Public Comment in Response to a Request for Information (Federal Register of April 12, 2009) by the National Vaccine Program Office

Includes comments received by

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ORGANIZATION COMMENT #1

Natural Solutions Foundation

www.HealthFreedomUSA.org
"Health Freedom is Our First Freedom!"

March 14, 2009

National Vaccine Advisory Committee (NVAC)
Washington, D.C.
Via Internet: mailto:nvpo@hhs.gov

VACCINATION CLAIMS RESEARCH STATEMENT
Comments and Recommendations to NVAC

Introduction

1.0. Overview:

The Natural Solutions Foundation, Inc. (hereinafter referred to as "the Foundation") and all those who hereafter join in, bring to the attention of the Committee the need for scientific research regarding the often repeated, but unsubstantiated claims made in the Advertising and Promotion of Vaccinations to the professional community and lay public. Both health professionals and the Public are lead to believe that Vaccines are both "safe and effective" through many millions of dollars in annual advertising expenditures and publications, without adequate substantiating immunological, sociological or epidemiological research. Under current inadequate standards, pharmaceutical companies do not have to prove that any particular vaccination actually produces immunity to a particular disease organism, rather, all that is currently required is to demonstrate that there is some anti-body production after vaccination, justifying the use of the vaccine. The link between the production of these antibodies and their effectiveness in disease prevention, and the demonstration that the vaccine is safe on either a long or short term basis, alone or in combination with other vaccines or factors, is not required. This is clearly inadequate to demonstrate that any vaccine is "safe and effective" to protect against disease.

The Foundation is a nongovernmental organization (NGO) incorporated in the State of Nevada and recognized as exempt under Section 501(c)(3) of the Internal Revenue Code. The mission of the Foundation includes educating decision-makers with regard to natural solutions to health care needs and challenges. The Foundation has about 200,000 citizens on its opt-in Health Freedom eAlert System.

1.1. This Statement is submitted in response to the Committee "seeking public input into the scientific research agenda being developed by the Centers for Disease Control and Prevention's

(CDC) Immunization Safety Office (ISO)…" see: Draft Agenda Recommendations, April 11, 2008, http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf

We make this Statement with regard to providing the Public truthful and not misleading information about both Mandated and Voluntary Vaccinations through Vaccination Advertising, Vaccination Information and Vaccination Labeling provided to physicians, patients, parents, and guardians.

1.2. We resolve and state that there is neither significant scientific agreement nor sufficient reliable and competent scientific evidence from reliable, independent and unbiased sources to allow the conclusion that individual and/or multiple vaccinations, particularly of young children, provide any measurable public health care benefit. This is true whether the vaccinations are mandated or voluntary.

Further, there is a large body of evidence which shows that repeated single and multiple vaccinations, especially in young children, can cause or precipitate, and has in fact caused and/or precipitated, devastating and irreparable harm to hundreds of thousands of the most vulnerable citizens: our children. Vaccination is an un-insurable medical risk which has never been demonstrated with convincing scientific rigor to be either safe or effective. For that reason, vaccination must never be mandated or offered on a voluntary basis without provisions for the broadest medical, philosophical, and religious exemptions. In addition, vaccination must only be offered under any circumstances upon fully informed voluntary consent.

1.3. Billions of dollars of special vaccine-dose assessment and tax funds have already been paid to families of vaccine-injured children under the auspices of the Federal Government's National Vaccine Injury Compensation Program (VICP} which was created by the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) in part to "establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines." In fact, vaccine injuries are so common that the VICP was established to deal with the devastating consequences of vaccination, of which parents and patients were not and are not informed. See: http://www.hrsa.gov/vaccinecompensation/ The VICP is a "no-fault" alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid.

1.4. The current vaccination injury compensation structure is at:
http://www.hrsa.gov/vaccinecompensation/table.htm

1.5. Serious negative vaccine consequences are so common that the Vaccine Adverse Event Reporting System (VAERS) catalogs tens of thousands of vaccine- related injuries and deaths. See: http://www.whale.to/vaccines/vaers.html; New England Journal of Medicine, 2007; 357: 1275-9. It is of major significance to note that the CDC, FDA and other agencies estimate that only 1 to 10% of vaccine adverse events actually occurring are reported, so the actual magnitude of the problem is unknown and , according to the US Government's own estimates, is highly likely to be substantially greater than current documentation of reported events suggests. (e.g., a National Vaccine Information Center survey of NY pediatricians found that only 2.5% report adverse events).

1.6. If the frightening facts reported in VAERS are consider, no reasonable regulator can permit the current system to continue. It must be halted immediately in order to stop the irreparable harm we demonstrate here and which full properly designed and implemented scientific research would amply confirm.

1.7. Further examples of both potential and actual harm to the Public abound and are very evident with many current Vaccination advertising practices.

1.8. For one example, a report cited on the Internet indicated, "Only after filing a lawsuit against the FDA was Judicial Watch able to uncover New FDA Records Detailing an additional 8 deaths among an additional1,824 Adverse Reaction Reports Related to Gardasil, Merck's Human Papillomavirus (HPV) Vaccine between May 10, 2007 and Sept. 7, 2007. The death reports include 12 and 13 year old girls." This brings the known total for this one vaccination to 3,461 adverse reactions, including 11 deaths, since the Food and Drug Administration (FDA) approval of the vaccine; see: http://ahrp.blogspot,com/2007/10/8-more-deaths-liked-to-gardasil-hpv.html

1.9. Current Vaccination Advertising and Labeling do not adequately warn the Public of the significant, but un-insurable, medical risks inherent in vaccinations, the complete lack of proven clinical efficacy in disease prevention inherent in the procedure which makes it, at best, experimental, nor do they disclose to the public their exemption rights. Full discussion of the risks and possible unproven benefits and informed consent waivers are not provided by physicians concerning the pros and cons of vaccination. Instead, like the students at the University of Maine campus, in December of 2007, who were vaccinated under duress, on pain of being locked out of their dormitories, eating halls, classrooms, libraries and all other University facilities unless vaccinated - or revaccinated - , patients, parents and guardians are not fully informed. No discussion of dangers, potential adverse events and other considerations pertaining to personal choice in the face of an un-insurable risk took place in Maine, nor was any discussion about personal exemptions, as established by law, permitted. The same is true in physicians' offices, hospital emergency rooms and other vaccination sites across the United States.

1.10. The same was also true on November 17, 2007, when 2,300 children were vaccinated, literally at gunpoint, with the presence of police dogs, in the Prince George's County Courthouse, Prince George's County, Maryland, under the watchful eye of a Maryland Judge. The parents, mostly minority, poor and many unable to read, were threatened with jail and fines if they refused vaccination in a state which provides for exemptions were never discussed with the parents. It is important to note that the Maryland States' Attorney, Mr. Genn Ivey, told our Foundation representative privately, and repeated during an international radio broadcast, that he had learned these vaccines were so dangerous that he availed himself of the exemption and did not allow his own children to receive the vaccines.

1.11. Thus the impact of misleading advertising, backed by coercion, was used to force 2,300 schoolchildren to be vaccinated; many against their parents' will, in the absence of either due process or full disclosure. Many children were re-vaccinated with all vaccines because, as the Prince George's County School District admitted, it had lost the children's' immunization

records. These children were put at an increased risk by this process because the neurological and other related damage following vaccination is directly proportional to the total body burden of toxins introduced by vaccination. This fact is not disclosed to parents and was not disclosed to the parents of the Prince George's County children. Instead, advertising, including unproven and scientifically flawed, weak professional documentation is used to portray vaccination as safe and effective in preventing diseases, creating an untruthful and misleading perception. All such advertising should stop until adequate warnings and disclosures can be approved and implemented and compelling scientific validation for these claims can be provided.

1.12. And by way of final example, the public media reported in late February and March, 2009 on the alleged "accidental" contamination of season flu vaccines delivered to 18 countries with live, infective human Avian Flu Virus. Had this contamination not been discovered in time, a world-wide Avian Flu Pandemic could have been triggered by mass vaccination. There is less than no proof that Avian Flu Vaccine is either safe or effective since the pandemic version of the disease does not yet exist. Although FDA approval to some versions of Avian Flu Vaccine has already been given in the absence of human testing, there is absolutely no evidence that any of these vaccines will protect against, either safely or otherwise, the development or severity of Avian Flu in human. Any claims for, or advertising of, these products must be halted until acceptable scientific proof can be provided. See: http://www.healthfreedomusa.org/?p=2191

II. Actions Requested

2.0. We urge the Committee to take the following actions (hereinafter, the Statement Action Requests):

2.1. Issuance of an immediate Recommendation to suspend advertising of vaccinations by the manufacturer, public health agency or any other entity or person whether protected from liability under such Federal Laws as Title 42, Chapter 6A, Subchapter XIX, Part 2, Subpart A, Section 300aa-16, Limitations of Actions, or not until all reasonable scientific research shows that any particular vaccine is safe and effective.

2.2. Issuance of an immediate Recommendation to halt Interstate Commerce regarding vaccines and vaccine related goods, until all reasonable scientific research shows that each particular vaccine is safe and effective. At that time, Interstate Commerce of that vaccine may resume.

2.3. Issuance of a Recommendation that any practitioner or entity administering vaccines should be required to notify patients, parents or guardians in their own language that vaccines are currently the subject of scrutiny because of their lack of proven protection in communicable disease and their dangers to persons receiving them. Patients, parents or guardians wishing to proceed with vaccination should have a waiver form explaining the dangers, uncertainties, un-insurability, presented to them and State and or Federal exemption opportunities provided to them. Signing such an explicit waiver is the minimum required for truly informed consent under the terms of the Declaration of Helsinki, 1964, http://www.wma.net/e/policy/b3.htm - which constitutes part of the Law of Nations under the United States Constitution.

2.4. Issuance of a Recommendation that all appropriate Federal Agency rules ensure the public that the un-insurable medical risk of vaccination injury will not be mandated over the medical, philosophical and religious exemption rights of Citizens. States which threaten to withhold services such as schooling from unvaccinated children, forbid admission of unvaccinated students to universities and colleges or access to facilities and services after tuition or its equivalent has been paid, and similar coercive activities based on inaccurate and misleading advertising of vaccine efficacy and safety should be denied all Federal scientific research or other funds.

2.5. The Foundation expresses carefully considered doubt that the involved Federal Agencies have exercised prudent judgment in the face of abundant scientific, empirical and other information, supported by adverse event reporting, in permitting the production, shipment, sale and injection of vaccines. Scrutiny should focus on all ingredients in vaccines: active, inert, intended, adventitious, unintended, trace and adjunctive; since all ingredients, alone or in combination with each other or constitutional, environmental, pharmaceutical or other factors, may cause responses in the body leading to harm. Squalene, for example, is an adjuvant used to enhance immune response which may be safe when ingested or used as a topical agent, but is the cause of serious auto-immune disorders when injected. Many new generation vaccines contain Squalene as an adjuvant.

2.6. The Foundation urges that the Committee Recommend that all future Vaccination Advertising and Labeling contain, at a minimum, the following Warning and Disclosure -

“WARNING: The safety and efficacy of vaccination has not been demonstrated by reliable, independent, unbiased, and competent scientific or clinical evidence. DISCLOSURE: You or your children may have a right under law to a medical, philosophical or religious exemption from this vaccination.”

2.7. Vaccination remains an experimental modality. Under the Declaration of Helsinki, it is imperative to assure that all recipients or their parents or guardians are fully informed about the dangers they may face if they allow themselves or their charges to be vaccinated. A waiver must be required from patients, parents or guardians indicating that pros and cons of vaccination were fully discussed with, and understood by, them and that all exemption rights were also fully discussed and understood. The waiver must state clearly that the recipient, parent or guardian fully understands that manufacturers of vaccines have no liability for any damage which they may cause, including death and that the risks in vaccination are un-insurable.

