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September 18, 2013

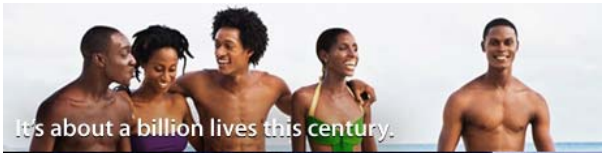
**Comment on Docket No. FDA-2013-N-0305**
**Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research**

I wish to submit the attached material, which includes comments I originally posted to my blog (http://tobacco.ucsf.edu/blogs/sglantz), including the comments submitted by a wide spectrum of academic and other leaders in the tobacco control community, for the FDA's consideration in evaluating the possible role of independent parties in industry sponsored research.

As detailed in the attached comments, creating such an arrangement is a very bad idea.

Thank you for your consideration.

Stanton A. Glantz, PhD
Professor and Director






# Ruth Malone is absolutely right in not going to the FDA's misguided "facilitated dialog" with the tobacco companies

Submitted by sglantz on Wed, 2013-01-30 17:15

The Food and Drug Administration is planning to hold a "facilitated dialog" between health researchers and the tobacco companies on the issue of industry-funded research. Ruth Malone, my colleague at UCSF and editor of the journal *Tobacco Control*, has written an eloquent letter to the FDA explaining why she is declining this invitation and calling on others to do the same.

I applaud Ruth for writing this letter and urge all scientists and public health professionals to do the same.

The FDA needs to cancel this misconceived enterprise and devote its energy to promoting public health by doing things like banning menthol.

Here is Ruth's letter:

Center for Tobacco Products
Food and Drug Administration
January 30, 2013

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,

Ruth E. Malone, RN, PhD, FAAN
Professor and Chair, Department of Social and Behavioral Sciences
University of California San Francisco
Editor, Tobacco Control

[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... 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.

Ruth's letter is also posted on the *Tobacco Control* blog here.

PS: In 2004, the American Cancer Society, American Heart Association, American Lung Association and Tobacco Free Kids wrote Philip Morris telling them to not claim be "partners" just because they were both supporting the idea that Congress should give the FDA authority over tobacco. The FDA should be regulating not facilitating meetings for the tobacco companies.

sglantz's blog Add new comment

## Comments

Submitted by Anonymous on Tue, 2013-02-05 17:19.

### FDA Not Legally Required to Give Tobacco Equal Billing

Nothing in law requires the FDA to treat the tobacco industry as equal "stakeholders" with the public and public health. There are two primary statutes that govern the right of the tobacco industry to participate in any rulemaking or other processes of the FDA.

The first is the Administrative Procedures Act:

§553(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

The second is in the Family Smoking Prevention and Tobacco Control Act:

§907(A)(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—

In carrying out duties under this section, the Secretary shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

Nothing in either statute requires that the tobacco industry be given any special or equal status just because it is the regulated industry. I think a strong case can be made that the FDA should give little or no weight to data from the tobacco industry because its history, as found in the RICO case, shows that it has no credibility. Thus, the industry cannot "make a significant contribution" to the workshop. It can always present what it wants in written comments.

Richard L. Barnes, JD
Center for Tobacco Control Research and Education
University of California, San Francisco
530 Parnassus Ave, Suite 366
San Francisco, CA 94143-1390

reply

Submitted by Anonymous on Tue, 2013-02-05 11:25.

## Is it time to suspend working with the FDA?

Thank you to Ruth Malone for publicly taking a stand to not participate in an FDA initiated meeting with tobacco industryrepresentatives and to Stan Glantz for offering this forum for further discussion of the issues.

As Ruth says, the FDA considers and treats the tobacco industry as a stakeholder. At a TRDRP conference, David Ashley, a top FDA staffer, told me that the public health community needs to step up to the plate and make sure that its voice is heard in order for the FDA to make decisions benefiting public health. He stated that If we don't do that then the FDA will have to rely largely on information supplied by the industry (in addition to its own staff, one supposes). It is this framing of the regulatory process by the FDA itself that is fundamentally flawed. **Until the FDA stops treating the industry and the public health community as equal stakeholders, it cannot make decisions that are based on people's well-being rather than on protecting corporate profits.**

For four years the public health community has participated in this flawed framework – we've been TPSAC members, offered public comments, been FDA consultants, and attended hearings and meetings. In doing so, we have legitimized the paradigm. It has gotten us nowhere. The decision to keep menthol cigarettes on the market is just one example of this. It is time to stop.

