

Vaccine Safety Activities: National Vaccine Advisory Committee (NVAC)

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Statutory Basis for the National Vaccine Program

Title XXI Public Health Service Act

(P.L. 99-660, Section 2102)

Coordinates and provide direction for:

- **Vaccine research**
- **Vaccine development**
- **Safety and efficacy testing of vaccines**
- **Licensing of vaccine manufacturers and vaccines**
- **Production and procurement of vaccines**
- **Distribution and use of vaccines**
- **Evaluating the need for and the effectiveness and adverse effects of vaccines**
- **Governmental and non-governmental activities**
- **Funding of federal activities**



United States Department of
Health & Human Services

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The National Vaccine Advisory Committee (NVAC)

Vaccine Safety Working Group

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(Updated 1/26/2009)

National Vaccine Program

National Vaccine Advisory Committee: Charter

The Secretary of Health and Human Services is mandated under Section 2101 of the Public Health Service Act to establish a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.

The National Vaccine Advisory Committee shall advise and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities.

Institute of Medicine (IOM) Review and Recommendations

Vaccine Safety Research, Data Access and Public Trust



IOM recommended “a subcommittee of NVAC [National Vaccine Advisory Committee] that includes representatives of a wide variety of stakeholders... review and provide advice on the Vaccine Safety Datalink (VSD) research plan... the group should meet publicly and allow interested persons to observe the process and provide input through established mechanisms.”

<http://www.nap.edu/catalog/11234.html>

Establishment and Initial Charge to NVAC Safety Working Group

- 1) Undertake and coordinate a scientific review of the draft CDC Immunization Safety Office (ISO) research agenda. Advise on:
 - Content of ISO draft research agenda (e.g., are the topics on the agenda appropriate? Should other topics be included?)
 - Prioritization of research topics
 - Possible scientific barriers to implementing the research agenda and suggestions for addressing them
- 2) Review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.

NVAC Vaccine Safety Working Group Members (1)

Name	Discipline	Group Representation	Additional Relevant Experience
Andy Pavia	Pediatric and Adult Infectious Diseases	Academia NVAC Member Chair, NVAC Vaccine Safety Working Group	Chief of Pediatric Infectious Diseases Professor of Pediatrics and Medicine University of Utah
Bennett Shaywitz	Neurology	Academia	Professor of Pediatrics and Neurology Chief , Pediatric Neurology Yale University School of Medicine Former member, IOM Immunization Safety Review Committee
Chris Carlson	Genomics	Academia	Affiliate Assistant Professor of Epidemiology School of Public Health - University of Washington
Corry Dekker	Pediatrics	Academia NVAC Member	Professor of Pediatrics & Medical Director of the Stanford-Lucile Packard Children's Hospital Vaccine Program; CISA Investigator
Gerald Medoff	Immunology	Professional Organization	Emeritus Professor at the Washington University School of Medicine; former member of the IOM Immunization Safety Review Committee
Gus Birkhead	Epidemiology	State Health Department NVAC Chair	Deputy Commissioner, Office of Public Health, New York State department of Health.
Jim Mason	Public Health,	Public Health NVAC Member	Former CDC Director Former Assistant Secretary for Health (HHS)
Lawrence Gostin	Ethics Public Health Law	Academia	Associate Dean and Professor of Global Health Law at the Georgetown University Law Center and Director of the Center for Law & the Public's Health at Johns Hopkins and Georgetown Universities
Lance Gordon	Immunology	Vaccine Industry NVAC Member	Former President and CEO, VaxGen Vaccine developer (Hib)

NVAC Vaccine Safety Working Group Members (2)

Name	Discipline	Group Representation	Additional Relevant Experience
Lynn Goldman	Toxicology/ Environmental Health	Academia	Professor Johns Hopkins School of Public Health Principal Investigator, Johns Hopkins National Children's Study Center
Marie McCormick	Maternal and Child Health	Academia NVAC member	Professor of Maternal and Child Health Harvard School of Public Health Professor of Pediatrics Harvard Medical School Former Chair, IOM Immunization Safety Review Committee.
Mark Feinberg	Immunology	Industry NVAC Member	Vice President for Medical Affairs & Policy Merck Vaccines
Paul-Henri Lambert	Global aspects of vaccine safety	Professional Organization	Centre of Vaccinology, University of Geneva; Chair, WHO Global Advisory Committee on Vaccine Safety
Sean Hennessy	Pharmacoepidemiology	Academia	Professor of Epidemiology University of Pennsylvania School of Medicine Member , FDA Drug Safety and Risk Management Advisory Committee
Steve Goodman	Biostatistics	Academia	Director , Division of Biostatistics Johns Hopkins Kimmel Cancer Center Former member, IOM Immunization Safety Review Committee
Tawny Buck	Parent of a child injured by a vaccine	Consumer /Public	ACCV member Director of Development, LINKS Parent Resource Center
Trish Parnell	Parent of a child with an infectious disease	Consumer/Public NVAC member	Executive Director, Parents of Kids with Infectious Diseases (PKIDS)

