



Congress of the United States
House of Representatives
Washington, DC 20515

March 27, 2014

Dr. Margaret A. Hamburg
Commissioner
The Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Hamburg,

I write today seeking information on the status of approval of a vaccine for Meningitis type B, a deadly yet preventable bacterial infection that has caused significant alarm on college campuses.

Breakouts of Meningitis type B have occurred at Princeton University in March 2013 and the University of California Santa Barbara (UCSB) in December 2013. At least twelve students were infected, including one case which resulted in the amputation of both feet. Following these outbreaks your agency took steps to make the vaccine available to students at both campuses. However, since persons who are vaccinated can still carry the bacteria, those who come in close contact with Princeton or UCSB students remain at risk of contracting the illness, according to the Centers for Disease Control and Prevention.

This crisis has hit close to home in my congressional district. I am sure you have read the story of Stephanie Ross. A native of Upper St. Clair near Pittsburgh, Pennsylvania, Stephanie was a bright sophomore student at Drexel University with a promising future. An active member of her sorority, Stephanie was an exemplary student. Always considerate of those less fortunate than herself, Stephanie decided to donate eight inches of her hair to a charity that makes wigs for children with cancer. In high school, she was just as active and successful, drawing accolades as an athlete and National Merit scholar.

Tragically, on March 10, Stephanie died from the Meningitis type B strain. According to the CDC, Stephanie had been in contact with students at Princeton the week before she became ill. Her family and friends are now left to wonder whether her death would have been prevented if the FDA had approved for broader use the Meningitis type B vaccine known as "Bexsero" when the manufacturer first initiated those discussions five years ago.

As you are aware, Novartis has since announced that it will seek expedited approval this year for the vaccine using the breakthrough therapy designation authorized by the Food and Drug Administration Safety and Innovation Act of 2012. However, the vaccine has

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Page 2

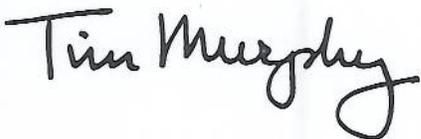
already been approved for use in Canada, Australia, and the European Union. On Friday, March 21, 2014, the UK Joint Committee on Vaccination and Immunization recommended that infants from two months of age be vaccinated with Bexsero.

The FDA has not approved the vaccine despite it having been shown to be both safe and efficacious in Phase I and Phase II clinical trials. It is my understanding that the manufacturer has been in conversations with the FDA about the vaccine since 2009 when negotiations on the design for the Phase III trial began.

Former FDA officials contend your agency should have approved the vaccine earlier, but did not do so because of a culture of "risk-aversion" that ultimately hurts public health and patient safety. They note that in this particular circumstance, the FDA could give "accelerated approval" of the drug, or pursue a reciprocity agreement to permit entry to the US market those medications approved for use in other western nations.

Given that most colleges require Meningitis vaccination for enrollees, Stephanie's parents and others must understand if these outbreaks could have been avoided, and if so, the steps needed to prevent any more tragedies in the future. Further, policymakers need to understand what the agency is doing in this regard. Towards that end, I request a briefing as soon as possible from you to explain why the FDA has not acted in the intervening five years, and what steps the FDA is taking now to bring to market a vaccine to prevent any future deaths or cases of Meningitis type B. I thank you in advance for your attention to this matter and look forward to your response. Please call my office at (202) 225-2301 to arrange a time when we can meet.

Sincerely,

A handwritten signature in black ink that reads "Tim Murphy". The signature is written in a cursive, slightly slanted style.

Tim Murphy
Member of Congress

TM:bdg