's neoliberal economic policies and demonstrated that they are harmful to Russia's economy. I am known also as a skeptic of Putin's policy of turning the other check to Washington's and Israel's aggressions. I appreciate and admire Putin's enormous self-control, but I have expressed concern that Putin's unwillingness to put down a hard foot fails to turn away wrath and instead encourages more aggression that sooner or later will result in thermonuclear war.

The Russian government is aware of my position, as is the Russian media where I am often interviewed. My position is also clearly expressed on my website, which is read internationally. So why does the Daily Beast and Wikipedia misrepresent my position?

Wikipedia and comment sections can work only if commentators are responsible people who are carefully monitored by knowledgable and responsible monitors. But this takes us back to peer-reviewed explanations that Wikipedia was created to avoid.

Historically, messengers are killed, so truth tellers have to expect smears or worse–Julian Assange was arrested this morning inside the Ecuadoran embassy in London. Mankind is fallen. Governments do evil. The most evil is done to those who oppose evil. Truth cannot be told without cost to he who tells the truth.

When I speak of truth-tellers, I am speaking of people whose motive is to tell the truth. Truth is their agenda. I am not saying that truth tellers are infallible and always right. I am saying that they strive to be. They do not intentionally write falsehoods and mislead.

Truth is not opinion. It is pointless to tell a truth teller that you disagree with him. You can present a case that his facts are wrong. You can present a case that there is a better explanation of the facts.

In my experience when most people say they disagree, they mean that they prefer another explanation that is more congenial to their feelings and emotions. For example, many Americans believed the preposterous Russiagate fib because they dislike Trump, just as today conservative talk radio has adopted the official explanation of 9/11 because it can be used against the outspoken female Muslim member of Congress. The facts have nothing to do with either belief. In both cases, the facts are resisted because the truth is not as emotionally comforting or as useful for the agenda at hand as the lie.

I have no objection if readers undertake to monitor and correct the account presented of me in Wikipedia. It will be an ongoing process, and will require the commitment of many of you. Those behind the attacks on me have a lot of money and a lot of hirelings, and they can erase your work as soon as you finish.

The digital revolution and the control mechanisms it provides makes it far more likely that we will end up in a locked down dystopia than would ever have been possible in the print age. But the digital revolution represents perhaps an even greater threat to humanity. It is making humans redundant.

What are humans to do when everything is automated? If the tech nerds have their way, we soon won't

be allowed to drive cars.

What will humans do when there is no need for their labor? Boston Dynamics, a Waltham Massachusettes company, has come up with a robot that replaces warehouse workers. The prediction is that 40 million more Americans will be shoved out of the workforce by robots over the next ten years.

Has anyone thought about who is going to be employed and have the money to purchase the products of robots? No doubt we will be promised all kinds of new and better jobs like we were promised to take the place of the offshored manufacturing and professional service jobs. The promised jobs never showed up. And no, this is not a luddite argument. Everyone can't be employed designing robots to replace humans.

Each warehouse will rush to increase its profits by laying off employees, and none will consider the aggregate effect on consumer demand for the products in the warehouses. Will the warehouses have to give back their gained profits in taxes to support the unemployed? Will the warehouses have any profits if people haven't income from jobs with which to buy the products in the warehouses? Does the robot age mean profits have to be socialized in order to sustain human life?

An intelligent approach to technology would be to focus on technology that enhances human performance, not on technology that eliminates the need for humans.

At Stanford University technology has emerged, or is emerging, that permits real time changes in the movements of a person's mouth as he speaks in order to broadcast a message different than the one the speaker is speaking. The mischief possible with this technology is unacceptable. Television could destroy any unwelcome politician or leader by showing him delivering a message designed to destroy him. If people catch on, it would mean the end of televised speeches as no one would believe any speech unless they were present in person.

People already find it challenging to comprehand reality. The emergence of technology capable of falsifying reality in real time presages a future in which fact and fiction become indistinguishable. The unintended consequence of this technology may well be the death of truth.

*

Note to readers: please click the share buttons below. Forward this article to your email lists. Crosspost on your blog site, internet forums. etc.

This article was originally published on the author's blog site: Paul Craig Roberts Institute for Political Economy.

***Dr. Paul Craig Roberts** is a frequent contributor to Global Research.*

Related Articles

Emotion Is Supplanting Evidence as the Basis for Truth
Sep 22, 2018

Wikipedia: Our New Technological McCarthyism
May 2, 2018

How Facebook, Etc., Suppress Key Truths
May 1, 2018