

FAX COVER SHEET

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Number of Sheets (including Cover Sheet): 4

Comments: Original letter will be mailed to your work address at 2331 Rayburn HOB, Washington DC 20515-3214.

Connie Lohs

The Vaccine Healthcare Center is a Congressionally supported collaborative network initiated by the Center for disease Control (CDC) and Department of the Defense (DOD) to enhance the quality of immunization healthcare services for members of the Armed Forces and their beneficiaries.

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REPLY TO
ATTENTION OF

**DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258**

The Honorable Carolyn Maloney
Committee on Appropriations
United States House of Representatives
Washington, DC 20515

Dear Representative Maloney,

Thank you for your September 16, 2008 letter concerning your interest in immunization healthcare for our service members and for providing us an opportunity to respond to your questions. Please find outlined below responses to each of the questions posed, with references and additional informational slides at the end.

**What exactly were the serious adverse events found in the military population?
What were the incidence rates of each?**

The serious adverse events that have been reported to the Vaccine Healthcare Center Network are reflective of those seen in the National Vaccine Injury Compensation Program table of reportable events and include the rare occurrences of myopericarditis, acute disseminated encephalomyelitis and eczema vaccinatum.

The presentation referenced was delivered at the National Institute of Health Conference titled "Vaccine Safety Evaluation: Post-marketing Surveillance Conference" on April 10-11, 2007 (<http://www.hhs.gov/nvpo/conf041007.html>) in addressing a rapidly changing and increasingly complex immunization healthcare world. Population diversity (ethnicity, gender, etc.) in response to drugs (safety or efficacy) is difficult to study in the pre-licensure phase. Pre-licensure studies are limited by small size and are not designed to examine real world factors as multiple drug exposures or effects of different genetic or disease factors. These are only evident after licensure when drugs are given to millions of people. As an allergist-immunologist, my focus is on the more severe or prolonged side effects having a serious impact on quality of life.

Like the Vaccine Adverse Events Reporting System (VAERS), our program is not in a position to provide incidence data but rather to refine case definitions and research questions to address the serious and the rare adverse events questions. The challenge in assessing these rare and/or serious adverse events is that most do not have a single cause defined and are recognizing that there are genetic risk factors in addition to different environmental exposures that combine to trigger disease onset.

Does the 1-2% rate of serious adverse events referenced on the third slide of the presentation apply only to service members or is the rate the same for all DoD personnel and their beneficiaries who receive immunizations? If the rate is lower for DoD personnel and beneficiaries, what would account for the difference?

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The estimate of 1-2% who may need an immunization healthcare consultation to address clinical questions raised applies to all populations and is an expert opinion estimate. There is a need for larger population surveys to improve our understanding of people's experiences and perceptions coupled with the new focus on enhanced post licensure safety surveillance efforts mandated by the FDA. The more drugs one is exposed to, the greater the likelihood of having an adverse event so as vaccine numbers increase, and we will see more people who have efficacy or safety issues. The consultation does not prove or disprove causality association but it is from these consultations that we have refined our understanding of the questions, a critical first step to future refinement of research agendas. It is our firm belief that increased research into side effects that are more severe but may be short duration, may help us understand more severe adverse events (more rare at 1 in 10-100,000). However, our work over the past years has been humbling in relation to the knowledge gaps which the Institute of Medicine Reports has also highlighted.

A statistic provided on the third slide of VHC's report indicates that 24,000-48,000 service members have suffered serious adverse events due to mandatory immunizations. Is this accurate?

No, this statistic refers to the potential number of service members, experiencing more serious side effects (not serious disease with prolonged duration), that may need a medical consultation about next dose and/or pre-treatment to reduce the severity of the side effects, etc.

Of the service members who have suffered serious adverse events, how many did not return to active duty or reserve assignments? What impact, if any, is this having on military readiness?

Our program has no ability to currently assess this but past reviews by the Armed Forces Epidemiological Board and the Institute of Medicine have not identified a population based impacting number of losses due to serious adverse events. There are limitations to the data available both within and outside the services and there is a need for enhanced efforts and new strategies to attempt to answer this question.

The report indicates (slides three, seven, and eighteen) that a possible risk factor in acquiring a serious adverse event is the administration of "multiple vaccines." What data does VHC have to support this? How does the administration of "complex immunization exposures" potentially affect the rate of serious adverse events?

We have preliminary findings from one of our many on-going research studies that suggest a relationship between adverse events and multiple vaccinations exist. These findings will require validation, but heighten our concern for the current clinical practice of multiple vaccinations.

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The standard of care is to minimize drug exposures because of the recognition that the more drugs being used, the greater the chance of a reaction and potentially a serious adverse event. The belief that vaccines are safe to mix is based largely on pediatric experience and with a much more limited spectrum of vaccines. The recommendation for more research on subpopulation risk factors in relation to multiple vaccine combinations has been included in the Institute of Medicine Report on Multiple Vaccines (<http://books.nap.edu/nap-cgi/skimit.cgi?recid=10306&chap=105-109>).

Again, thank you for your interest and inquiry. If we can be of further assistance, please let us know.

Very respectfully,



Renata J. M. Engler, MD
Colonel, US Army
Director, Vaccine Healthcare Centers Network