Blue Ribbon Panel Meeting
Summary Report
June 3 and 4, 2004

In March 2004, Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) requested that a diverse group of individuals be convened to review the vaccine safety monitoring and research activities at CDC. At a two-day meeting in June 2004, the participants engaged in frank and wide-ranging discussion of current vaccine safety programs and perceptions about the safety of immunizations. The participants accepted Dr. Gerberding's charge to report back on CDC's longstanding commitments in vaccine safety monitoring, research and communication. The discussion highlighted that vaccine safety is a subject that requires much broader governmental and public involvement in keeping with the evolving epidemiology of disease and expanding clinical and laboratory science. In addition, community expectation for vaccine safety standards increases as the burden of disease decreases as a result of successful immunization programs.

Links on This Page:

CDC BACKGROUND

Rationale for convening this meeting:

Vaccines are cited as one of the greatest achievements of biomedical science and public health in the 20th century. This achievement is based on the remarkable success in controlling numerous infectious diseases which used to be widely prevalent in the United States. While there has been great progress in reducing the number of cases of vaccine-preventable diseases such as polio, measles, rubella and meningitis, the threats posed by these diseases remain because the organisms that cause them have not been eliminated.

The public health importance of immunizations cannot be disputed; however, an equally important aspect of the immunization program is ensuring the safety of all vaccines, particularly because they are sometimes administered to entire populations and are often mandatory. CDC recognizes its role in collaboration with FDA and other partners in ascertaining the risks involved in vaccinations as well as its responsibility to communicate these risks to the public. Public confidence in the immunization program is essential and must be based on understanding and communicating the benefits and risks of immunization. At the same time, it is critical that public health officials listen to and understand concerns that are expressed by the public around vaccine safety.

Although CDC is not solely responsible for the complex issue of vaccine safety, it has a unique role in surveillance, monitoring and engaging in and supporting research on immunization. Respect and confidence in the quality and integrity of these scientific efforts is an essential component of our national immunization program. CDC is actively involved in detecting and investigating vaccine safety concerns and supporting a wide range of vaccine safety research to address safety questions. Given this role, CDC is deeply committed to ensuring that vaccine safety monitoring and research is undertaken with the highest degree of integrity and scientific quality. CDC recognizes

its dual roles in promoting immunization to prevent disease and ongoing assessment of vaccine safety. In addition, given the concerns some have expressed about potential conflicts of interest in fulfilling these roles, CDC appreciates that the assessment of immunization risk warrants both adequate resources and appropriate oversight.

Therefore, Dr. Gerberding made the important decision to convene a group of individuals who have been engaged in the area of vaccine safety and who could provide individual opinions on a variety of issues related to the vaccine safety program at CDC. By holding this meeting and encouraging an open and honest exchange of ideas on vaccine safety, CDC hoped to demonstrate its commitment to strengthen the collaboration between public health agencies, public interest, professional and advocacy groups, industry and the general public. Furthermore, CDC hoped the discussion among the participants will continue to provide a foundation upon which further trust and confidence can be established on these very important public health issues.

Meeting Participants:

The group consisted of 17 individuals (see , Meeting Participants) from a variety of professional organizations, public interest and advocacy groups, government advisory committees, and government agencies. In an effort to create balance among the participants, including complementary skill sets, diverse points of view, and general interest in safety issues (specifically in area of vaccine safety) while maintaining a size that would promote productive and manageable discussion, the following guidelines were utilized to choose participants:

- Broad understanding and knowledge of risk assessment, risk management, and quality assurance and/or,
- Interest and/or knowledge of vaccine safety issues and/or,
- Partners with diverse perspectives who work with CDC on vaccine safety issues and its research agenda and/or,
- Partners with diverse perspectives who work with CDC in an advocacy role for public health issues and/or have engaged CDC in discussions on this issue and/or,
- Individuals who actively seek credible vaccine safety information which include healthcare providers, consumers, other federal agencies, industry, professional groups and others.

