National Vaccine Advisory Committee (NVAC) February 6, 2009 Meeting on the draft strategic National Vaccine Plan: Goal 1 - Develop new and improved vaccines

Participants:

Cornelia Dekker	NVAC member and Moderator
Angela Shen	National Vaccine Program Office (NVPO)
Jovonni Spinner	NVPO
Allison Mawle	CDC
Chris Colwell	McKenna Long, Merck
Rebecca Sheets	NIH
George Curlin	NIH
Jaime Fergie	NVAC Member
Lance Gordon	NVAC Member
Richard Clover	NVAC Member
Lisa Jackson	NVAC Member
Clem Lewin	Novartis
Shannon Dzubin	Novartis
Margaret McCluskey	USAID
Laura York	Wyeth
Mark Feinberg	Merck
Elaine Esber	(No affiliation noted)

Telephone participants:

Carmen Denis
Mia Hass
Lisa Hunter-Ryden
Sarah Landry
Ken Reibel
Katherine Walker
Theresa Wrangham

Indicators for Goal 1

- Within one year, create an evidence based list of new vaccine targets to prevent infectious diseases that are high priorities for development.
- Strengthen the wording and link to "promises" i.e., implementation accountability and funding
- Identify X candidate vaccines (e.g. for HIV, malaria, TB and a cross protective vaccine for Influenza) and advance Y priority vaccine candidates along the research and development pipeline including Z candidates into advanced clinical trials. -- delete

Objective 1.1 *(Prioritize the needs for developing new vaccines)* Prioritize needs

- Need broad consensus and support
- Support NVPO commission appropriate body (e.g. IOM) to include all stakeholders

- Cornerstone of the goal
- Linkage to benefits of development of priority vaccines (e.g. addressing barriers such as regulatory approval, streamline acip recommendations, reimbursement)

Objective 1.2 *(Support research to develop new vaccine candidates and improve current vaccines to prevent infectious diseases, particularly those determined to be priorities)*

- Separate out develop new and improve current vaccines. Sensitivities were expressed about phrasing (e.g. "optimize" vs "improve" vaccines)
- Participants felt strongly about maternal immunizations and felt there should be an indicator addressing (e.g., hold workshop to discuss barriers to developing these vaccines)
- Needed discussion on development of vaccines where the benefit of the vaccine is not realized by the one being vaccinated.

Objective 1.3 *(Support research on novel vaccine delivery methods)*

- Clarify delivery – as physical method of administering vaccines

Objective 1.4 *(Support development of vaccine candidates and the scientific tools needed to evaluate these candidates for licensure)*

- Reorder strategies in a more logical sense and aligned with regulatory timeline
- Clarify language – e.g., having a process for manufacturing clinical grade material i.e., contract manufacturing

Objective 1.5 *(Increase understanding of how the host immune system influences vaccine response)*

- Clarify this section and call out a role for genomics

Objective 1.6 *(Strengthen the science base for the development and licensure of safe and effective vaccines)*

- Link this section to safety as a whole and clarify that pre-licensure safety should also inform post-licensure safety (i.e., hand off of safety information)

General Comments:

The National Vaccine Plan needs to have a broader, more comprehensive public education campaign section. For example, CDC could develop a campaign discussing the value of vaccines because they are considered a credible source. However, they typically have small budgets in terms of being able to develop a large scale campaign. There have been occasions where companies will do unbranded or branded campaigns; but the government needs to play a role as well.

One participant felt that more money could be spent on vaccine safety to increase the confidence in consumers to vaccinate and therefore increase uptake of vaccines. Increased uptake is an important public health goal and would also be important to manufacturers (increased market). The participant asked vaccine manufacturers to speak to a point raised at the Institute of Medicine's expert committee meeting on February 2, 2009 on the National Vaccine Plan's Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers. The participant asked for clarification from industry as to the discrepancy between money spent by CDC on vaccine safety research (said to be $20 million) and monies spent on vaccine promotion (said to be $300 billion). The participant asked for a discussion on why, given the importance and need for increased money for safety research (as discussed at the earlier IOM meeting) more money is spent on communication for vaccine promotion versus safety.

In response, many stated they were confused by the question. One facilitator stated many safety studies are needed, and already conducted, to license a vaccine. In addition, post-licensure safety research already occurs, handled by agencies such as FDA, including mandated post-licensure safety studies and investigations when signals about vaccine safety problems are discovered.