**It is time to change tactics – to withhold our knowledge, expertise and reputations in order to delegitimize the FDA's current approach.** Ruth has taken a first step in refusing to participate in a meeting. Is the public health community willing to try another strategy and say no to the FDA when it asks us to serve on committees, do research, and meet with them? What about resigning from TPSAC?

I know how hard this will be – there's the temptation to think "If I don't participate, then my position will not be heard." We have been participating for four years and what do we have to show for it? I ask you, are the results enough? For the past four years I've heard, "Be patient, the bureaucracy works slowly." Now I hear, "Obama was re-elected, things can change." I don't think that things will change as long as the industry is a stakeholder. Perhaps silence will accomplish what words have failed to do.

Kim Klausner
Industry Documents Digital Libraries Manager
University of California, San Francisco

reply

Submitted by Anonymous on Tue, 2013-02-05 13:55.

## Response to Kim: Big Pharma is another FDA "stakeholder"

Kim said, "I don't think that things will change as long as the industry is a stakeholder." I think that statement holds a lot of merit.

One of my favorite sayings that is almost always true is "how you do anything is how you do everything."

The FDA's relationship with the pharmaceutical industry should shed light on what we can expect its relationship to be with the tobacco industry.

The link below will take you to a transcript of a segment shown on PBS's Frontline that was posted online 10 years ago! The transcibed interviews with a public citizen watchdog group, FDA insider and a pharmaceutical representative show how the pharmaceutical industry participated in influencing how the FDA
deals with industry.

Substitute "tobacco" everywhere it says "pharmaceutical" and you will find a story that is relevant to our current discussion.

Following is an example of a question asked to and responded by the Director of the public citizen group in the posting:

Question: "How is the pharmaceutical industry making its inroads into the FDA? Where is it exerting its influence?"

Response: "The pharmaceutical industry's influence gets exerted in a number of ways...the FDA started looking upon the industry as their client, instead of the public and the public health, which should be the client. A second way in which the industry influence occurs is by having leaders in the [FDA] who are spineless and gutless, and who don't like controversy... and avoiding conflict means doing what the industry wants."

http://www.pbs.org/wgbh/pages/frontline/shows/prescription/hazard/independent.html

Maybe none of this is news for most of us, but the evidence of how the FDA relates to its "clients" and "stakeholders" should provide insight as to what our expectations should be in terms of how the FDA relates to the tobacco industry.

So, as suggested by Ruth and Kim, should we step away? I am also wondering if we can work on changing the FDA's relationship with its "client and stakeholder" - the tobacco industry?

If we step away how do we still access those resources upon which the FDA sits? I have colleagues who are submitting grant proposals to the FDA. What do
we say to them?

Valerie Yerger, Associate Professor UCSF; Founding member of the African American Tobacco Control Leadership Council; Board member of NAATPN

reply

Submitted by Anonymous on Tue, 2013-02-05 13:40.

## Can we Trust the Cat to Watch the Milk?

Thanks Stan for sharing. Kim succinctly captures the prevalent sentiment.

To tobacco industry profit comes first and foremost which is to keep manufacturing products that kill people or place them on a path of morbidity and never ending addiction. It is hard to imagine how they could even be on the same table where we discuss preventable disease or saving people from nicotine addiction.

Viewing them as stakeholders is like “trusting a cat to watch the milk.” What a perfect way to exercise democracy and what could be a better example of heights of capitalism!! Can anyone offer a simple explanation why or how we should take them as stakeholders?

Can we find examples where these tobacco industry stakeholders are more for public health and less for profit? This is an industry whose 24-7 is devoted to: how can we take advantage of loopholes? How can we fool people? How can we circumvent the law and manufacture products (began with *snus* and now the e-cig, and tomorrow, a nicotine laced drink or pop). How can we entice some deceitful and hypocritical people to serve on their bandwagon and promote their products? How can we entice scientists to accept their grant in the name of academic freedom and socialize them in the public eye?

Enough is enough.

Thanks to Ruth for fomenting the discussion.