2.8. At a minimum, to meet international standards regarding medical experimentation, such as the Declaration of Helsinki, a physician, upon appropriate consultation, must be permitted provide a valid medical excuse from current and future vaccinations recommended by any Federal Agency for any child who has suffered a reaction of any type to any previous vaccination. The child’s medical history, as reported by the parent, shall be taken to provide conclusive evidence of such reaction. No child shall be subjected to any vaccination unless the physician administering the vaccination shall have certified in writing that it is both safe and necessary that the particular child is vaccinated against that particular disease or diseases and why such vaccination is necessary. Physicians who find no justification for vaccination shall not

be liable to censure, discipline and/or harassment by their state medical boards of jurisdiction or other professional organizations including, but not limited to, the American Medical Association (AMA), American Association of Pediatric Physicians (AAPP), and State Medical Associations.

2.9. As an executive agency advisory committee, the NVAC must "Take Care that the Laws be faithfully executed" (Article II, Section3, United States Constitution)

2.10. Further, the Committee should consider medical ethics as set forth in the AMA Code of Ethics, The Hippocratic Oath, the Oath of Maimonides, the UN Declaration of Human Rights and the Declaration of Helsinki. The Foundation urges the Commission to consider the overriding importance of the injunction to "…first do no harm…"

III. Statement in Support of Statement Requested Actions

3.0. When the Centers for Disease Control (CDC) recently recommended that infants and toddlers be subjected to the flu vaccine, the States began the process of mandating the vaccination before the child could be admitted to pre or public school. New Jersey became the first state to mandate the flu vaccination for children, publishing the final rule on January 7, 2008, effective January 2009. Such mandates condition the acceptance of a public benefit ("free public education") or a private one (attendance at preschool) upon submission to a questionable, experimental and potentially dangerous medical procedure.

3.1. This is particularly troubling since those doses of flu vaccine supposedly manufactured without mercury continues to contain "trace" amounts of mercury since even the allegedly "mercury free" versions use mercury in the manufacturing process, adding a "trace" amount to the administered dose. There have been no safety studies done on Thimerasol (manufactured by Eli Lilly) since the 1929 study done by K.C. Smithburn on patients dying from meningitis. All patients to whom Thimerisol was administered died but Smithburn concluded that Thimerisol was safe since the patients would have died from other causes anyway. AllMSDS for Thimerasol states, "Exposure to mercury in utero and in children can cause mild to severe motor coordination impairment." Eli Lilly MSDS June 13, 1991. None the less, this toxic component is being offered to patients, including pregnant women and children, increasingly as a mandated vaccination. Other components of vaccines are also highly troubling for similar reasons: the science establishing their safety is either non-existent, absurd or deeply flawed.

3.2. The Foundation, asking how much mercury is enough to cause harm, submits the following: "Most worryingly, exposure levels were not particularly high, Hair concentrations in the [Japanese] villagers averaged 4 micrograms of mercury per gram of hair. This is just a tenth of the level considered dangerous for adults by the World Health Organization, and not much higher than that found in many countries. In the US and Japan, for instance, the average mercury concentration in hair is around 1 and 2 micrograms per gram respectively." This tends to show that the CDC's claimed "trace" levels of mercury remaining in vaccines may very well be dangerous. See: http://www.eurekalert.org/pub_releases/2003-06/ns-esmo61103.php

3.3. According to the New York Times on April 5, 2003, "The Food and Drug Administration has begun using the Environmental Protection Agency's much lower safe level for mercury in

the human body, an official of the food and drug agency said this week, 'Before the change, the F.D.A. guidelines set a safe level that was four times as high as that of ..environmental agency.. standard.'" See: http://query.nytimes.com/gst/fullpage.html?sec=health&res=9507EFDD1538F936A35757\C0A9659C8B63

3.4. Therefore, a question for scientific research becomes: "Is there a 'trace' amount of Mercury or other toxins in the recently recommended flu vaccination?" How much of a "trace" is needed in any vaccination to cause harm.

3.5. According to Centers for Disease Control (CDC), "Thimerosal still may be used in the early stages of making certain vaccines. However, it is removed through a purification process." leaving a "trace" amount of "less than 0.3 mcg" in the final dose. See: http://www.ageofautism.com/2007/12/emails-from-cdc.html Additional research is necessary regarding the direct and cumulative effects of such trace dosages.

3.6. The existence of any trace amount of mercury is very troubling, especially as the "trace" amounts add up and accumulate over repeated vaccinations. Recent analysis shows that contrary to earlier reports, there is a measurable relationship between autism and mercury toxicity. See: http://mcs-america.org/January2008pg17.htm - citation: J Child Neurol. 2007 Nov; 22(11); 1308-1311. In this context we note the mushrooming autism rate appears to be in direct correlation with introduction of new vaccines (e.g., MMR), and we further note the conspicuous absence of autism in religious and other populations that do not vaccinate. This contradicts various authorities' assertions that vaccines do not cause autism. On November 9, 2007 the Federal government's lawyers conceded a Court of Federal Claims case involving autism caused by vaccines; there are 4900 other pending autism-vaccine injury cases before the Vaccine Injury Compensation Program. See: http://www.huffingtonpost.com/david-kirby/government-concedes-vacci_b_88323.html. Other more recent cases seem to hold otherwise and the parents of injured children still believe they are not being treated fairly.

3.7. The Natural Solutions Foundation, however, does not limit its concern to mercury adulterated vaccinations. Even if vaccines become truly mercury free, they would still (a) lack proven effectiveness and (b) continue to contain other ingredients, such as Squalene, which assault healthy immune systems. The Foundation continues to object strongly to any mandated or voluntary vaccination which may cause harm to individuals either through its component or synergistic parts or through the impact of single or multiple vaccines on the immune system. These impacts are anything but trivial: although they can be immeasurable, extremely worrisome, troubling, debilitating and/or lethal. Despite deceptive advertising to the contrary, there are safe and effective alternatives to dangerous vaccinations that can, in a modern society with proper hygiene, prevent the spread of infectious disease. The Foundation reminds the NVAC that many diseases for which vaccinations are administered are self limiting and pose little or no human health threat. If not confronted successfully by the immune system, these diseases can be well treated using modern medical methods.

3.8. It is a serious affront to basic, inalienable human rights to force or mislead individuals, especially parents and guardians of minor children, to accept invasive medical treatments

without fully informed, voluntary consent. See the discussion below regarding the World Medical Association's Declaration of Helsinki in this regard; see: http://www.wma.net/e/policy/b3.htm

IV. Legal Authorities in Support of the Statement

4.0. This Statement is grounded in fundamental principles of inalienable right, law and equity.

4.1. The primary legal basis for submitting this Statement to the Commission is the First Amendment to the Constitution of the United States: "Congress shall make no law… abridging… the right of the people… to statement the Government for a redress of grievances."

4.2. We also cite the World Medical Association 1964 Declaration of Helsinki; see: http://www.wma.net/e/policy/b3.htm This Declaration has the force of International Law and it clearly forbids experimental medication or medication without fully informed consent.

4.3. The Acts establishing the authority of the Federal Agency under which the Committee deliberates are also a legal basis for the Statement. The Department of Health and Human Services (HHS) exists solely to protect the Public, within the limits established by the Constitution of the United States of America. Among the principles established by the Laws and Regulations, long the explicit policy of the Federal Government, is that all commercial advertising must be "truthful and not misleading."

4.4. The statute in the derogation of the common law and Constitutional limitations, establishing exemptions from liability of Vaccine Injuries, 42 USC 300aa-16 (and the Vaccine Injury Compensation Program, there under) is further cited as a law that must be strictly construed in favor of patients, guardians, parents and children, and strictly construed against the economic interests of the pharmaceutical industry and other exempt persons.

4.5. Basic common law principles prohibiting forced acquiescence under duress and limited or intentionally distorted information, as exemplified by the United States Supreme Court decision in the case of Thompson v Western States Medical Centers – 535 U.S. 357 (2002), as further described below.

4.6. Additionally, the Statutes authorizing the Federal Agency contain general provisions that support the actions requested in this statement. Federal Law includes provisions that grant the responsible persons in the Federal Agency broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."

4.7. The United States Supreme Court has spoken forcefully, enforcing the consumers' right OR consumers' rights to truthful information about healthcare issues. See: Thompson v Western States Medical Centers, 535 U.S. 357, where Justice O'Connor wrote, "If the First Amendment means anything, it means that regulating speech must be a last-not first-resort. . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. . . Even if the Government did argue that it had an

interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring . . . a warning that . . . its risks were unknown."

4.8. The basic rule, announced by the case, to determine constitutionality permitted government restrictions on Commercial Speech (speech that makes or is about an offer for a transaction, such as the sale of Dietary Supplements or vaccinations) is a two prong test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the Government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance "the governmental interest and (3) the regulation of Commercial Speech cannot be "more extensive than is necessary to serve that interest" (quoting Central Hudson v Public Service, 447 US 557, at 566).

4.9. The Federal Government, through the Federal Trade Commission, has stated its general rule for the advertising of products that are alleged to have health benefits, to ensure that such advertising is "truthful and not misleading."

4.10. In this context, it is useful to recall the 1996 comments of then FTC Commissioner Starek, at the National Infomercial Marketing Association (comments the Federal Trade Commission (FTC) maintains on its web site). He explained the issue to which the Supreme Court alluded in Thompson – preventing misleading advertisements: "As many of you know, the FTC is charged with protecting consumers from unfair or deceptive acts or practices. In advertising and marketing, the law requires that objective claims be truthful and substantiated. The FTC does not pursue subjective claims or puffery—claims like 'this is the best hairspray in the world.' But if there is an objective component to the claim—such as 'more consumers prefer our hairspray to any other' or 'our hairspray lasts longer than the most popular brands'—then you need to be sure that the claim is not deceptive and that you have adequate substantiation before you make the claim. These requirements apply both to explicit or express claims and to implied claims. Also, a statement that is literally true can have a deceptive implication when considered in the context of the whole advertisement, even if that implication is not the only possible interpretation.

"The substantiation requirement exists because every time an advertiser makes an objective claim, the advertiser also implies that there is a reasonable basis for the claim. This reasonable basis is substantiation. What constitutes a reasonable basis for a particular claim can vary, depending upon the nature of the claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable. Health and safety claims generally require competent and reliable scientific evidence. And if a marketer makes a representation that a claim has a particular level of support—for example, 'clinical studies prove…'– the law requires at least that level of substantiation."

4.11. The required level of substantiation for alleged claims about medical products such as vaccines is "significant scientific agreement." In the case of vaccines, there is no significant scientific agreement by unbiased sources regarding the vaccines and manufacturers' claims for the safety and efficacy of the product which satisfies the rule against false advertising; especially where and when the public is misled by not being warned of either the dangers of the product or

of any right of members of the public to refuse vaccination on religious, medical or philosophical grounds. We urge the Committee to consider that the advertising of vaccinations is clearly a case where "requiring… a warning that… its risks were unknown…" (Thompson v Western States, supra.) is the minimum required by Law to protect the public, and especially the most vulnerable among us, our children. No scientific research agenda which does not warn the Public of the unknown risks is a legally responsible agenda.

III. Conclusion

Due to the emergent nature of the risk of unscientific pseudo-justifications for vaccination claims and with the lives of innocent children, adolescents and adults at stake and hanging in the balance, The Foundation urges the Committee to act immediately to Recommend appropriate Warning and Disclosure language, such as suggested herein, be required with all vaccination communication to assure the Public that a proper scientific agenda has been adopted for vaccination research. Scientific research is needed regarding the cumulative effect of multiple vaccinations which continue to contain "trace" or larger amounts of mercury and other toxins. Populations which do not vaccinate, such as the Amish, need to be studied since it appears that such populations have not experienced horrific elevation of autism rates and other deleterious effects of vaccinations.
Vaccination remains an unproven, experimental medical procedure subject to the restrictions of the Declaration of Helsinki.