NVAC Vaccine Safety Working Group: Liaison Members

- Dan Salmon, NVPO/HHS
- Larry Pickering, NCIRD/CDC
- John Iskander, ISO/CDC
- Karen Midthun, CBER/FDA
- Robert Ball, CBER/FDA
- Florence Houn, CBER/FDA
- Carmen Collazo, CBER/FDA
- Geoff Evans, VICP/HRSA
- Barbara Mulach, NIAID/NIH
- Jessica Bernstein, NIAID/NIH
- Alice Kau, NIH/NICHD
- Peter Scheidt, NIH/NICHD
- Renata Engler, DoD

ISO Agenda Draft Recommendations

Item	A. Specific Vaccine Safety Questions
A-I	Are vaccines (e.g., influenza vaccines, meningococcal conjugate vaccine [MCV4]) associated with increased risk for Guillain-Barré Syndrome (GBS)?
A-II	Is live, attenuated influenza vaccine (LAIV) associated with increased risk for asthma and/or wheezing, particularly in young children or persons with history of wheezing?
A-III	Is exposure to thimerosal associated with increased risk for clinically important tics and/or Tourette syndrome?
A-IV	Are acellular pertussis vaccines associated with increased risk for acute neurological events, particularly hypotonic-hyporesponsive episodes (HHE)?

ISO Agenda Draft Recommendations

Item	A. Specific Vaccine Safety Questions (Hypotheses)
A-V	Is immunization associated with increased risk for neurological deterioration in children with mitochondrial disorders?
A-VI	Is combination measles, mumps, rubella, and varicella (MMRV) vaccine associated with increased risk for febrile seizure and, if so, are there sequelae?
A-VII	Are varicella vaccines (varicella and MMRV) associated with increased risk for clinically important events related to varicella vaccine virus reactivation?

ISO Agenda Draft Recommendations

Item	B. Thematic Area: Vaccines and Vaccination Practices
B-I	Bivalent human papillomavirus (bivalent HPV) vaccine (Cervarix™)
B-II	Zoster vaccine (Zostavax®)
B-III	Annual influenza vaccination in children and adolescents (trivalent inactivated influenza vaccine [TIV] and LAIV)
B-IV	Non-antigen components of vaccines (other than thimerosal and ASO4 adjuvant HPV vaccine)
B-V	Simultaneous vaccination
B-VI	Safety of different products within the same vaccine category
B-VII	Off label use of vaccines
B-VIII	Vaccine-drug interactions

ISO Agenda Draft Recommendations

Item	C. Thematic Area: Special Populations
C-I	Premature and low birth weight infants
C-II	Pregnant women
C-III	Adults aged ≥ 65 years
C-IV	Persons with primary immunodeficiency
C-V	Persons with secondary immunodeficiency
C-VI	Persons with autoimmune disorders
C-VII	Children with inborn errors of metabolism

ISO Agenda Draft Recommendations

Item	D. Thematic Area: Clinical Outcomes
D-I	Autoimmune diseases
D-II	Central nervous system demyelinating disorders
D-III	Encephalitis/ Encephalopathy
D-IV	Neurodevelopmental disorders, including autism spectrum disorder (ASD)
D-V	Vasculitis syndromes
D-VI	Myopericarditis (not associated with smallpox vaccine)
D-VII	Clinically important outcomes related to post-immunization fever
D-VIII	Post-vaccination syncope and sequeale

Institute of Medicine (IOM)

Review and Recommendations



IOM recommended “a subcommittee of NVAC [National Vaccine Advisory Committee] that includes representatives of a wide variety of stakeholders... review and provide advice on the Vaccine Safety Datalink (VSD) research plan... ***the group should meet publicly and allow interested persons to observe the process and provide input through established mechanisms.***”

Vaccine Safety Research, Data Access, and Public Trust

<http://www.nap.edu/catalog/11234.html>

Vaccine Safety Panel to Include the Public in Setting Priorities

April 13, 2008

WASHINGTON (AP) — The government began an unprecedented effort Friday to give vaccine critics a say in shaping how the nation researches immunization safety questions.

