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Criteria for evaluating tobacco control research funding programs and their application to models that include financial support from the tobacco industry

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Much has been discussed and written about the purposes, outcomes and ethics related to tobacco industry funding of research.^{1–9} The issue is controversial because of tobacco industry funding mechanisms that have been used by the tobacco industry to gain credibility and to advance the industry's interests, which may come at the expense of public health;⁶ at the same time others have argued that, given the scarcity of funding from other sources, tobacco industry support may be defensible, at least under some circumstances.¹⁰ These concerns raise the question of whether there could be a model of tobacco company funding that would be acceptable to the tobacco control research community. This paper presents a set of criteria for evaluating funding models and applies them to four diverse models.

While tobacco consumption and prevalence rates have declined in many developed countries over the past 40 years, the projections are that worldwide tobacco-related deaths will increase in the 21st century.¹¹ Despite the disproportionate toll tobacco use takes, there remains only a modest investment in research to better understand tobacco products, tobacco product marketing, addiction, treatment and consumer behaviour. For example, in the USA, where tobacco causes almost 30% of all cancer deaths, only 2.3% of the National Cancer Institute's 2003 budget was spent on tobacco-related research funding.¹² This level of research investment is inadequate relative to the magnitude of the damage caused by tobacco use.^{13,14}

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Competing interests: MZ works for Pinney Associates, which provides consulting services to GlaxoSmithKline Consumer Healthcare on issues related to treating tobacco dependence. TE has consulted with the National Association of Attorneys General on issues related to potential reduced exposure products (PREPs) and PREP testing; he has received free of charge smokeless tobacco products from RJ Reynolds so he could test them in his laboratory; neither RJ Reynolds nor any other company has ever had any input into any work performed in his laboratory, nor have they had any input into any reporting of results. TE conducts laboratory studies of PREPs that are funded by the US National Institutes of Health (NIH). SL has consulted for Pfizer and J&J Pharmaceuticals, and has given presentations for Pfizer.

At the same time, the tobacco industry has funded tobacco and health related research at universities. In the current context of limited funding, individuals and institutions may welcome additional sources of support. However the evidence is now clear that the tobacco industry participated in a long-standing conspiracy to defraud the public regarding the health risks of smoking. In 2006, the Honourable Gladys Kessler concluded in *United States vs Philip Morris* that the defendants “suppressed, concealed, and terminated scientific research; they destroyed documents including scientific reports and studies; and they repeatedly and intentionally improperly asserted the attorney–client and work product privileges over many thousands of documents (not just pages) to thwart disclosure to plaintiffs in smoking and health related litigation and to federal regulatory agencies, and to shield those documents from the harsh light of day”.¹⁵ Importantly, the Court found that the fraud continues to this day. At the Third Conference of the Parties of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) held in South Africa in November 2008, guidelines were adopted that proclaimed a “fundamental and irreconcilable conflict” between the interests of the tobacco industry and public health.¹⁶

That tobacco companies have worked systematically to subvert the scientific process and continue to do so makes many in the scientific community justifiably apprehensive about voluntary contributions direct to academic institutions. Indeed, a number of academic institutions have instituted policies prohibiting the acceptance of research support from tobacco companies or affiliated organisations,¹⁷¹⁸ some funders will not support research teams that accept funding from tobacco companies,³⁴¹⁹ some journals will not publish research that has been funded by the tobacco industry,³ and some organisations have policies for their members that discourage the acceptance of tobacco industry money for research.³ Given the public's negative view of the tobacco industry, scientists and universities who accept tobacco industry funding may see their reputation suffer. These concerns are the impetus for a search for less problematic funding models.

Since 2003, a series of meetings have been held to explore the issues raised by tobacco industry funding of academic research. The first was a post conference symposium following the annual meeting of the Society for Research on Nicotine and Tobacco (SRNT) in 2003 in New Orleans, Louisiana, USA. Sessions were also held at the 2005 SRNT meeting in Prague, Czech Republic and the National Conference on Tobacco or Health in 2005 in Chicago, Illinois, USA. While these discussions and debates were robust, a key question remained unanswered: is there a funding model through which the tobacco industry could support research that would be credible to the broader science and policy community and in particular, acceptable to the tobacco control research community by addressing the concerns that have been raised?