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ORGANIZATION COMMENT #2

April 13, 2009

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 715–H
Washington, DC 20201
Attention: Vaccine Safety RFI
vaccinesafetyRFI@hhs.gov

Re: Solicitation of Written Comments on Draft National Vaccine Advisory Committee Vaccine Safety Working Group Recommendations to the Immunization Safety Office

Dear National Vaccine Program Office;

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,500 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP would like to note that pharmacies and pharmacists, from both the ambulatory and the extended (long term care) environments should be included in the administration of vaccine discussions. NCPDP also has membership from the electronic prescribing environment that could provide valuable input to the prescribing and dispensing workflow.

When discussing incentives, it should be noted that a pharmacist may administer vaccines. The NCPDP Telecommunication Standard, which is used in billions of pharmacy transactions each year, supports the reporting and the billing of vaccines from the pharmacy, which are included in the pharmacy benefit of the patient. Commercial, Medicaid, and Medicare programs (Medicare Part D) support vaccines as part of the pharmacy benefit. Further, the claims and reporting transactions then become part of the medication history of the patient, which are then exchanged via the industry standard for electronic prescribing, the NCPDP SCRIPT Standard.

In addition, NCPDP has member companies in the manufacturing, distribution, and drug knowledgebase companies, as well as rebate processing and pharmacy pedigree which would provide valuable input for standardized practices. NCPDP and its members are very willing to participate in further discussions and opportunities.
If I can be of further assistance, please contact me.

Sincerely,

Lynne Gilbertson
VP, Standards Development
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
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cc: Lee Ann Stember, NCPDP President
cc: NCPDP Board of Trustees

ORGANIZATION COMMENT #3

To Whom It May Concern:

The study of metabolic diseases, mitochondrial disorders/dysfunction and the neurological pathways associated with detoxification, including the PST pathway as well, should be studied in great detail. I strongly feel that science needs to look at the children whom recovered from vaccination reaction, autism, SPD, and other neurological conditions and back track from recovery to reaction/damage/diagnoses of said neurological disorder. Why I don't understand has anyone asked the recovered how it was done? Children should not have to detox mercury, pesticides, and viruses out of their bodies.

I strongly suggest major funding for mitochondrial disorders/dysfunction because not only will it prove revelations in Autism, but it will also benefit Parkinson's and Alzheimer's diseases as well as other mitochondrial disorders/disease.

"(17) The Working Group recommends ISO include the vaccination of children with mitochondrial disease, mitochondrial dysfunction,
and other metabolic diseases as a priority scientific area for research to develop clinical guidance."

Sincerely,

Diane Renna
Indigo Impressions
PO Box 501
Speonk, NY 11972
http://www.meghanstriumphoverspd.com
"Meghan's World: The Story of One Girl's Triumph over Sensory Processing Disorder"
Giving hope and inspiration to children living in an over stimulating world.

ORGANIZATION COMMENT #4

National Vaccine Program Office,
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 715-H
Washington, DC 20201
Attention: Vaccine Safety RFI.
vaccinesafetyRFI@hhs.gov

National Vaccine Information Center
407 Church St., Suite H
Vienna, VA 22180

May 13, 2009

In response to the National Vaccine Program Office (NVPO) solicitation for public comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group draft Recommendations to the Centers for Disease Control and Prevention's (CDC) Immunization Safety Office (ISO), the National Vaccine Information Center (NVIC) is submitting the following statement.

NVIC would like to thank NVPO for the opportunity to comment on this report and acknowledges the significant effort that has gone into this report. The efforts to engage the public and solicit input are appreciated.

As a participant in previous and more recent vaccine-oriented public engagement processes, including the Salt Lake City Writing Group (SLCWG), NVIC affirms the critical need to have continuing and meaningful public input into vaccine policymaking at federal, state and local levels. We encourage NVAC to construct further meaningful processes by which the public and consumers of vaccines can affect vaccination policies that have substantial implications for the health of all Americans.

The public engagement work to date, including that which served as a basis for the NVAC Draft Report on the CDC ISO Scientific Agenda (Task 1 Report) is a start, but it is not sufficient. The Task 1 Report contains a number of modifications to the SLCWG language - as well as critical health policy and scientific assumptions - that should be addressed in order for the final NVAC Task 1 Report to reflect the needs and concerns of the American public. Although the stated purpose of the Task 1 report is to address specific concerns related to ISO work, the document spans a number of additional policy and scientific arenas which complicate our ability to formulate a targeted response.

A theme throughout the report is that scientific and policy deficiencies should be addressed or coordinated by either the CDC or various federal agencies. The frequently used phrase “federal vaccine safety system and/or research agenda” is, at its core, limiting and in need of revision. Instead, NVAC should consider that what is most

needed is a “national vaccine safety system” – one that is accountable to the American people and not to the federal government. A “federal” system is, by definition, limited in scope and will not solve the current problems or improve public trust and confidence.

While this concern may appear to be a matter of semantics, it is not. At its core, this perspective has substantial implications for how the problems of the existing system are conceptualized and corrected and it affects the tone and content of the entire report.

For example, recommendations acknowledging gaps in vaccine safety infrastructure and science generally include language that ISO coordinate with other agencies or study topics such as molecular immune responses, basic physiological mechanisms of vaccine-associated injury, and genomics. Recognizing that the Task 1 Report is in response to a CDC request, the report frequently includes recommendations for ISO to perform work that is beyond the scope of its expertise and needs to be considered within a broader national framework.

It was interesting to note that, in some cases, the scope of recommendations in the Task 1 Report extend beyond the ISO’s request to NVAC and in others, it does not address the needs ISO identified. Specifically, ISO provided NVAC with a list of vaccine-associated topics to be prioritized – specific questions as well as specific vaccines, vaccination practices, special populations and clinical outcomes. The NVAC VSWG then applied the SLCWG criteria (modified) to only the ISO “Specific Vaccine Safety Questions” reasoning that a “lack of specificity provided in the broad topical categories in draft ISO Scientific Agenda, the [Vaccine Safety] Working Group encountered difficulty evaluating the content and prioritizing certain sections of the Agenda.”

Yet, the topic “simultaneous vaccination” was not in ISO’s initial list of “Specific Vaccine Safety Questions” and appears to have been reframed as “Do multiple vaccinations increase risk of immune system disorders?” at least partly in response to several related SLCWG recommendations and numerous public comments from the community meetings. The question was then prioritized by the VSWG along with the ISO Specific Vaccine Safety Questions.

While we agree with the VSWG decision to elevate this concern and also agree it deserves a “high” priority rating, we do not agree that the evaluation of health outcomes should be confined to immune system disorders which also was not the intent of the SLCWG. The point being that there are many other very important research topics that were identified as ISO gaps and discussed in substantial detail at the SLCWG meeting which also need to be prioritized and included in the core Task 1 recommendations and elevated to level of “Specific Vaccine Safety Question.”

We noticed that the text for some of Prioritization Criteria labels and defining issues has been modified and, in some cases, appears to decrease the neutrality of the criteria. For example, the SLCWG struggled with the label for the fourth item and determined that "Status of Existing Scientific Knowledge" was clear and neutral. Currently, the item

is labeled "Scientific Concern and Degree to which Science Warrants Further Study" has been changed in a way that is less neutral and lacks breadth in that its application will be difficult, if not impossible, for topics for which there is little or no existing relevant scientific evidence. Perhaps a better choice would be "Scientific Concern and State of Existing Evidence".

Some of the general principles for application of the criteria developed at the SLCWG have been removed and should be re-instated. In particular:

- Criteria should be applied in a transparent process with stakeholder input throughout the process to enhance accountability and enhance public trust and confidence.
- The following criteria are proposed so that prioritization decisions are made in a consistent and fair fashion.
- In order to achieve accountability, NVAC will provide an explanation of how they applied the criteria to the issues on the research agenda.

Of particular concern to the National Vaccine Information Center is that the recommendation by the SLCWG for the outsourcing of a feasibility analysis, which would evaluate the methodology for conducting a study of vaccinated and unvaccinated children, be in the NVAC core recommendations and be given a high priority in any national vaccine safety research agenda. The nearly unanimous affirmation by the diverse stakeholder group that met in Salt Lake City of the importance of this study, together with the considerable interest in this study on the part of vaccine consumers, including those whose children have vaccine associated brain and immune system dysfunction, make it a key component to include in any credible recommendation regarding national vaccine safety research priorities.

The degree to which vaccine educated and concerned consumers take the recommendations of the Vaccine Safety Working Group seriously depends upon how substantive those recommendations are with regard to answering outstanding questions about vaccine safety. We hope that core recommendations, which are promulgated by this Committee, live up to the spirit and intent of the stakeholder public engagement initiative in which we participated this year and in years past. We also hope that the process utilized in the Task 2 initiative will be true to the spirit and intent of public engagement and participatory democracy principles that include transparency and a true willingness to engage the public to honestly address genuine and legitimate concerns about vaccine safety science.

Again, thank you for the opportunity to provide written comments, in addition to our participation at Salt Lake City and in previous NVAC meetings, to the information that NVAC and NVPO are considering when making recommendations on this very important subject.

Sincerely,

Barbara Loe Fisher
President

Vicky Debold, PhD
Director of Patient Safety

ORGANIZATION COMMENT #5

May 13, 2009

National Vaccine Program Office
Attention: Vaccine Safety RFI
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 715-H
Washington, DC 20201

Dear Ms. Vannice:

On behalf of the Pediatric Infectious Diseases Society (PIDS), I am writing to provide comments on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group draft Recommendations to the Centers for Diseases Control and Prevention's Immunization Safety Office (ISO). The PIDS Clinical Affairs and Public Policy Committees reviewed the NVAC Vaccine Safety Working Group draft Report from April 14, 2009, and propose the following suggestions:

- The Executive Summary, paragraph 3, lines 1-2 the "... Working group deliberated the draft ISO scientific Agenda from April 2008 through June 2009." We assume that the date should be June 2008.

- Considering that the document will likely be read by individuals other than its main target audience, we favor expanding the background with a paragraph explaining the extensive safety requirements for vaccine licensure.

- While many of the abbreviations are defined in the text, there appear to be numerous instances in the appendices and tables where abbreviations are used without definition in the tables and appendices. If we cannot have them in the tables or appendices themselves, a glossary of terms and list of abbreviations would be useful.

- Through out the document and beginning with the introduction the document refers to “highly visible public concern” or “significant public concern” related to vaccine safety. In our opinion this statement should be changed, for example what does it means when the document refers to significant public concern? It could be interpreted as a majority of the population. Would it be appropriate to state that there are increasing concerns, but that a large majority of children continue to be immunized? We are concerned that the current language validates beyond a reasonable scientific level the issue vaccine adverse vents, at a time when the majority of the children in most areas of the country are appropriately vaccinated.

- As an additional item for the research agenda, we propose the study of the impact of well designed and executed scientific studies on the attitudes and beliefs of individuals who refuse vaccination for themselves or their children. Would their beliefs and behaviors be modified based on any of the multiple proposed areas of research? Clearly the issue of vaccine safety is of paramount importance and needs to be studied carefully even in the absence of specific concerns from any particular group but it appears that at least some of the study recommendations are targeted to certain specific groups.

- In relation to recommendation 10 on increasing the number or reports to VAERS I believe that we are interested specifically in increasing reports by healthcare providers only. Or at least the data could be analyzed by category of reporter,

- In relation of the study of adverse events in "Special Populations" the document should specify which populations and the rationale for the specific population. I am concerned that there could be an extremely large group of special populations and interest groups that would like their special populations studied that would make the design and execution of any study unfeasible.

- Despite the working group's desire to have broad public engagement, the document should describe the number of individuals that participate in each meeting and the potential biases associated with their participation. We are concerned that the methodology of the public engagement process could have selected for a specific segment of the population. In particular it should be highlighted through the document that Ashland, Oregon was selected as it is an area with a large number of families who object to vaccination.

- Figure 2 lists adverse health events following immunizations but provides no counterbalance with a list of the beneficial health events following immunization. We realize that the focus of this draft report is safety, but safety must be viewed relative to the benefit. For example fever and local reactions are adverse health events but may seem small in comparison to protection against a potentially lethal health event that might occur without the immunization.