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The National Vaccine Advisory Committee (NVAC)

Opportunities to Inform Recommendations of the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group

The National Vaccine Advisory Committee (NVAC), a Federal advisory committee to the Department of Health and Human Services (HHS), is seeking broad public input into the scientific research agenda that is being developed by the Centers for Disease Control and Prevention's (CDC) Immunization Safety Office (ISO). Comments and input from members of the general public, citizens groups, parents, physicians, nurses and other health care providers, public health practitioners, academics, and policy makers will contribute to NVAC recommendations to CDC/ISO on the scientific agenda.

As a key component of a broad vaccine safety system, CDC's ISO has significant responsibility for monitoring the safety of vaccines after they are licensed and used among children and adults in the United States (<http://www.cdc.gov/vaccinesafety>). ISO's scientific agenda identifies vaccine safety issues to consider for scientific study over the next five years, in addition to any new questions that may arise. Since not all questions and issues can be addressed at once, setting priorities is important.

ISO's draft scientific agenda can be found at:

http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf and the addendum at http://www.cdc.gov/vaccinesafety/00_pdf/draft_recommendations_add_080410.pdf

11DATE

Request for Information

- Federal Register - January 2, 2009
- Requested public comment on three areas:
 - Concerns about vaccines and immunization safety, including personal experiences
Comments on what values, considerations, or factors are most important to consider in prioritizing scientific research
 - Specific comments on the draft ISO Scientific Agenda
- Deadline: February 2, 2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Solicitation of Written Comments on Draft Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda**

AGENCY: Department of Health and Human Services, Office of the Secretary.

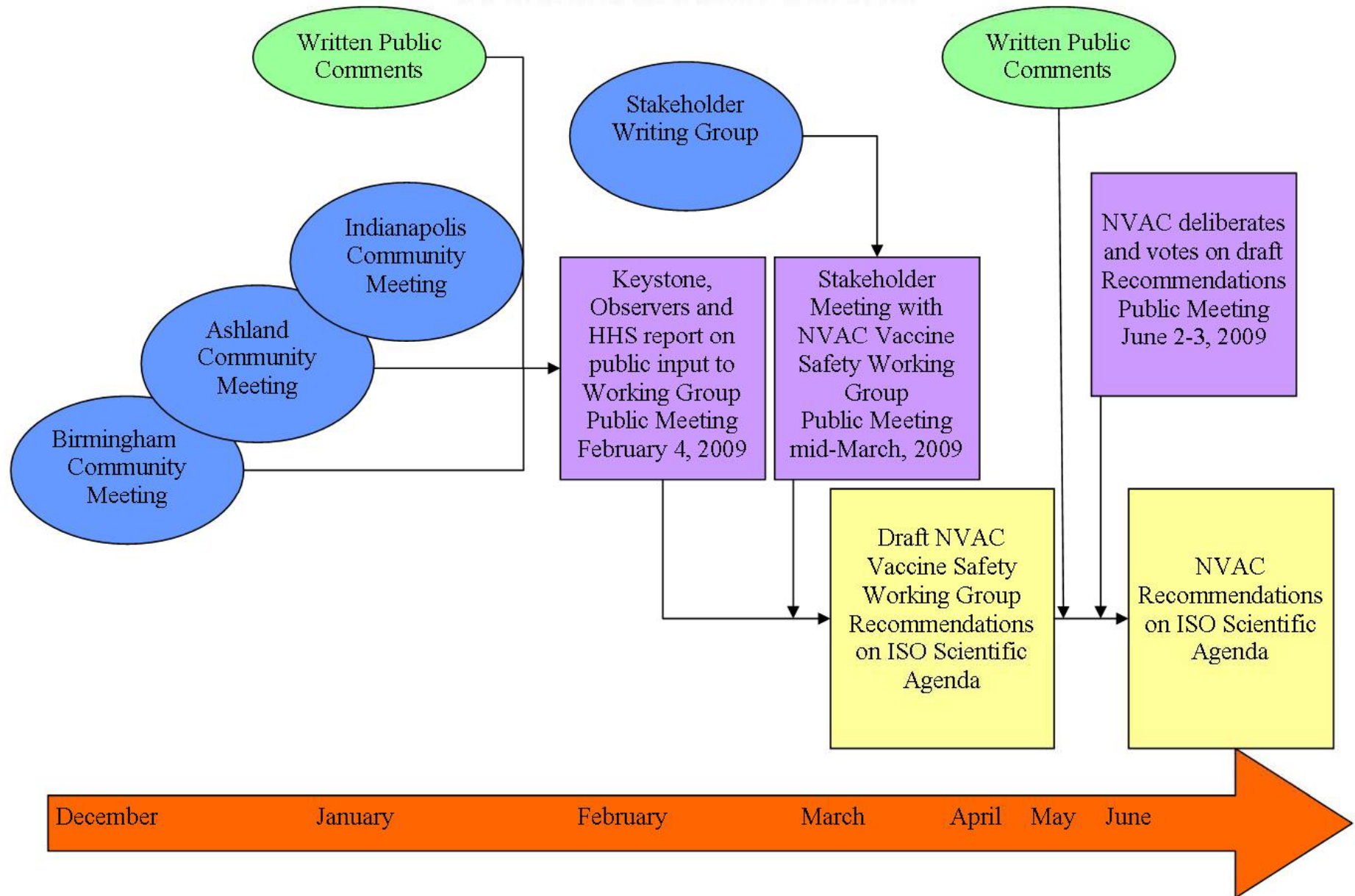
ACTION: Notice.