At the 2007 SRNT meeting in Austin, Texas, USA, a workshop was held to advance the dialogue on the contentious issue of what to do about the offer and acceptance of tobacco industry money for research and to explore potential models of research funding. The 30 participants included researchers, advocates and funders, as well as individuals outside of tobacco control who have experience with alternate funding models. Attendees represented the full spectrum of views from personally accepting tobacco company money for research to holding the view that tobacco control researchers should not accept tobacco industry funding for research. The objective of the workshop was to identify which funding models, if any, would be acceptable to pursue further through a continuing dialogue on alternate funding models for tobacco control research (broadly defined to include basic research, product evaluation, prevention, cessation, etc.).

All participants agreed that the strengths and weaknesses of the various funding models should be analysed further. In addition, participants felt that an objective set of criteria

needed to be compiled that could be used to analyse any potential funding model. The purpose of this paper is to go beyond previous discussions, editorials and debates on the issue of tobacco company funding of research by proposing shared criteria that could be used to evaluate any possible funding model that includes financial support from the tobacco industry, and applying them to assess four diverse funding models.

EIGHT CRITERIA TO EVALUATE FUNDING MODELS

Eight evaluation criteria were identified based on concerns that have been raised in previous discussions of the issue and from the literature on conflicts of interest in research. Collectively, criteria 1–7 relate to the need for a rigorous process for awarding and administering funds and ensuring freedom from industry influence. The final criterion addresses the issue of feasibility. Each criterion is described below.

Transparency and independence

The funding mechanism should be transparent and independent. For example, the process for evaluating and selecting projects for funding should be transparent; that is, the process should be explicit and clear, including information such as application deadlines, review meeting dates, review committee membership, scoring criteria, etc. The selection process should also use independent peer review, using reviewers who are not employees or contractors of the tobacco industry.

Competitive funding process

A competitive funding process is essential for ensuring that high quality science is funded. Poor science may be vulnerable to threats to scientific integrity and to misuse and is a waste of valuable resources. Additionally, a competitive funding process helps ensure that funding decisions are based on explicit scientific criteria rather than on factors such as personal relationships. The selection process should utilise peer reviewers with appropriate expertise relevant to the research being reviewed.

Ownership of data and freedom to publish

These are essential criteria for ensuring the scientific integrity of any research endeavour and would extend to using data and results broadly (ie, not limited to print publication). For example, there has been substantial discussion regarding researchers' freedom to publish findings from clinical trials sponsored by pharmaceutical companies. A sponsor may be reluctant to publish findings that are unfavourable to the product being tested. Thus, there have been calls for including language in clinical trial contracts to protect researchers' freedom to publish, and medical journals have encouraged sponsors and researchers to register trials before they are started.²⁰ Moreover, there are past examples where researchers funded by the tobacco industry were prohibited or discouraged from publishing work that might be damaging to the industry's interests.²¹

Independent research agenda

To ensure unbiased and relevant research results the research agenda needs to be set independently of the tobacco industry and other interested parties who may have a potential conflict with the outcome. Organisations created by the tobacco industry have been extensively criticised, not because the integrity of individual funded investigators was suspect, but rather that the research agendas for the programs were limited to funding projects that were intended to directly benefit tobacco companies.^{1522–26} There are other case studies where the involvement of tobacco industry scientists has had a negative influence on a research agenda, such as the participation of industry scientists on the National Cancer Institute (NCI) Tobacco Working Group.²⁷ A funder may influence the

research agenda even when the funding explicitly comes with “no strings attached;” merely the presence of funding can influence the research agenda,²⁸ as funding recipients may be influenced by a sense of obligation, an awareness of priorities, or an expectation of future funding.

Governance

The credibility of a funding entity is enhanced when there is a transparent and effective governance structure. A Board of Directors would oversee the operation of all aspects of the funding agency and programs, without requiring approval from the sponsor. The Board should be independent and not affiliated with the industry sponsor. Board members would be respected senior leaders recognised for their integrity, science and/or public policy expertise. An independent research committee, comprised of internationally-regarded subject experts, could determine the research agenda and prepare requests for applications.

Protection against conflict of interest

Any funding model is strengthened by having adequate protections in place to guard against potential conflicts of interest on the part of funding applicants and reviewers. There should be a written conflict of interest policy and mechanisms for enforcement. For example, the policy would govern disclosure of relevant financial relationships, including salary or wages, consulting fees, honoraria, fees for expert testimony, or speaking fees from a commercial entity that may be affected by the research outcome. Some relationships should be prohibited, such as a researcher holding equity in a company whose product is being evaluated in the study. While surveys describe current practice at academic institutions, there is no single widely used model conflict of interest policy;²⁹ further, it should be acknowledged that current practices and university conflict of interest policies have been criticised as inadequate.^{30–32} Appropriate governance, a competitive funding process and independence and transparency, as discussed above, will also help to protect against potential conflicts of interest.

