

October 14, 2011

Margaret Hamburg, M.D., Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

Since the passage of the Family Smoking Prevention and Tobacco Control Act by Congress in 2009, the FDA has made unprecedented strides in the regulation, surveillance and control of cigarettes and many types of smokeless tobacco products. Now, we respectfully request that FDA build on these successes and move swiftly to issue a strong regulation that would legally treat or deem all tobacco products, including cigars, pipe tobacco, and hookah tobacco and accessories, as subject to the Tobacco Control Act. We appreciate FDA's past work to issue this important regulation. Now, we ask that you provide us with an update on the agency's progress and anticipated timeline for completion of this regulation, commonly known as the "deeming" rule. In addition, we would appreciate the opportunity to discuss the specifics of this new rule with you, and would also ask that you respond to this letter with a date indicating your availability for such a meeting.

On July 13, 2011, Dr. Lawrence Deyton, Director of FDA's Center for Tobacco Products, met with Senators Blumenthal, Sherrod Brown, and Merkley to discuss FDA's regulatory decision around Star Scientific's products Ariva-BDL and Stonewall-BDL, two recently-developed dissolvable tobacco lozenges. In June, FDA deemed both products to be outside the direct regulatory authority afforded the agency under Chapter IX of the Family Smoking Prevention and Tobacco Control Act, thus requiring FDA to issue an additional regulation in order to assert authority over such products. While we continue to respectfully disagree with this decision, we were encouraged during this meeting to hear of FDA's commitment to swiftly issue such a "deeming" regulation, and were pleased to hear of an anticipated October release.

The tobacco industry has moved quickly and creatively to both undermine provisions of the Tobacco Control Act, and to develop new forms of product that encourage the continued harmful addiction of our nation's children and adults. As tobacco control efforts have increased, the tobacco industry has responded by continually introducing new products. Of the estimated 70 million Americans that are users of tobacco, roughly 11 million, or 16%, use forms of tobacco other than cigarettes. While cigarettes still account for the largest share of tobacco products, other forms of tobacco usage can serve as a gateway to lifelong addiction.

Additionally, tobacco companies have countered increasing restrictions over cigarettes by developing and marketing these newer or less common tobacco products oftentimes as "safer" alternatives to traditional cigarette usage; claims that a tobacco product is less harmful should only be permitted if FDA determines such as claim is supported by scientific evidence and is appropriate for the protection of public health. Tobacco consumed in any form is carcinogenic, and while great strides have been made, tobacco usage still costs our nation annually more than 400,000 lives and a \$193 billion economic burden.

The "deeming" regulation allowing FDA to assert its rightful authority over these additional tobacco products is a key tool in the fight against tobacco. FDA's decision around Star Scientific's dissolvable tobacco lozenges only served to highlight the current limits of FDA's current jurisdiction. While FDA's new authority over tobacco products immediately applied to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the Tobacco Control Act appropriately gave FDA the authority to assert jurisdiction over all other types of tobacco products. Different requirements may be appropriate for different products, but all tobacco products should be regulated in a manner appropriate for the protection of public health.

It is critical to exercise all available regulatory authorities to rapidly and dramatically reduce tobacco's harmful physical and economic costs to our nation. We applaud the action FDA has taken to regulate the manufacture, sale and marketing of cigarettes and smokeless tobacco products. We look forward to hearing from FDA regarding the progress of this anticipated next step to assert authority over all tobacco products.

Signed:

Senator Richard Blumenthal, Senator Frank Lautenberg and Senator Sherrod Brown