SUMMARY: The National Vaccine Program Office (NVPO) is soliciting public comment on the Centers for Disease Control and Prevention's Immunization Safety Office (ISO) draft Scientific Agenda related to scientific research questions in vaccine safety.

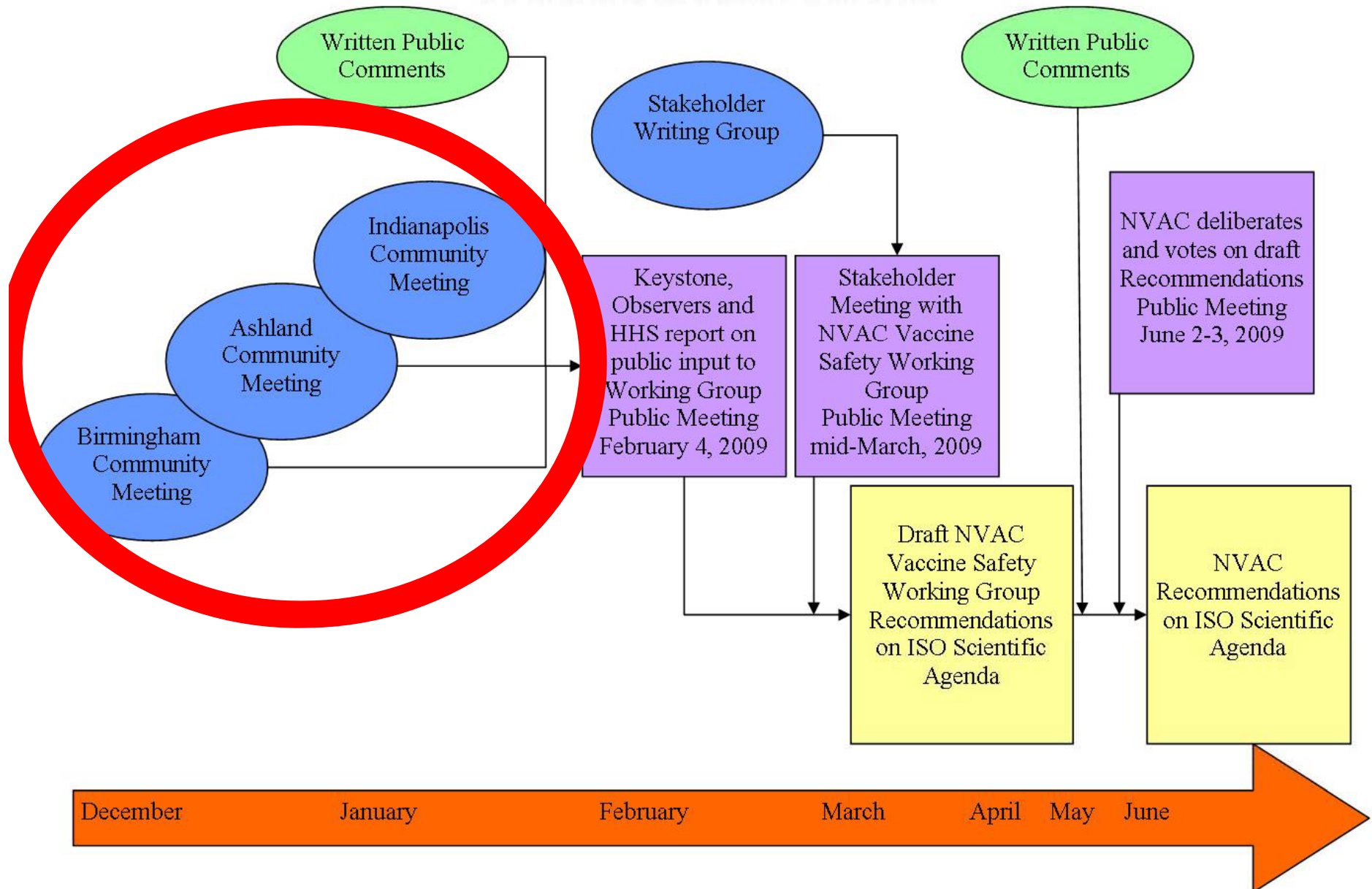
DATES: Comments on the draft ISO Scientific Agenda should be received no later than 5 p.m. on February 2, 2009.