Industry public relations (PR) gains that counteract public health

Industry PR gains realised from the funding of research that counteract public health should be minimised. Tobacco companies use their external funding to gain respectability and credibility by association in courts of law, in courts of public opinion and with legislators.^{33–38} Tobacco company image is critical as it can impact on companies’ “marketing success, legislative success, financial ratings, and ability to hire and retain good employees”.³⁹ Ultimately, such public relations gains can negatively impact tobacco control and regulatory efforts, which in turn can adversely impact public health.⁴⁰

Feasibility

If a model has a very low probability of being implemented for political, economic, legal, social or other reasons, this should be acknowledged. This is not to say if a model is inherently flawed it should be implemented for reasons of feasibility or that norms are static or universal; in tobacco control contexts change, sometimes quite radically and relatively quickly. Just because a particular model is not feasible today, in a particular country, does not mean that it would not be feasible in the future or somewhere else. While active work is ongoing to try to change current norms, it is crucial to identify the short-term and long-term feasibility of achieving the various models in order to have a realistic vision of what might be possible.

APPLYING THE EVALUATION CRITERIA TO FOUR FUNDING MODELS

To demonstrate how the eight criteria could be applied, we identified four diverse funding models for examination. The first two models are qualitatively different from the second two where the tobacco industry itself decides whether to fund research at all; indeed, funds for the first two models are acquired as a “spin-off” benefit of other tobacco control efforts. However, we have included them here because they are legitimate mechanisms by which tobacco control research could be funded. Each of the four models is briefly described, along with an application of the criteria.

Legislative initiative: dedicated tobacco tax or manufacturer license fee

This model derives from a legislative initiative. It involves either a tax on all tobacco-related products, or a licensing fee for tobacco manufacturers, with a portion of the funds generated earmarked for tobacco control research. The government would need to oversee distribution of the funds, presumably through some existing infrastructure that does not involve any input from the tobacco industry (eg, in the US by the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention). Importantly, the state of California has successfully implemented this model for many years using a dedicated tobacco tax. Because these initiatives are legislated, the model has a degree of permanency and funding amounts involved are likely to be predictable.

Transparent, competitive funding; independent peer review; and data ownership and publication—This model has the potential to score very highly on these criteria if it is established effectively through the legislative process.

Independent research agenda and transparent and effective governance structure—While a proposal might be made to establish an independent research program funded through a dedicated tax or licensing fee, the legislative process may yield a program that is less than ideal. For example, a legislative compromise might allow for tobacco industry representation on an oversight panel or scientific review committee. Thus, there are potential risks in pursuing this model. However, if established and maintained successfully, this model would score very highly on these criteria.

Protection against conflict of interest—Given the assumptions that funds will be transferred to an organisation that is independent of industry, there is little risk of any potential conflict of interest related to tobacco industry affiliation. However, to prevent other potential conflicts of interest, the model should also employ standard conflict of interest policies used by other grant making organisations, such as ensuring that applications receive independent peer review.

Potential PR gains for industry—The risk of PR gains for the tobacco industry is virtually non-existent under this model. A dedicated tax or licensing fee are mechanisms forced on the industry through legislation. Additionally, given that tobacco companies have no control over how the funds are allocated, they cannot claim plausible ownership over the funded research and related findings. It is conceivable that during the legislative process tobacco industry representatives could publicly voice support for a tax-funded or licensing fee-funded research program and potentially gain some positive publicity; however, the impact of such an action would be limited.

Feasibility—This model already exists in California but may not be easily applied in many jurisdictions. This model requires legislation to impose a new tax on the purchase of tobacco products or a licensing fee on manufacturers and to ensure that the funds are dedicated to

research. As a significant change to the status quo, this would likely be challenging to achieve. A successful legislative outcome would produce a mechanism with a substantial degree of permanence and independence. However, pursuing this model is not without risks, as the legislative process is unpredictable and may not yield the desired results. Enabling regulations often needed for program administration can also offer opportunities for stakeholders to influence program structure at latter stages of implementation.