- On page 23, the comment on studying common adverse events as surrogates for rare adverse events if biologic mechanisms are related or shared. If this is taken forward, it will be critical to have concise and precise decisions about what is considered a related or shared biologic mechanism.

- On page 24, when discussing underlying genetic disorders, it also is critical that only precise and well defined conditions that provide a plausible vulnerability be considered. This cannot be a total fishing expedition aimed at the unknown or as yet undefined potential genetic or metabolic disorder.

- On page 25, we agree with the appropriateness of enhancing communication of existing science. This appears to be a major problem amongst the lay public at this time. Executive summary type analyses should be employed and used to communicate the essence of the existing data particularly for interactions or conditions which have already been studied. This

- On page 29 there is a call for external review of VSD and CISA research and the ISO agenda. It is unclear who or what bodies of reviewers would constitute a reliable and objective external review source. Some attention should be given to this concept. In the last line of this page, the paper states the *apparent* increase in risk of Guillain-Barré syndrome following swine flu vaccination. Would it seem more objective to say the *possible* increase in risk because experts continue to debate this issue?

- Given that we are in the midst of a pandemic of influenza, it would be more pertinent and perhaps more *real* to include lessons from this current pandemic in addition to or instead of the 2003 smallpox experience which had minor impact on the general public health.

- Also on page 31 there's a statement that AEFI may or may not be causally related to immunization. This concept needs to be emphasized as well as the passive nature and inexact relationships between AEs and immunization in some datasets, particularly in the VAERS data set. We suggest that a table be created showing the adverse effects concept as well as the data set which might be evaluated with the temporal but not necessarily causal relationship identified. The potential contributors to the datasets also need to be identified. For example, how many AES are reported by medical professionals versus patients versus members of the legal profession. There also needs to be an emphasis that all adverse effects listed in package inserts may not be causally related to immunization particularly if they occur with similar frequency in a control group.

- We request insertion of a section that calls for defining the background rate of conditions that also could be possible immunization related adverse effects in populations who have not received the vaccine but are in similar age, gender, and ethnic groups. For example the data on the number of cases of Guillain-Barré syndrome in the general population in each group should be well-defined (some data already exists on this) and made easily available to the public. This also facilitates better power calculations for prospective studies as well as early identification of any data that falls outside of the normal or expected epidemiologic range and post marketing evaluations.

- On page 32, there is a statement that says that the working group does not necessarily agree with all the language in the writing group's statement but with its general intent. This appears to say that the working group does not agree with itself. This can only add confusion to people trying to read this draft report. We assume that means that there are differences of opinion among working group members. Would it be better to have minority reports on areas where there is a strong difference of opinion on specifics but not general intent, with the signatories identified who created the minority reports on specific items?

- On page 33, there's a statement about the “outcomes to assess include biomarkers of immunity and metabolic dysfunction”. The sentence does not appear to have the proper number of verbs. This should be clarified. In addition more specific suggestions should be included about what would be considered biomarkers of immunity and specifically what metabolic dysfunctions the working group intends to the studies to assess.

- On page 43 they want to “consider common, less severe AEFI as proxies for rare, severe AEFI.” Sounds interesting but is there any evidence that a less severe AE (such as rash) can be a proxy for a rare, severe AEFI (such as a neurologic complication)? They are also interested in obtaining prevaccine samples. Other than the Guthrie cards, prevaccination blood is hard to obtain. Obviously, more work needs to be done on the scientific exploration of possible AEFI. A lot of work will be needed on developing a biological specimen repository.

- On page 51, paragraph 1, line 3 should read "...preparations are available" not "presentations."

- On page 53, Gaps in Specific Vaccine Safety Questions, the last paragraph discusses merits of alternative schedules; this paragraph needs to be balanced by at least some mention of the potential consequences of alternative immunization schedules (missed doses, possible increased cost, possible exposure to disease when not fully immunized, etc). We are strongly supportive of section B-VII Off label use of vaccines; if they wanted an example, the recommendation to use Rotateq (RV-5) between 12 weeks and 6 days and 14 weeks and 6 days (a time period not covered under FDA licensure) would be ideal here. PIDS has some concerns about including "children with inborn errors of metabolism."

- On page 61, line 4, without some discussion of the rationale. While one would surmise that this is in reference to mitochondrial disorders and vaccines, does the use of "inborn errors of metabolism" mean that they will be looking at other conditions (PKU, galactosemia, etc)? We also have concerns about the wording in the next paragraph regarding "special populations" which may be "under represented" in clinical trials. No doubt there are many types of patients who would qualify as a member of a "special population" not included in typical vaccine trials. Who will be making these decisions and on what scientific bases will one "special population" be selected for study over another?

- On page 65-66, while examining immune response profiles among patients with ASD and an AEFI in comparison with normal controls with a similar history of AEFI sounds interesting, our opinion is that one should also include normal controls who did not experience an AEFI as well as ASD patients who did not have an AEFI for comparison for immunology studies in children.

- In Table 3, regarding question #4, "Are acellular pertussis vaccines associated with increased risk for acute neurologic events, particularly HHE"- has this not already been reasonably well studied? Increased risk compared to what, we know that the risk is lower than the original whole cell pertussis vaccine. Finally, we applaud the effort to improve VAERS reporting and, although a passive reporting system, to obtain more information, including biological specimens, from persons with rare or unusual adverse events (although not further defined here) in responses from the public/stakeholders seems worthwhile.

- Appendix 2 (Page 75) has a long list of ingredients identified by the public and/or stakeholders with a statement, "are there harmful ingredients?”. In the second column are levels of evidence for some specific and some nebulous situations. There should also be levels of evidence for ingredients and outcomes that have already been studied for which data are available. For example thimerosal not being causal for autism and the level of evidence.

- On page 76, in the final column is a statement about particular risk window for adverse effects. It is critical that this be considered also in regard to the risk window for the disease that is the target of the immunization.

- On page 77, there are too many abbreviations, for example PPD, which has at least five possible medical meanings including the ingredient used in tuberculin skin testing. In the second column on page 77 the statement about neurologic deterioration should include the word *defined*, for example deterioration in children with defined mitochondrial dysfunction, not potential or unknown dysfunctions. In the third column of this table, there is an incomplete citation to work by Thompson et al. in 2007. This should be a complete citation because appendices should be able to stand alone.

- On page 78, in the third column, it should be made clear that outcomes in unvaccinated, vaccine delay, and vaccinated children should include not only adverse effects but also disease outcome.

- We feel that it would be senseless to do a "vaccinated" versus "unvaccinated" study.

- Recommendations on 5-Year Research Needs
  A-VIII. The last paragraph as written implies the concerns related to an alternative immunization schedule are only those of the IOM.
  Suggested language: While variations in the actual immunization schedule……, the working group shares the concern expressed by the IOM that utilization of alternative schedules may contribute to lower immunization coverage and its potential consequences, increased morbidity and /or mortality from vaccine preventable disease.

- **B-III.** The recommendation that a regular summary report on the safely profile of the expanded influenza vaccination program is vague. Suggest a specific time frame be requested.

- **C Special Populations:**
  The first paragraph indicates agreement with all special populations listed in the draft. It is unclear why children with inborn errors of metabolism are included. Perhaps the working group can provide the rationale. The last sentence in the first paragraph mentions "other groups" that may be at increased risk for AE's that were not included. This is a generalized statement. Suggest providing an example, deleting the sentence or modifying the sentence to indicate that while a number of special populations have been identified, the list is not all inclusive and with continued surveillance of adverse effects others maybe identified in the future.

- **C-VIII**
  How sibling is defined should be carefully addressed in an era where a number of children do not have both parents in common in the same household thus making shared genetics more challenging to determine.

Please accept these comments as a means to help in your effort to develop cogent recommendations for the ISO Scientific Agenda. Should you have any questions, please contact Christy Phillips, Executive Director of PIDS at (703) 299-9865. Thank you for your efforts to ensure better health care for our children.

Sincerely,

Penelope H. Dennehy, MD
President

ORGANIZATION COMMENT #6

SafeMinds
16033 Bolsa Chica St. #104-142, Huntington Beach, CA 92649 • v. 404 934-0777 • f. 770 631-9272 • www.safeminds.org

May 13, 2009 ****** VIA EMAIL ******

National Vaccine Program Office,
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 715-H
Washington, DC 20201
Attention: Vaccine Safety RFI.
vaccinesafetyRFI@hhs.gov

SafeMinds is pleased to offer the following in response to the National Vaccine Program Office (NVPO) request for public comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group draft Recommendations to the Centers for Disease Control and Prevention's (CDC) Immunization Safety Office (ISO).

Additionally, we would like to state our appreciation of our inclusion in the public engagement efforts, particularly the inclusion of our Executive Director, Sallie Bernard, in the Salt Lake City Writing Group (SLCWG), as we believe public engagement in the midst of a growing crisis of faith in our immunization program is appropriate and will serve to rebuild trust. We are encouraged these recent efforts by the NVPO and believe that every opportunity to engage the public in this important process is necessary and is aligned with the current administration's policy for greater public involvement and transparency in government.

In general, we believe the VSWG recommendations must put primary emphasis on a "Safety First" agenda. As noted frequently throughout the public engagement efforts, gaps in vaccine safety research, and safety in general, is a primary concern held by the public. The public's concern in this sense must not be marginalized, but addressed through the closing of research gaps to restore trust in vaccines. Baseline data on the health outcomes of unvaccinated [and alternatively vaccinated] children should not be optional, but required by basic principles of ethics, scientific curiosity, as expressed in Section 27 of VICA in 1986. It is simply impossible to achieve the goal of safer vaccines, or to assess progress, without having an accurate baseline benchmark for acute and chronic disease in unvaccinated children. Without such basic data, there is no way to know the relationship between acute and chronic disease and adverse reactions caused by vaccines.

As such, SafeMinds applauds the draft's recognition the need for a study of vaccinated vs. unvaccinated populations. However, we would state that a "feasibility study" falls short of the mark in restoring public trust. The recommendation should be that a comprehensive study of vaccinated vs. unvaccinated populations for long-term effects of vaccines to determine total health outcomes with regard to vaccine toxicants (e.g. – mercury, aluminum, formaldehyde, etc.), possible detrimental effects of current timeline of immunization schedule and the number of vaccines given at any one time be conducted from both a prospective and retrospective manner immediately, as well as on an on-going basis.

There are no special methodological or design issues that make this program of research somehow unique or difficult compared to the remainder of the body of recommended research. Additionally, it is highly ethical to prospectively study children who self-select for exemptions for religious or philosophical reasons or to retrospectively study such children. We understand that care needs to be taken in the design of the research program to ensure that the cases and controls are sufficiently equivalent in all other aspects for vaccine exposure to make a comparison of their health outcomes meaningful, as well as accounting for possible differences in health services seeking behavior. However, these types of concern are no different than the types of issues that must be dealt with in the design of any epidemiological research program, such as the "body" of studies that purport to exonerate vaccines of safety issues routinely cited by those who feel there are no vaccine safety issues of concern. It is not necessary to delay this array of study for one or two years while a feasibility study is undertaken. Such a delay will only serve to further jeopardize public confidence in vaccine safety.

In order to further the goals suggested with regard to independence and transparency, the Institute of Medicine should not be assigned the task of feasibility or oversight of this program of research, as there is no assurance than an IOM panel will have the breadth and diversity of representation necessary to meet these goals, as well as the fact that the IOM is not required to fully comply with the Federal Advisory Committee Act, thus limiting transparency and public engagement.

We also note that portions of the Prioritization Criteria labels and defining issues have been modified and would recommend the use of the labels from the SLCWG, which appear to be more clear and neutral in tone. Some of the general principles for application of the criteria developed at the SLCWG have also been removed and we would recommend their reinstatement with particular attention to the principle

- Criteria should be applied in a transparent process with stakeholder input throughout the process to enhance accountability and enhance public trust and confidence.
- The following criteria are proposed so that prioritization decisions are made in a consistent and fair fashion.
- In order to achieve accountability, NVAC will provide an explanation of how they applied the criteria to the issues on the research agenda.

