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Center for Tobacco Products
Food and Drug Administration

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Dear colleagues:

I was very surprised to be invited to present as part of an FDA-sponsored "Facilitated Dialogue" panel also featuring tobacco industry representatives, which would be focused on the topic of industry-funded research. This very type of industry engagement with senior public health figures is straight out of the tobacco companies' public relations "corporate social responsibility" playbook and was something that at least one tobacco company anticipated as a favorable result of FDA legislation. [1, 2] Such "dialogues" have long been part of this and earlier industry public relations campaigns. Public health authorities and scientists – to say nothing of the federal agency charged with regulating this industry -- should not lend their legitimacy to the tobacco companies' efforts to position themselves as socially responsible.

I would be very willing to come to Rockville and share my perspectives with the FDA on the issue of third parties and tobacco products research. However, I cannot in good conscience participate as a panelist in this "Facilitated Dialogue" with the tobacco industry. Further, I strongly urge that other researchers from the public health community decline participation on such panels. The FDA should consider other means of determining a suitable framework for addressing the many issues related to industry-funded research. While this is clearly an issue about which I have thought and written extensively, I think this meeting as currently envisioned is a very bad idea.

My reasons are:

First, involving the tobacco companies as "stakeholders" on a panel with the public health community in this way suggests that all parties share a common or at least congruent goal. This is a flawed assumption. Public health advocates (and presumably the FDA) have a stake in saving lives. Tobacco companies have a stake in protecting profits. The research evidence has repeatedly demonstrated that they will do whatever it takes to continue to promote the use of cigarettes, their single most deadly product. While the companies may have an interest in reducing the numbers who die prematurely from using their products (so that they will live to purchase more of them), they have never indicated any willingness to pull from the market the products that kill half their longtime users and continue to be sold. Absent such willingness, the

practical goals of public health and the tobacco industry are in direct conflict. No "dialogue" will change that.

Second, any such discussion among "stakeholders" would require a minimal level of mutual understanding about the nature and purpose of science. However, a large body of academic research based on the industry's own internal documents, as well as federal Judge Gladys Kessler's extensive findings of fact in the successful U.S Department of Justice racketeering case against the major tobacco companies, [3] demonstrates that research is an arena in which the tobacco industry is particularly untrustworthy. This fact was also repeatedly noted in the Institute of Medicine (IOM) Report on Scientific Standards for Studies on Modified Risk Tobacco Products.[4] As the Kessler decision found, the tobacco industry engaged in a conspiracy to cover up and distort the evidence of their products' harmfulness, and they have a long track record of egregious manipulation of science. The courts also found that this behavior is continuing and likely to continue in the future; I see no reason to differ with this conclusion. For this very reason, *Tobacco Control*, the journal that I edit, and other reputable scientific journals including *PLoS Medicine* no longer publish tobacco industry-funded research. [5, 6]

To engage the industry as a legitimate partner in the discussion of how to deal with industry science is to ignore this large body of evidence.

Third, as noted briefly above, such engagements have long been envisioned by tobacco companies as facilitating their image reform efforts while creating divisions within the tobacco control community. As we demonstrated in our papers examining Philip Morris's support for FDA regulation of tobacco products [1]and its development of Project Sunrise, which sought to create and exploit divisions within tobacco control, [2]engagement with public health organizations allows tobacco companies to position themselves as reasonable and responsible, and position those who refuse to engage as extremists. In fact, shortly after the failure of a previous bill giving FDA authority to regulate tobacco, top Philip Morris executives were exploiting public speaking opportunities in which they falsely claimed to have "partnered" with leading public health organizations in supporting regulation. (see attached letter rebutting this claim). This is precisely the type of mileage tobacco companies can achieve from engaging in "facilitated dialogues" such as those envisioned by FDA.

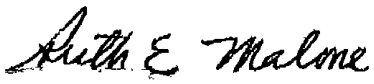
Fourth, tobacco industry denormalization is a key part of successful tobacco control efforts. Convening a meeting of this sort undermines those critically important efforts by creating a forum for re-legitimation through association with respected public health agencies and leaders. Lending the FDA imprimatur to a public meeting featuring tobacco company speakers suggests that something has indeed changed and the industry is no longer harming people through its promotion of deadly products. But this is patently untrue. And, as we recently showed in an extensive review, a robust body of evidence supports tobacco industry denormalization as an effective population-level tobacco control strategy that contributes to reduced smoking prevalence among young people, reduced youth smoking initiation, increased

intentions to quit and reduced perceived peer smoking prevalence. [7] It is very puzzling that the FDA would act in a way that undermines this important work.

The FDA may be required to interact with the industry for the purposes of discussing proposed regulation of tobacco products and what tobacco companies must do to comply. The FDA is not, however, required to "facilitate" dialogue as though it were acting as a neutral mediator between two parties with equally valid but divergent interests. In positioning itself as some sort of neutral party, FDA is unwittingly acting as an agent for the tobacco industry's public relations initiatives and undermining a strong tobacco control strategy. This is very problematic and to those of us who have spent more than a decade researching industry strategies, enormously naive.

For these reasons I am declining to participate in this meeting and urging my colleagues to do the same.

Sincerely,



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[1] McDaniel PA, Malone RE. Understanding Philip Morris's pursuit of US government regulation of tobacco. Tobacco Control. 2005;14(3):193-200.
[2] McDaniel PA, Smith EA, Malone RE. Philip Morris's Project Sunrise: weakening tobacco control by working with it. Tobacco Control. 2006;15:215-23.
[3] United States District Court for the District of Columbia. Amended Final Opinion, U.S. Department of Justice versus Philip Morris et al. Civil Action No. 99-2496 (GK). http://publichealthlawcenter.org/sites/default/files/resources/doj-final-opinion.pdf 2006.
[4] Institute of Medicine Committee on Scientific Standards for Studies on Modified Risk Tobacco Products. Scientific standards for studies on modified risk tobacco products. Washington, DC: Institute of Medicine; 2012.
[5] Malone RE. Changing Tobacco Control's policy on industry-funded research. Tobacco Control. 2013;22(1):1-2.
[6] PLoS Editors. A new policy on tobacco papers. PLoS Medicine. 2010;7(2):e1000237.
[7] Malone RE, Grundy Q, Bero LA. Tobacco industry denormalisation as a tobacco control intervention: A review. Tobacco Control. 2012;21:162-70.