

Tobacco companies are not public health stakeholders

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When assessing information presented by the tobacco industry, the US regulator, the Food and Drug Administration (FDA) and regulatory bodies in other countries, should be aware that they are dealing with companies with a long history of intentionally misleading the public. They therefore should actively protect their public-health policies on smoking from the commercial interests of the tobacco industry and not consider the industry as a stakeholder, concludes a study by experts from the US and Germany published in this week's *PLOS Medicine*.

The researchers, led by Stanton Glantz from the Center for Tobacco Control Research and Education at the University of California, San Francisco, reached these conclusions by analysing previously secret documents from the <u>tobacco industry</u> and the Institute of Medicine related to the Institute's landmark 2001 report, Clearing the smoke—a report that set the tone for the development and regulation of <u>tobacco products</u> in the US, particularly those claiming to be less dangerous.

The authors found that tobacco companies developed and implemented strategies with consulting and legal firms to access the IOM proceedings (that led to the FDA-commissioned Institute of Medicine report on tobacco products) and that the companies used this access to deliver specific, carefully formulated messages designed to serve their business interests.

Although the authors found no evidence that the efforts of tobacco companies exerted direct influence on the IOM committee, the analysis



shows that tobacco companies were pleased with the final report, particularly its recommendation that tobacco products can be marketed with exposure or risk reduction claims provided the products substantially reduce exposure and provided the behavioral and health consequences of these products are determined in post-marketing surveillance and epidemiological studies ("tiered testing"). Recommendations within the report have policy implications that were continuing to reverberate in 2012.

The authors say: "There was a lack of clear policy on tobacco industry engagement by the [Institute of Medicine] which, combined with the general presumption of honesty upon which all scientific discourse is based, created an opportunity for the tobacco companies to advocate positions that supported their interests."

They continue: "The presence of tobacco industry representatives on the FDA's Tobacco Products Scientific Advisory Committee, combined with the FDA's official consideration of the tobacco industry as a "stakeholder," increase the likelihood that the tobacco companies will continue to successfully manipulate the scientific discourse around tobacco product regulation, to the companies' benefit and to the detriment of public health."

The authors conclude: "To prevent such an outcome, the FDA and counterpart organizations in other countries need to remain cognizant of the guidelines for implementing FCTC Article 5.3* and that they are dealing with companies with a history of more than 50 years of intentionally misleading the public and who were found by two federal courts to have participated in "a pattern of racketeering activity" in violation of the RICO Act** when assessing the role of the tobacco companies and the information they present as part of the regulatory process."



In an accompanying Perspective, Thomas Novotny (uninvolved in the study) from the University California, San Diego says: "[The tobacco industry] should never be treated as a stakeholder because it is unlikely that the industry will ever be part of the solution to the public health challenge of tobacco use."

Novotny continues: "The profits from selling cigarettes and alternative tobacco products are simply too great for the tobacco industry to simply fade into history. Thus, the public health community needs to do what it does best: to rally popular support for strong, science-based approaches to prevention of tobacco use, to expose the truths about the harms of tobacco use to current users, and to support government agencies in carrying out their legislatively mandated duties to protect public health."

More information: Tan CE, Kyriss T, Glantz SA (2013) Tobacco Company Efforts to Influence the Food and Drug Administration-Commissioned Institute of Medicine Report Clearing the Smoke: An Analysis of Documents Released through Litigation. PLoS Med 10(5): e1001450. doi:10.1371/journal.pmed.1001450

*The World Health Organization's Framework Convention on Tobacco Control, developed in response to the globalization of the tobacco epidemic. Article 5.3 relates to the protection of public health policies with respect from tobacco control from commercial and other vested interests of the tobacco industry.

**Racketeer Influenced and Corrupt Organizations Act is a US federal law that provides for extended criminal penalties and a civil cause of action for acts performed as part of an ongoing criminal organization.

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