

Summary

Tobacco Funding & Scientific Research Workshop Ethical, Legal and Policy Issues

Overview: On February 22 and 23, 2003, the American Legacy Foundation, the National Cancer Institute and the California Tobacco-Related Disease Research Program convened a group of approximately 75 people in New Orleans to discuss the ethical, legal and policy issues around the funding of scientific research by the tobacco industry. These individuals represented non-profit organizations, government agencies, tobacco control advocates, universities and the tobacco industry.

There are arguments both for and against accepting tobacco industry funding for research. The purpose of the *Tobacco Funding & Scientific Research Workshop* (“*Workshop*”) was to explore some of the issues, and to frame a broader discussion of challenges faced by scientists and research institutions who receive funding from the tobacco industry. Two specific questions were explored:

1. *What are the potential risks and benefits of tobacco industry sponsorship of scientific research?*
2. *Are there procedures or mechanisms that could help protect against the types of research conduct abuse that have occurred in the past?*

The two-day Workshop included three sessions:

- **Session #1 - Ethical and Legal Perspectives, Is the Tobacco Industry Different?** An in-depth discussion on the ethical and legal implications of receiving tobacco industry funding of scientific research. Discussion included reflection on how these issues developed with respect to other industries like pharmaceuticals, lead paint and asbestos.
- **Session #2 - Research Funding Practices.** Pro and Con Perspectives from scientists on taking tobacco industry money and the implications for how industry funded research is perceived.
- **Socratic Dialogue** - A moderated discussion that brought together a diverse group of individuals with divergent viewpoints on tobacco funding issues to discuss what ethical decisions they would make in a variety of hypothetical situations.
- **Breakout Discussion Groups** – The audience broke into small groups to further discuss issues raised during the day and recommend next steps.

Introduction: Tobacco companies have an interest in portraying a positive corporate image. Scientists have an interest in unrestricted research grants. The tobacco control community has raised – and continues to raise - concerns about tobacco industry funding of external research. While the tobacco industry continues to set up external funding programs, several U.S. schools of public health and organizations that fund tobacco-related science have instituted formal

policies restricting their faculty from accepting tobacco industry funds. In September 2001, the Society for Research on Nicotine and Tobacco (SRNT) adopted a position statement to encourage its members not to solicit or accept support from the tobacco industry, to continue refusing support from the tobacco industry for Society activities, and to “not endorse the support of its members’ research or their participation in other activities funded by the tobacco industry.” Appendix A includes the policies of American Legacy Foundation, American Medical Association, Centers for Disease Control and Prevention, and Society for Research on Nicotine and Tobacco regarding acceptance of tobacco industry funds.

A Continuum of Opinion: Prior to and during the Workshop, it became evident to both organizers and participants that there was not consensus about what the key issues with regard to the acceptance of tobacco industry funding. A continuum of opinion was represented at the Workshop with those at one end who believed that research scientists should not take tobacco industry funding in any situation to those at the other end who received funding from the tobacco industry. In the middle, however, key issues and recommendations emerged:

- **Procedures are Needed to Prevent Possible Abuses** – Whether or not one agrees with the tobacco industry funding of scientific research, some scientists and research institutions continue to accept tobacco industry support for research. It is important to develop standards and criteria to control and regulate tobacco industry funding.
- **Transparency is Crucial** – Currently, tobacco companies do not make public comprehensive information about the individual scientific research projects they support through grants and contracts. Such transparency is essential to help protect against potential conflicts of interest and bias. This would include a full and annual disclosure of research and philanthropic funding made by the tobacco industry.
- **Dialogue Must Continue** – There is a need for ongoing dialogue between researchers, funders, academic institutions, public health advocates and tobacco industry scientists. This Workshop was the first step in that process and that process must continue, including more dialogue between industry and public health advocates and people from outside the field, such as experts in research integrity.
- **Divergent Views on Regulations and Policies Will Always Exist** - During the Workshop, it became clear that participants had diverging views of regulations and policies around the tobacco industry funding of scientific research. This included information about the impact of restrictions on the amount and range of research that would be funded by the tobacco industry. These views were not insurmountable, but more information about the regulations and policies of government agencies, foundations and universities needs to be distributed to participations in a digestible and objective manner. It was agreed that divergent views on regulations and policies may always exist and that it was best to recognize these differences rather than seek consensus.
- **Investigate Feasibility of an Independent Funding Institution** – A middle-ground idea of creating an independent funding institution that would distribute tobacco industry funds to scientists and institutions based upon funding priorities, needs and scientific

legitimacy was proposed. Staffed by independent policy experts and scientists, the funding institution could help protect against industry influence on research conduct. Prior to funding occurring via this process and institution, there would need to be a better understanding of the downstream consequences of taking research dollars from the industry as well as discussion about what the exact funding model for research would look like.