Unfortunately, many key stakeholders who have been deeply involved and dedicated to issues around vaccine safety were not invited to participate in the meeting. The primary reason for not inviting additional groups and/or individuals was not to exclude any particular points of view but simply to maintain a smaller group of individuals to allow for productive discussion. This summary report will be posted on the CDC website for public comment and we invite those who were not able or invited to participate in this meeting to provide their comments. The public comments along with the summary report will be provided to the Director of CDC.

OBJECTIVES FOR THE MEETING PARTICIPANTS:

The meeting participants were asked to review and discuss three objectives during their two-day meeting. The purpose of providing objectives for the participants was to assist them in discussing the vaccine safety program at CDC on a broader level; therefore, they were not convened to discuss specific vaccine safety studies such as the thimerosal issues, the recent IOM report or other more specific details of the vaccine safety program.

Individuals were asked to provide individual opinions on the following three objectives:

1. Review the structure, function, credibility, effectiveness,

efficiency and support of CDC's vaccine safety program and assess how it can be maximized and sustained.

- Assess the program's ability to detect emerging or rare adverse events.
- Assess the capacity of the program to provide comprehensive monitoring of the growing number of vaccines.

2. Review the intramural and extramural collaborative activities of the vaccine safety program and determine their effectiveness and efficiency.

   - Assess additional steps CDC can institute to enhance coordination with other federal agencies and partners, including consumer and advocacy groups.

3. Determine the optimal organizational location for vaccine safety activities within the CDC to ensure scientific objectivity, transparency and oversight while at the same time ensuring that program priorities are appropriately established and are relevant to the immunization program and other stakeholder needs.

SUMMARY OF MEETING:

The two-day meeting took place in Atlanta, Georgia on June 3 and 4, 2004. Prior to the meeting, the participants were provided with a notebook of informational materials and an agenda for the meeting. To ensure a productive meeting, the participants were asked to review the materials prior to the meeting. Specifically, the notebook consisted of supplemental materials and recommended sources for other information on vaccine safety. While the meeting was not open to the public, the discussions of the meeting were transcribed.

June 3, 2004:

On the first day of the meeting, the Chair, Dr. Louis Cooper as well as CDC's Chief of Science, Dr. Dixie Snider, provided opening remarks to the participants. Then, each individual present, including CDC staff attendees, offered a personal introduction. Finally, the objectives for consideration by the participants were reviewed and the meeting continued with presentations given by CDC and other Department of Health and Human Services (DHHS) staff.

The presentations by the staff ranged in topic, beginning with a broad overview of the vaccine safety activities in the DHHS coordinated through the National Vaccine Program Office (NVPO). There were presentations on CDC's overall activities in vaccine safety and then the focus of the presentations narrowed to specific overviews of the National Immunization Program (NIP) and its activities in vaccine safety. The Immunization Safety staff presented on specific functions and activities within the immunization program which involve surveillance, monitoring and research in vaccine safety. Specifically, activities such as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) Project were outlined and there was background given on other efforts such as the Clinical Immunization Safety Assessment (CISA) Network and the Brighton Collaboration. There was a presentation on CDC's Data Sharing Program and finally, to stimulate thinking and further discussion, options were presented regarding the current and potential organizational location for vaccine safety activities within CDC.

The range of topics presented was intended to give the participants a sense of the depth and complexity of the issues that CDC and specifically, the Immunization Safety staff tackle on a daily basis. Throughout the day, while presentations were given, the participants were encouraged to ask questions of the

staff. The questions and comments from the participants were direct and at times constructively critical of the vaccine safety monitoring and research activities at CDC. The immunization staff's honest and direct answers stimulated additional substantive and productive discussion.

The discussion demonstrated the complexity of the issues and often revealed sources of tension between CDC and some members of the public as well as among CDC staff. At times, it was clear that some of the staff have experienced a great deal of stress and frustration, including personal harassment, while dealing with the vaccine safety issues and allegations by some of loss of public trust in CDC's work. However, the pride and dedication that the immunization staff have regarding their effort in vaccine safety was equally clear and impressive to the participants.

