

January 4, 2016

Michelle Davis, Executive Director

Keith Grellner, Chair

Washington State Board of Health

P.O. Box 47990

Olympia, Washington 98504-7990

Re: *Technical Advisory Group (TAG) Proposed Recommendation for Quadrivalent Meningococcal Vaccine (MCV4)*

Dear Ms. Davis and Mr. Grellner:

I am writing in response to the TAG's December review of the proposed MCV4 school-entry requirement. Because the general public could not comment at this meeting, there are several points I would like to raise based on my attendance.

First, it has been over nine years since a TAG has convened to review a new vaccine for inclusion as a school-entry requirement. In 2006, the TAG refined the criteria used to assess three specific antigens (Pertussis, tetanus and diphtheria). The December review utilized these same criteria to evaluate the proposed MCV4 school-entry requirement. The framework for establishing these criteria was based on the following principle:

"...vaccine requirements for children entering child care and/or school are justifiable when without them"

- *An individual's decision could place others' health in jeopardy*
- *The state's economic interests could be threatened by the costs of care for vaccine preventable illness, related disability, or death and by the cost of managing vaccine preventable outbreak*
- *The state's duty to educate children could be compromised*

Second, there was significant discussion and failure to arrive at consensus among the TAG members whether or not to postpone the MCV4 review until the BOH could revisit the criteria. The framework became a sticking point for several members on the TAG with one member vocalizing that herd immunity should be a key consideration. However, I would offer that herd immunity is not germane to this particular discussion. A single case of meningococcal disease places people in harm's way, especially if they are in close contact with an infected person. As experience has shown, even sporadic cases of meningococcal disease can trigger a large, rapid response that is costly and burdensome for health departments and schools. The TAG voted on the nine-point criteria individually using three columns:

- 1st column: “Yes” vote for recommending both a primary and booster dose of MCV4 as a school-entry requirement
- 2nd column: “No” vote for recommending an MCV4 school-entry requirement
- 3rd column: “Unsure” vote for recommending one dose of MCV4 as a school-entry requirement

For each criterion, there were more “Yes” than “No” votes except for the criterion regarding the reduction in person-to-person transmission (i.e., criterion #6). Specifically, the final “Yes” count was 85, and the “No” count was 24. Notwithstanding these vote totals, the TAG ultimately voted not to recommend requiring both primary and booster dose for school-entry. Again, the public and the members were confused by this voting process. The question remains why the TAG conducted a final vote if all but one criterion received an overwhelming majority of the “Yes” votes.

Third, in 2013 the Washington State Vaccine Advisory Committee (VAC) recommended full acceptance of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) recommendations for use of MCV. Members of the WA VAC also stated that MCV4 coverage rates for the primary dose are not as high as they hoped for in their state. Getting persons in their mid-to-late teens to return to a provider for the second dose of MCV4 is considered even more challenging. The CDC states that one important strategy to increase immunization rates is the establishment of school entry requirements.¹

After voting not to recommend adding MCV4 as a school-entry requirement, the TAG voted to revisit the nine-point criteria. Sanofi Pasteur respectfully recommends that the Washington State Board of Health table the findings of the December TAG review until the Department can revisit the framework and criteria. Of the three states which use these criteria, Utah recently established a school-entry requirement for seventh grade. To date, almost 30 states require a primary dose of MCV4 for school-entry. If the BOH were to approve the TAG recommendation, it would create a gap between what ACIP recommends and what WA supports for school-entry. The State is missing an important opportunity to improve immunization rates against a disease that can take away a young life in as little as 24 hours or lead to substantial and long-term sequelae of 1 in 5 survivors.

Sanofi Pasteur, the vaccines division of Sanofi is a global company that provides more than one billion doses of vaccine each year. Our company manufactures pediatric, adolescent, adult and

¹ Centers for Disease Control and Prevention. *Improving Vaccination Coverage Fact Sheet*. April 2015.



travelers vaccines. Our vision is a world in which no one suffers or dies from a vaccine preventable disease.

For additional information, contact Elizabeth Brewer, Sanofi Immunization Policy and State Affairs at (973) 718-0044.

Sincerely,

Elizabeth Brewer

Director, Immunization Policy & State Affairs

Sanofi Pasteur