PS: These are my personal professional opinion and not a view associated with the agency.

Thanks.

Surendra Bir Adhikari
Ohio Department of Alcohol & Drug Addiction Services, Columbus, OH

reply

Submitted by Anonymous on Tue, 2013-02-05 13:33.

## Re: Is it time to suspend working with the FDA?

Thank you Kim Klausner for your comment. This is a splash of well needed reality. I have been saying this for many years—with lots of resistance to this along the way.

Michael Givel

reply

Submitted by Anonymous on Tue, 2013-02-05 12:47.

## Response to Kim Klausner

I think it is very naive to assume that our silence would impact the FDA. The reality is we've not hired lawyers and prepared for decades how to work the system as the industry has. Nor do we have resources to invest in this effort in order to counter what the industry is doing to the FDA. Simply, holding our nose, and walking away, however, is not the answer. Defining what realistic goals can be accomplished within the framework of FDA regulation and holding the agency accountable for their achievement is our job. The debate over menthol was a side show created by a badly written law. A regulated market place where the regulatory incentives tilt the opportunity for profits to be made for less dangerous products is probably the best we can hope for. What the incentives will be and how to get them in place is really the challenge we confront. Simply turning our back on FDA is not the answer. Mike Cummings

reply

Submitted by sglantz on Tue, 2013-02-05 13:26.

## If Mike is right, we should stop working with the FDA

If all we can expect from the FDA is creating regulatory incentives for the tobacco companies to make money from (hypothetically) less dangerous products, then public health people should probably spend their time on more productive activities, like pursuing smokefree laws, large scale state tobacco control programs (with strong media campaigns), and tax increases.

The reality is that the FDA actually has quite a lot of power if it wanted to use it. For example, right now the FDA could, if it wanted to:

Ban menthol as an additive in all regulated products (not just as a characterizing flavor), something that has been languishing for two years since the TPSAC report
Initiate an enforcement action to stop cigarette companies from flaunting the law by replacing the banned words "light" and "mild" with color coded packs
Initiate an enforcement action to stop e-cigarette companies from making therapeutic claims until such time that the veracity of these claims has been demonstrated

The FDA could also stop talking about the tobacco companies as "stakeholders" and start referring to them as "the regulated industry."

And, directly to the point of the current issue, the FDA could recognize that, while they have an obligation to listen to the tobacco companies, the FDA is under no obligation to provide a forum for them by putting them on panels.

Stanton Glantz

reply

Submitted by Anonymous on Tue, 2013-02-05 02:41.

## Ruth Malone's letter to FDA

Dear Ruth,
I applaud this letter that you have written to FDA. I am sharing it with my colleagues in India so that they understand a stand that an honest tobacco control scientist need to take. Thank you for the guidance and inspiration.
mira

reply

Submitted by Anonymous on Mon, 2013-02-04 08:33.

## Impact of FDA actions on RICO remedy

To me the whole thing looks very transparent. It has a lot to do with timing. The need for the publication of the apologies under the DOJ recent decision is imminent.

A large portion of these required public apologies has to do with the way people were made to believe that real science was taking place by TI in the early 50ies and onwards.

What is more natural than seeking today "facilitation" on scientific matters, which inherently means: "look folks, may be in the 50ies something was wrong with this science, but, this is ancient history, nobody remembers what it was all about, it had something to do with the generation of your grandparents, **But ever since, our science is so great that even the reputable FDA is taking very seriously!**",

This way, the weight of the apologies will be light as a feather. The DOJ worked over 14 years to achieve them. And the idea now is to make them meaningless and worthless.

What is really sought here is not facilitation, but rehabilitation.

Amos Hausner
Isreal

reply

Submitted by Anonymous on Sun, 2013-02-03 18:15.

## Harm reduction strategies matter and you should pay attention

That attitude might have been credible 10 years ago. But now most of the tobacco companies are considering 'harm reduction' strategies of one sort or another - whether through electronic clean nicotine delivery, smokeless tobacco or novel 'heat not burn' tobacco products. Several are also looking at reducing the toxicity of the emissions in smoked tobacco - a strategy that may make some difference, no difference or even be harmful. Harm reduction strategies have the potential to substantially reduce the burden of disease caused by smoking. Longer term they may transform the nicotine market and save millions of the one billion lives that the WHO expects to be lost in 21st Century to smoking-related disease on current trends. Harm reduction is one of the very few areas where tobacco company and public health interests may align. It may well be worth having industry funded research on it - the idea of a facilitated discussion is to work out if there is a case. No credible scientist should approach that question with her or his mind already made up.