Overall, the presentations given by the staff and questions asked by the participants generated frank dialogue on important and challenging aspects of vaccine safety by a unique, diverse group of individuals, including the CDC and NIP staff, representatives from parental and advocacy groups, vaccine manufacturers, professional organizations, advisory committees and government officials. Although disagreement was clear on some issues, the interaction underscored a common theme, a clear dedication to the safety of vaccines and the importance of broad public and professional understanding about the benefits and risks of immunization.

For additional details, the presentations and discussions can be reviewed in the official transcript.

June 4, 2004:

The second day of the meeting was reserved for discussion among the participants regarding the three objectives (mentioned earlier) as well as specific considerations dealing with vaccine safety activities at CDC. With the exception of senior staff who were asked to remain as resources, other CDC staff were excused from this session, allowing the participants the entire day to engage in thorough and open discussion regarding the objectives as well as the issues presented the previous day.

To begin the discussion, Dr. Cooper asked all participants to share their most important impressions and views following the June 3rd session. The participants each provided insightful and direct remarks concerning, but not limited to the presentations and the interactions with the immunization staff. An emphasis was placed on vaccine safety issues where improvement is feasible and critical.

Following the opening remarks, the participants continued the discussion on the three objectives but also considered some other specific questions/issues regarding vaccine safety. Again, the participants were encouraged to speak freely and openly regarding their views and as a result, the discussion was extremely thoughtful. The comments made during both the opening remarks and the remaining session seemed to revolve around very specific themes. As a result, even though the participants were not convened to come to a consensus and/or make recommendations as a group regarding what CDC should do to improve the vaccine safety activities at CDC, these themes seemed to resonate throughout the day. Individuals did not restrict their comments solely to the role of CDC, but directly mentioned other governmental entities, industry, the provider community and the public. Some of the themes are highlighted in this report as a framework for moving forward to make improvements in the area of vaccine safety. (These themes are not prioritized.)

There is a tremendous need for strategic planning for

vaccine safety research and for greater coordination and collaboration among federal agencies and community leaders.

Vaccine safety research and monitoring is not just an activity at CDC. Therefore, collaboration is considered critical if the activities around vaccine safety are going to be improved and strengthened. The collaboration, however, must occur on many levels. It is important to harness the strengths of all stakeholders in the vaccine safety arena which translates into not only involving the federal government agencies such as FDA, CDC, National Institutes of Health (NIH), Health Resource and Services Administration (HRSA), Department of Defense (DOD), and others but allowing for public and community leaders and/or key advocates to be an integral part of the process. Additionally, the advisory committees, manufacturers, and other partners who have important stakes in vaccine safety need more clearly defined roles in this process.

There is a need for a more formalized process to coordinate activities and promote collaboration and priority setting among all federal agencies working in vaccines, specifically CDC, FDA, NIH, HRSA, DOD, and others. Some of the participants mentioned that NVPO could assist a great deal more in the coordination of vaccine safety activities, particularly among the federal government agencies; however, it was acknowledged that NVPO lacks the resources and the authority to drive such activity. Some participants expressed the need for creating an interagency coordinating group to review the vaccine safety activities and/or a scientific advisory board for research. Others suggested that a Task Force on vaccine safety to include NIH, CDC, FDA, HRSA, and others should be formalized. The participants were reminded that at one time, there was a Task Force on Childhood Vaccines that could be reactivated with clear definition of its role in vaccine safety. Currently, it should be noted that there is an Interagency Group on Vaccines (IAVG) comprised of senior staff from many of the agencies noted above; and it convenes via teleconference every two weeks. Overall, participants expressed the tremendous need to strengthen coordination on vaccine safety activities. More importantly, the discussion highlighted the need for defined roles of responsibility and accountability for resource allocation and plan implementation across the various federal government agencies. These activities must be accompanied by an ongoing review of results to ensure further responsibility and accountability.