- **Call for Papers on Tobacco Industry Funding** – The ideas outlined in the Workshop and future discussions needs to be further reviewed within the larger scientific community through a call for papers to be published in respected scientific journals. Optimally, these papers would detail specific recommendations to make the abstract ideas concrete.

Immediate Next Steps – Building on these agreed upon issues and ideas, there are several immediate next steps that Workshop participants and organizers could begin addressing:

- **Develop Rules of Engagement for Tobacco Industry Funding** – A first draft of the principles that would guide the funding of scientific research needs to be developed. These principles would provide a basis for further discussion and would be the first step toward developing rules of engagement for scientists, funders, institutions and the tobacco industry. An advisory group that includes individuals from diverse viewpoints could develop the criteria and outline potential rules.
- **Collect Information About Funding Policies** – Currently, complete information is lacking regarding how many institutions have a policy restricting acceptance of tobacco industry funds, what the content of those policies is, and how they are enforced. A comprehensive survey of academic medical research institutions and funding agencies is needed to provide an up-to-date picture of policy trends and attitudes.

Conclusion: Although significant progress was made during the Workshop – particularly in humanizing the players and education about the issues involved – there continues to be widespread disagreement on the primary question of: *Can a scientist receive funding from the tobacco industry without compromising the integrity of their research and their research institution?*

Given that tobacco companies in the United States continue to conduct scientific research using either internal or external researchers, research funding practices will continue to generate debate. Simultaneously, there is a lack of funding for many scientists and research institutions, especially in areas such as harm reduction and potentially reduced exposure products. The tobacco industry money could provide needed resources, especially for younger up-and-coming scientists, to conduct important research. Yet further work is needed to identify procedures and mechanisms that may help protect against past abuses of research conduct.

The *Tobacco Funding & Scientific Research Workshop* has helped to initially frame the dialogue and to identify the questions that need to be answered in order to truly understand the costs and

benefits of tobacco industry funding of scientific research. Some of those identified questions include:

- What are the potential costs of receiving industry funding?
- What are the potential benefits?
- What are the implications of accepting or restricting funding for research institutions?
- What should be the rules of engagement?
- Who decides what the rules are?
- If rules are set in place, how is the funding process managed?

It is imperative that answers and solutions to these questions and issues recognize the continuum of opinion from the Workshop if scientific research on tobacco smoking is to move forward positively. To recognize and respect that continuum is to discontinue the status quo, which is in the best interests of scientists, research institutions and smokers.

Appendix A. Policies on Accepting Funds from the Tobacco Industry

American Legacy Foundation

Refusal of Funds From Tobacco-Related Entities.

The Grantee agrees that it shall not accept any grant or anything else of value from any tobacco manufacturer, distributor, or other tobacco-related entity.

American Medical Association

-490.983 AMA Investment in Tobacco-Related Industries.

It is the policy of the AMA: (1) not to invest in tobacco stocks; (2) to urge medical schools and their parent universities to eliminate their investments in corporations that produce or promote the use of tobacco; (3) to encourage state and county medical societies and members to divest of any and all tobacco stocks; and (4) to encourage state and local medical societies to determine whether the candidates for federal, state and local offices accept gifts or contributions of any kind from the tobacco industry, and publicize their findings to both their members and the public. (Sub. Res. 19, A-86; CME Rep. D, A-87; Res. 507, A-92; Sub. Res. 424, A-94; CLRPD Rep. 2 - I-94)

H-500.979 Tobacco Industry Business Tax Deduction for Advertising and Promotion.

