

'Rules' of Engagement: Academic Science and the Tobacco Industry in an Evolving Tobacco Regulatory Environment

Scott J. Leischow, PhD
Mayo Clinic

Lead: Research on Health Equity And Community Health Program
Co-Lead: Cancer Prevention and Control Program, Mayo Clinic Cancer Center

Email: leischow.scott@mayo.edu

Disclosure Information

I have the following financial relationships to disclose (last 5 years):

Consultant for:

Pfizer, GSK, Cypress Bioscience, eNicotine Technology

Grant/Research support from:

McNeil, GSK, Pfizer

Editor-in-Chief: Tobacco Regulatory Science

Academic Community Engagement with Tobacco Industry

Has taken many forms, including and not limited to:

- Accepting funds for unrestricted research
- Conducting contract research
- Serving as experts in litigation
- Helping TobInd undermine research findings that run counter to TobInd interests (eg with media)
- Providing expertise regarding tobacco regulatory matters (research, strategic planning, etc)
- Implementation of conferences and journals
- Discussions to gain intelligence regarding TobInd activities (ie no financial support by TobInd)

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John Slade, MD

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Why Should Anyone Care about Academic Engagement with the Tobacco Industry?

- History of TobInd Falsehoods, diversions, and misrepresentation
 - Creating and disseminating poor and misleading science in the past
 - Undermining sound and independent science, creating uncertainty in findings adverse

• Legal finding in United States v. Philip Morris USA, Inc., et al.:

• “Defendants attempted to and, at times, did prevent/stop ongoing research, hide existing research, and destroy sensitive documents in order to protect their public positions on smoking and health, avoid or limit liability for smoking and health-related claims in litigation, and prevent regulatory limitations on the cigarette industry.”

• Institute of Medicine, 2011

Why Should Anyone Engage with the Industry?

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- Has this changed? Yes, and no.
 - Companies admit in litigation that they spread misinformation and error; science seems to be more solid
 - Creating and selling NRT and legitimate reduced harm products,
 - To beInd statements about eventually moving out of the combustible business, but....
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Market Realist:

“According to André Calantzopoulos, Philip Morris’s chief executive officer, “we aim to become the undisputed leader of the Reduced-Risk Product category with the highly ambitious objective of having RRP s ultimately replace combustible products to the benefit of adult smokers, society and our company.”

<http://marketrealist.com/2016/09/philip-morris-shares-its-future-outlook/>

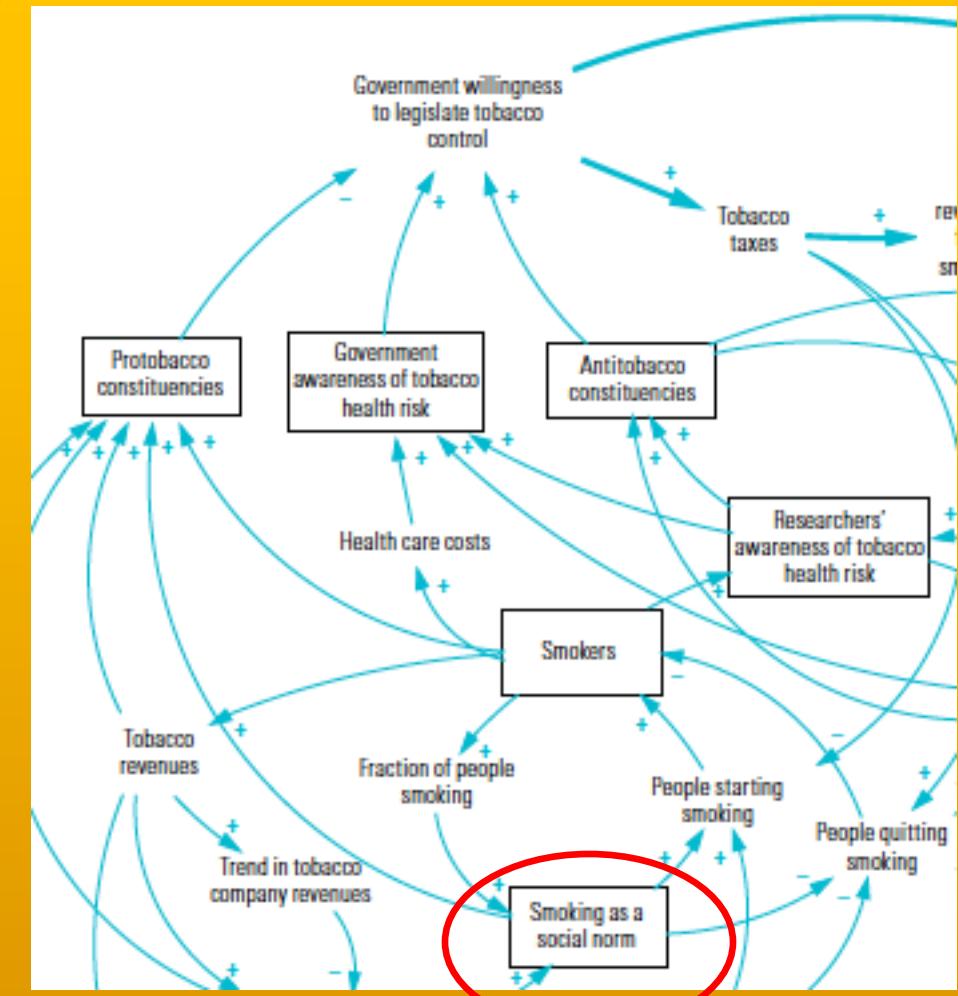
Why Should Anyone Care about Academic Engagement with the Tobacco Industry?

