



**Statement regarding lawsuit filed by R.J. Reynolds Tobacco Company regarding conflict of interest among FDA committee members**

February 25, 2011

R.J. Reynolds Tobacco Company, together with Lorillard, Inc., and Lorillard Tobacco Company, filed a lawsuit in Federal District Court in Washington, D.C., against the Food and Drug Administration (FDA) and others, over the conflicts of interest and fixed views among several members of the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) and its Constituents Subcommittee.

"Over the past eight months, R.J. Reynolds Tobacco Co. has sent the FDA seven letters raising concerns about conflicts of interest among several members of the Tobacco Products Scientific Advisory Committee," said Martin L. Holton III, executive vice president and general counsel for R.J. Reynolds. "The FDA has not provided a response to the specific arguments presented in our letters. We believe the only way now to have our concerns taken seriously is through the courts."

Reynolds Tobacco's letters to the FDA explain that three committee members have direct financial conflicts stemming from both their paid expert testimony in tobacco-products litigation and from their compensation from pharmaceutical companies that market nicotine replacement and smoking cessation products. These companies stand to potentially benefit from future FDA actions based on advice and recommendations from the TPSAC.

Additionally, the Federal Advisory Committee Act requires that the TPSAC be "fairly balanced in terms of the points of view represented." The Committee lacks fair balance on many topics, including a role for dissolvable and other smokeless tobacco products in tobacco harm reduction. That issue divides the public-health and tobacco-control communities.

"Four of the eight members of the committee have publicly opposed a current role for smokeless products in tobacco harm reduction," Holton said. "No one on the committee represents the opposing view in the public health and tobacco-control communities. It's apparent that the committee is not fairly balanced."

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