I don't wish to trouble you too much with European experience, but the most successful tobacco control intervention in Europe is driven by a tobacco company. Sweden has adult smoking prevalence of 13% compared to the EU average of 28% and next lowest at 23% [Eurobarometer p.7], and it has lower rates of smoking related disease as a result. I understand that smokeless tobacco use and e-cigarette use is on a steep rise in the United States, but these developments are very poorly researched so far.

People can rave about the tobacco industry putting itself out of business, but they are wasting their breath. The one thing the tobacco industry can do, and probably the only useful thing it can do, is to engineer the transformation of the nicotine market into something more benign than it is now. I would expect the FDA and tobacco control community to be extremely keen to see that happen and interested in how it might come to pass. It's legitimate to ask if the tobacco industry should fund research in this area, in a manner analogous to pharmaceutical funding as drugs are developed.

But I'm surprised by the absence of scientific curiosity. Don't the you feel you have a professional responsibility to understand these developments, and hear about them at first hand? Perhaps even influence them? And what are you so worried about? That you will somehow be contaminated by their badness and be unable to stop yourselves believing things that are wrong? A meeting or discussion isn't an endorsement or capture, it's just a discussion without prejudice. Reasons 1-4 are very poor reasons not to engage in dialogue on such important public health issues.

I urge you to welcome the FDA's initiative and accept their invitation.

Clive Bates

reply

Submitted by Anonymous on Mon, 2013-02-04 18:08.

## nothing stops the industry from doing harm reduction

It could do it today.

It could stop aggressively marketing its lethal product.

It could stop engineering it for addiction and for initiation ("smooth smokes").

It could stop undermining tobacco prevention.

It could stop its lobbying and litigation and PR campaigns that push up smoking.

It could stop lying and stonewalling about what its product does to the customer and to the people closest to the customer.

It could stop any and all of those things today. Right now. That would reduce harm.

It chooses to keep on doing these things. Because it puts its profits over people's lives.

That's where this industry stands on harm reduction.

reply

Submitted by sglantz on Sun, 2013-02-03 19:57.

## Clive, like the FDA, seems to be ignoring the RICO ruling

Clive, like the FDA, is ignoring the fact that the major tobacco companies have been found to have violated the Racketeer Corrupt Influenced Organization (RICO) Act because of perpetrating a massive *ongoing* fraud, with the distortion of science being a central element of that fraud. Both the trial court (Judge Kessler) and the Court of Appeals, in upholding Judge Kessler, focused on the *ongoing* manipulation of science in concluding that the companies had defrauded the public, were continuing to defraud the public, *and likely to continue to do so in the future.*

This is a completely separate issue from the contentious question of harm reduction. The question at hand is, should the FDA be treating these racketeers as equal "stakeholders" with public health?

While the FDA has to allow the companies to submit their ideas (and they have made submissions on the issue of harm reduction), the FDA -- and everyone else -- needs to consider the massive record accumulated by the US Department of Justice, accepted by a judge after a 9 month trial at which the industry vigorously defended itself, upheld on appeal, and left in place by the US Supreme Court when deciding how to interact with the companies.

Any reasonable reading of this record leads to the conclusion that what the FDA is planning to do will damage the pubic health.

Stanton Glantz

reply

Submitted by Anonymous on Mon, 2013-02-04 05:01.

## Sceptical and open-minded is the right approach

The appropriate response for a health-maximising public official or credible academic in this situation is scepticism and open-mindedness, not absenteeism. You don't have to believe everything they say (and you certainly shouldn't). But nor should you disbelieve everything on principle or shut out their views. Judge Kessler is damning, but I don't think that should mean a block on discussing all subjects for all time. It's always wise to know what people you disagree with are actually saying and why, not least to check that you do actually disagree with them. But in the case of harm reduction there is at least the possibility that their incentives are better aligned with public health, and that they have superior knowledge of some aspects of this

field (eg. knowledge of users, chemistry and psychopharmacology, device design etc). Keep the focus on health, rather than an anti-industry campaign, and you'd approach this differently. The emergence of harm reduction strategies means the two are no longer one and the same.