Court-ordered initiative: legally-mandated contributions from tobacco companies

Under this model, contributions are court-ordered and dedicated in whole or in part to tobacco control research. This model requires a court case that is decided against the industry and a resulting remedy ordered by the court that the industry must provide funds for this research, or, a court-supervised settlement where the parties stipulate in the settlement that the industry will provide funds for tobacco control research. Distribution of the funds depends upon who receives them; government might use existing infrastructure (eg, NIH in the US), but a third party organisation may need to develop that infrastructure. In the case of a judge's verdict, the tobacco industry will not have input into how resources are allocated, but in the case of a settlement it may provide broad input as to how research dollars may or may not be used. Because contributions are court-ordered, the model likely will have a fixed period in which to operate, but may not be permanent.

Transparent, competitive funding; independent peer review; and data ownership and publication—This model has the potential to score very highly on these criteria, given the manner in which this funding will have come into existence and the structures for administering the funds.

Independent research agenda and transparent and effective governance structure—Even if funding results from a settlement rather than a ruling on the merits, the opportunity for the industry to make decisions on spending amounts and funding is low. Companies will be legally bound to provide a specified level of funding for a defined length of time. It is unlikely that the industry will have any input into areas of funding and the selection of investigators. However, a settlement or court order might allow for industry representation on an oversight panel or scientific review committee. Because of the high degree of independence in this model, tobacco control researchers would be expected to be comfortable seeking funding via this mechanism.

Protection against conflict of interest—The potential for conflict of interest is likely low.

Potential PR gains for industry—The potential for industry PR gains is non-existent if the funding results from a decision on the merits against the industry. The potential for an industry PR opportunity is marginally higher if the lawsuit is settled without a ruling against the industry.

Feasibility—This model has been used but may be difficult to implement in many jurisdictions. Filing and proceeding with a lawsuit against tobacco companies is costly and time-consuming. Likelihood of success is also hard to predict, a factor of relevance to the feasibility of this model. Furthermore, most countries do not have a legal system or culture that facilitates litigation against the tobacco industry.

Voluntary tobacco company contributions administered through an independent third party

The third party organisation could be an existing or novel one (using existing or novel infrastructure), but its charter would specify that resources are to be used for tobacco control research. The money devoted to tobacco control would be known, but those amounts might vary over time. The program itself might exist for a fixed period, thus its permanence could be uncertain. Because contributions from the tobacco industry are voluntary, there may be an industry expectation of input in the way resources are allocated or pressure to withdraw support in response to research results.

This approach has already been employed on multiple occasions in the past, and it has failed in large measure because the third party is either not truly an independent third party (ie, it was controlled by the tobacco industry) or there were insufficient firewalls such that the tobacco control community never trusted the process to be fair (although these organisations were successful in their intended purpose of promoting tobacco company interests).¹⁵²⁵⁴¹⁴² Thus, one fundamental assumption of this model is that the third party is structured and implemented to be independent: its organisational existence cannot be solely dependent on the tobacco industry; the process of screening, reviewing and making decisions on grant funding must be devoid of tobacco company influence; and the process of determining grant funding must be transparent.

Transparent, competitive funding; independent peer review; and data ownership and publication—These criteria can be met by this model if the third party organisation is empowered to do so. A non-tobacco example of how this was accomplished is the Health Effects Institute (HEI) (<http://www.healtheffects.org>), a third party organisation that receives funding from the automobile industry and the Environmental Protection Agency. Though the funding mechanism is a corporate/government partnership, the funding process meets the criteria above and is thus a respected source of funding.

Independent research agenda and transparent and effective governance structure—Although some of the specific components of governance would likely need to be different with tobacco industry funding, particularly given the current absence of a regulatory agency, HEI could serve as a valuable model for a third party funding mechanism. For example, the mission and mandate for the Institute set the scope for research, and research priorities are determined via a strategic planning exercise where sponsors and a wide range of stakeholders can comment on the draft plan, with the institute's research committee making the final decisions independently. Because this model relies on voluntary contributions, it would be dependent on the continued support of tobacco companies. It is possible that the tobacco industry would discontinue contributions if it were not satisfied with the research being funded, though a fixed term of contribution (eg, 5-year contractual agreement as is ordinarily the case with HEI) can be a mitigating factor.

