



AMERICANS FOR LIMITED GOVERNMENT

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Dear Dr. Samet and Members of the Tobacco Products Scientific Advisory Committee:

On behalf of the members of Americans for Limited Government (ALG), I am writing to express grave concern that the Tobacco Products Scientific Advisory Committee (TPSAC) will soon issue a final report without addressing clear conflicts of interest among TPSAC's members.

ALG's concern about conflict of interest among TPSAC's members is not new. Beginning in May, 2010, ALG noted that at least four members of TPSAC have conflicts of interest by virtue of receiving "payments from special interests with billions of dollars riding on the outcome of the committee's analysis."

The conflicts were specified in an ALG letter to Commissioner Margaret Hamburg, M.D., of the U.S. Food and Drug Administration on July 13, 2010, which is attached to this letter. In that July 13 letter we stated: "These irreconcilable biases jeopardize the neutrality that examination of this issue demands and requires. It also threatens to erode Americans' confidence in government. It creates an anti-government sentiment that leads the public to question decisions, a dynamic that certainly is not healthy for our democracy.... We can envision no greater conflict. We urgently request that you revisit these disqualifying conflicts of interest."

Citizens for Responsibility and Ethics in Washington raised similar issues involving the specific ties of two panelists to smoking cessation businesses, saying those links would undermine public confidence in regulation of the tobacco industry. Elton Malone, representing the Office of Inspector General of the Department of Health and Human Services, responded on July 2, 2010, saying that it had "found no evidence supporting any violation of criminal law." In a follow-up letter on July 16, 2010, Joshua M. Sharfstein, M.D., then the FDA's principal deputy commissioner, referred to the OIG's finding and said it

concluded that a conflict did not exist. This correspondence can be found at the website of Citizens for Responsibility and Ethics, <http://www.citizensforethics.org/>.

Regardless of the OIG's narrow legal finding – that there was no violation of “criminal law” – we continue to believe that TPSAC's deliberations have been infected since Day One by conflicts and biases.

In fact, they are irreconcilable biases. TPSAC's members include those who have stated opinions on scientific matters, who have testified in court cases on tobacco-related matters, and who have taken grants from pharmaceutical companies that stand to profit if TPSAC votes to ban menthol in cigarettes. On July 16, 2010, Dr. Sharfstein addressed TPSAC and outlined conflict of interest procedures. In those remarks, he outlined procedures that would lead to recusal or the granting of waivers to participate. To date no TPSAC members have been recused and none granted waivers. Despite the clear conflicts of interest, these important tools have stayed on the shelf.

Government advisory committees must be independent and impartial. Conflicts of interest erode the confidence of Americans in government. ALG believes that the TPSAC members at issue have demonstrated bias that interferes with their ability to render impartial, objective advice on scientific issues to the FDA on the issue of menthol in cigarettes. It is difficult to understand how the public can be assured that any data accepted for inclusion in the final report, and any recommendations drawn from that data, has been independently evaluated by members who approached the issue with an open mind.

ALG reiterates its call that TPSAC and the FDA revisit these disqualifying conflicts of interest. It is not too late for TPSAC to address the conflicts of interest. At the very least, the four members of TPSAC should recuse themselves immediately from further deliberations or from voting on the final TPSAC report.

Sincerely,



William Wilson, President – Americans for Limited Government

Attachment: July 13, 2011, letter to FDA Commissioner Margaret Hamburg