



**The National Vaccine Advisory Committee (NVAC)
Vaccine Safety Working Group Stakeholder Meeting
Hubert H. Humphrey Building, Room 800
Department of Health and Human Services
June 13, 2011**

Meeting Summary

Welcome, introductions, meeting purpose, agenda review, and ground rules

NVAC Chair - Guthrie Birkhead

Overview VSWG Charge 2 work to date

VSWG Co-Chairs - Tawny Buck, Marie McCormick and Andy Pavia

Medical Association panel and discussion

Moderated by: VSWG Co-Chair Tawny Buck

Dr. Kathryn Edwards American Academy of Pediatrics

- Education of healthcare providers about vaccine safety -- particularly early career physicians who have not witnessed firsthand many vaccinepreventable diseases -- is an essential element that we urge the Committee to devote additional consideration to its inclusion
- Supports enhanced research and research capacity, interdisciplinary collaboration, communications, and sufficient resources
- The AAP supports formal external mechanism of review and accountability of the federal vaccine safety system (note: no stated preference for options 1-4).

Dr. Bernard Gonik American Congress of Obstetricians and Gynecologists

- General support for recommendations
- Encouragement for advancement of knowledge base and public education on importance of vaccination in older adults and young adults -research, monitoring and funding for these initiatives.
- Encouragement for research agenda items to forward scientific base for vaccination during pregnancy – current state of science lacks adequate data on efficacy and safety; despite permissive recommendations for use in pregnant patients. Support any agenda item including advance of research to examine safety of vaccination in pregnancy
- Concern that VICP fails to adequately address pregnant host and fetus. Recommendation to include call for future research to elucidate data; ensure public of safety of vaccination during pregnancy.

Dr. Bonnie Ward Infectious Disease Society of America

- Supports all recommendations. Following indications are areas where recommendations could be further strengthened
- Recommendation 1 – Understand potential benefit from communications perspective but have concern about presenting the false image that safety is not a current HHS priority

- Recommendation 2.1 – Support for ISTF reporting to NVAC
- Recommendation 3.6 – Support for temporary expert committee, emphasis on the importance of attention to detail when planning and implementing such a mechanism.
- Recommendation 4.2 – Suggestion to expand recommendation to include a call for expansion of the Vaccine Safety Datalink
- Recommendation 8.1 - Not opposed, but unclear whether action is needed or is duplicative of other federal efforts
- Recommendation 8.4 – Support Option 1, secondary support for fixed tenure panel outside HHS if that were IOM (Option 2b)

Advocacy panel and discussion

Moderated by: VSWG Co-Chair Dr. Marie McCormick

Richard Greenaway Every Child By Two

- Overall readability of the report precludes the general public from providing useful comments.
- There is a minimal probability that a member of the general public will be able to comprehend this report and provide relevant feedback.
- We are greatly concerned that this report, even in draft format, portrays a system that is in crisis, which ECBT strongly contests.
- We recommend that the focus be on the clear communication of the scientific rigor of pre- and postlicensure activities, and the critical importance of maintaining immunization rates needed to fight deadly diseases.
- There is a distinction to be made between lack of confidence with vaccines themselves and lack of confidence with the U.S. safety system. Vaccine coverage is high.
- A complete overhaul of a system that has proven to be highly successful at identifying and responding to safety issues is neither realistic nor necessary.
- Generally supportive of recommendations with some modifications, except as noted below
- Recommendation 3.4 focused on ascertaining public concerns should be for communications and not scientific purposes
- Not supportive of Recommendation 7 on public and stakeholder engagement
- Strongly opposes recommendation 8.4/options 2 and 3, which suggest the development of panels outside HHS to monitor NVP and NVAC, a Presidential Commission, IOM oversight, or an entirely independent agency.
- Supports the enhanced collaboration between the Immunization Safety Task Force (ISTF) and NVAC