The discussion around collaboration revealed that a strategy for setting the agenda on vaccine safety research is critical but that it must be done in a way that is coordinated and incorporates the strengths of each participating agency and/or partner. Again, NVPO, with additional resources and a clearer definition of authority was mentioned as an appropriate key player in the process of providing more formal collaboration on the development of a strategy for looking at vaccine safety issues.

When speaking to the strengths of the various agencies, CDC's strengths in epidemiological studies and outbreak investigations were acknowledged. However, it was emphasized by many that epidemiology is not the only scientific research that should occur around vaccine safety. There was a discussion about NIH and its' focus and strength in basic and clinical research. Additionally, there was acknowledgment that the genetic component of any chronic disease must be studied as well as the genetic predisposition to any serious adverse event (acute or chronic). Again, NIH has the potential to bring additional strength and expertise to conduct such research.

Regarding vaccine safety monitoring, there was a strong support for CDC's role in surveillance and epidemiology; however, there was less clarity regarding differentiation of CDC's role and FDA's role in vaccine safety research

matters such as post-licensure trials.

Once it was recognized that a need exists for a formalized collaboration across the agencies and beyond, another theme emerged which demonstrated that the specific roles of each agency within the federal government are not as clearly defined when it comes to vaccine safety research. It is certainly a cross-cutting issue with tremendous overlap and at the same time, some gaps.

FDA is responsible for the regulatory oversight and review of pre-licensure studies conducted by manufacturers and the question came up as to who is responsible for post-licensure studies? Currently, within the federal government, both CDC and FDA are involved in these types of studies. As part of a post-licensure commitment, FDA may request that a manufacturer conduct certain post-licensure studies, and FDA is also responsible for the regulatory oversight and review of these studies. Although this process seems to be working and must continue, it can also be improved. There was a sense among the participants that there is real need for improvement in post-licensure research. It was mentioned that some manufacturers have an active role in conducting post-marketing trials, both on their own initiative as well as in response to agreements with FDA.

CDC and FDA have important functions in surveillance and some participants emphasized that the performance has generally been strong in this area. However, concern was expressed that most monitoring/surveillance systems are not specific to a particular vaccine and there are not enough studies of possible adverse effects of new vaccines in combination with existing vaccines. Therefore, as the number of vaccines increases, the number of unresolved hypotheses which need new studies might also increase. Who will be responsible for prioritizing and doing these studies? Another point raised was that post-marketing research results may not necessarily be included in the vaccine package insert unless they are submitted for FDA review by the manufacturer.

Additional questions focused on the perceived increase in national morbidity from chronic diseases—and the role, if any, that vaccines may play regarding such conditions as asthma, neuro-developmental and learning disabilities, diabetes and autoimmune disorders. While CDC does conduct research on chronic diseases, it was not completely clear what the roles are for the agencies in conducting research on chronic diseases that could be linked to a vaccine and/or drug (i.e. product/drug-induced disease) and whether this type of research should fall only within the purview of FDA, since it is a regulatory agency. The challenge of determining whether a chronic disease is product-induced was recognized. There is great difficulty in determining whether a valid signal exists for a relationship between vaccines and chronic conditions. Some participants questioned the sensitivity of existing vaccine safety tools, such as VAERS and VSD in picking up signals around chronic diseases.

There is a need for external oversight and community/public involvement in setting the research agenda.

Another key theme that emerged is the underlying need to involve the public to a greater extent in the decision-making process on vaccine safety research. The public has a critical stake in the vaccine safety research agenda and therefore, could play a larger role in this process. Some participants stated that in the current environment, there is controversy about vaccine safety research and some of this may stem from the lack of trust that some members of the public have towards those setting and monitoring the research agenda. If coordination of vaccine safety activities could be improved and public participation could be enhanced in this process, the trust could be strengthened

between the government and the public. Some individuals felt strongly that the process whereby the Advisory Committee on Immunization Practices (ACIP) and the Institute of Medicine (IOM) make recommendations for research priorities is working well and must continue, but might be strengthened with the addition of greater public participation. Others believed more substantive changes within and outside these existing relationships would be necessary to reduce what some perceive as inherent conflicts of interest.

