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Lawrence Deyton, MD
Director, Center for Tobacco Products
U.S. Department of Health & Human Services
Food & Drug Administration

February 6, 2013

Dear Dr. Deyton and tobacco control colleagues,

I do appreciate the attempts of the Center for Tobacco Products to respond to the issues raised in my previous letter declining the invitation to be part of the planned "dialogues" panel with the tobacco industry. But while I applaud the dropping of the "facilitated dialogues" meeting characterization, the proposed revised format (which clusters invited presentations from government, academics and public health representatives on day one, followed by invited presentations from the tobacco industry on day two) does not adequately address the substantive issues raised in my letter. It remains the same meeting, with the same agenda and purpose, merely rearranging the program. Therefore, I must again respectfully and regretfully decline your invitation to attend this particular meeting.

The first point raised in my previous letter related to regarding tobacco companies as equivalent "stakeholders" with public health. I see nothing in the revised format that changes this, since public health and tobacco company representatives continue to be placed on the same meeting agenda as coequals, albeit now on different days. Tobacco companies are stakeholders only in the promotion of tobacco product use, not promoting public health, which is the purpose of the Family Smoking Prevention and Tobacco Control Act. While the tobacco companies have every right to express their opinions and submit materials for the FDA's consideration, you are not required to treat the regulated industry "equally" as though they had demonstrated materially that they share the goal of protecting public health. They have not done so.

My second point addressed the absence of mutual understanding of what constitutes legitimate science and ethical conduct in science. The revised format does nothing to reassure me that a reasonably comprehensive understanding of Judge Kessler's extensive Findings of Fact in her ruling in the Department of Justice RICO case (*USA v. Philip Morris et al*.) is now informing the FDA's activities or has been incorporated into the agenda. (These Findings of Fact are clearly relevant for the FDA to consider in its decision making, as indicated by the fact that Congress included three findings (numbers 47, 48, and 49) from Judge Kessler's ruling in the Family Smoking

Prevention and Tobacco Control Act.) While there has been a proliferation of smaller tobacco and nicotine device companies that are not defendants in the RICO case, the fact remains that the major cigarette companies continue to dominate the market both in this country and in the world, that they continue patterns of acquisition of the more promising smaller companies, and that the federal court found their fraudulent conduct was continuing and likely to continue into the future. This is highly material to any discussion of industry-sponsored tobacco products research.

Third, it is clear that this meeting has indeed had the effect of contributing to divisions within tobacco control, as some invitees now feel they must attend and others (including me) feel they must decline. Whether it is officially called "facilitated dialogue" or "public workshop" seems less important in this regard than the fact that it is still one and the same meeting with the chairs rearranged, and it did not have to happen this way. It is disturbing when public health agencies contribute to such divisions.

Fourth, the tobacco companies have every right to make comments and one would expect them to do so, and the FDA has a responsibility to give comments from the regulated industry fair consideration. But legal colleagues have advised me that while the FDA is certainly permitted to invite industry speakers to present at a meeting on how to deal with industry science, there is no legal requirement that they do so, and in the absence of such a requirement, I continue to question why FDA feels it must give the industry a stage. They certainly do not have such status even on the TPSAC, where they are separated by being non-voting members. Your legal mandate is to regulate this industry in the service of public health, not to provide it a podium for its propaganda.

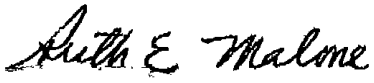
The leading tobacco companies have repeatedly demonstrated antipathy to the FDA, creating multiple obstacles to its ability to carry out its responsibilities for implementing the Family Smoking Prevention and Tobacco Control Act. Far from being equal "stakeholders" in the FDA's mission, some have sued to block implementation of health warning labels and others are openly flouting FDA's regulations banning the use of "light" and "mild" and other descriptors, simply replacing these words with color coding. These are only the most obvious examples.

Our current moment does not call for a cautious, prolonged and exorbitantly expensive replay of the infamous "safer cigarette" debacles of the past, in which the tobacco industry "partnered" with health researchers in a cynical ploy to buy decades more time at the expense of millions of lives. What is called for now is the political courage to acknowledge and incorporate decisively in policy planning the vast evidence demonstrating that tobacco companies are untrustworthy—hence the need for strong, rapidly enacted and well-enforced regulations to protect the public from suffering another century of tobacco-caused deaths. What is called for now is informed, savvy leadership. I urge FDA to provide it.

Please enter this letter and the earlier letter to which it refers into the record of the meeting. If necessary, I would be willing to arrange for someone to attend and read these into the record.

Thank you for your consideration.

Sincerely,



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