

# This is an Official Montana State DPHHS HAN Info Service Message

Distributed via the DPHHS Health Alert Network (HAN) System

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This is an official

CDC Health Advisory

Distributed via Health Alert Network

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FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain Barre Syndrome

**The information below is provided largely for local public and private vaccine providers. Local Public Health Agencies should forward the VFC-related information to their local pediatric vaccine providers.** If any vaccine providers or the public has information about an adverse event presenting as weakness or abnormal sensations in the arms or legs, occurring two-four weeks after the administration of Menactra, they are asked to report to the Vaccine Adverse Event Reporting System through the DPHHS at 406-444-5580 or directly to VAERS at the web address or phone number provided below. This action will assist with the evaluation of the Menactra vaccine.

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The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are alerting consumers and health care providers to five reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature.

Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization.

Meningococcal infection, which Menactra prevents, is a major cause of bacterial meningitis, affecting approximately 1 in 100,000 people annually. The infection can be life threatening:

10-14 percent of cases are fatal and 11-19 percent of survivors may have permanent disability.

According to Jesse Goodman, MD, Director of FDA's Center for Biologics Evaluation and Research, at the present time there are no changes in recommendations for vaccination; individuals should continue to follow their doctors' recommendations. FDA and CDC are not able to determine if any or all of the cases were due to vaccination. The current information is very preliminary and the two agencies are continuing to evaluate the situation.

Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge

of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. Individuals can report to VAERS on the web at <<<http://www.vaers.hhs.gov/>>> www.vaers.hhs.gov or by phone at 1-800-822-7967.

The five cases of GBS reported following administration of Menactra occurred in individuals living in NY, OH, PA, and NJ. All five patients were 17 or 18 years of age and developed weakness or abnormal sensations in the arms or legs, two-four weeks after vaccination. All individuals are reported to be recovering or to have recovered. More than 2.5 million doses of Menactra vaccine have been distributed to date. The rate of GBS based on the number of cases reported following administration of Menactra is similar to what might have been expected to occur by coincidence, that is, even without vaccination. However, the timing of the events is of concern. Also, vaccine adverse events are not always reported to FDA so there may be additional cases of which we are unaware at this time.

Prelicensure studies conducted by Sanofi Pasteur of more than 7000 recipients of Menactra showed no GBS cases. CDC conducted a rapid study using available health care organization databases and found that no cases of GBS have been reported to date among 110,000 Menactra recipients.

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The goal Montana's Health Alert Network is to transmit information to local public health authorities as quickly as possible, and assign a suitable priority to the message that is sensitive to the impact of a health-related event providing information of immediate utility relative to the public health and safety of Montanans. For questions or comments relative to Montana's HAN system you may contact the Montana State HAN Coordinator Jim Aspevig at <<mailto:jaspevig@mt.gov>> or the Associate HAN Coordinator Gerry Wheat at <<mailto:gwheat@mt.gov>>

**Categories of Health Alert messages:**

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

**Info Service Message:** provides general information regarding a situation or opportunity; does not typically require immediate action.

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