A consistent message in the discussion supported the value of an integrated research effort to answer research questions. Some views were expressed that highlighted the desire by independent researchers to conduct research different from that research which the government is funding. For example, while there have been some changes implemented in the past several years (i.e. movement from whole cell pertussis to acellular pertussis as well as from oral polio to inactivated polio), there is a feeling among some participants that CDC can sometimes seem unaware of some concerns among the public and even at times dismissive of new ideas. This was another key reason why some participants believe that more public participation in setting research priorities will be a step towards additional collaboration and trust around these issues. The biases mentioned included:

1. Extramural investigators whose hypotheses or initial findings raised questions about the safety of certain vaccines did not get a fair review of grant applications from any government agency.
2. Vaccine safety research, in general, has no strong advocates involved in prioritization and allocation of resources and thus, does not seem to be a priority at NIH, the major source for biomedical research within the federal government.
3. An exception has been made for funds related to vaccines considered to be useful for protection against bio-terrorism. Anthrax and Smallpox are examples, including National Institute of Allergy and Infectious Disease's recent creation of centers to study atopic disease associated with smallpox vaccine.
4. Funding for long-term studies of vaccine safety is very limited or not available.
5. Clear mechanisms are too limited for rapid responses to new concerns around vaccine safety. The public's role in evaluating the level of concern and prioritization for limited resources has been even more limited.

Additionally, the peer review process for government-funded research was questioned and there were suggestions that the research needs to be more results-oriented and customer-directed. An external prior peer review process is critical to evaluate the technical merit of proposed research protocols and also to assess the competence of the investigators to perform the research. Some participants believe that an additional external peer review process to assess research results should include people with different disciplines than the "usual suspects" with the technical expertise. Other members encouraged external peer review for both intramural and extramural research.

Some participants felt that the public should be involved throughout the process. Whereas, others felt that the technical review should be left to those scientists with the expertise and the public can contribute with the scientific community in recommending vaccine policy. Furthermore, it was mentioned that different patterns of review are needed. When new issues arise around vaccine safety, it should be possible to re-evaluate and do additional follow-up research as needed. Some suggested that while the CDC has demonstrated the ability to respond to signals, sometimes the response does not appear to be appropriate to the significance of the signal. Some believe that this demonstrates peer review of research results alone does not

represent a final answer on a scientific issue. If there were more public participation in the process of setting research priorities, some felt that that this would reduce the risk of research being terminated "prematurely" in areas viewed as problematic.

Finally, once a research agenda has been set, there needs to be an external oversight process in place to monitor the research being conducted by the various agencies and others to ensure that ideas raised by members of the public are being addressed and the scientific integrity of the research is maintained. Additionally, and some believed most importantly, external oversight is needed to protect the science. While there are currently oversight mechanisms in place, some participants who noted that there is a need for improvement around the quality of the oversight. Others expressed concern that if an independent advisory board is set up to provide oversight to management, there is a risk that decision-making could effectively come to a halt. It was apparent that external oversight was essential if the results are to have the high credibility that the modern era of consumerism and evidence-based medicine demands.

There is a need for greater transparency in terms of how research priorities are set, how research designs are developed, how and what research is being conducted, how data are being analyzed, and how those data are used for policy making. This transparency could help the public understand what research is being done and why it is being done – this knowledge may help create a greater sense of participation in the process itself.

As the participants discussed the need for increased participation by the public in the process of setting the research agenda for vaccine safety, there seemed to be a sense that almost as important is the need for greater transparency into the research being done within the federal government. It was expressed by some that in the current environment, it is unclear who decides the priorities of vaccine safety research, how this research is funded and who ultimately does it. These are fundamental issues into which some members of the public would like to have more insight.

