March 30th, 2017

President Donald J. Trump The White House 1600 Pennsylvania Avenue, NW Washington, DC 20500

Dear Mr. President:

We, the undersigned physicians, scientists, and organizations, write to express our strong support for an independent Vaccine Safety Commission comprised of stakeholders from the public health, scientific, and consumer advocacy communities. Given that the rates of chronic childhood conditions, including neurodevelopmental disorders such as autism, have increased dramatically, it is imperative that we convene an unbiased commission to study vaccine safety and establish whether or not our expanding vaccination schedule is contributing to the significant rise of serious health problems in the United States.

An independent Vaccine Safety Commission is necessary due to allegations of scientific misconduct from within the government agency, Centers for Disease Control and Prevention, which is responsible for vaccine recommendations. CDC scientist William Thompson, Ph.D., stated: "I regret that my coauthors and I omitted statistically significant information" related to specific risks of the MMR vaccine.<sup>1</sup> Furthermore, a dozen anonymous CDC scientists recently formed an organization, Scientists Preserving Integrity, Diligence and Ethics in Research (SPIDER), which contends that while most of the scientists at CDC operate with the utmost integrity and ethics, "some staff are intimidated and pressed to do things they know are not right," and that circumventing the mission and the Congressional intent for the agency "is becoming the norm and not the rare exception."<sup>2</sup>

We are convinced that the science on vaccine safety is not settled. In fact, science, which is a process of inquiry rather than demonstration, is never settled. It is very likely that the causes of neurodevelopmental and neuroimmune disorders are numerous and synergistic. It is biologically plausible that vaccines or vaccine ingredients are among contributing factors. There is an emerging body of peer-reviewed biomedical research relevant to vaccine safety concerns, suggesting: a) deleterious effects of immune activation on prenatal and neonatal brain development, which is when some vaccines are administered; b) neurotoxic and neuroinflammatory potential of aluminum adjuvant-containing vaccines; and c) risks of acetaminophen exposure during pregnancy, neonatal development, as well as postvaccination. This body of research provides a strong rationale for re-examining the safety of prenatal and childhood vaccination recommendations and adjunct medications in relation to long-term outcomes in children's health. We have attached an addendum with some of the studies representing each of these important areas of research.

 $<sup>^{1}\</sup> https://morganverkamp.com/statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/$ 

<sup>&</sup>lt;sup>2</sup> https://usrtk.org/wp-content/uploads/2016/10/CDC\_SPIDER\_Letter-1.pdf

Mr. President, we welcome an independent Vaccine Safety Commission that will collect and review all of the available scientific evidence, recommend further vaccine safety studies, and help shape public health policy that prioritizes the health of the American people.

Sincerely,

Paul Thomas, MD, FAAP, ABIHM Adrienne Carmack, MD Aimee Stotz, DO Alan Ross, MD Alex Zaphiris, MD Alisa Roberts, DO Alon Gitig, MD Alvin H. Moss, MD Andrea Young, DO Andrew David Shiller, MD Andrew M. Goldman, DO Andrew Wakefield, MD Anette K. S. Mnabhi, DO Ann M. Sousa, DO Anna Lups, MD Anthony Capobianco, DO Anthony Phan, MD Arash Jacob, DO Ashok Patel, MD Barbara Mitchell, MD Beth McDougal, MD Bose Ravenel, MD Branko Furst, MD Brian S. Hooker, PhD Brittany Lyons, DO Bryon Tarbet, PhD Carmen Hering, MD Carol Squyers, MD Caroline Schier, MD Carolyn Brooks, MD Catherine Fehrmann, MD Cathie Lippman, MD Chantelle Baldwin, DO Charles Beck. DO Charles W. Barnes, MD Christina Steele, DO Christopher Brown, DO Cilla Whatcott, PhD

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#### **Organizations:**

Age of Autism Alliance for Human Research Protection Association of American Physicians and Surgeons Autism Action Network Autism Is Medical Children's Medical Safety Research Institute Focus For Health **Generation Rescue** Health Choice Health Freedom Action Connecticut Health Freedom Idaho Maine Coalition for Vaccine Choice Mississippi Health Care Professionals for Informed Consent Moms Across America National Vaccine Information Center **Oregonians for Medical Freedom** People Advocating Vaccine Education, Inc.