Thank you for this opportunity to offer comment. Please don’t hesitate to contact us with any questions regarding our statement.

Sincerely,

Theresa K. Wrangham,
President

INDIVIDUAL COMMENT #1

My daughter has lost life as she knew it to the Gardasil vaccine. Her story is below. Even worse than her illness has been the callousness of doctors who are convinced by the CDC of the complete and utter safety of this vaccine. To have your child so ill and know that the only explanation is this vaccine and to have doctors rudely discount what you are telling them. Even when they can find no other explanation! I stopped at one injection regardless, but others continued getting them even though they were terribly ill becasue doctors insisted there could be no relationship. These doctors must be educated and we must mandate that they listen to their patients... what about the oath to 'do no harm' - As far as I am concerned they are all liable for this tragedy.

http://www.caringbridge.org/cb/viewHome.do

Jenna Bear
330-688-3505

INDIVIDUAL COMMENT #2

To Whom it May Concern,

I am a physical therapist in a school district, and mother of 3. All 3 of my kids experienced adverse vaccine reactions (one was mild, but two developed symptoms of autism). Tradtional therapies completely failed, however "alternative" treatments such as chelation, dietary changes, and targeted supplements worked like a charm. Two no longer have autistic symptoms, and the other is doing tremendously better, but has not fully recovered yet. Why aren't these "alternative treatments" being used by main stream pediatricians? They work!

It's my feeling that **the CDC needs to be removed from anything to do with vaccine safety**! Most in the autism community do not trust the CDC anymore, given their sorry track record. **I consider anything coming out of the CDC to be in the category of JUNK SCIENCE**, which is a shame. It didn't use to be that way.

It's obvious by now that genes can not account for the dramatic rise in autism, and **environmental factors must now be given priority** and appropriate funding. For starters, **we need a study comparing VACCINATED VS NEVER-VACCINATED CHILDREN!!!** If the CDC had truly been interested in finding the cause of the autism epidemic, this study would have been done 2 decades ago. It defies common sense to have refused to do this study for so long. Their excuses fot not doing the study are patheitc, and I consider them criminal.

Also, I hope someone is looking into the recent events with the IAAC where one week they voted to do the much-needed vaccine research. Then, a "surprise vote" was announced at the following meeting that resulted in the removal of the vaccine study from their plans. Seems only the governemt members of this panel were aware of this vote ahead of time. Those representing the public side didn't have a clue. Yet another criminal act was allowed with no opposition.

I come from a very "main stream" medical family (my father is a pharmacist, my step-father and grandfather were physicians and I am a physicla therapist). I have always been proud of the way we practice medicine in the US. That is no longer the case. I am ashamed of the pediatricians who have kept their heads in the sand and allowed all these children to be damaged needlessly, year after year after year. The AAP no longer serves the needs of the children, they are sacrificing them instead, to cover their own butts. I am furious with the CDC for purposely blocking anything that might involve properly studying the vaccine-autism connection. The studies they've used as "proof" that vaccines do not cause autims have been extremely flawed, and openly critisized, yet they still spout the party line of "the question has been asked, and answered". Makes me absolutely sick that they are allowed to get aweay with this garbage, yet voices of reason are attacked and in some case their careeers have been ruined.

I had to wait 8 years for my little girl to be able to say "I love you" after her vaccine injury. Our life was pure hell for years. We got to enjoy round-the-clock screaming and agression, lack of sleep, feces smeared all over our home. Until we found a good DAN doctor and began biomedical treatments, we were prisoners in our own home. Plus, my husband was a Navy pilot, so in addition to autism challenges, we also had to deal with 6 month deployments, and relocating our family every 2 years , only to start over with finding specialists, doctors, schools, etc. in each new state. It wasn't easy, to say the least. He would have stayed in the Navy past his 20 years, but the strain on our family was too much, so he opted

to retire. The Navy lost a great pilot and officer due to autism, and I blame much of our trouble on the CDC's unethical handling of this epidemic. They could have stopped it right from the start, but they were cowards, if not out right greedy, and did nothing.

My kids were born in 1993, '95 and '97. The CDC was well aware by then of potemtial problems with their overly aggressive vaccine program. How many more thoudsands of children are going to have their lives needlessly destroyed before someone in the position to make changes actually steps up and does the right thing?!

Really, how do any of these people sleep at night?! I could go on for page- after- page, but you get the idea. The phamaceutical companies run the CDC, and they both have too much say over what we, as parents, are forced to inject into our children. No more vaccines for our family until there is a complete overhaul of vaccine safety (which includes getting the CDC the hell out of any decisions), and they can assure me they can identify the susceptible populations, **and are willing to protect those children from harm.**

I'm sure many parents will contact you. I hope you take them seriously for a change.

Sincerely,

Katherine Anne Jakus

INDIVIDUAL COMMENT #3

PUBLIC COMMENT ON FEDERAL REGISTER BELOW

1. I AM A STAKEHOLDER BECAUSE I AM AN AMERICAN CITIZEN WHO WANTS TO SEE OUR KIDS HEALTH, NOT AUTISTIC.

2. THE PARENTS LIVE WITH THE KIDS AND KNOW WHEN THEIR KIDS GET SICK. SOME MEDICAL DOCTOR WHO HAS NEVER SEEN THE KID BEFORE SAYS THEY KNOW WHAT IT IS WHEN THEIR DIAGNOSIS HAS NOT REAL INFROMATION ON THE CHILD - THAT IS ABOUT AS STUPID AS IT GETS. I AM SICK OF THE DOCTORS SAYING THE PARENTS DONT KNOW WHAT GOES ON WITH THEIR KIDS. THERE ARE VERY VERY INTELLIGENT PARENTS OUT THERE WHO KNOW THAT BIG PHARMA AND THE MEDICAL INDUSTRY ARE WAY OUT OF LINE. BIG PHARMA IS IMPORTING VACCINES FROM CHINA, THE SITE OF ALL THE POISONS THAT COME HERE. CHINA TIME AFTER TIME AFTER TIME SENDS AMERICAN POISONOUS GOODS. CHINA HAS ZERO QUALITY CONTROL ON DURGS. ZERO. NO REGULATION AND THEN THE STUPID MEDICAL INDUSTRY COMES ALONG AND SAYS WE MANDATORILY HAVE TO PUT THESE CHINESE VACCINES INTO OUR KIDS. THEY ARE OUT OF THEIR MINDS.

ABSOLUTELY OUT OF THEIR MINDS.

ALL AMERICAN PARENTS ARE STAKEHOLDERS. IT IS TIME YOU WORK FOR US AND NOT JUST FOR BIG PHARMA AND BIG MEDICINE. I PERSONNHALLY VERY MUCH ABHOR WHAT NIH AND CDC ARE DOING SINCE THEY ARE OBVIOUSLY IN THE POCKET OF BIG PHARMA AND BIG MEDICINE AND NOT AT ALL INTERESTED IN WORKING FOR SAFETY AND HEALTH OF THE AMERICAN PEOPLE. IT IS ALL ABOUT THEIR OWN MONEY IN THEIR POCKET. I THINK BRIBES ARE GOING ON.

WE DO SEE EVIDENCE OF MONEY FLOWING FROM BIG PHARMA TO BIG MEDEICINE FOR THEIR ALLEGED 'RECOMMENDATIONS". THIS IS FAR TOO FREQUENT. THE ETHICS ARE MISSING, WHICH MEANS THE RECOMMENDATONS ARE HIGHLY SUSPICIOUS.

THESE COMMENTS ARE FOR THE RECORD.
B. SACHAU 15 ELM ST FLORHAM PARK NJ07392

INDIVIDUAL COMMENT #4

Hello,

I would like to give testimony to the National Vaccine Advisory Committee about the relationship between vaccines and chronic illness.

I am a retired registered nurse who has been totally disabled with systemic lupus, systemic vasculitis since 1984 caused by the Hepatitis B vaccine I received while working as a registered nurse. I also have been diagnosed with Sjogren's and degeneration spinal cord in the last couple of years.

I'm also a professional writer with many publications to my credit. My book of essays, Body Language: First Of All Do No Harm will be published by Purdue University Press in July, 2009.

The funding of vaccine safety research must be increased and based on sound data that investigates all potential adverse events. Independent scientists must be able to assess the VAERS data to see how patients who have experienced adverse events are doing, or if they're still alive. The safety of the vaccines should be ensured before a pharmaceutical company receives licensure for a vaccine.The effect of multiple doses of vaccines given to an infant should be investigated. If the child receives his vaccinations from a multiple dose vial, the bottle contains thimerosal as a preservative. The only reason a preservative is placed in a vial is so that the pharmaceutical company can get more doses out of one bottle.

I sincerely hope that President Obama's administration takes a serious look at the link between the increased number of vaccines that our children receive and our epidemic of autism in our children.

Best wishes,

Constance Studer, RN (retired) MA
740 Copper Lane, #202
Louisville, CO 80027
303-945-1296
cstjam@yahoo.com

INDIVIDUAL COMMENT #5

i am unable to attend meeting but would like to onpass my message / voice: i know a little long winded and many points are already well know but also please take some time to look at my families personal account - we try not to judge but are tired, frustrated, broke and know that something more / different needs to be done...thanks...bill knapp

would like to voice my opinion / comment & position in hopes that the NVAC + stakeholders on 16-March-09, will recognize and embrace the fact that reform is needed within the national vaccine program / government agencies to better facilitate / promote / direct more rigorous, unbiased & transparent vaccine safety assessment / research. Additionally, ensure that members of the Autism community are represented & help shape / dictate future policy / research direction / funding. Further & to cut right to the chase - I cut / past below points of cotention previously penned by other, more informed / motivated individuals deeply engaged with the task at hand amoung others to expand / promote more & better research....+ i could not summarize any better & is exactly how I feel...based on much frustration, research & living with / for Autism since 2005 - also please see below for my family's personal account.

• The CDC's vested interests in vaccine promotion precludes their ability to conduct unbiased vaccine safety research. This research must be overseen by an independent agency and conducted by unbiased researchers. Parent stakeholder involvement in all aspects of research is paramount in this process.
The CDC's ISO lacks the budget and infrastructure to conduct adequate safety research and relies on the flawed and deficient VAERS and VSD databases to detect adverse effects. The funding of safety research must be increased and based on sound datasets capturing all potential adverse events.

• In the interest of transparency, the unrestricted use of CDC's VAERS and VSD datasets must be made available to outside, independent scientists immediately in a manner that preserves patient privacy.

• The ISO studies vaccine safety only after a vaccine has been licensed, relegating safety as secondary to vaccine promotion. Vaccine safety policy should ensure that comprehensive research is transparent to the public and conducted to examine the effects of the total vaccination schedule, not just individual vaccines, before licensure.

• NVPO must ensure that a comprehensive program of vaccine safety research is initiated through the establishment of the expert panel recommended by the Writing Group, which shall be charged with recommending an array of research on health outcomes in vaccinated versus unvaccinated populations.

• The treatment of our children as guinea pigs in the ever expanding and untested vaccine schedule is unethical. Billions of dollars are spent to license, promote and pay for vaccinations, while the CDC shamefully spends only about $20 million annually for safety research. At a minimum, vaccine safety should have the same priority as vaccine development and promotion. The U.S. government needs a "Safety First" agenda for vaccines.

