Congress of the United States
Washington, DC 20515

February 7, 2014

Dr. Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg,

We are writing to express our concerns regarding the FDA's response to the outbreak of Meningitis type B (MenB) at two universities (and possibly a third) in the U.S.

There are 20,000-80,000 cases of MenB diagnosed in the world each year. The disease is highly contagious and can cause brain damage, deafness, loss of limb, and in 10% of cases, death. In March, 2013, a Princeton University student was diagnosed with MenB. A second outbreak occurred at the University of California Santa Barbara (UCSB) in December, 2013. In total, 12 students at these two universities have been infected, with one student having both feet amputated. In addition, we would call your attention to another case, which was conveyed to Forbes Magazine by a reader in January 2014 and reportedly resulted in the death of a college student at Michigan's Kalamazoo College.

Today, the U.S. has a vaccine for every type of meningitis except MenB, which was the cause of 32 percent of meningococcal cases last year. One MenB vaccine, called Bexsero, has been approved by regulators in the European Union, Australia, and Canada, and is available in those countries. However, the approval of this vaccine has been held up for three years by the U.S. FDA's bureaucracy, despite the fact that there have been successful clinical studies. The FDA has slowed the testing and approval process, leading officials at the affected campuses to appeal to the government for special permission to import and administer the vaccine.

This situation could have been avoided if the FDA had pursued its commitment to seek reciprocity of approvals with certain foreign governments. Rather than approving the vaccine, which would have made possible proactively immunizing susceptible college students before a meningitis outbreak occurred, the lack of an approved vaccine has resulted in the FDA and the Centers for Disease Control scrambling to respond to public health crises like those at Princeton and UCSB. If the FDA had moved quickly and permitted Bexsero to come to market, at least some of the cases at Princeton and UCSB could have been prevented.

We are writing to ask the FDA to take steps to prevent another MenB outbreak. One option would be to recognize reciprocity agreements and immediately approve the drug for distribution. A second option would be for the FDA to grant the manufacturer a special license to produce Bexsero, which would allow state and school health officials to quickly respond should another MenB outbreak occur. In previous emergency circumstances, the FDA has granted accelerated approval of vaccines, which allow manufacturers to bypass bureaucracy so that vaccines can be made quickly available to the public.

We would also be interested in hearing what actions the FDA will be taking to improve the review process for life-saving drugs and better respond to such outbreaks in the future.

Thank you for your consideration of these important issues.

Sincerely,

ERIK PAULSEN
Member of Congress

DANA ROHRABACHER
Member of Congress

MARSHA BLACKBURN
Member of Congress

LEONARD LANCE
Member of Congress

JACKIE WALORSKI
Member of Congress

GLORIA NEGRETE MCLEOD
Member of Congress