

Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Joel Nitzkin [jln-md@mindspring.com]

Sent: Monday, February 04, 2013 3:31 PM**To:** Glantz, Stanton A**Cc:** Dave Cundiff [cundiff@reachone.com]

Stan:

I would be perfectly happy for you to post this entire e-mail exchange, including the letter and including what I have said about both my relationship to R Street and what they have disclosed to me about their relationship to the tobacco industry. Please advise as to what you mean when you accuse me of failing to disclose the relationship of with tobacco and R Street. Do you have information not available to me that documents that R Street is generously funded by the tobacco industry, and therefore sees itself as a mouthpiece for that industry. If so, please advise.

Joel

From: [Glantz, Stanton A](#)**Sent:** Monday, February 04, 2013 5:03 PM**To:** [Joel Nitzkin](#)**Cc:** [Dave Cundiff](#)**Subject:** RE: FDA Dialogue with Tobacco Industry re 3d Party Research

I would be happy to post a note on this entire interchange and your failure to disclose what the relationship with tobacco and R is, together with a PDF of the email string.

From: Joel Nitzkin [mailto:jln-md@mindspring.com]**Sent:** Monday, February 04, 2013 3:02 PM**To:** Glantz, Stanton A**Cc:** Dave Cundiff**Subject:** Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

There are also, as I understand it, for many entities, no federal guidelines requiring such disclosure, leaving it to the organization to decide what to disclose.

I don't think that is the real issue here. R Street, for what I understand to be commonly accepted practice in their field, has opted to limit disclosure to general statements. As I understand your perspective, however, even a penny of tobacco industry funding would make them beholden to the industry and a mouthpiece for them.

You still haven't answered the second of the two questions – relative to your view of the tobacco related research.

Also, I am getting the impression from this dialogue that you will not be posting my original communication on your listserve. Am I correct?

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 4:52 PM

To: [Joel Nitzkin](#)

Cc: [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

There are no federal guidelines prohibiting disclosure.

From: Joel Nitzkin [<mailto:jln-md@mindspring.com>]

Sent: Monday, February 04, 2013 1:11 PM

To: Glantz, Stanton A

Cc: Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

I am not evading you.

R Street follows the guidelines which it considers appropriate to its corporate structure, as defined by federal law. The information I have provided to you is the information provided to me. They have a hard time understanding your perception that any receipt of tobacco industry related funding, no matter how small must means that they are laundering the money and setting their priorities accordingly. Again – can you conceive of a neutral agency that is, at its core, neither pro-tobacco nor anti-tobacco?

This then extends to the second question – which I would really like an answer to. If you, as a representative of the public health community will simply dismiss any research they fund, either directly or through a third party, and the public health agency policy is against any consideration of tobacco harm reduction – then there is no honorable and credible way for such research ever to be done. Do you agree with this perception? If not, why not?

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 1:57 PM

To: [Joel Nitzkin](#)

Cc: [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

I am disappointed by your continuing evasion.

From: Joel Nitzkin [<mailto:jln-md@mindspring.com>]

Sent: Monday, February 04, 2013 11:35 AM

To: Glantz, Stanton A

Cc: Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

I see by this response that you envision a world divided between “anti-tobacco,” and “pro-tobacco,” with no such thing as “neither pro nor anti, but still concerned about federal government management of tobacco-related issues based on a value orientation having nothing to do with tobacco.”

Also please advise as to the second of the questions I asked – beginning with “With regard to the issue at hand”

Thanks

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 12:46 PM

To: [Joel Nitzkin](#)

Cc: [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

What I mean is either

- (1) An unequivocal statement that R does not and has not taken any money from tobacco or their agents, or
- (2) A list of the specific amounts and sources.

From: Joel Nitzkin [jln-md@mindspring.com]

Sent: Monday, February 04, 2013 10:25 AM

To: Glantz, Stanton A

Cc: Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

Even when I was working with no financial support at all, on behalf of AAPHP (whose only sources of revenue are and have been membership dues and an occasional federal grant) I was constantly faced with the presumption that the only reason anyone would ever support tobacco harm reduction as a policy option would be because I or we were being funded (directly or indirectly) by tobacco company money.

I’m curious as to what you would consider “specific information to the contrary” that might alter your opinion.

I assure you that, if I thought the support I receive from R Street was on the basis of “laundered money,” I would not accept it.

With regard to the issue at hand – having to do with tobacco companies directly or indirectly funding research to support their claims of lower risk and/or the impact of their proposed marketing on non-users of tobacco products – I can only presume that you would simply dismiss all such research, without reading it, as biased and likely falsified, on the basis that it was or might have been supported directly or indirectly by tobacco company dollars.

I look forward to any wisdom you might have to offer as to how best to explore these issues with

honor and credibility.

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 11:02 AM

To: [Joel Nitzkin](#)

Cc: [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

I don't see how you can criticise people for taking pharma money and not be willing to disclose the true source of your funding. Would you think it ok if pharma laundered its money through a third party like this?