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- Has this changed? Yes, and no...
 - Companies admit in litigation that there was tobacco industry misinformation and error; science seems to be more solid
 - Creating and selling NRT and legitimate reduced harm products,
 - TobInd statements about eventually moving out of the combustible business, but....
 - But...they continue to challenge existing evidence accepted by the scientific community and strive to increase sales of combustibles globally (particularly emerging markets)

Given Past and Current Tobacco Industry Behavior, What are the Risks?

Some examples include:

- Tobacco industry influence on policy
- Risk that such engagement could put pressure on the TobInd (eg smokers)
- Risk that current and future smokers could be marginalized
- Compromising personal or professional integrity of institution



NCI, 2007

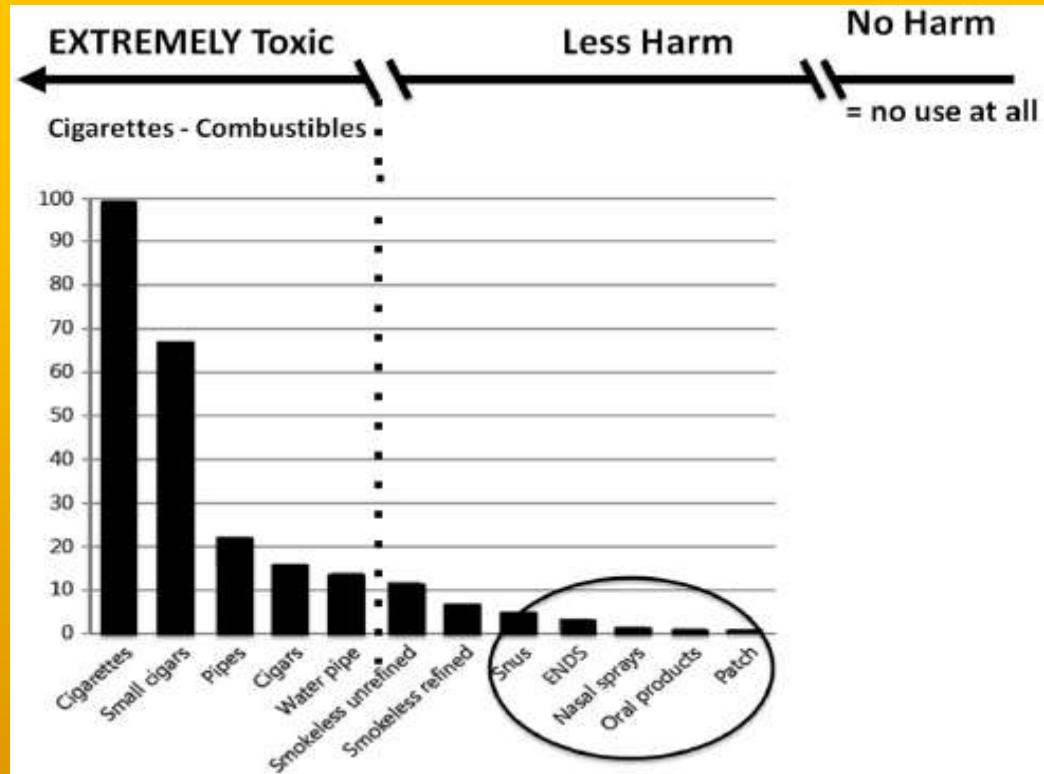
Risks of Engaging with Tobacco Industry (Research, Publishing, Partnering)