• Scientists like Dr. Wakefield, have been persecuted for conducting safety research where findings are viewed as unfavorable by those with vested interests in vaccine uptake. The U.S. government must support scientists currently engaged in much needed safety research; they must not be persecuted for conducting research that closes acknowledged vaccine safety research gaps.
On a personal note...I will try to summarize as brief as possible - but anyone familiar w/ Autism knows there is nothing brief about this subject:

1. My wife received 3 x injections of rhogam - up to / during breast feeding
2. Our Son, William Vaughn Knapp was born 6 weeks premature / 29-May-03
3. We followed CDC recommended vaccine schedule
4. Within 7 days of MMR injection, my son Will suffered from high fever, rash / skin blotches, could not sleep, inconsolable - we consulted with Dr regarding disposition / symptoms and have in writing "probable MMR vaccine reaction" - at that time we had little idea what that meant
5. During the next year my son suffered numerous infections (constant rounds of antibiotics), loss of speech / eye contact, sever diarrhea , asthma (required nebuliser / daily), stimming / self stimulatory behavior, motor planning issues, sensory integration disorder, etc...etc...etc...
6. Our son Will was diagnosed w/ Autism at age 2yrs old / 2005 by the Texas Childrens Hospital / Houston. At the time, 9 month wait list to start evaluations w/ TCH - we were lucky and able to get him in sooner due to cancellation
7. Medical treatment was minimal at best - upon diagnosis we were handed a couple pamphlets & suggested intervention by OT, PT & SLP therapists & given I year annual follow up eval. His condition was evaluated / treated as a mental nervousness condition / as per DSMR III
8. More then a year went by following mainstream medical protocol - with little improvement. Never did our Dr's consider / evaluate physiological / chronic medical condition / disease(s)
9. At age 4yrs old, results of Will's yearly Autism Evaluation at TCH gave him avg / at best 1 year old level for all his developmental milestones
10. After much research on our own we abandoned mainstream medical advise and sought treatment through a small group of Doctors (Thoughtful House / Austin, TX) who specialize in the eval / treatment of autism with a biomedical approach.
11. It was quickly determined among other things that Will suffered from chronic, treatable conditions....not a mental disorder.
12. Will has medically documented: GI / immune dysfunction, his metabolic system is a wreck, many & sever food / environmental allergies, inability to shed toxins, medically documented mercury & lead toxicity... he was not only sick but in pain and unable to tell us because he could not talk
13. We have effected a rigid / strict GFCF + dairy free diet, nothing but organic / USA grown produce & meat (which he etas very little of), removed as many environmental contributors as possible - ie cleaning products, plastics, only glass bottled water, etc...even the microwave is gone...additionally Will at present takes 9 x supplements / 4

14. At 5 yrs old Will was again evaluated at TCH (need diagnosis / eval for our insurance) - with only several months of biomedical intervention under his belt, he amazed all his doctors and was given on avg at level or just below for all his developmental milestones..he still has a way to go but if you could have seen him a year ago...
15. **What is even more amazing is while our mainstream medical Dr's (TCH & peditrician) continue to be astonished by his progress, there is no desire to truly understand / embrace what we have done to get him where his is today - this is a reflection, in general of attitude / function / poor training & understanding of mainstream medicine and our government agencies (CDC, NIH, AAP et al)...I really do not know where Will / our family would be had we continued on the course that mainstream medicine was blindly guiding us. The Autism Community - comprised of all the deicated, good, smart people (many of which are Doctors / Scientists) infromed us / and directed us & are helping recover my Son**
16. **i** could go on but will leave it at that....much detail to fill in between the lines but our story is similar to the 10's of thousands of other families....I leave it to you all now - I know I feel better tonight and will get at least 5 hrs solid sleep now....bill knapp

INDIVIDUAL COMMENT #6

public comment on federal register below

the working group has been sleeping for years. getting paid big bucks from tax dollars and producing vaccines that harm and hurt our kids and adult citizen.

big pharma profiteers simply do not care if they harm people or not - they got our traitorous govt to insulate them from liability suits when they kill kids or injure them with lifelong injuries. they could care less. their clinical trials are a sham and a fake and done in third world countires where nobody is watching what kills and what doesnt. they bribe doctors to prescribe their products with all kinds of fully paid for conferences at resorts all over the world - big time bribery. the vaccines they got approved are unsafe. completely unsafe but money talks in america these days. greed is good so they say and big pharma and big medicine have been linking arms against the public good for a long time now.

iso has been sitting on its butt as far as safety. they dont know what resultsl have happened after vaccine application. they are as ignorant as a newborn babe and could care less about having any health or unhealthy reports sent to them. these people should be fired. their record of seeing to safety in america is dismal.

we want safe products. we donot want assaults of vaccineson our newborn babies. the numbers of doses of vaccines has tripled since the l980's. it is time to see just what that tripling has done to health. we have an autism epidemic. we know that vaccines have multipled up to 3 times a smany. and nobody knows how that is influencing health. No

this whole system is as corrupt as the sec and wall street and just as bad for america.
jean public 15 elm st florham park nj07932

INDIVIDUAL COMMENT #7

This comment was anonymous. It was transmitted to the NVAC Vaccine Safety Working Group, but was not included in the comments posted online, as stipulated in the Federal Register notice (Federal Register of April 12, 2009).

INDIVIDUAL COMMENT #8

Please step- up and study vaccinated children vs unvaccinated children. As a mother of two perfectly healthy boys who are NOT vaccinated I would definitely participate in such a study.

Thank you for your time.

Debbie Voss
Burgaw, NC

INDIVIDUAL COMMENT #9

May 13, 2009

National Vaccine Program Office
Department of Health and Human Services
Room 443-H
200 Independence Avenue SW
Washington, DC 20201

RE: Vaccine Safety RFI

Dear Sirs:

I appreciate the opportunity to comment on the Vaccine Safety RFI. As a grandfather of a 5-year-old grandson with autism, I have lost all confidence in our federal health agencies. The government's protection of the National Vaccine Program at the expense of damaging a generation of children with autism is appalling. The concept of a "one size fits all" national vaccine program is idiotic. The apparent stonewalling and cover-up by our government is criminal.

I strongly support the Vaccine Safety RFI recommendation for a safety study comparing the medical outcomes of vaccinated vs. unvaccinated children. Such of study must be performed by an independent organization with no ties to federal health agencies or pharmaceutical companies.

I have taken the liberty to enclose a recent letter drafted by Safeminds that elegantly describes the needs for an overall of this country's vaccine safety program.

Sincerely,

Garry W. Cooke

INDIVIDUAL COMMENT #10

Dear Vaccine Safety RFI:

As the father of a child still struggling with autism, and another who has completely recovered from autism due to bio-medical interventions I strongly support research looking at the neurological health of vaccinated and unvaccinated children.

Similarly, I believe it's difficult for the CDC to both promote vaccines as well as honestly study them for potential negative effects.

All the best,
Kent Heckenlively, Esq.
Legal Editor, Age of Autism

INDIVIDUAL COMMENT #11

to whom it may concern: we need to do a vax/unvax study here in usa..we need to look at the pre-screened 5,0000 cases of injuried babies and children in federal court system..we need to put safety for our children above profit making and marketing for big pharma..parents are sick of the propaganda of fear mongering..we want real science..and we are intelligent enough to figure it out..when stats are being manipulated...mostly we want our precious babies our once in a life-time babies to stop being injured ..by goverment immunization programs where safety is last..thank you Candace

INDIVIDUAL COMMENT #12

1) As a parent I am very concerned with possible conflicts of interest among committee members. Are there public or private members of the committee who are financially vested in the vaccination program? Are there members of organizations whose membership includes vaccine makers?

We need to see total transparent, independent leadership. Public members of the committee must be parent of parent organizations only, organizations with no pharmaceutical ties.

2) Why is no effort being made to study the effects of multiple vaccines? Babies regularly receive 3, 4, and 5 vaccines at visit, as my child did.

We have no idea how the interaction of the viruses, live and preserved affect a baby's immune system. We also have no idea how the myriad of toxic adjuavants- formaldehyde, lead, aluminum, affect the developing brain. I do not want to hear that "there is mercury and lead in the air we breathe." Injecting these substances directly into the bloodstream is not the same.

3) Why are their NO plans to study the effects of multiple vaccines as more and more shots are added to the schedule? Why not answer safety questions BEFORE adding more vaccines to the world's most crowded infant and toddler vaccine schedule?

INDIVIDUAL COMMENT #13

Why don't you spend research dollars looking into the overall health and outcomes of vaccinated children vs. unvaccinated children? No study has ever looked at this, and it would be extraordinarily valuable information to have. Thank you.
Jennifer O'Leary
Hackettstown, NJ

INDIVIDUAL COMMENT #14

WE NEED A RELIABLE AND VIABLE COMPLETE STUDY OF VACCINE/AUTISM ASSOCIATIONS COMPLETED WITHOUT BIAS OR INFLUENCED BY INTERESTS OF INDEPENDENT FOCUS GROUPS, PHARMACUDECAL COMPANIES AND POLITICALLY CHARGED PLATFORMS. WE OWE THIS TO THE AUTISTIC COMMUNITY AND THE FAMILIES THAT SIMPLY WOULD LIKE SOME ANWERS.

DEB RANKIN
402-981-7094

INDIVIDUAL COMMENT #15

From: Rosanne Achin

We need to study the incidence of autism in vaccinated vs. unvaccinated children. I think its rediculous that this research hasn't been done yet.

INDIVIDUAL COMMENT #16

I fully support the efforts to obtain more research and better information regarding vaccinations. Studying the vaccinated and unvaccinated population is critical.
No one and I repeat no one can scientifically demonstrate that they know for a fact that multiple and continued vaccines do not permanently damage the natural immune system given to us by God.
If they can not do this, they should not be able to mandate vaccines.

period the end

thank you

Judi Fouchet

INDIVIDUAL COMMENT #17

My entire extended family is strongly in favor of a comprehensive study comparing vaccinated Vs. unvaccinated populations for all relative health and neurological impairments. Without a study of that nature nothing can accurately be determined about our current practices.
Paula Bryant-Trerise

INDIVIDUAL COMMENT #18

My 4 year old son, Matthew, has Autism and heavy metal poisoning...which is due in part to his baby vaccines. I have come to learn that he has the MTHFR (double defect) mutation which means his body is low in Glutathione (which he needs to detox). [And when he was a baby, his pediatricians told me to give him Tylenol (which further lowers glutathione) before & after each shot series.]

Matthew was fully vaccinated up to age 2, but he will NOT be receiving any more vaccinations in the future. I have lost faith in his pediatricians/the AAP and do not trust the CDC. I am not alone, most of the parents I know are now questioning vaccine safety and are choosing to delay or completely skip their children's shots.

Our lives have been turned upside down b/c of Matthew's ASD & comorbidities..I do not want any more families to have endure the hell we have gone through. * I am BEGGING that someone other than the CDC (who has MAJOR conflicts of interest) conduct vaccine safety research.* We need to stop injecting live viruses and neurotoxins into innocent children whose bodies cannot handle them.

Thank you,
Cynthia Newton

INDIVIDUAL COMMENT #19

From: Laure King

I would like to voice my support for an independent study on vaccination population vs. unvaccinated population. I feel that this study is long overdue, not just testing vaccination schedule but it changing age minimums and vaccination requirements. The rise in developmental issues and increase of vaccines in the vaccination schedule trends toward there being something wrong with this. Particularly, that infants are given the same vaccination dosage as older children and adults. It is not just a thimersol issue, it is an overall overload on the systems of our children.

It would be wonderful to see not just vaccinated vs. unvaccinated results, but also to add a third population with a minimal vaccination schedule.

INDIVIDUAL COMMENT #20

To whom it may concern,

I am a mother of three children, twin boys age 8 and one daughter age 5. My two sons have autism and have had their full round of vaccines except for their boosters. My daughter remains unvaccinated and will never receive a vaccination under my watch.

My boys descent into illness and autism began at six months of age two days after receiving their six month shots. They both ran high fevers and were very lethargic. I felt that one of my sons never really recovered from that shot. He continued to be very "lumpy" as
we called it and never seemed to regain the same level of liveliness.
One week later both boys had their first ear infection and continued to be plagued by them. One of my sons finally had to have tubes place to stop the chronic infections. As each vaccination ensued over the course of the next year I watched in horror as they both slipped away into autism and constant illness. I was never comfortable vaccinating them but I listened to my pediatrician and went against every motherly instinct I know that was telling me not to do it. Now I spend every day of my life trying to undo the harm that was done to them. Ultimately they are the ones who have had to pay the price for their health and their life.