ADDRESSES: Electronic responses are preferred and may be addressed to vaccinsafetyRFI@hhs.gov. Written responses should be addressed to National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Washington, DC

THE PROCESS FOR PUBLIC INPUT INTO THE NVAC RECOMMENDATIONS ON THE ISO DRAFT SCIENTIFIC AGENDA



THE PROCESS FOR PUBLIC INPUT INTO THE NVAC RECOMMENDATIONS ON THE ISO DRAFT SCIENTIFIC AGENDA



Public Engagement

The Keystone Center

“... seeks to solve our society’s most challenging environmental, energy, and public health problems. We bring together today’s public, private and civic sector leaders to confront these issues and we arm the next generation with the 21st Century intellectual and social skills required to effectively approach the questions they will face.”



Community Meetings

What They Are Not; What They Are

What they are not:

- A statistically verifiable random sample of views in the U.S.
- Designed with intention to persuade communities to any particular viewpoint



What they are:

- A sampling of what 3 communities in different parts of the U.S. think about vaccines and vaccine safety
- Intended to encourage dialogue and increase understanding about where community members have comfort or concerns regarding vaccines and vaccine safety
- Designed to illuminate values that underpin community views regarding vaccines and vaccine safety

Community Concerns

- Safety
- Effectiveness
- Special populations
- Trust
- Access
- Education

Safety: Concerns about vaccines as currently given

- Ingredients
- Number of vaccines given
- Schedule
- Combinations (of vaccines, of ingredients)
- Side effects (short-term, long-term)
- Interactions with meds, allergies, cosmetics, personal care products, environmental factors
- Do vaccines cause the disease they target?
- Manufacturing security, safety of supply

Safety: Concerns about data, studies , and the vaccination system

- Why hasn't there been a study of vaccinated and unvaccinated populations?
- Do studies ask the right questions?
- Are reporting data accurate? Are people reporting the right things?
- Have alternative perspectives have been excluded from the dialogue about vaccine safety?
- Does the vaccination system work right? Does it track the right information? Does it have the right approach to safety?

Effectiveness: Do vaccines work?

- In the long term? In the short term?
- Do we get enough to be truly immunized?
- Do we have enough supply?

Special Populations: Are the risks and benefits the same for everyone?

- Genetically pre-disposed
- Different demographic groups (race, gender)
- Elderly
- Immune compromised
- Premature babies
- Pregnant

Trust: Who can we trust to tell us the truth?

- Secrecy of decision making, studies, reporting, etc.
- Who's on NVAC? Who's in charge?
- Conflict of interest; pharmaceutical companies and government
- Scientists – are they independent?