Some examples include, but are not limited to:

- Tobacco industry receives public relations value from that engagement, resulting in improved public image of TobInd
- Academic engagement could change social norms and reduce pressure on the TobInd (eg social, political, etc)
- Risk that current and future science-based tobacco control could be marginalized
- Compromising personal or organizational core values, eg medical institution
- Compromised science, ie conscious or unconscious bias
- Conflicts of interest, or perceived conflicts of interest, that could undermine confidence in data and products (eg ENDS)

What About ENDS/ANDS?

- Early e-cigarettes market in China, 2006/7 in Europe had little impact on sales of minimal. Some sales of tobacco products in the US
- By 2013/14, major tobacco companies and the competition has developed new products and tobacco products are less harmful and can deliver nicotine



Kozlowski & Abrams, 2016, Adapted from Nutt, 2014

What About ENDS/ANDS?

- In the new regulatory environment, independent ENDS-related and tobacco industry companies will need to implement research to show reduced harm in order to stay on the market in the US; academic community is being asked to conduct research and provide guidance to both groups
- Are the ‘rules’ of engagement different for tobacco companies, including those that make ENDS products, and independent companies that only make ENDS? Again, Yes and no....

Yes...Because Many Restrictions on Engaging with Tobacco Companies Exist

Concerns about real or perceived bias, conflict of interest, TobInd efforts to expand sales of combustibles and to undermine tobacco control have led to:

- Multiple academic institutions prohibit acceptance of tobacco industry funding, eg Mayo Clinic, MD Anderson Cancer Center, Johns Hopkins School of Medicine¹
- Some funding agencies take acceptance of tobacco industry funding into account when deciding whether to fund, eg Cancer Research UK² and NIDA³
- Multiple scientific journals have elected to not accept research funded by the tobacco industry, eg Tobacco Control, PLoS Medicine, BMJ, Tobacco Regulatory Science
- Some clinical and scientific societies prohibit members from collaborating with tobacco companies, eg European Respiratory Society
- FCTC Article 5.3..." Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."
- Significant social pressure for academics to not accept TobInd funding

¹<http://senate.ucsf.edu/townhallmeeting/UniversityTobaccoPolicies.pdf>;

MAYO CLINIC²http://www.cancerresearchuk.org/sites/default/files/code_of_practice_on_tobacco_industry_funding.pdf;

 ³<https://www.drugabuse.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/council-statements/points-to-consider-regarding-tobacco-industry-funding-nida>

No...Because Transparency is Needed for Both (and Pharma)

Increasing recognition that transparency and disclosure of potential conflicts are needed, but few standards exist:

- Financial and non-financial disclosure that could reflect bias
 - Institute of Medicine (IOM, 2013) recommended creation of an international standard and database
 - Association of American Medical Colleges (AAMC) IOM
- non-financial disclosure
 - However, some organizations have minimum thresholds for disclosure, etc.



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<https://www.aamc.org/initiatives/convey/>

Yes...Because Transparency is Needed for Both (and Pharma)

Increasing recognition that transparency and disclosure of potential conflicts are needed, but no standards exist:

- Research Design and Implementation Disclosure
 - New Clinicaltrial.gov criterion, includes public/private studies, requires full protocol, AEs, outcomes, baseline data, etc – this should be global
- Access to Data and Publishing Results
 - Need consistent agreements regarding academic access to data and that there will be no restriction on publishing results

'Rules' of Engagement: Summary and Conclusions

- Engaging financially with the tobacco industry, particularly those that sell combustibles, will continue to be problematic for many/most academics because the companies have made no fundamental changes
 - Engagement will likely be driven by personal/organizational factors, but regulatory research will likely be straight contract work with non-academic research companies
 - Mechanism involving independent grant-making organization using TobInd funds for academic research could(s) work¹
- But, there is potential value (in my view) for academics to engage in conversations with TobInd (eg, attending TobInd conferences), to gain science insights not possible in any other way
- Standards for transparency and disclosure are needed to document engagement where any financial or non-financial factors might contribute to bias, and some examples exist. Because of the changing environment, ongoing discussions are warranted as laws and the environment changes. SRNT might be a good organization to lead such an effort

¹Cohen, et al, Tobacco Control, 2009

Thank you!



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