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Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
Division of Dockets Management  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

November 11, 2011

Docket: FDA-2010-P-0089

Dear Dr. Hamburg:

Tobacco use remains the leading and preventable cause of death and disease in the United States. The Food and Drug Administration (FDA) plays a critical role in evaluating the products that can be used to treat tobacco dependence and reduce that death and disease toll.

As the current presidents of the Association for the Treatment of Tobacco Use and Dependence (ATTUD) and the Society for Research on Nicotine and Tobacco (SRNT), we are eager to receive an update as to where the FDA stands with its review of our Citizen Petition from February 2010 (FDA-2010-P-0089). Our petition, and two similar petitions, all remain pending with FDA. The first was filed nearly four years ago.

While we did receive the required confirmation in August 2010 that our petition was being considered, including noting that our petition "raises significant issues requiring extensive review and analysis by Agency officials," we have received no further correspondence or enquiries from FDA.

We note that FDA hosted a public workshop in October 2010, on one of the issues we raised in our petition (long-term use of nicotine). At that meeting, a senior FDA official publicly announced that the Agency intended to bring this topic soon to a full Advisory Committee meeting. But no such meeting has been scheduled in the year since the agency's workshop.

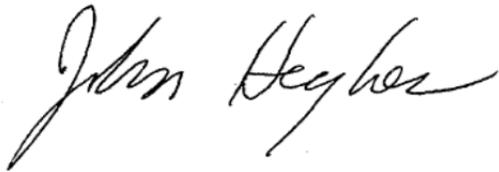
As you are aware, the FDA is obliged under Section 918 of the Family Smoking Prevention and Tobacco Control Act to report back to Congress on "how best to regulate, promote, and encourage the development of innovative products and treatments" to reduce tobacco use. The deadline for

completing this report is March 2013, and the legislation specifically requires FDA to consult one of our organizations (SRNT) when preparing the report.

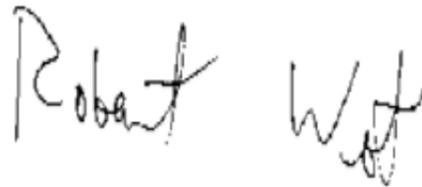
We would strongly encourage the FDA to reach out to experts and move expeditiously to respond to our petition. Almost four years since the first petition was filed on these specific matters (FDA-2008-P-0116), FDA has taken no direct action on our petition to make it easier for current smokers to quit smoking. In the meanwhile, the clinical and treatment communities continue to embrace the suggestions in our petition. For example, a recent review (from September 2011) in the Clinical Practice section of the *New England Journal of Medicine*, recommends reducing smoking with NRT for smokers unwilling to make a quit attempt. This review was authored by the chair (Dr Fiore) and a member of the 2008 Public Health Service Guideline panel that updated clinical practice guidance in this area. This is but one example of how the current labeling for NRT is becoming out-of-date with medical consensus.

Hopefully FDA will act quickly to allow approved labeling and indications to become consistent with best practice and the current evidence.

Sincerely

A handwritten signature in cursive script that reads "John Hughes".

John Hughes, MD  
President, ATTUD

A handwritten signature in cursive script that reads "Robert West".

Robert West, PhD  
President, SRNT