Clive Bates

reply

Submitted by sglantz on Mon, 2013-02-04 08:11.

## The law permits the industry to submit its views

There is no question that the law allows the industry to submit its views for the FDA's consideration.

The issue is the FDA's elevation of the industry as coequal "stakeholders" while ignoring the decades long history and playing an active role in facilitating the industry's public relations efforts.

"Harm reduction" is nothing new. The last time the US government engaged the industry as a partner in "harm reduction" was the National Cancer Institute's "Tobacco Working Group" in the early 1970s. The government treated it as an earnest effort to make a safer cigarette, the industry used it for intelligence gathering and to steer the process to meet its ends.

You can read about it in Chapter 4, "The Search for a Safe Cigarette", in our book *The Cigarette Papers*.

You may claim that this is ancient history, but you need to remember that the courts have found that the racketeering behavior *is continuing and likely to continue in the future*.

Stanton Glantz

reply

Submitted by Anonymous on Sun, 2013-02-03 10:16.

## Lessons for Europe

Ruth's letter and the comments that have followed are extremely important for us in Europe. We are still reeling from the events that surrounded the dismissal of the last EU Health Commissioner, in circumstances that are still extremely suspicious. The EU Tobacco Products Directive is proceeding slowly towards becoming law but we have many concerns arising from growing evidence of links between Commission officials and the tobacco industry. Unfortunately, the European Commission seems to be unwilling to provide the transparency needed to allay these concerns. We also have the situation whereby the Polish government, showing a complete disregard for those of its citizens who will die lingering deaths from tobacco-related disease, seems intent on watering down or even blocking the Directive.
Those of us committed to the Eurpoean ideal are increasingly frustrated at how our representatives are discrediting the European institutions.
The points being made here will be echoed in Europe as we fight for transparency, integrity, and freedom from corruption.

Martin McKee

reply

Submitted by Anonymous on Sun, 2013-02-03 08:22.

## FDA needs to read the DOJ RICO record

Whomever at the FDA decided this policy should be required to read the entire DOJ case transcript and everyone at the FDA who is involved with tobacco should, at the very least, be required to read Judge Kessler's DOJ opinion. It is incomprehensible that the FDA would willingly sit down at a table with representatives of the tobacco industry in this manner.

A bigger question for me is why does a supposedly "civilized" society tolerate a product, that is legal only by historic accident, that kills a half a million Americans every year. In another Federal regulatory environment all Boeing 787's have been grounded because of battery malfunctions which has not caused one accident much less a fatality.

Instead of sitting down with Big Tobacco the FDA should be working on an Endgame plan to eliminate tobacco use in the foreseeable future. Other progressive societies, New Zealand, Scotland, Finland are considering that strategy. We just need the political courage to begin the discussion. If we do not begin talking about returning to the norm, mid-late 19th century, when cigarettes were not a product of note, we will continue to talk and plan for reduction and have reducing prevalence goals that continue into late 21st century. That to me is unacceptable for a product that kills 60% of the users.

The FDA has the authority to begin the process but of course it blinked at the very first juncture by not eliminating menthol. We the people who see the devastation caused by tobacco on a daily basis and see firsthand how difficult tobacco dependence is to treat must be heard and provided help from the FDA on all fronts from more effective products to treat patients to regulating and reducing the attractiveness of the tobacco products.

Why do we tolerate this? We do not have to and we should not.

Richard D. Hurt, MD
Mayo Clinic

reply

Submitted by Anonymous on Sun, 2013-02-03 09:16.

## Spot on Dr. Hurt

Spot on Dr. Hurt.

David Dobbins
Legacy

reply

Submitted by sglantz on Sat, 2013-02-02 18:22.

## How the FDA should proceed to address the underling question

Quite independent of the fact that the FDA (and the rest of us) are dealing with the tobacco industry, I do not understand why it is the role of a federal regulatory agency to help a regulated industry figure out how to interact with its critics.