There were some concerns raised that it already seems as if some of the research being done in vaccine safety has been in response to political pressures, inaccurate public perception of the vaccine safety issues and other external factors. Given these issues, some of the participants believe that many of the research priorities are being set in a reactive versus proactive mode. There was concern expressed by some participants that research is being determined in response to external criticisms that are not based on science. These criticisms pose serious risks to priority-setting for use of limited resources. Responsiveness to public concern is important, but a mechanism must be implemented to balance these concerns with protection of science and the scientists. Some comments supported the importance of allowing science to drive the research agenda. While it was also expressed that the government research agenda should be driven by the health needs of the general public, the driving force for the research agenda should be based upon the "best science." Oversight, regardless of where it is based, should utilize measurable objectives that are consonant with the needs of the general public. Otherwise, oversight alone tends to lead to micro-management and stifles creative outreach for solutions.

There were also comments regarding the need for the peer review process to have increased transparency. Overall, transparency in the governmental planning and implementation process in setting our nation's vaccine safety agenda could potentially lead to increased public confidence.

Data access for external review and research is critical. Recommendations were varied as to how public access

could be increased safely but there was agreement that data access needs to be increased. Additionally, this access would allow for increased extramural research.

Providing additional access to vaccine safety data to external researchers for the purpose of conducting vaccine safety research was another recurring theme. Some participants believe that the data must be publicly posted as this would increase public confidence in CDC's credibility and accountability in these issues, while others place greater emphasis on audits. While a data sharing mechanism to allow access to the Vaccine Safety Datalink (VSD) Project data has been in place at CDC since 2002, some expressed their continued interest in having broader access to the VSD database to allow outside researchers to replicate and validate the studies that have already been done by CDC. However, others emphasized that CDC should more fully assess the current mechanism before expanding access. Some participants felt that in providing transparency and public participation in the research process, access to data is a key aspect of strengthening the trust around these issues.

Adequate safeguards for data must be in place to ensure the health plans' willingness to continue participating, and to protect the privacy of both patients and the participating health plans. It was recognized that the health plans involved in the VSD Project can choose at anytime to discontinue participation and this would be an irreplaceable loss to vaccine safety research. During the discussion, it was emphasized that CDC and HHS must define conditions that protect the health plans and their patients, maintain the integrity of the science and continue to allow public access to the data. The participants all recognized that achieving these objectives was technically, legally and logistically challenging.

The Vaccine Adverse Event Reporting System (VAERS) is not sufficient to detect signals due to underreporting and doesn't have the granularity needed to identify who is affected. There is a need to bolster and improve VAERS.

In reviewing some of the specific processes in place dealing with vaccine safety, concerns were raised regarding VAERS, a system collaboratively managed by both CDC and FDA. It was not clear to all participants that VAERS was designed only to identify signals, not respond to them. Nevertheless, several participants expressed little confidence in VAERS. Even if CDC can respond rapidly to signals, some participants perceive that CDC cannot respond adequately. Others expressed that VAERS has been sensitive in detecting signals and that CDC has demonstrated the ability to respond rapidly and decisively to clear-cut signals of vaccine adverse events. There was considerable discussion around what constitutes a signal and what represents a reasonable response. Intussusception following vaccination with the rotavirus vaccine was reviewed as an illustrative example.

Concerns were expressed that there may be important signals missed due to under-reporting; and therefore some participants questioned whether VAERS has the breadth and depth of signal reporting to allow for an appropriate response. Some expressed the opinion that in order to have a system that is truly effective, there would need to be mandatory reporting of adverse effects to VAERS by those who administer vaccines. Others discussed the importance in determining who does not report to VAERS and why they are not reporting. This latter concern was related to special or under-represented populations that may be at differential risk, due to genetic and/or environmental factors. Examples mentioned were racial and ethnic minorities, immigrants and the poor. Some thought that there may be additional ways to encourage reporting to VAERS and that this is another area where external input can be beneficial. Programs to educate the public and professionals about the importance of VAERS were proposed as potential ways to improve the sensitivity of signal detection by VAERS.