Barbara Loe Fisher National Vaccine Information Center

- Public trust in vaccination safety is paramount.
- Despite good intentions of those staffing public health agencies, NVIC acknowledges their jobs are difficult when having competing roles and responsibilities.
 - Research and development, licensing and testing, recommendations, promotion and distribution, injury compensation. NVIC believes all of these responsibilities should not be in the same arena as safety.
- Support of no further enhanced role for NVAC, NVPO, ISTF or other HHS entities, in lieu of Option 3.
- Concerned about effort marginalization of individuals and families with vaccine injured children with an outdated compensation program. Report should better address need for restructuring of VICP
- Recommendation 8: Full support for Option 3
- Recommendation 2: oppose expanded role of ISTF due to lack of public representation and transparency in the task force.

- Recommendation 1- Concern with the effectiveness of 1.1. Support for 1.2 with the inclusion of public representation
- Recommendation 3 – Supportive of the research agenda items, but concerns with the dependence on ISTF, and effects on public trust of that research. Indication to elevate safety research to higher program funding priority. Full support for public access to data to increase public trust.
- Recommendation 4- Suggests inclusion of statement on the importance of provider reporting to VAERS
- Recommendation 5- Support for barcoding, no support for role of ISTF.
- Recommendation 6 & 7 Support and expand public representation.
- Recommendation 9 – Support for costing of recommendations.

Dr. Deborah Wexler Immunization Action Coalition

- I am alarmed that the draft document, as currently constructed, will lead unnecessarily to children becoming sick with vaccine-preventable diseases. As a family physician, it is frightening to think that a group such as this working group, a body of physicians, nurses, scientists, administrators, and other healthcare professionals and concerned citizens, could lose track of the first rule of patient care: do no harm.
- This document should focus specifically on addressing the vaccine safety system of the United States. It should not include the harm-producing references questioning the safety of vaccines that currently run throughout it.
- IAC urges everyone to consider seriously the unambiguous analysis provided to the Vaccine Safety Working Group by the American Medical Association.
- Parents, anti-vaccine groups, and the media who spread their views could easily interpret this report to indicate that the safety system is inadequate
- The headline of the online article read, "Report Reveals Vaccine Safety System in Crisis." This was followed by the lead sentence, "Reading through the bureaucratism in the draft white paper, the report reveals a vaccine safety 'system' in shambles."
- Limited support for many of the draft recommendations. In particular, objections to public and stakeholder engagement, ascertainment of public concerns and perceptions for safety research, vaccine administration errors are outside the scope of vaccine safety, making all the information described publicly available will not enhance the safety system.
- Supports enhanced role of NVAC for the National Vaccine Plan but does not support 8.1 or 8.2
- Supports option 1 (NVAC) for recommendation 8.4 but opposes other options

Sallie Bernard Safeminds

- Recommendations pale in comparison to need for independent agency as embodied in Recommendation 8.4, Option 3. Strongly support this option. Feels that this prioritization of vaccine safety would go far to increase public acceptance and trust.
- Need for meaningful consumer involvement, independent from agencies
- Recommendation 1 - Support changes to NVAC charter in assuming 8.4 Option 3 safety agency is established
- Enthusiastic about 3, 4, 5 – open VSD and CISA to outside scientists, reporting of all cases of AE to VAERS and study under CISA.
- Recommendation 3 – Research should include specific focus on interaction of other childhood exposures with vaccines, larger samples, longer follow-up, and fully vaccinated vs unvaccinated study.
- Recommendation 2 - Don't support expanding ISTF without transparency, under FACA, inclusion of consumers
- Suggestion for inclusion of a call for an objective grading system on quality of evidence in evidence base
- Recommendation 7 – Fully support maximum consumer involvement in developing communication programs

- Suggestion for a recommendations centered on ethical and informed choice for vaccination, and a safety net for compensation of individuals potentially injured by vaccines.