The question that the FDA is trying to address in its planned meeting is the following recommendation from the Institute of Medicine in its report (commissioned by the FDA), *Scientific Standards for Studies on Modified Risk Tobacco Products:*

"Recommendation 10: MRTP sponsors should consider use of independent third parties to undertake one or more key functions, including the design and conduct of research, the oversight of specific studies, and the distribution of sponsor funds for research. ***Such independent third parties should be approved by the FDA in advance of the research.*** [emphasis added]"

At this point, the FDA should simply drop the currently planned meeting and refocus on the last sentence of this recommendation, namely whether it is appropriate for the FDA to pre-approve third party research organizations for the tobacco companies and, if so, what the FDA's standard should be for approving such third parties.

Any such consideration of Recommendation 10 should include a evaluation of how the industry has, since the 1950s, become extremely well-practiced at setting up fronts that appear to be neutral third parties. There is a large well-developed literature on this point, as well as an excellent discussion of these issues in Judge Kessler's findings of fact. It is also particularly relevant that the Court of Appeals took note of this fact as evidence of ongoing racketeering in upholding Judge Kessler's ruling. The industry is especially good at running things through lawyers so they can hide such relationships and management controls behind claims of attorney-client privilege.

Given this history, I would urge the FDA to reject Recommendation 10 as simply impossible to implement in a reliable manner.

Another reason to reject Recommendation 10 is that it is inappropriate for a regulatory agency -- whose job is evaluating the evidence placed before it -- to play an active role in pre-certifying agencies that produce that evidence. Doing so creates an immediate conflict of interest.

Rather than holding a meeting on this issue, the FDA should open a docket on the question of whether and, if so, how, the FDA should implement the last sentence of Recommendation 10. That way all interested parties, including the tobacco companies, could offer considered written submissions that the FDA could then use to formulate a proposed position then put that out for public comment.

Stanton Glantz

reply

Submitted by Anonymous on Mon, 2013-02-04 10:18.

## Comment on implementing IOM Recommendation 10

I am persuaded by Ruth's argument, and by the additional related points made by others. However, I am not persuaded by Stan's suggestion that FDA should reject Recommendation 10 of the IOM report on Scientific Standards for Studies on Modified Risk Tobacco Products.

The tobacco industry has a problem in credibly carrying out and disseminating scientific studies because of their long history of distorting science. Few will accept the findings of their studies at face value. They could directly give grants to independent researchers/research organizations to do the research, but most researchers/universities in this field refuse to take tobacco industry funding, and if they did, it would likely be treated with skepticism due to the direct financial relationship with the tobacco company. So on the one hand public health states that there is inadequate evidence for any harm reduction claims, but on the other we would not accept any evidence they produce nor directly fund.

My understanding, as a reviewer of that IOM report, was that the idea behind Recommendation 10 was to set up an independent organization, presumably with rules of governance approved by the public health side, to act as a distributer of tobacco industry funds for research. I presumed that this would not simply be an industry-appointed money laundering front organization, simply to pass the research money through. Rather it would be an organization (which conceivably could already be in existence) that would accept funds and a research question/agenda from a tobacco company, and would then announce a competitive RFA to bid for the funds to do that research, using a public process much like that currently used by NIH. I assumed that the rules of governance would ensure that the industry could not exert influence on the research organization, the independent review process, or influence the interpretation and publication of the results.

While I agree with Ruth's central point that a public dialog between "stakeholders" facilitated by FDA could unintentionally facilitate the tobacco industry PR machine, I am not persuaded that IOM Recommendation 10 is "simply impossible to implement in a reliable manner." Rather we should be striving to ensure that it IS implemented in a reliable manner.

Stan argues that it is inappropriate for a regulatory agency like FDA play an active role in pre-certifying such independent agencies. If not FDA, who should organize this process? Opening a docket is not a speedy or adequate solution. It simply provides FDA with a pile of suggestions. Maybe separate meetings , without any presentation as "a dialog of stakeholders" would be more appropriate?

Jonathan Foulds

reply

Submitted by Anonymous on Fri, 2013-02-01 17:49.

## Some thoughts on Ruth's

Some thoughts on Ruth's letter:

Of course we should help the FDA make intelligent use of the powers that have been granted it; that is our obligation as public health professionals. But Ruth Malone is certainly right that the "facilitated dialog" planned by this august agency, with the industry participating as equals, is ill-advised. Her refusal to participate sends a message, and a powerful one, that scholars are finally starting to realize how dangerous it can be to partner with the industry.