Absent specific information to the contrary, I am going to tell people to assume that you are funded by the tobacco companies, albiet through a third party.

From: Joel Nitzkin [jln-md@mindspring.com]

Sent: Monday, February 04, 2013 8:20 AM

To: Glantz, Stanton A

Cc: Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan: R Street (and I think this is true of all of the others) does not disclose amounts of donations or their donor lists. I can only tell you that I find the description I provided to you from their Executive Director as credible after exploring the full range of R street statements, and on the basis of how they have been dealing with me.

I certainly wish it would be possible for me to continue to do substantial work in this arena with no such support. As far as I could determine there is no possibility of any support from any governmental entity that does not conform to their current policy orientation.

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 9:16 AM

To: [Joel Nitzkin](#) ; [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

Your are providing the standard tobacco industry third part evasive answer.

Do they get any money from tobacco companies or their agents? If so, who, when and how much?

From: Joel Nitzkin [jln-md@mindspring.com]

Sent: Monday, February 04, 2013 7:13 AM

To: Glantz, Stanton A; Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

They do accept money from anyone that wishes to donate to them. That being said, Their decision and priority process, as best I can tell, is not driven, even to the slightest degree, by tobacco interests or any other individual donor group. Libertarian think tanks, as I have come to learn, differ substantially in

terms of how far they are to the right of center. Compared to the Heritage Foundation, or even the Heartland Foundation that R Street split from last year, R Street is much closer to the political center. For example, rather than deny global climate change as a legitimate issue, R Street recognizes global warming as a critically important issue, while being concerned that some of what is proposed as governmental response may be relatively ineffective and an excessive burden on industry not justifiable in terms of the anticipated global change benefits.

It really took some searching to find a source of support that would enable me to travel and otherwise spend a significant amount of my time on tobacco related issues that would not make me beholden to governmental, pharmaceutical or tobacco industry stakeholders. The initial work that I did that led to my support of tobacco harm reduction as the most feasible and probably the most effective means of sharply reducing tobacco-attributable illness and death in the United States, and maintaining these benefits into the long-term future, was done on behalf of the AAPHP Tobacco Control Task Force, with no financial support from any source. Not having a salaried job, to support me, there were severe limits to the time and travel I could do on behalf of tobacco-related issues without some source of external support. I am self-employed as a health-care and public health policy consultant. My paid work is all on a special project basis for governmental and private sector entities, with expert witness work as a substantial portion of what I do.

Meanwhile – will you be posting my letter on your listserv?

Joel

From: [Glantz, Stanton A](#)

Sent: Monday, February 04, 2013 8:43 AM

To: [Joel Nitzkin](#) ; [Dave Cundiff](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

But do they take money from tobacco companies or tobacco company agents?

As you probably know, the tobacco companies have a big network of direct and indirect funding to libertarian think tanks.

I do think people should disclose pharma money. I don't take any.

From: Joel Nitzkin [jln-md@mindspring.com]

Sent: Monday, February 04, 2013 6:15 AM

To: Glantz, Stanton A; Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

Stan:

I receive limited travel and other support from the R Street Institute. This is a libertarian think tank, independent of government, pharmaceutical and tobacco industries that is committed to what they refer to as “real solutions” based on “free markets.” They have taken on tobacco harm reduction as an issue based on their perception that FDA actions to date relative e-cigarettes, smokeless tobacco warnings and the excessive burdens of proof to be imposed on the lower risk tobacco products represent undo governmental interference with market forces not justified to protect the health of the public. They are engaged in this issue based on the perception of their board that this is the right thing

to do. They are not, in any way, a front group or spokespersons for any tobacco industry stakeholder, or the tobacco industry as a group. They have, from time to time, received small donations from tobacco companies, but none of those dollars have been or will be used to support me. Most of their revenue is from property and liability insurance companies. They have no say and do not review or approve any of my verbal or written statements. Their decisions are made and priorities set by the Executive Director, Eli Lehrer, with guidance from their Board – that has no tobacco or pharmaceutical representation.

Having made this disclosure, I would be interested in your perspective as to whether those persons, programs and institutions opposing tobacco harm reduction should disclose any support they receive from pharmaceutical firms. The pharmaceutical firms have much to lose if smokers learn that they can secure the same benefit at substantially lower cost and with better satisfaction by switching to e-cigarettes or any one of a number of smokeless tobacco products.

I do reference my relationship with R Street in my signature block. I do include disclosure statements where it seems appropriate to do so.

Meanwhile, please advise as to your willingness to post my letter, as noted below, to your listserv. If not, I will proceed to copy the individuals who have weighed in on this topic, as best I can determine who they are and their e-mail addresses.

Joel

From: [Glantz, Stanton A](#)

Sent: Sunday, February 03, 2013 6:38 PM

To: [Dave Cundiff](#) ; [Joel Nitzkin](#)

Subject: RE: FDA Dialogue with Tobacco Industry re 3d Party Research

Yes, I am the only person who can post to the listserv.