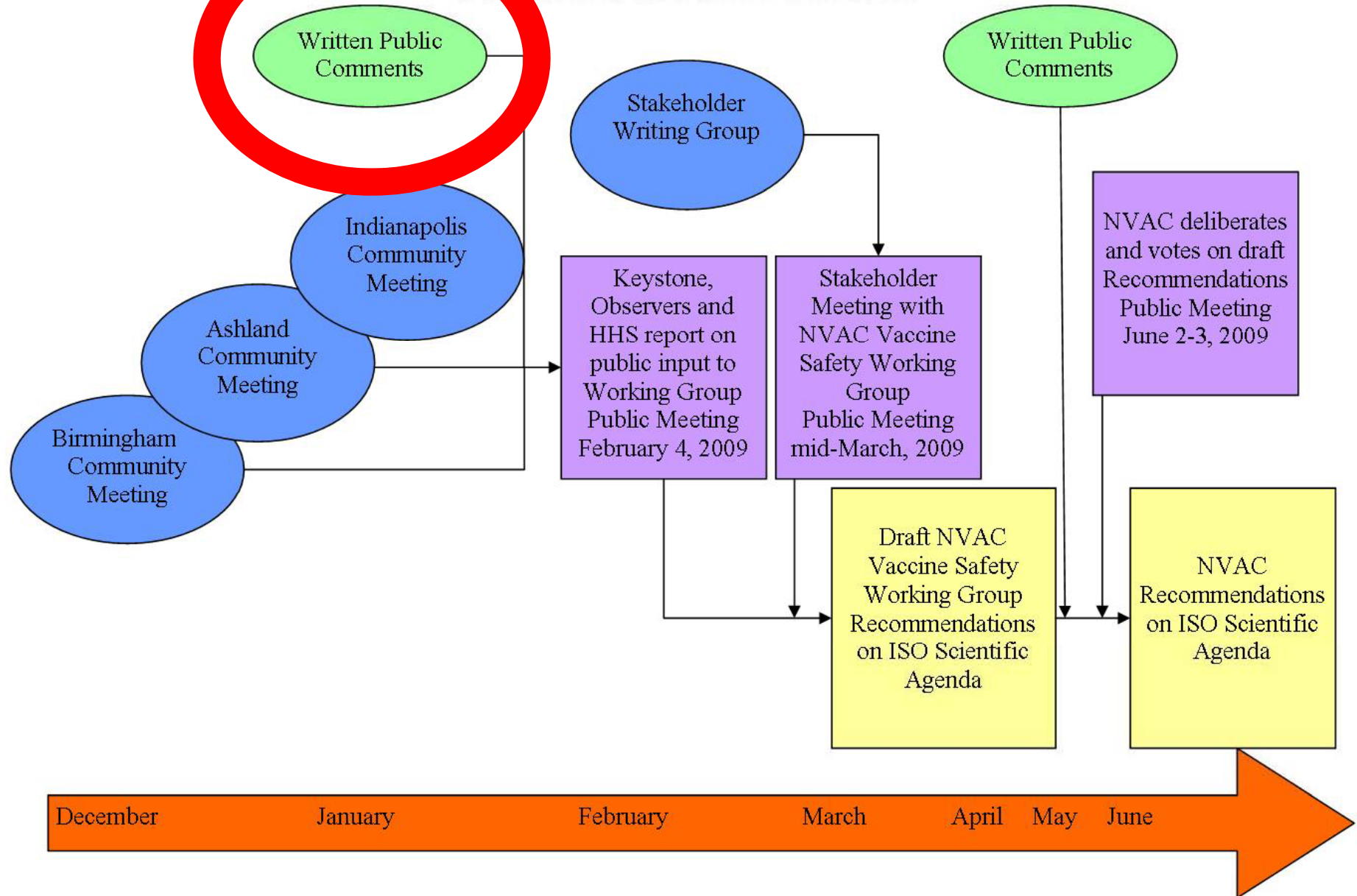
Access: Not everyone who wants to be vaccinated can get vaccinated

- Cost of vaccinations
- Insurance coverage
- Access to health care

Education: Access to information about risks and benefits is lacking but very important

- Do doctors know about the risks and benefits?
- Parents can't learn about risks and benefits because doctors won't spend the time because insurance companies won't pay.
- People should have access to study data—they want to know who is doing the studies, what the results are, and what it means. “It's safe” isn't enough.
- Where can people go to get complete and accurate information?

THE PROCESS FOR PUBLIC INPUT INTO THE NVAC RECOMMENDATIONS ON THE ISO DRAFT SCIENTIFIC AGENDA



IACC Public Comment on the NVAC Vaccine Safety Working Group Scientific Agenda

January 26, 2009

Communication between the IACC and NVAC will permit each group to be informed by the expertise of the other, enhance coordination and foster more effective use of research resources on topics of mutual interest.

Examples of such topics include:

- Studies of the possible role of vaccines, vaccine components, and multiple vaccine administration in autism causation and severity through a variety of approaches;
- Assessing the feasibility and design of an epidemiological study to determine if the health outcomes, including ASD, differ among populations with vaccinated, unvaccinated, and alternatively vaccinated groups
- Investigating the reasons as to why some sub-groups may be a higher risk for vaccine injury and how to identify such risk factors

Summary of Comments Received to Date

Comments in their entirety have been provided to the NVAC Vaccine Safety Working Group and are available on the NVPO website at:

www.hhs.gov/nvpo/nvac/vaccinesafety.html

NOTE:

This summary is not intended to replace thorough reading of each comment

Creating the Summary: Methods

- Comments were stratified by submission on behalf of organizations vs. individuals
- Each comment was read to identify general themes
- Comments were then re-read and tagged for identified themes as well as unique perspectives

Summary of Comments Received

- Received 91 comments
 - 10 from organizations
 - 81 from individuals
- 59 comments included research items
- 47 comments included personal experiences
- Many comments were not specific to the Research Agenda but showed interest in the vaccine safety system and policy. These will be reviewed for input on the Working Group's second charge

Summary of Comments Received

- Concerns about vaccines and immunization safety, including personal experiences
 - Comments on what values, considerations, or factors are most important to consider in prioritizing scientific research
 - Specific comments on the draft ISO Scientific Agenda
- Many
 - Few
 - Few

Summary of Comments Received: Organizations

- Age of Autism
- Bedrok Community
- Georgetown Medical Center Alumni Association
Hongkong Branch Ltd.,
- Autism Speaks
- Active Healing
- Interagency Autism Coordinating Committee
- SafeMinds
- Maryland Coalition for Vaccine Choice
- American Academy of Pediatrics