There were recommendations for structural changes at CDC (i.e. where to locate vaccine safety activities), ranging from very specific to very diffuse.

One question which continued to be discussed throughout both days of the meeting had to do with the placement of vaccine safety programs– both within CDC as well as outside of CDC. Opinions varied on where vaccine safety activities should be placed within CDC and how vaccine safety activities should be organized. Although options were presented by Dr. Wharton as to where vaccine safety might be placed within CDC, including pros and cons provided for each option, there seemed to be a tacit understanding by the participants that the placement of vaccine safety activities is largely a management decision. It was hoped that the tone of discussion would be useful to management as it reviews options for placement of vaccine safety activities.

One overarching issue that was raised had to do with CDC's expertise in outbreak investigation and the necessity to continue to have the best science. Opinions were expressed by some that the vaccine safety activities must remain within the purview of skilled scientists and not be distorted by passions of the moment, current public trends or perceived conflict of interest. It was acknowledged that all individuals have biases and that conflicts of interest are inherent. Oversight structures, which can include external participation, may offer helpful approaches for managing and balancing these conflicts.

Strong sentiment was expressed to "do no harm" to the good work currently being done in any decision regarding where vaccine safety will be placed organizationally. CDC has a different role than NIH or FDA in responding to emergencies and there was an expressed desire to not jeopardize this ability with any changes that are instituted. Recognition of the need for CDC to maintain a workforce both interested in and desirous of responding to emergencies as well as doing safety research was also discussed. It was also noted that currently little support exists for only a small cadre of scientists with particular skills in the pharmaco-epidemiology of vaccines and the nascent field of pharmaco-genetics.

CDC must be able to detect potential safety problems quickly and address them systematically and effectively. Some believe that CDC should maintain leadership of the vaccine safety program while others felt the vaccine safety program should be moved outside of CDC. It was also noted that criticism of some study results will still exist regardless of where vaccine safety programs are placed. Other participants believe that the vaccine safety activities are best located where they are within the NIP and that additionally, there must be a formal enhancement of coordination of activities.

Comments were expressed concerning strong, positive interactions between policy, surveillance and research, thus making a case for continuing to house these activities together. There were comments that moving the vaccine safety monitoring outside of NIP could create more problems and there was a question of how public health benefits by moving the vaccine safety activities. Specifically, there were several remarks on the placement of the risk management, risk assessment and risk communication activities at CDC. Some participants questioned whether risk management for vaccine safety belongs in FDA (or outside of CDC) but they felt that it should not remain in NIP. Some noted that public perception must be considered and that generally, maintaining the management of risk and assessment of risk in same location would continue to raise questions. Some believe that while these two areas dealing with the assessment of risk and the management of risk should be separated, there are other ways to achieve this separation other than reorganization. There were suggestions that risk communication should be moved outside the Immunization Safety Branch or the

NIP.

Strong concern was expressed that the CDC scientists and their research work need to be protected from undue outside influences. From the presentations, it was clear that there are many personnel issues around vaccine safety. One issue includes high levels of stress due to increased public criticisms of CDC's vaccine safety research and other vaccine safety activities. Another issue is the number of people with the expertise to do this type of work is limited and the incentives to keep people in the field are limited. Other personnel issues of concern included recruitment, training and retention and the career ladders for personnel with appropriate training and skill sets in vaccine safety. It was further noted that regardless of the placement of vaccine safety activities, the staff in the broader immunization program and in the Immunization Safety Branch must have the support of the Director of CDC.

Overall, there seemed to be a sense among some that the work CDC and the immunization safety staff have been doing in this area has been very good. Some participants were extremely impressed with the breadth and depth of accomplishments presented by the staff. It was noted that there is tremendous respect for the Immunization safety staff. On the other hand, some noted that while the staff presented accomplishments with great pride, this expression of pride can often be misinterpreted by some in the public as arrogance and/or a lack of openness to listening.

There was a clear sense that vaccine safety activities are under-funded within the federal government.

The lack of funding dedicated to vaccine safety may have been the most common th