The AMA continues to support legislation to reduce or eliminate the tax deduction presently allowed for the advertisement and promotion of tobacco products; and advocates that the added tax revenues obtained as a result of reducing or eliminating the tobacco advertising/promotion tax deduction be utilized by the federal government for expansion of health care services, health promotion and health education. (Sub. Res. 204, A-93; Sub. Res. 406, I-95)

-490.940 Support from the Tobacco Industry.

(1) The AMA strongly discourages all medical schools and their parent universities from accepting research funding from the tobacco industry, and urges all scientific publications to decline such funded research for publication; (Res. 430, I-92; Res. 413, A-96) (2) The AMA defines the Tobacco Industry as companies or corporate divisions that directly produce or purchase tobacco for production or market tobacco products along with their research and lobbying groups, including the Council for Tobacco Research, the Smokeless Tobacco Research Council and the Tobacco Institute; (3) As a matter of policy, the AMA does not accept financial support from the tobacco industry; (4) A company or corporate division that does not produce or market tobacco products but that has a tobacco producing company as or among its owners will not be considered a prohibited part of the tobacco industry as long as it does not promote or contribute to the promotion, sale and/or use of tobacco products. If such promotional practices begin, the company will be placed on an "unacceptable for support" list. (5) All medical schools and their parent universities will be advised of this policy. (BOT Rep. SS, A-93; CLRPD Rep. 2 - I-94; Sub. Res. 405, I-95)

Centers for Disease Control and Prevention

Accepting Funds from the Tobacco Industry: CDC Guidance For Collaboration with the Private Sector

Background

Recently, the tobacco industry has approached state and local agencies with proposals to financially support the implementation of youth tobacco prevention programs. Decisions about whether to accept money directly from the tobacco industry to implement youth tobacco prevention programs have sparked controversy and divisiveness among those committed to preventing tobacco use. Several constituents have contacted CDC to request its opinions as they consider these proposals.

Decisions about collaborative relationships with private sector partners must be made at the level of the proposed relationship, i.e., either at the national, state or local level. CDC encourages national, state and local agencies to consider developing a set of guiding principles for forming collaborative arrangements with outside entities. Agencies should work together and use existing partnerships with national, state, and local education and health agencies, community-based organizations, universities, and others to fully consider and discuss the positive and negative outcomes that may occur as a result of any proposed partnership.

Criteria

The CDC has developed its own criteria for collaborating with the private sector that might be of assistance to national, state and local agencies. These criteria were developed to provide guidance to CDC's Centers, Institutes and Offices in assessing the appropriateness of entering into a partnership with an outside agency, organization, or industry. These criteria include:

- **Be clear how the potential collaboration fits within its overall mission and priorities and the private partner's mission and priorities.** For example:
 - Why does the organization want to work with the agency?
 - How does the project relate to the organization's mission and goals?
 - Will the potential collaboration have a reasonably large impact relative to the resource required? Will the project be designed so that it is scientifically defensible?
- **Assess the effect of the private partner's products or services on health and whether they are compatible with your mission.**
- **Assess the behavior of the private partner in conducting business and determine whether the partner's behavior is consistent with your mission and the principles guiding private sector collaboration. Questions regarding a variety of aspects about the organization's behavior should be asked.** For example:
 - What is the history of the organization's previous collaborations with you or another public health agency?
 - Do the organization and you adhere to similar scientific, ethical, and legal principles and practices?
 - Will the organization comply with your policy and regulations?
 - What are the organization's practices in promoting its products or services and its interests?
 - Could you stand behind the organization's practices?
 - Does the organization's motivation for pursuing the collaboration fit with your mission and priorities?
 - How has the organization behaved in the past when its product or service was found to be harmful?
- **Assess not only the specific area of mutual interest but the public impact of the partner's broad public mission and image.**

For highly controversial issues, multiple collaborators should be sought that represent a broad spectrum of opinions and interests. For example, the overall perception of the partner will inevitably color the public's view of the appropriateness of the collaboration.
- **Avoid participating in indirect collaborations unless it would participate in a direct relationship with the partners.**

For example, indirect relationships should not be established solely to distance you from a specific partner, thereby avoiding an external perception of an inappropriate collaboration. An indirect relationship often provides relatively little protection from the perception that the agency is inappropriately working with a private organization. This is especially true when a third party is the intermediary between the agency and a single organization.
- **Be willing to make public the existence of a collaboration.**
- **Ensure that any stand taken on issues of public health importance is supported by the interests of the partner, the public, and the agency.**