On the other end of the spectrum, my daughter has never known anything but true health. She has progressed normally and never, I mean NEVER, had an ear infection. I don't know one other parent that can say that other than my friends who did not vaccinate their children. I have brought my daughter to the pediatrician only for well visits and I believe one sick visit. She is five!!! I can honestly say that I rarely here of any children with such few visits.

I know that this is for certain. My boys have suffered unnecessarily because of being vaccinated. There is a genetic component that made them susceptible to immune system issues when their immune system was pushed too far. The result was autism and illness. Through much testing, we know that their systems are broken. Let's please not break anymore!!!!! No one should have to suffer like my boys and millions of other children have. FIX THIS!!!

Sincerely,
Suzie Morabito

INDIVIDUAL COMMENT #21

TO WHOM IT MAY CONCERN:

The government has not done its job in monitoring vaccines for safety

It is possible that the current vaccine regiment is actually linked to autism, asthma and numerous learning problems now epidemic in our children

please SUPPORT the essential epidemiological studies comparing immunized and non immunized children so we can start to design a immunization program that we feel will not harm our children

Eunice Carlson, Professor
Teacher of Immunology and Toxicology
Dept Biological Sciences
Michigan Technological University
Houghton MI 499312

INDIVIDUAL COMMENT #22

If the government does not accommodate the reasonable request of thousands of parents to study vax populations v. non-vax populations, the vaccine program will be in more and more trouble as time goes on.

Rita Palma
www.mykidsmychoice.com

INDIVIDUAL COMMENT #23

Please do a vaccinated vs. unvaccinated study which focuses on autism in each group of kids.

My son was born 2.5 years ago and we made the difficult decision not to vaccinate because the safety is not proven. I would like to be able to trust vaccines but at this point I do not.

I do not think that any studies to date have proven that vaccines are safe and do not cause autism. I think the wording that is used to say they are safe and do not cause autism are tricky. I have read articles that state that no "causal relationship" has been determined in cigarette smoking and lung cancer but we all know that it does. The wording is tricky and promotes distrust.

Design a study that looks at vaccinated vs. unvaccinated kids and autism.

Thank You

Susan Carter

INDIVIDUAL COMMENT #24

TO WHOM IT MAY CONCERN:

I am writing to express strong agreement with the working group's assessment that vaccine safety research is severely flawed and incomplete. The 17 general and 15 specific recommendations point this out.

The most significant hurdle is the acute need for *"a comprehensive program of human and animal research centered on an examination of the acute and chronic health outcomes of unvaccinated children to establish baseline data against which adverse events following immunization (AEFI's) could be measured."*

This is by far the most important recommendation coming from the senior vaccine advisory committee as it is a recognition of this crucial gap in safety science. The 1986 Congressional mandate for safer vaccines set forth in Section 27 of VICA simply cannot be carried out without adequate baseline data on the health of unvaccinated children.

Also, I would like to stress that CDC is completely conflicted and inadequate to properly conduct vaccine safety research. A consortium of independent research firms and centers focused strictly on vaccine safety should function separate and outside the auspices of the CDC.

Research in the short term should focus on the development of reliable screening mechanism[s] that would help identify those most at risk and/or susceptible to a severe vaccine reaction. Development of safer vaccines should be ongoing but reprioritized as a more of a long-term goal.

Related to safety indirectly is the deplorable one-size-fits-all mandate for school entry that exists -- in some states without a conscientious recourse! Please address this as well, encouraging a more individualized respect for the human component living at the center of this issue. Fear should certainly not rule the day. However, neither should blindly marching ahead in a sort of comatose patriotism.

Thank-you,
Tim Smith, citizen and parent of a vaccine-damaged child,
Madison, MS

There is everything to be gained and nothing to be lost by studying the unvaccinated populations. We need to lay to rest the theory of a link between autism and vaccines and, as you can tell, you are dealing with a very educated, active population of citizens

that know when a study is run by a party with conflicts of interest. The study MUST be run by a completely neutral party for us to be satisfied with the results. Until this is done, you will continue to see the vaccine rates decline.

Angela Day

National Autism Association of Central Texas

http://www.naacentraltexas.org

formally FEAT Austin

To help families struggling with autism:

http://www.naacentraltexas.org/donations.htm

To help adults with autism:

http://www.countrysidetexas.org

INDIVIDUAL COMMENT #25

I am writing on behalf of my 6 year old son. Please consider a vaccinated vs. unvaccinated study. My son spiraled downward after receiving his 4 month old vaccines and was hospitalized with the Roto Virus. Please give my son and countless others the respect the they deserve as they work everyday to heal. Please consider the study. The truth can save many, many children.

Thank you, Christy Will
Noah's biggest fan!!!!

INDIVIDUAL COMMENT #26

This letter is to express my support of research to study the health of unvaccinated children. As the vaccine schedule in the U.S. has increased, so have the rates of chronic disease. I have one child who was fully vaccinated, one who was partially vaccinated, and one who is unvaccinated. I know that my sample is small and not statistically significant, but in my own family I can see a significant difference in the health of my unvaccinated child versus my children who were immunized.

I have never been able to understand how a vaccine "safety" can be determined without a true control group. In medical research when a drug is tested, the control group is given a placebo. However, in vaccine research, the control group is given an older or prior version of the vaccine. How can the safety truly be determined? What looks to be normal and acceptable could truly be abnormal and eggregious if the vaccinated were compared with the unvaccinated. We know that unvaccinated children are out there. Many homeschooling families, and certain religious groups choose not to vaccinate their children.

Please do not ignore this very basic and necessary step of scientific research. Give us a study that compares the unvaccinated to the vaccinated so that we can, perhaps, begin to trust in the science behind vaccine approval again!

Sincerely,

Sarah Coleman
Starkville, MS

INDIVIDUAL COMMENT #27

Hi,

I'm a 39 year old mother of three children and I'm writing to encourage you to review current vaccine safety measures and subsequent recommendations for the pediatric vaccine schedule in this country.

I and most of my family and friends are declining recommended pediatric vaccines for our children due to lack of sufficient evidence of safety of the current vaccine schedule and numerous parent accounts of children's declining health after routine vaccinations. I don't believe this the right thing for this countries overall health, however, it is the only option at this juncture given that there is, in my opinion, lack of sufficient data to the safety of the current childhood schedule. I would like more options!

I believe that vaccines are a great tool against disease, however the new childhood illnesses are on the rise (!) and many times life long and extremely difficult to treat.
I do not blame vaccines for these relatively new sicknesses, however until there is some better safety measures taken on the current, very full schedule of childhood immunizations, caution is mandated on my part as a parent to prevent lifelong health problems for my children.

I currently support the exploration of a comprehensive study of children who have had no vaccines compared to children who have received all of the recommended vaccines looking for all diseases. I believe it is warrented when so many children today have developed autism, ADHD, allergies, asthma and autoimmune disease.

Thank You,

Amber Berry
9599 Winston
Redford, MI 48239

Did you know:

- 1 in 150 children is diagnosed with autism
- 1 in 94 boys is on the autism spectrum
- Boys are four times more likely than girls to have autism
- 67 children are diagnosed per day
- A new case is diagnosed almost every 20 minutes
- More children will be diagnosed with autism this year than with AIDS, diabetes & cancer combined

- Autism is the fastest-growing serious developmental disability in the U.S.
- Autism costs the nation over $90 billion per year, a figure expected to double in the next decade
- Autism receives less than 5% of the research funding of many less prevalent childhood diseases
- There is no medical detection or cure for autism

INDIVIDUAL COMMENT #28

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 715-H
Washington, DC 20201

Attention: Vaccine Safety RFI

I support the The Vaccine Safety Working Group of the National Vaccine Advisory Committee's draft report on April 14 making 17 general and 15 specific research recommendations to improve vaccine safety research at CDC. The most important recommendations being:

A comprehensive program of human and animal research centered on an examination of the acute and chronic health outcomes of unvaccinated children to establish baseline data against which adverse events following immunization (AEFI's) could be measured.

In 1991, my son was mistakenly given an MMR at 8 months of age and then given his correct vaccines of DPT#3 and HIB#3 on top of it. Seven vaccines, two injections containing mercury, was too many, too soon.

My son was perfect at birth. After the vaccine error he developed high functioning autism. The harm caused to my son is a direct result of multiple vaccines and toxic vaccine ingredients.

The "status quo" at the CDC needs to be corrected. The CDC is completely conflicted and inadequate to properly conduct vaccine safety research. It is impossible for CDC to be both lead vaccine cheerleader and, at the same time, adequately evaluate vaccine safety. The agency needs to be completely severed from the influence of the pharmaceutical industry.

Lila White
Mom to Mark, 18 and recovered
Springfield, IL

Buy a puzzle piece from me for $1.00 and support Autism Research Institute. Each one-dollar Piece represents a son, daughter, grandchild, neighbor or friend. You are the missing piece.

INDIVIDUAL COMMENT #29

To whom it may concern, I am deeply passionate about the need for studies of vaccinated vs unvaccinated population groups. myself and other moms have noted the positive differences, others that were teachers noted changes in health once retired etc, and I think a full study THAT IS NOT BIASED or funded by parties linked with vaccinations is ESSENTIAL. I fully support that type of study.
Dr. Debra Barnes

INDIVIDUAL COMMENT #30

Dear Working Group:

I read in the Federal Register that *"In addition to general comments, NVPO is seeking input on any additional gaps not addressed in the ISO Scientific Agenda nor the NVAC Vaccine Safety Working Group draft report, and/or prioritization criteria and its application to the ISO Scientific Agenda."* Here are my comments:

1) **I would recommend research on the health of vaccinated versus unvaccinated children**. It seems that in the last 20 years, chronic childhood diseases such as allergies, asthma, juvenile diabetes, and neurological diseases such as learning disabilities and autism have skyrocketed. I believe my own son was vaccine damaged. I have noticed that friends who chose not to vaccine their children seem to have healthier children. I understand that the Amish, who also vaccinate selectively, if at all, do not see these kinds of problems in their children. I know that such a study has not been done. If the CDC wants to restore trust in its vaccine program, then such a study would go a long way toward establishing credibility. I don't see the ethical problems with reviewing an unvaccinated population, since there are sizable groups of people who have already made this choice in states that allow religious or philosophical exemptions.

2) **I would recommend research into possible subgroups that may indicate a population vulnerable to vaccination and genetically predisposed to autism.** Mitochondrial dysfunction is one area that should be explored. One of the Vaccine Court cases wherein a family was compensated for vaccine damage involved a young girl who had mitochondrial dysfunction, was vaccinated, and developed autism. I am speaking of the Hannah Poling case. I think my own son falls into this category.

3) **I would recommend research into the effects of administering multiple vaccinations at once.** This has never been studied to my knowledge. Doctors know that different prescription drugs in combination can cause problems in patients; it is not a far stretch to think that multiple vaccines given at the same time could wreak havoc on a young child's immune system.

4) **Finally, I would recommend research on the safety of other ingredients found in vaccines**. I understand the the vast majority of them have never been tested for safety. Specifically, I think you should look at known neurotoxins, such as aluminum and thimerosal. I know that many shots still contain thimerosal (e.g. flu shots); even those where the thimerosal has supposedly been removed contain traces...possibly more, since the FDA admits they don't monitor companies' manufacturing processes. Aluminum is still in vaccines and needs to be examined for its role in triggering encephalopathy.

I know that if I had to make the choice all over again, I would not vaccinate either of my children. The CDC and the FDA have lost my trust. the website

www.fourteenstudies.org has shown me how flawed previous research has been. It will take serious, unbiased research in the areas I have outlined above to regain my trust. And I know I am not alone.

Sincerely,

Aimee Doyle
2512 Heatherwood Court
Hyattsville, MD 20783

INDIVIDUAL COMMENT #31

I am the parent of two young children and about to give birth to a third. **Please put the necessary resources forward allowing a study of vaccinated versus unvaccinated children**. There is no good reason why this study has not been conducted to date. Our children deserve it. Parents deserve to have full information to make informed decisions for their children's health. This is a wonderful opportunity for the CDC, FDA, and AAP to demonstrate the safety of the current vaccine schedule they preach to parents and the public despite the research supporting the safety of the full schedule and various combinations of shots.

