



AMERICAN ACADEMY OF  
FAMILY PHYSICIANS  
STRONG MEDICINE FOR AMERICA

June 6, 2011

National Vaccine Program Office  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW, Room 739G.5  
Attention: Vaccine Safety c/o Kristin Goddard  
Washington, DC 20201

Dear Ms. Goddard:

The American Academy of Family Physicians (AAFP) is pleased to provide comments on the draft report and recommendations of the Vaccine Safety Working Group White Paper regarding the Federal vaccine safety system. The AAFP strongly believes in the use of vaccines for the prevention of disease and works with the Advisory Committee on Immunization Practices (ACIP) in the development of immunization recommendations.

The overall safety of vaccines in the United States is excellent. Vaccines are held to the highest standard of safety and are continually monitored for safety and effectiveness. The Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) programs are used successfully to monitor the safety of vaccines after they have been licensed for public use. However, like any medication, vaccines can cause side effects. The majority of these are non-serious such as discomfort at the injection site. Serious side effects such as allergic reactions are very rare. The AAFP recognizes there are concerns regarding the safety of vaccines and believes that the benefits of vaccines outweigh the rare occurrence of serious side effects.

After review of the draft white paper, the AAFP makes the following comments:

1. Some description of the incidence of serious vaccine related adverse events would be very informative and would place the rest of the discussion in context. Serious vaccine related adverse events are rare.
2. When the Vaccine Injury Compensation Program (VICP) is discussed, we would recommend describing the number of claims and a brief description of the outcomes. A description of the time involved would also be useful. Then compare the time and outcomes to the general liability system.

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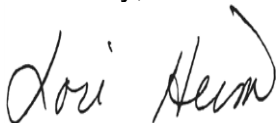
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3. One of the key issues with vaccine safety is that some sectors of the public do not trust government and industry studies. The solution would seem to be to fund more independent, peer reviewed research on vaccine safety.
4. Representatives from primary care physician and midlevel provider groups should be on all vaccine safety committees and oversight groups. Given that physicians are the main source of information on vaccine safety to most patients, it is important to keep primary care physicians involved with and apprised of vaccine safety efforts.
5. The suggestions regarding new vaccine oversight commissions seems ill advised given the low magnitude of the problem. Serious vaccine adverse events are rare. We do not need an extensive and expensive oversight structure. Making any oversight commissions subject to political appointments seems particularly ill advised. Vaccine safety should be made a standing commitment of the NVAC though a standing sub committee with representation from all primary care provider organizations. If additional oversight is needed, perhaps a periodic review from a committee within the Institute of Medicine (IOM) would be the best approach.
6. There is no mention of vaccine safety activities in other countries. Perhaps the U.S. could coordinate with other countries and share information on vaccine safety and collaborate on vaccine safety research.

We appreciate the opportunity to review and comment on this draft white paper for vaccine safety.

Sincerely,

A handwritten signature in cursive script that reads "Lori Heim". The signature is written in black ink and is positioned to the left of the typed name.

Lori Heim, MD  
Chair  
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