We should also not forget that the industry has never admitted the most important facts about cigarettes -- and the companies' long history of malfeasance:

1. No tobacco company has ever admitted marketing to children;
2. No tobacco company has ever admitted that millions of people have died from smoking;
3. No tobacco company has ever admitted having conspired to hide the hazards of smoking;
4. No company has ever admitted that the cigarettes sold today are as dangerous as any ever smoked;
5. No company has ever admitted having manipulated the chemistry of cigarettes to create and sustain addiction;
6. No company has ever admitted that the "filters" on virtually every cigarette are fraudulent;
etc., etc. etc.

The cartel is still in place, and as Judge Kessler has correctly ruled, the industry is still being run by the same crowd of racketeers and cigarette-friendly lawfirms. And the single biggest myth we face, apart from tobacco being "old news" and a "solved problem," is that Big Tobacco has changed. On the most important issues, including the fraudulent and deadly nature of the product itself, they have not.

One further point: While it might seem a "balanced" approach to have all "stakeholders" involved in such discussions, the reality is that by making the industry an equal partner the FDA is de facto endorsing -- or at least perilously overlooking -- the companies' decades-long conspiracy of doubt-mongering and duplicity. These are adjudicated racketeers with a long history of using science as an instrument of deception, and treating them as anything more or less is a disservice to public health -- and the sacred trust we place in our federal regulatory agencies.

Robert N. Proctor
Professor of the History of Science
Stanford University
rproctor@stanford.edu

reply

Submitted by Anonymous on Sat, 2013-02-02 11:05.

## Great points

Great points. We must remember they are unprosecuted criminals, but criminals nonetheless.

John R. Seffrin, PhD
Chief Executive Officer
American Cancer Society, Inc.

reply

Submitted by Anonymous on Sat, 2013-02-02 20:10.

## Unprosecuted Criminals

The analysis is correct about them being criminals. The type of murder via poisoning that they commit is called "universal malice" murder. Definitions, court precedents, and other background are at http://medicolegal.tripod.com/tobaccomurder.htm

reply

Submitted by Anonymous on Thu, 2013-01-31 20:16.

## great letter, important message

When we fail to learn from history, we make the same mistakes over and over and over.

The clear lesson of history is: the tobacco industry is not a partner in protecting health. Period.

The clear lesson of history is: every time we accept the industry as a partner, public health loses.

The clear lesson of history is: when the industry gets a seat at the table, it uses that to polish its image, validate its pretense of being part of the solution, deceive the public, manipulate health groups, undermine prevention, increase its profits, and ultimately spread more addiction, disease, disability, and death.

This has been the long bloody history of "safer" cigarettes, the new "reformed" industry, "reasonable" restrictions, and a "global settlement".

FDA has failed to learn from history. Everyone else doesn't have to be that stupid.

reply

Submitted by Anonymous on Thu, 2013-01-31 15:29.

## The FDA should also take note of FCTC Art. 5.3

I share in offering applause.

However, Ruth's letter leaves off another powerful rationale, FCTC Article 5.3. The issue here connects directly with international standards, codified in Art. 5.3 and the implementing guidelines. One hopes the FDA will take note.

By way of brief mention, the Guiding Principles of the Guidelines make clear the "fundamental and irreconcilable conflict between the tobacco industry's interests and pubic health policy interests." Furthermore, Recommendation 2.1 ("*Parties should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products.")* articulates almost precisely what is shared in Ruth's concluding paragraph, which deserves repetition:

"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."

Ruth's arguments are strengthened, and meanwhile the living force of the 5.3 Guidelines is similarly strengthened, when we discuss concerns regarding government engagement with the tobacco industry by incorporating Art. 5.3 as non-binding, but nonetheless vital and persuasive authority in the United States.
Mark Levin, Professor of Law

Wm. S. Richardson School of Law

The University of Hawai'i at Manoa

reply

Submitted by Anonymous on Wed, 2013-01-30 23:02.

## Ruth Malone's letter

Great letter: exactly right. The FDA approach seems inconsistent with FCTC, WHO policy, and everything we have learned about dealing with the tobacco industry over several decades. I recall their trying to persuade me forty years ago that "we must have common ground". We didn't in 1973 and we don't now.
Mike Daube

reply

Submitted by Anonymous on Wed, 2013-01-30 20:08.