Public Health panel and discussion

Moderated by: VSWG Co-Chair Dr. Andy Pavia

Jacob Mbafor

National Association of City and County Health Officials

- Report could be shortened, edited, and provide tools to those on front lines providing vaccines.
- Support for Recommendations 1,2,7,9 as written
- Recommendation 3: Support. Suggestion for inclusion public health departments
- Recommendation 6- Support. Suggestion for the inclusion of partners and stakeholders as disseminators of research findings.
- Section 5.4 – expand in more detail on the consequences of not vaccinating.
- Enable providers with tools to communicate
- Recommendation 8.4 – Support for Option 2b IOM committee. Concern for how it would be viewed if NVA were responsible for policing themselves.
- Research, Post Licensure Surveillance and Communications are the most important recommendation

Claire Hannan

Association of Immunization Managers

- White paper lacks clarity and purpose, contains statements that are interpretive opinion, and may be misunderstood or taken out of context by readers and the media.
- Needs an executive summary
- The report does not provide a clear explanation of the components of the vaccine safety system and how they work together to assure the safety of vaccines.
- Overall need for strong editing
- We believe that the first recommendation should be to maintain and support the existing vaccine safety system. The Vaccine Safety Working Group should clearly recognize and endorse the existing vaccine safety system, its successes and strengths. The foundation of our system must be sustained.
- Generally support other recommendations
- Supports option 1 for recommendation 8.4 – enhanced role of NVAC

Dr. Evone Nwankwo

American Public Health Association

- APHA fully supports recommendations as written
- Recommendation 1 – This is extremely important and imperative. Suggested inclusion of the Office of Minority Health as well.
- Recommendation 3 –Research is a vital concern to APHA. Full support.
- Belief that confidence in the system could be compromised if issues viewed as concerns by the public are not adequately addressed.
- Recommendation 5 – Support. Make sure to include a cadre of clinicians-don't neglect public health professionals.
- Recommendation 6 – Support. Suggestion to focus on publicizing means by which members of the public can obtain this information. This section of the recommendation needs to be well fleshed out.
- Top two priorities are recommendations 7 and 8, followed by Recommendation 1. Critical to address mistrust of vaccine safety, and challenges that has previously impeded work of other groups.
- Option 2 is the best option and preference of APHA, but we acknowledge this may have higher costs. APHA did not fully flesh out whether 2.a./b./c. is best.
- Consider developing consumer advisory boards to forward getting Recommendations 6, 7,8 taken seriously.

Kathy Talkington Association of State and Territorial Health Officials

- Concern that the tone and word choice in the introduction portrays that there is not a good system currently in place. Recommend language editing to better characterize the current system and activities in safety.
- Recommendation 1- Support for 1.1 and 1.2. Focus should be placed on reenergizing the system in place rather than creating new elements.
- Recommendation 2 – Support expansion of ISTF to include CMS, AHRQ, and USAID but hesitant to expand role of ITSF as it seems duplicative with NVPO and NVAC current functions.
- Recommendation 4 – Support
- Recommendation 5 – Support, with the clarification that NVPO would determine entity responsible for these activities
- Recommendation 7 - ASTHO supports the notion that the ASH should direct NVPO to work with NVAC to develop and maintain an ongoing program of stakeholder engagement around vaccine safety – which it has been doing as is clear by this report.
- Recommendation 8.4 – Support for Option 1.