This responsibility must be borne out in fact and in appearance because of the importance of the public's trust in the agency.
- **No appearance or fact of personal gain should result from the collaboration.**

This responsibility becomes critical when collaborations are with a single organization or concern controversial subjects.
- **Assess how its name and participation in a collaborative project will be used and whether such usage is consistent with the agency's public role.**
- **Assess whether the partner will attempt to use its name to endorse a product.**
- **A formal review and advisory process should be established for examining potential collaborations according to the principles, criteria, and recommendations described in this document.**

For further information, please refer to CDC's Guidance for Collaboration with the Private Sector.

This document identifies principles that underlie the public health mission and sets forth guidance for evaluating potential collaborations. Electronic copies of the document are available at:
<http://www.cdc.gov/maso/GAMG81.HTM>.

Society for Research on Nicotine and Tobacco

SRNT Policy on Competing Interests

The science of nicotine and tobacco research, as does all science, must be beyond reproach. The presence of undeclared sources of support and financial interests has the possibility of undermining the reputation, influence, and actions of SRNT regardless of whether the financial factors emanate from tobacco or non-tobacco industries. The issue of credibility is especially salient because nicotine and tobacco research is conducted in a charged political environment. Therefore, the Society believes that full disclosure of potential competing interests is essential for its officers and committee members and is desirable for all members.

Definition of Competing Interest

A competing interest exists when a member has a financial relationship with an organization that has the potential to bias actions taken on behalf of SRNT. The existence of a competing interest does not necessarily mean that a conflict of interest exists, but it does indicate that such a situation is possible. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment or his or her decisions made on behalf of SRNT. Financial relationships (such as employment, research or educational grants, consultancies, ownership of stock shares, honoraria, paid expert testimony, patents) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of actions taken on behalf of SRNT.

Policy for SRNT Officers and Committee Members

Because of these considerations, it is SRNT policy that all officers of the Society, candidates for office in the Society, and all current and prospective committee members of the Society must disclose all relationships that could be viewed as potential competing interests. This information will be collected and updated annually and will be posted on the SRNT Website. Candidates for office will be required to include this information in their ballot statements.

Individuals are required to disclose, to the best of their recollection, all financial support for the past 3 years and any pending proposals for funding from:

- the tobacco industry (defined as a tobacco company, the Council for Tobacco Research, Center for Indoor Air Research, and law firms or other interests representing one or more tobacco companies to conduct research or provide consultation)
- the pharmaceutical industry or other for-profit company that makes smoking cessation products or other relevant products (e.g., educational materials, test kits)
- government agencies (e.g., NIH, CDC)
- private foundations that fund nicotine and tobacco research or programs (e.g., Robert Wood Johnson Foundation, American Legacy Foundation)
- Advocacy organizations
- any other source of funding that represents a potential competing interest.

The type of funding to be disclosed includes:

- employment (e.g., salary)
- consultancy,
- honoraria
- research or educational grants or contracts,
- ownership of stock shares or equity (not to include ownership of mutual funds that may include these stocks),
- paid expert testimony,
- patents,
- receipt of product for research or educational purposes.

Policy for SRNT Members

While full disclosure is required of officers and committee members, all SRNT members are encouraged to provide this information whenever they are commenting on relevant matters on the Listserve, in the Newsletter, or in other Society communications. All members are required to declare their current employer or affiliation (or last employer, if retired or no longer employed) when applying or renewing SRNT membership. All members must also sign the following statement:

I affirm that I support the goals of the Society to stimulate new knowledge concerning nicotine, to foster the exchange of scientific information on nicotine and tobacco dependence, and to encourage research on public health efforts for the prevention and treatment of cigarette smoking and tobacco use.

Because full disclosure of competing interests is not required for SRNT Listserv participation, the following statement will accompany all Listserv postings:

This listserv is unmoderated and open to all SRNT members. Individuals who post messages are expected to disclose any potential conflict of interest that is relevant to the topic of discussion. Unless specifically stated, messages posted on this listserv represent only the views of the individuals posting the messages, and SRNT does not endorse the accuracy of any statements.

Statement approved by SRNT Board of Directors 2/18/03