Joel can post a comment on the blog. If he does so, he should sign it at the end of the comment.

One other question: I have been told that the Heritage Foundation (or other similar group(s)) have been supporting Joel's work. Is that correct? If so, that fact should probably be disclosed.

From: Dave Cundiff [cundiff@reachone.com]

Sent: Sunday, February 03, 2013 4:12 PM

To: Joel Nitzkin; Glantz, Stanton A; Dave Cundiff

Subject: Re: FDA Dialogue with Tobacco Industry re 3d Party Research

I don't think anyone but Stan can post to Stan's listserv. Will forward to Stan for his consideration.

Stan wasn't part of creating the FDA bill, and (unlike many in mainstream "tobacco control") he saw a lot of this coming. I've seen several people in Stan's camp, though, arguing that the law's wording gives FDA ample authority to reject "facilitated dialogue."

I agree with you, Joel, that the nicotine industry is not just the cigarette companies any more. But everyone else in the nicotine industry -- Big Pharma and e-cig makers alike -- still needs the big cigarette companies and the entertainment industry to get the kids addicted in the first place. I admire Stan for his work on the entertainment industry, which may be the largest still-unregulated "soft spot" in

the nicotine-addiction-creation industry.

Thanks!

Dave Cundiff
(Sent from mobile device)

On Feb 3, 2013, at 1:35 PM, "Joel Nitzkin" <jln-md@mindspring.com> wrote:

Dave:

Can you post this on the UCSF listserve on my behalf?

Thanks

Joel

From: Joel Nitzkin
Sent: Sunday, February 03, 2013 3:19 PM
To: workshop.CTPOS@fda.hhs.gov ; stanglantz-l@listserve.ucsf.edu
Cc: [AAPHP ResolutionsPolicyLegis Committee](#)
Subject: FDA Dialogue with Tobacco Industry re 3d Party Research

Caryn Cohen (at FDA), Ruth Malone and UCSF Listserve:

I commend FDA on stepping forth to facilitate dialogue between federal regulators, stakeholders in the tobacco community and medical/public health academia.

This note is in response to both Dr. Malone and those who have endorsed her January 30 communication on this topic. She urges FDA not to facilitate such dialogue because she feels that the tobacco industry should not be treated as a “stakeholder” deserving a seat at the policy table.

Like it or not, the current FDA Tobacco Law changes forever the respective roles of “big tobacco,” other tobacco industry stakeholders, federal regulators and the public health community.

The text of the law was negotiated between Matt Myers of Tobacco Free Kids and Altria/Philip Morris. Once drafted, Tobacco Free Kids and the public health community, acting on behalf of Altria/Philip Morris, opposed any amendments that might have strengthened the bill from a public health perspective. Now we have to live with the consequences of both the law and the process by which it was adopted.

To add insult to injury, FDA, in a press conference in July of 2009, condemned e-cigarettes as laced with trace carcinogens and other hazardous contaminants. They failed to note that the nicotine replacement therapy products approved by FDA (Nicorette, Commit, etc.) are laced with similar contaminants in about the same concentrations. FDA then tried to remove e-cigarettes from the market on the basis that they were unapproved “drug-device combinations.” They were taken to court, and lost.

The point is this – while some in the public health community prefer not to see tobacco industry players as legitimate stakeholders, entitled to a seat at the FDA policy table, Congress, the President and the Courts see them as such. Congress, the President and the Courts outrank the public health community.

Dr. Malone opposes “lending the FDA imprimatur” to tobacco industry stakeholders. This “imprimatur” is already in place, through the action of Congress and the President, as noted above, with the enthusiastic endorsement of almost the entire public health community. The court, in ruling against the FDA in the e-cigarette case portrayed FDA as acting on the basis of bias and poor judgment in its dealings with a tobacco industry stakeholder. By this means, any perception of moral purity or

superiority by the FDA and public health community has been severely eroded.

Dr. Malone, in objecting to FDA respecting the tobacco industry as a stakeholder or group of stakeholders, strengthens the hands of the biggest cigarette companies and mutes the voices of those within the tobacco industry that are ready, willing and able to partner with the public health community in pursuit of public health objectives.

Dr. Malone, in her portrayal of the “tobacco industry” as a single or unified entity, is also guilty of stereotyping. Public health has long opposed stereotyping of Blacks, women, gays, and others as inimical to our pursuit of public health objectives. The same is true of the tobacco industry (or, more accurately, cluster of tobacco-related industries), most of which have not engaged in antisocial or racketeering behavior.

FDA is to be commended for initiating an effort to assure that future tobacco industry funded research will be honest, accurate and supportive of public health objectives. I, for one, would be honored to have the opportunity to help shape the policies and procedures needed to assure FDA success in this endeavor.

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