Jessica Gutierrez
4423 Rocky Meadows Dr.
College Station, TX 77845
gutierrez_jessica@yahoo.com

INDIVIDUAL COMMENT #32

I am writing to urge that the federal government immediately commence a study of health and developmental outcomes in vaccinated vs. unvaccinated (and fully vaccinated vs. partially vaccinated) children. As a teacher and child safety advocate, I am deeply troubled by the sudden and dramatic increase in my county of children with autism, ADD, ADHD, learning disabilities, asthma, and food allergies. I am also intrigued by research indicating that too many vaccines leads to a condition in animals called vaccinosis, in which their own immune systems break down, giving rise to a whole host of health and developmental problems. If this is possible in animals, why not in humans?

Please undertake research to swiftly answer whether humans may also be prone to vaccinosis. The health and well-being of an entire generation of children hangs in the balance.

Sincerely,
Lisa S.

INDIVIDUAL COMMENT #33

Please please please get serious about vaccine safety!!

It is insane to think it is safe to vaccinate day of birth given our ignorance of immune function, immune development, long term effects of vaccines....and for a diseases virtually only trnasmitted by sex, IV drug use and blood transfusions, for which babies are virtually not at risk.

..and the multiple vaccines simultaneously with absoluely no research...

...and the almost worthless monitoring...

...and the inadequate studies that you utilize as your basis for licensing..

...and the ridiculous conflicts of interest of you advisory people.

It is sooo tragic what you people have allowed to happen. Don't you get it? Every day this current program continues is damage to 10's of 1,000's of more kids- get urgency!

This needs to be a part of a bigger objective- pushing back the profit motive from controlling medical research and public health. We have allowed Big Pharma and greed way to much power. This is a moral failure of us, as a society.

Three suggestions I have right now are: 1.) Legistlation for conflicts of interests restrictions for public health employees, similar to those which apply in the defense industry. 2.) Returning to the early '90's with respect to publicly funded university research not directly profiting from their scientific work. 3.) Restricting advertising for Big Pharma back towards the way it used to be 30 years ago...they not only 'own' the scientists who want to have food for their families, but also media.

It looks like the Obama era is our chance. Do you want us to become extinct? Get serious folks.

Please please please. I beg you!

Chris Bogert
San Jose, CA

INDIVIDUAL COMMENT #34

I want to add my voice to those calling for a study of unvaccinated versus vaccinated individuals. It is imperative that the community be fully informed in a transparent way as to the safety and efficacy of the vaccine program. Many parents no longer trust the vaccine program.

The vaccine industry and the CDC can reassure them until they are all blue in the face, and spin out more and more of their "studies" designed to reassure us, but without credible, INDEPENDENT studies, responsibly conducted, with all conflicts of interests removed, why should parents believe them?!

Please do the necessary studies to make sure that the vaccine program is as safe as it can possibly be.

Please make sure that the CDC is not conducting the study, or any of the other agencies that are invested in the vaccine program.

Please do it for the children who deserve every chance at full and healthy lives free of brain injury and chronic health problems.

Thank you,

Shannon Young (mother of a child with autism who was vaccine injured)

INDIVIDUAL COMMENT #35

I strongly support further study of safety issues regarding vaccinations. I truly feel that this area is inadequately studied and clouded in political issues that obscure good science. - Brenda Kirkland 662-341-9889

INDIVIDUAL COMMENT #36

First-Ever Gene Therapy Treatment Shows Promise for Parkinson's

Scientists Use Targeted Gene Therapy to Alleviate Certain Symptoms of the Degenerative Disease

By KATHARINE STOEL GAMMON

ABC News Medical Unit

June 22, 2007

"The researchers injected a harmless gene-bearing virus into the brains of 11 men and one woman with moderately severe Parkinson's disease. Using viruses to get genes into people is not new; Kaplitt first used this particular virus 13 years ago.

"Viruses exist in nature mainly to transfer their own genes to the host cell," Kaplitt said in a press release issued Thursday. "So, we modify the [virus] in such a way that the only gene it carries is the one we want to deliver to the therapeutic site."

*****I wonder if we could reverse our thinking here w/ this discovery and look into viruses that have the capability of causing Parkinson's disease.*

A scientist by the name of Lindquist has been doing studies using a protien called alpha-synuclein. By first injecting it in yeast she was able to observe processes taking place at cellular level to predict the effect on animal cells. She then injected the protein into mice to induce cortical spreading depression (CSD) which occurs in migrains, stroke and traumatic brain injury. She found there were problems with hypoxia especially when the body could not meet high energy demand (made me see a connection to mitochondrial weakness increasing damage in this process). Mutant forms of the protien alpha-synuclein-induces Parkinson's symptoms by taking transport protein away from performing its natural purpose thus causing cell death. Problems in this process are also linked to Altzsheimers and Huntinton's disease although through a different mechanism. She found symptoms reversed and neurons were restored to normal health by increasing levels of the transport protein. Parkinsons is caused by the death of brain cells which produce dopamine. Dopamine is a neurotransmitter associated w/ movement.

*****I think this research needs to be persued as dopamine is a common thread in the neurological dysfunction of children being injured.*

There is a **high association of sleep related breathing disorders and mental impairment**. Treating sleep related breathing disorders holds promise in preventing mental impairment. There is a strong link found w/ women who additionally carried the gene for altzheimer's (a variation of the apolipoprotein E gene known as APOE e-4), sleep apnea linked to other health issues such as high blood pressure and cardiovascular disease.

Allergy studies- recently finding allergies are causing sleep disorders by causing breathing issues (swollen tonsils). http://www.webmd.com/sleep-disorders/features/parasomnias-often-under-recognized-misunderstood

Mark W. Mahowald, MD, director of the Minnesota Regional Sleep Disorders Center at Hennepin County Medical Center and professor of neurology at the University of Minnesota in Minneapolis

"Taking the research a step further, other scientists have implicated the same faulty brain chemistry in both disorders. In a recent study of 13 people with the condition and 27 healthy individuals, Mayo Clinic researchers found REM sleep behavior disorder is associated with low stores of dopamine -- the same neurotransmitter known to be deficient in Parkinson disease. The greater the loss of dopamine in the brain, the more severe the symptoms, the researchers reported in the journal Neurology.

Other researchers have done brain imaging scans of people with REM sleep behavior disorder. They found abnormalities in the region of the midbrain where Parkinson's originates -- even in patients who did not yet have signs of neurological problems.

From pubmed article titled "Parasomnias Often Under-Recognized, Misunderstood" :

"**Of the dozens of otherwise healthy people with REM sleep behavior disorder that Mahowald and Schenk have followed since the 1980s, two-thirds have gone on to develop Parkinson's disease or other related neurodegenerative disorders**, Mahowald says. Most are men, over 50 years old, with the average time between the development of the sleep problem and the neurological disorder being 13 years.

Though the work is still early, it suggests that REM sleep behavior disorder can be the first symptom of Parkinson's disease, Mahowald says. "If we can develop a drug that protects against Parkinson's, this will be very important."

*****I think sleep disorder research needs to be persued as night terrors seem to be a symptom of severe neurological disorder*.

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http://findarticles.com/p/articles/mi_m1200/is_v131/ai_4664211/

heart peptide goes to the head

Article describes how during the fight or flight mechanism the heart sends a peptide to the brain controlling the amount of cerebral spinal fluid to be made to cusion the brain from injury during the traumatic event.

*****I believe this natural fight or flight mechanism malfunctions during over vaccination with toxic ingredients causing the over production of spinal fluid causing injury to the weakest parts of ones brain often the skull base area.*

I think swines should be used in studies as they are similar in this critical area of common injury (brain base).

Information on hydrocephalus from http://www.webmd.com/sleep-disorders/features/parasomnias-often-under-recognized-misunderstood:

1 in a 1000 births effected by hydrocephalus and in some instances acquired after birth. **"Hydrocephalus is considered congenital when its origin can be traced to a birth defect or brain malformation that causes an increased resistance to the drainage of CSF. A variety of factors can cause congenital hydrocephalus. Among the possible causes:**

*** Toxoplasmosis, or T gondii, is a type of organism that can be transmitted by eating undercooked meat, contact with contaminated soil, or by direct contact with an animal or bird that already has the infection.**

*** Cytomegalovirus (CMV) belongs to the herpes family of viruses, and normally produces symptoms that resemble that of the common cold.**

*** Rubella, or German measles, is known to cause fetal malformations during pregnancy, one of which is hydrocephalus.**

*** X-linked hydrocephalus is almost exclusively a genetic disorder passed from mother to son on the X chromosome. It is inherited only through the mother, and is predominantly seen in males (approximately one in 20). There is also a small chance that first cousins of children with uncomplicated congenital hydrocephalus can also inherit the disorder. Congenital hydrocephalus can be linked to other complications. A 17-year study that concluded in 1987 tracked four major congenital neurological malformations: anencephaly, spina bifida, encephaloceles and hydrocephalus. Of 370 births with these defects, 10.5 percent (39) resulted in stillbirths. Although a majority of live-born infants with hydrocephalus were free of other complications, 37 percent had congenital malformations which were unrelated to the hydrocephalus. Of those, the most common malformations were tracheoesophageal fistula (an abnormal communication between the trachea, or windpipe, and the esophagus), and anomalies with the reproductive, urinary, and cardiac systems (Thomas E. Wiswell et al., "Major congenital neurologic malformations: a 17-year study," American Journal of Diseases in Children 144, no. 1, January 1990: 61-7). "**

"Acquired hydrocephalus

Hydrocephalus can be acquired later in life if something causes an increase in the resistance to the drainage of CSF, such as an obstruction. Acquired hydrocephalus can also be caused by brain tumor, arachnoid cyst, intracranial or intraventricular hemorrhaging (IVH), trauma to the head, or by infections such as meningitis. "

"Brain tumors and cysts

Hydrocephalus may also be acquired as a result of brain tumors or cysts. Most brain tumors are detected in children between the ages of five and ten years old. Seventy-five percent of these tumors occur in an area at the back of the brain, known as the posterior fossa. Other types of brain tumors that can cause hydrocephalus include intraventricular tumors, and in extremely rare cases, tumors of the choroid plexus (including papilloma and carcinoma)"

*******Do vaccines have the capability to cause hydrocephalus?*

I also think TIA (Transient Ischemic Attacks, mini strokes) need to be studied. Dr. Mouldor ???

*****Altzheimer's drug Enbrel (AKA etanercept)- improvement in brain function occurring in Altz's patient immed. after injection (pre shot couldn't agitated and couldn't name state and post shot 10 minutes later could calmly name state). "**Studies have suggested that a protein involved in inflammation known as TNF-alpha is involved in the development of Alzheimer's disease**, the investigators note. Etanercept blocks this protein. Further studies looking at the effects of TNF-alpha blockers on symptoms of dementia are warranted, the researchers conclude. Dr. Edward L. Tobinick, from the University of California at Los Angeles, and Dr. Hyman Gross, from the University of Southern California in Los Angeles, describe the case in the Journal of Neuroinflammation."

Sorry that I had to throw my information together.

I believe the mechanism for vaccine injury has to do with toxic overload internally causing a traumatic event. Chemically the heart sends a peptide to the brain causing the over production of cerebral spinal fluid to cushion the brain from injury (fight or flight mechanism). Unfortunately the mechanism is dysfunctional and doesn’t shut off causing injury to the brain at its weakest areas such as the skull base.

Also ADEM should be further studied.

Thank You for your consideration

INDIVIDUAL COMMENT #37

To Whom It May Concern (NVPO):

It is vital to support funding for a comprehensive study of both vaccinated and unvaccinated children. These studies must be carried out with transparency and by a research team independent of the CDC and other government agencies whose purpose is to protect vaccines. Safety must be established in order to restore public trust in the vaccine program.

Sincerely,

Theresa Cedillo
Yuma, AZ