The Canary Party The Weston A. Price Foundation The Westreich Foundation Vermont Coalition for Vaccine Choice Vermont Coalition for Vaccine Choice/Voices for Choice Virginia Autism Project Virginians for Medical Freedom West Virginians for Health Freedom

#### Addendum

## Immune Activation During Prenatal and Neonatal Development

Studies	Quotes
Neonatal vaccination with bacillus Calmette–Guérin and hepatitis B vac- cines modulates hippocampal synaptic plasticity in rats. Li et al., J Neuroimmunol, Vol. 288, 2015	"Immune activation can exert multiple effects on synaptic transmission. Our study demonstrates the influence of neonatal vaccination on hippocampal synaptic plasticity in rats under normal physiological conditions. The results revealed that neo- natal BCG vaccination enhanced synaptic plasticity. In contrast, HBV hampered it."
PMID: 20531088	Sur work highlights a critical role of neonatal vaccination in synaptic plasticitywhich suggests the necessity of further stud- ies on the association of vaccination with brain development."
Maternal immune activation yields off- spring displaying mouse versions of the three core symptoms of autism.	"Maternal immune activation (MIA) yields male offspring with deficient social and communicative behavior, as well as high levels of repetitive behaviors, all of which are hallmarks of au- tism."
Malkova et al., Brain Behav Immun, Vol. 26, 2012	
PMID: 22310922	
Activation of the maternal immune sys- tem during pregnancy alters behavioral development of rhesus monkey off- spring.	"In this rhesus monkey model, MIA yields offspring with abnor- mal repetitive behaviors, communication, and social interac- tions. These results extended the findings in rodent MIA models to more human-like behaviors resembling those in both autism and schizophrenia."
Bauman et al., Biol Psychiatry, Vol. 75, 2014	
PMID: 24011823	
Maternal immune activation in nonhu- man primates alters social attention in juvenile offspring.	"The use of noninvasive eye tracking extends the findings from rodent MIA models to more human-like behaviors resembling those in both autism spectrum disorder and schizophrenia."
Machado et al., Biol Psychiatry, Vol. 77, 2015	
PMID: 25442006	
Impaired synaptic development in a ma- ternal immune activation mouse model of neurodevelopmental disorders.	"Our results suggest that a possible altered inflammatory state associated with maternal immune activation results in impaired synaptic development that persists into adulthood but which can be prevented with early anti-inflammatory treatment."
Coiro et al., Brain Behav Immun, Vol. 50, 2015	
PMID: 26218293	

"Central nervous system inflammation during critical stages of childhood development could disrupt the balance needed for neurophysiological actions of immune processes, producing di- rect, pernicious effects on memory, neural plasticity and neuro- genesis into adulthood."
"maternal immune activation during late gestation predispose the offspring to increased neuroinflammation and potentiate the autoimmune response and clinical manifestation of EAE." Note: EAE = experimental autoimmune encephalomyelitis