Summary of Comments Received: Individuals

- Many personal experiences
- Nearly all identified vaccine safety concerns
- Most common research topics/studies proposed:
 - Autism (60/81)
 - Simultaneous vaccination/vaccination schedule (36/81)
 - Non-antigen vaccine ingredients, particularly thimerosal (35/81)
 - Unvaccinated vs. vaccinated study (32/81)

Summary of Comments Received: Individuals

- Additional research topics/studies proposed:
 - Genetic predispositions for vaccine reactions
 - Vaccination of children with mitochondrial disease
 - Combination vaccines
 - Number of vaccines
 - Susceptible subpopulations, such as those who regressed following vaccination

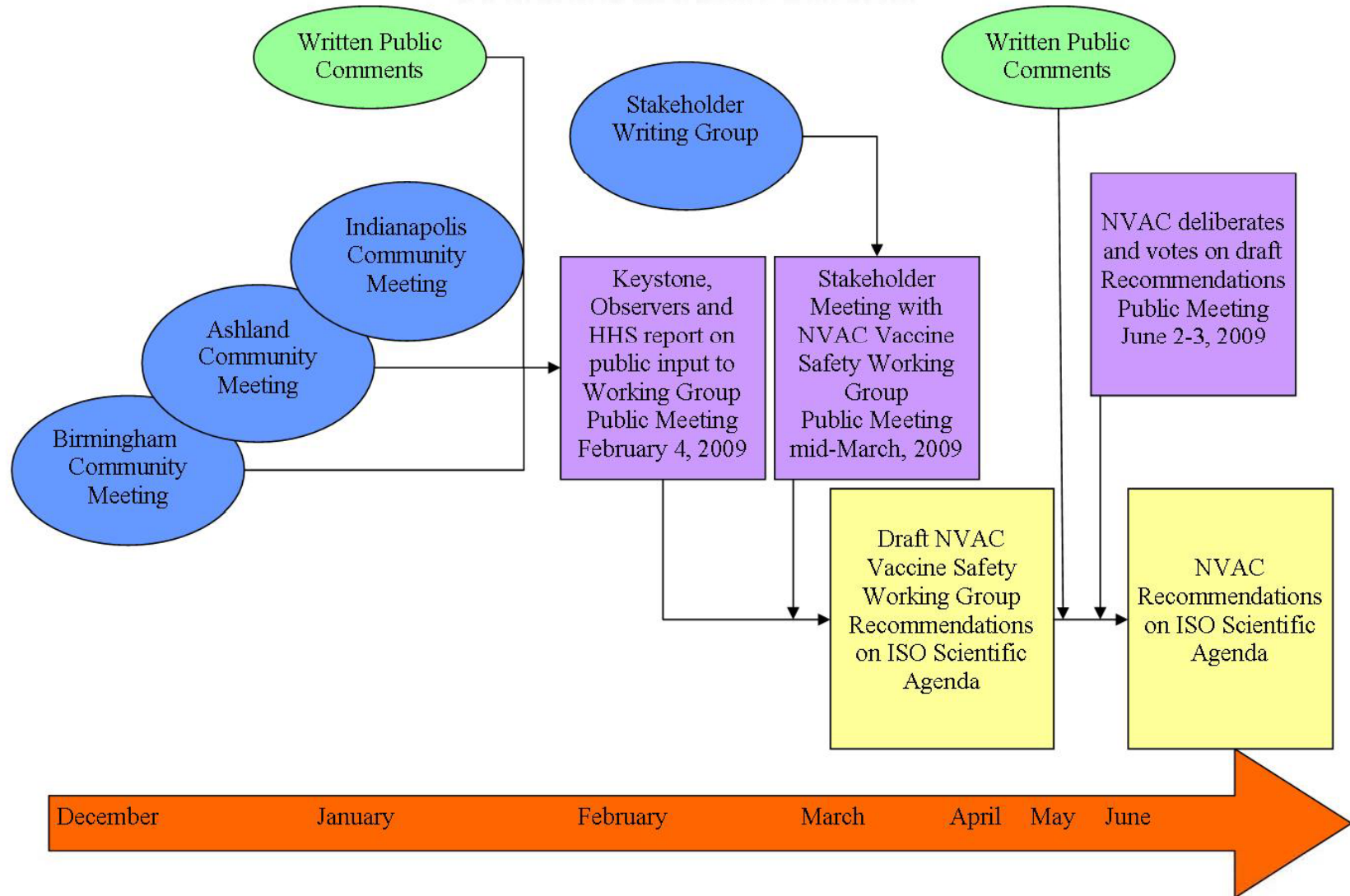
Summary of Comments Received: Individuals