Other Perspectives panel and discussion

Moderated by: VSWG Co-Chairs

Sara Radcliffe Biotechnology Industry Organization

- The United States has a first class vaccine safety system that is respected throughout the world. As with any complex system, there are opportunities for enhancement and BIO and its members support activities that will positively impact the system’s effectiveness and value. There is most assuredly a role for continuous quality improvement in this process.
- Concern that the Report does not clearly outline the overarching goals of the Working Group.
- Suggest that the report be re-structured to more clearly describe the effective aspects of the vaccine safety system and to then outline those recommendations that will enhance and further strengthen this system.
- List the highest priority recommendations with some discussion of the expected benefit, cost and proposed timeline.
- Only programs that have the likelihood of providing concrete improvements to the current safety system and that are deemed reasonable investments of time and resources should be put forward to the ASH for implementation.
- Strongly supports the Working Group’s conclusion that the current system is fundamentally sound and effective.
- The proposal to put vaccine safety under the Assistant Secretary of Health and the NVPO raises concerns regarding increased bureaucracy, additional levels of management, and duplication of existing processes.
- Decisions related to safety issues should reside within the scientific and regulatory community
- Recommendations 1, 2, 6, and 8.2 – no comment
- Recommendation 3 generally support however 3.4 (ascertainment of public concerns) should not necessarily be linked to research rather than communications
- Some concerns about recommendation 4.1 (post-licensure surveillance plans for new vaccines) supports 4.2 and 4.3
- Generally supports recommendation 7 (public and stakeholder engagement)
- Supports 8.1 (role of NVAC and NVPO) and 9 (cost evaluation)
- Concerns about 8.3 (causality assessment)
- Opposed to 8.4

Kevin Conway

Esquire, Conway, Homer and Chin-Caplan, P.C.
Firm represents Vaccine Injury Compensation cases

- Recommendations if adopted would increase safety of vaccines, elevate public confidence in safety of vaccines and assist in keeping immunization rates at appropriate levels.
- Suggestion for additional recommendations in reference to the VICP
 - Statute of limitations must be amended to be no less generous to minors and mentally impaired persons than state statutes currently are.
 - Standard of proof must be more generous to petitioners –modeled after the Veterans Affairs Standard

Sarah Despres

Current: Senior Officer, Pew Charitable Trusts
 Former counsel, Committee on Government Relations
 Former counsel, Committee on Energy and Commerce

- Comments are at 30,000 foot level, that's where congress operates.
- Cannot talk about vaccine safety in a vacuum – risk has to be balanced against benefit. Vaccines are very safe and have saved many lives. Acknowledge risk of AE and know they need to be minimized.
- General comments of implementation of recommendations
 1. Coordination. – In order to leverage assets, activities of agencies should be coordinated and complement each other. If NVAC/NVPO can't do it, outsourcing won't help.
 2. Science – Support for research recommendations. Need for robust vaccine safety research infrastructure; needs to respond to emerging concerns and researchers need to anticipate future concerns. IOM state of the science for vaccine safety research reports are helpful. IOM reports this summer will be useful and should be considered in this report if time permits. This is a distinct set of reports, different from IOM in 8.4.
 3. Strong regulator – Concern for addressing funding of FDA – don't want to suggest that NIH or CDC funding is less important, but from personal experience FDA is the public health agency to be maligned, see budget cuts or see cuts to authority. Urge committee on reaffirmation for strong regulator of medical products.
 4. Communication – Focus recommendation on understanding what type of vaccine safety infrastructure exists, understanding the system and risk/benefit of vaccines.
- Focus on current infrastructure. Remaking it could do more harm than good. Need to include more balance on risk/benefit – safety is not in a vacuum.

Alan Greene

Pediatrician, www.drgreene.com

- Establishing trust in our vaccine safety infrastructure will require bold steps to create unassailable objectivity and transparency of an evidence-based decision making process.
- 3 most important attributes are objectivity, transparency and participatory.
- Recommendation 8.4 is the most important but no indication of which option is preferred

Paul Kim

Current: Partner, Foley Hoag, LLP
 Former counsel to Congressman Henry Waxman
 Former deputy staff director for Senator Edward Kennedy

- 3 most critical recommendations are 3, 4 and 8
- No major gaps in recommendations
- Most critical attributes of system are evidence based decision making, responsiveness and accountability
- Supportive of recommendations
- 8.4 – supports option 1 – role of NVAC