# Aluminum Vaccine Adjuvant and Neurotoxicity/Neuroinflammation

Studies	Quotes
Non-linear dose-response of alumini- um hydroxide adjuvant particles: Se- lective low dose neurotoxicity. Crépeaux et al., Toxicology, Vol. 375, 2017 PMID: 27908630	"Aluminium (Al) oxyhydroxide (Alhydrogel®), the main adjuvant licensed for human and animal vaccines, consists of primary nanoparticles that spontaneously agglomerate. Concerns about its safety emerged following recognition of its unexpectedly long-lasting biopersistence within immune cells in some indi- viduals, and reports of chronic fatigue syndrome, cognitive dys- function, myalgia, dysautonomia and autoimmune / inflammatory features temporally linked to multiple Al- containing vaccine administrations."
	"Alhydrogel® injected at low dose in mouse muscle may selec- tively induce long-term Al cerebral accumulation and neurotoxic effects."
Slow CCL2-dependent translocation of biopersistent particles from muscle to brain. Khan et al., BMC Med, Vol. 11, 2013 PMID: 23557144	<ul> <li>"Intramuscular injection of alum-containing vaccine was associated with the appearance of aluminum deposits in distant organs, such as spleen and brain where they were still detected one year after injection."</li> <li>"alum has high neurotoxic potential, and planning administration of continuously escalating doses of this poorly biodegradable adjuvant in the population should be carefully evaluated by regulatory agencies since the compound may be insidiously unsafe."</li> </ul>
Administration of aluminium to neona- tal mice in vaccine-relevant amounts is associated with adverse long term neu- rological outcomes. Shaw et al., J Inorg Biochem, Vol. 128, 2013 PMID: 23932735	"Injections of a "high" and "low" Al adjuvant levels were de- signed to correlate to either the U.S. or Scandinavian paediatric vaccine schedules vs. control saline-injected mice. Both male and female mice in the "high Al" group showed significant weight gains following treatment up to sacrifice at 6 months of age. Male mice in the "high Al" group showed significant changes in light-dark box tests and in various measures of behaviour in an open field. Female mice showed significant changes in the light-dark box at both doses, but no significant changes in open field behaviours. These current data implicate Al injected in ear- ly postnatal life in some CNS alterations"
Aluminum hydroxide injections lead to motor deficits and motor neuron de- generation. Shaw et al., J Inorg Biochem, Vol. 103,	"Aluminum-treated mice showed significantly increased apop- tosis of motor neurons and increases in reactive astrocytes and microglial proliferation within the spinal cord and cortex." "Behavioural analyses in these mice revealed significant im-
PMID: 19740540	"The demonstrated neurotoxicity of aluminum hydroxide and its relative ubiquity as an adjuvant suggest that greater scrutiny by the scientific community is warranted."

Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. Petrik et al., Neuromolecular Med, Vol. 9, 2007 PMID: 17114826	"Behavioral testing showed motor deficits in the aluminum treatment group." "Aluminum-treated groups also showed significant motor neu- ron loss (35%) and increased numbers of astrocytes (350%) in the lumbar spinal cord."
Behavioral abnormalities in female mice following administration of alu- minum adjuvants and the human papil- lomavirus (HPV) vaccine Gardasil. Inbar et al., Immunol Res, 2016 [Epub ahead of print] PMID: 27421722	"Vaccine adjuvants and vaccines may induce autoimmune and inflammatory manifestations in susceptible individuals. To date most human vaccine trials utilize aluminum (Al) adjuvants as placebos despite much evidence showing that Al in vaccine- relevant exposures can be toxic to humans and animals." "It appears that Gardasil via its Al adjuvant and HPV antigens has the ability to trigger neuroinflammation and autoimmune reactions, further leading to behavioral changes."

## Acetaminophen Exposure during Prenatal and Neonatal Development, or Post-Vaccination

Studies	Quotes
Acetaminophen (paracetamol) use, measles-mumps-rubella vaccination, and autistic disorder: the results of a parent survey.	"This preliminary study found that acetaminophen use after measles-mumps-rubella vaccination was associated with autistic disorder."
Shultz et al., Autism, Vol. 12, 2008	
PMID: 18445737	
Paracetamol (acetaminophen) admin- istration during neonatal brain devel- opment affects cognitive function and alters its analgesic and anxiolytic re- sponse in adult male mice. Viberg et al., Toxicol Sci, Vol. 138, 2014 PMID: 24361869	"exposure to and presence of paracetamol (acetaminophen) during a critical period of brain development can induce long- lasting effects on cognitive function."
Associations between acetaminophen use during pregnancy and ADHD symp- toms measured at ages 7 and 11 years. Thompson et al., PLoS One, Vol. 9, 2014	"These findings strengthen the contention that acetaminophen exposure in pregnancy increases the risk of ADHD-like behav- iours."
PMID: 25251831	

Neurodevelopmental problems at 18 months among children exposed to paracetamol in utero: a propensity	"Previous studies showed that children exposed to paracetamol during fetal life might have an increased risk of neurodevelop- mental problems. Since paracetamol is one of the most common-
score matched cohort study.	ly used medications during pregnancy, even small increases in
	the risk of neurodevelopmental problems may have considera-
Vlenterie et al., Int J Epidemiol, 2016	ble implications for public health."
[Epub ahead of print]	
	"Long-term exposure to paracetamol in utero was associated
PMID: 27585674	with modestly increased risks of motor milestone delay and im-
	paired communication skills among children at 18 months."
	Note: paracetamol = acetaminophen