- Other themes raised in comments:
 - Perception that CDC has a conflict of interest
 - Desire for independent research/agency to conduct and evaluate vaccine safety research
 - Lack of trust of government and of pharmaceutical companies
 - Not an issue of “parents vs. science”
 - Frustration with the Interagency Autism Coordinating Committee
 - Desire for more attention to be paid to parental concerns
 - Dislike of mandates

Opportunity for Additional Input

- At the request of the NVAC Vaccine Safety Working Group, we will solicit written comments a second time (estimated to begin April 1, 2009)
- This RFI will request additional public input on a draft of the Working Group's report on the ISO Scientific Agenda

THE PROCESS FOR PUBLIC INPUT INTO THE NVAC RECOMMENDATIONS ON THE ISO DRAFT SCIENTIFIC AGENDA



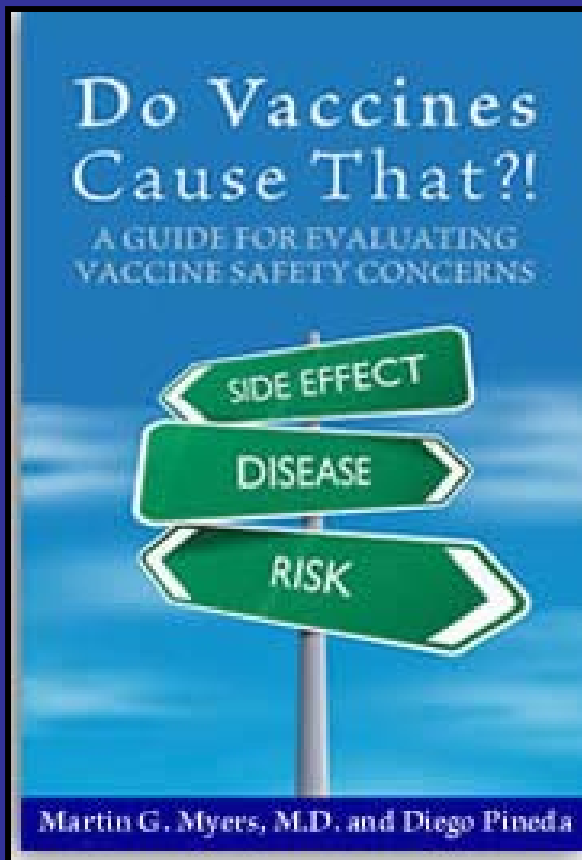
2008 Draft Strategic National Vaccine Plan

Goals

1. Develop new and improved vaccines
2. Enhance the safety of vaccines and vaccination practices
3. Support informed vaccine decision-making by the public, providers, and policy-makers
4. Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States
5. Increase global prevention of death and disease through safe and effective vaccination

Goal 2: Enhance the Safety of Vaccines and Vaccination Practices

Selected Indicators



- By X year, X % of infants, children, adolescents, adults, and pregnant women will be under active surveillance for AEFIs
- Develop and disseminate plans for further investigations, if any, of newly detected AEFI signals and the rational for those plans within X months of signal detection
- Conduct research to explore host factors and biological mechanisms associated with serious AEFIs report results annually

Stakeholder Input into the National Vaccine Plan

- **Priorities:**
 - What should be the top priorities be?
- **Goals, Objectives and Strategies:**
 - Should the Plan be aspirational or achievable?
 - Are the draft Goals, Objectives and Strategies the right ones?
 - What should be added, revised or removed?
- **Indicators:**
 - Are they the right ones?
 - What should the targets be?
- **Roles/Responsibilities for Federal/Non-Federal Stakeholders:**
 - Which stakeholders should have responsibility for achieving the objectives and strategies
 - *What role will you play?*

Comments on Draft Strategic National Vaccine Plan

- National Vaccine Advisory Committee:
Stakeholders Meeting: February 6, 2009
- Draft plan can be accessed at
http://www.hhs.gov/nvpo/vacc_plan/
- Comments can be sent to
NVPComments@hhs.gov

Institute of Medicine: Review of Priorities for the National Vaccine Plan

IOM Stakeholder Meetings

Initial Guidance for an Update of the
National Vaccine Plan

A Letter Report to the National Vaccine Program Office

Committee on the Review of Priorities in the National Vaccine Plan
Board on Population Health and Public Health Practice

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Washington, D.C.
www.nap.edu

- Goal 4 (July 24, 2008)
- Goal 1 (December 1, 2008)
- Goal 3 (February 2, 2009)
- Goal 2 (April 14, 2009)
- Goal 5 (June 4, 2009)

<http://www.iom.edu/CMS/3793/51325.aspx>

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January 26, 2009

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