## Ruth Malone's letter regarding "facilitated dialogue"

Ruth Malone gets it. Her letter is not simply eloquent, it speaks the truth. It's too soon to forget or put aside the industry's conduct simply because they are now "regulated." To this day, they remain racketeers. End of story. Check back with me in 50 years and I'll revisit the issue.

Sharon Eubanks

reply

Submitted by Anonymous on Wed, 2013-01-30 18:23.

## Flawless logic

Eloquent letter Ruth, with flawless logic. Such dialogue should be contingent on widespread evidence that the industry is actively reducing its global sales of combustibles, and desisting in its virulent opposition to tobacco control measures that threaten to reduce such use. As your letter points out, neither of these things are occurring for very obvious reasons.

I recently reviewed a paper for a leading journal which examined industry document evidence of how the industry thinks about Harm reduction products. Their thinking is all about "as well as" not "instead of". A lot of naivety has re-entered our field.

Simon Chapman

reply

Submitted by Anonymous on Mon, 2013-02-04 19:24.

## Meeting with Racketeers

I prefer not to meet with representatives of an industry that have been convicted by the federal court of racketeering

The states empowered the federal government to regulate tobacco products and set limits on a renegade industry so the harm they do to the nation ends. I can find nowhere in the FDA Law authority or Congressional intent use of funds or authority to carry out such a meeting.

Such forums offer opportunities for the industry to rebuild social legitimacy where they have none and are particularly disturbing in light of their evasion and hostile actions against the FDA in carrying out the law that is now almost four years old with many still holding their breathe.

I don't think Thomas Jefferson would attend such a meeting and maybe it should be a requirement of federal officials who hold high appointed office to read the recent biography of Jefferson "The American Lion" to put in perspective what their role should be.

Regretfully, in this brave new world of Washington, decision making or lack thereof appears more based on the marketplace's ability to exercise political economy that counters basic principles of social democracy.

We should never forget what has occurred over the many decades by the selfless commitment of hundreds of thousands of American citizens and thousands of communities across our nation to right a very evil wrong.

At every point of our struggles we faced an enormously powerful foe that never showed interest in dialogue but simply crushing local citizen attempts to right obvious harm.

To think we live in different times and the tobacco industry has redeemed itself and deserves the same treatment that is afforded to other companies that contribute to the development and health of our nation seems perplexing.

How appropriate an action may appear to be, It does raise questions of knowledge, competency, moral justice and understanding of what a social democracy is about?

Greg Connolly

reply




# Ruth Malone: Same meeting, different day – FDA fails to make real change to tobacco product consultation

Submitted by sglantz on Wed, 2013-02-06 17:04

Ruth Malone has just posted an entry on the *Tobacco Control* blog explaining why she is again declining the FDA's invitation to participate in a meeting hosted by the FDA on "Third Party Governance of Industry-Sponsored Tobacco Product Research." (Her original letter and reactions to it is available here.)

I strongly agree with Ruth and urge others to follow her lead.

For those who feel compelled to attend the FDA meeting with the tobacco companies, I urge you to make the same comments to the FDA. Regardless of divided opinion on whether it sends a stronger message the FDA to decline to attend its meeting or to attend and speak, there seems to be a broad consensus that the FDA is not doing its job to protect the public health. ***Those who decide to attend the meeting need to be strong and forthright in supporting the views that Ruth advances in her letter.***

**Here is the introduction to Ruth's new letter on the *Tobacco Control* blog:**

Following Ruth Malone's earlier letter declining to be part of a "facilitated dialogue" with the tobacco industry sponsored by the US Food and Drug Administration (FDA), the FDA revised the schedule and invited her again to a meeting with public health, academic and government tobacco control leaders on the first day and invited tobacco industry presentations on the second day. In the letter below, she explains why she is again declining to participate:

**Here is the new letter:**

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.

Ruth E. Malone, RN, PhD, FAAN
Professor and Chair, Department of Social & Behavioral Sciences
Editor-in-Chief, Tobacco Control

The actual letter is available on the *Tobacco Control* blog here.

sglantz's blog Add new comment