



**FDA Antiviral Drugs Advisory Committee Meetings
NASTAD Testimony**

Merck's Boceprevir (NDA 202-258), April 27, 2011

Vertex's Telaprevir (NDA 201-917), April 28, 2011

Good afternoon. My name is Murray Penner and I am the Deputy Executive Director at the National Alliance of State and Territorial AIDS Directors, or NASTAD. Neither NASTAD or I have a financial relationship with Merck. NASTAD does receive funding from Vertex to support our viral hepatitis program but Vertex did not contribute to support my travel to participate in or attend this meeting. NASTAD is a non-profit organization that represents the nation's chief state health agency staff who have programmatic responsibility for administering HIV/AIDS and viral hepatitis education, prevention, care and supportive service programs funded by state and federal governments.

I am pleased to have the opportunity to speak briefly about your consideration of this new drug application for boceprevir. While not necessarily in the purview of the Antiviral Drugs Advisory Committee, I must point out some very important considerations regarding this new treatment and the public health infrastructure that will impact access and uptake of this important new drug.

Given the lack of public health infrastructure for viral hepatitis and the many barriers to care for persons living with chronic hepatitis C, the cost of this new treatment will significantly impact affordability and comprehensive coverage of patients. NASTAD encourages Merck and the FDA and other government agencies to work together to ensure that un- or under-insured patients who need treatment are able to afford not the drug and also the entire standard of care, given that this new treatment will be added to, and not replace, the current hepatitis C therapy of peginterferon alpha and ribavirin. Further, coverage must include ancillary medical costs such as liver and viral tests, liver biopsies and management of treatment side effects such as anemia, rash and mental health complications.

As you know, this new treatment will not eradicate hepatitis C. A cure must rely on infrastructure such as funding for screening and testing, staff capacity in medical settings and educated health providers in order to

identify those who need treatment in the first place. In order for this new treatment to work, new diagnoses are required. Unfortunately, 75 percent of people living with chronic hepatitis C (or up to 3 million people) do not know they are living with infection and must be identified.

The IOM recently reported a lack of knowledge and capacity among providers to identify infection and deliver expert care, and a lack of knowledge among the public, most importantly among populations at high risk of infection. Even with this new treatment, low provider awareness will continue to lead to lower-than-anticipated utilization of this drug and missed diagnoses. In addition, there are limited specialists such as infectious disease doctors, hepatologists and gastroenterologists available to treat hepatitis C. Further, low public awareness will continue to lead to misinformation, missed opportunities for prevention and treatment.

Targeted and difficult to reach populations must have access to this new drug as well as appropriate care. Treatment will need to be given in tandem with other important public health and social services being provided in public health settings.

If we do not capture the 75 percent of persons living unknowingly with chronic hepatitis C, the costs associated with liver cancer caused by chronic hepatitis and the care and treatment of persons living with chronic hepatitis are high. In the absence of significant increases in screening and care above current medical management, an actuarial study from Milliman Inc. projects medical costs for patients with chronic hepatitis C will go from \$30 billion to over \$85 billion over the next 15 years.

Finally, further postmarketing studies of this drug must be conducted by Merck in order to further define potential risks, other drug interactions and impact on certain populations, including Blacks, where there is evidence of lower sustained virologic response.

Thank you for the opportunity to provide comments on this important new hepatitis C treatment.