Potential conflict of interest for recipients of funds—Conflict of interest is potentially low assuming that the third party would establish a peer-review process with decisions for funding that is transparent and not determined by a tobacco company. The critical factors pertain to the nature of the third party organisation (ie, is it truly independent) and the nature of the review and funding process (ie, is there a firewall that prevents companies from impacting review and decision-making).

Potential PR gains for industry—It is likely that some PR gains will be realised by the funders as funding amounts may be detailed in company annual reports and possibility also in any corporate social responsibility reports. It is possible that, as in the past, tobacco

companies would only make voluntary contributions under conditions in which they benefit, and thus PR gains would be greater.

Feasibility—This model is likely a low or moderately feasible approach (there has not yet been a circumstance in which tobacco companies contributed research funds to a truly independent third party). It is not created and subject to ongoing scrutiny by legislatures or courts, and thus allows for some flexibility on the part of tobacco company funders. If it is not working the way the funders want it to work, they can discontinue the funding. In addition, this approach potentially creates a perception that the companies are responsible corporate “citizens”, thus making it more to their liking.

Voluntary tobacco company contributions direct to academic institutions

Currently, tobacco companies fund tobacco control research through direct voluntary contributions to a researcher's institution. With this model, the tobacco industry directs fund distribution and can control the topics that do, and do not, get funded. Dollar amounts are uncontrolled and may be unknown until awarded, and the program period is uncertain.

Transparent, competitive funding; independent peer review; and data ownership and publication—Institutions using this model may choose to invoke contractual language that ensures that the institution owns the data and the investigator is free to publish results without interference from the industry funder. However, the extent to which this language is/will be invoked universally, and adhered to, is unclear. This model can operate in the context of a competitive funding process that uses a peer-review system to evaluate proposals (eg, Philip Morris External Research Program); however, the transparency of these features of the model can be uncertain and the independence of an industry-backed peer-review system has been questioned.^{43–45}

Independent research agenda and transparent and effective governance structure—One of the most troubling issues associated with the direct voluntary contribution model involves industry control of the research agenda. Recently, the industry has suggested particular research questions to an individual investigator, and then funded a proposal submitted by that investigator.⁴⁶ Industry control of the research agenda may lead to a pro-industry emphasis that would not otherwise exist. In this model, governance is not independent from the tobacco companies.

Protection against conflict of interest—Once a funding stream controlled by the tobacco industry is initiated, the continuation of that stream may depend on research questions and/or results congenial to industry positions. This seeming dependence is made more acute when research funding is scarce. Importantly, the appearance of a conflict of interest does not imply wrongdoing on the part of a sponsor, institution, or investigator. However, when a funding stream is associated with a strong appearance of a conflict, all parties must examine how best to manage that appearance. Management strategies may include disclosure of funding sources and independent review of research and results, but, in some cases, may require a decision to avoid the appearance of conflict by not accepting the funding.

Potential PR gains for industry—There is an extremely high potential for public relations gains when tobacco industry sponsors capitalise on their contributions to prominent universities and researchers through PR announcements and court testimony.

Feasibility—Of the four funding models described here, this is the most feasible and the most widely used.

SUMMARY OF APPLICATION OF THE EVALUATIVE CRITERIA

The application of the evaluative criteria to the four models has been summarised along two dimensions: acceptability (criteria related to the integrity of the research process) and feasibility. Overall, the most feasible models may well be the ones that are the least acceptable to the public health and tobacco control communities. Models with moderate feasibility tended to offer a medium level of acceptability, and the most acceptable models scored low on feasibility.

DISCUSSION

We have presented eight criteria that we think are useful and important for evaluating funding models. Some of the criteria may be considered generic and not necessarily unique to the issue of tobacco company funding of research, and we acknowledge that there is some overlap across the criteria. Nonetheless, we consider them to be essential elements in the evaluation of any funding model and thus have chosen to explicitly include them.

Given the importance of the science to be provided under any of the models cited and the history of controversy around earlier efforts to obtain credible science using tobacco industry funding, a requirement for periodic external oversight and review, with authority, by a prestigious external group would be beneficial to ensure the provision of independent, high quality and relevant research. A requirement for such a review, perhaps on a regular 5-year basis, would be an important addition to strengthen the operation of the models cited. Such a review would be conducted by competent subject matter experts and would be expected to yield a publicly available report that evaluates the integrity of the structure and implementation by the institution in the context of the criteria and other factors. Such a periodic external review would have value as a regular feature for all of the models.

Our evaluation of the four funding models according to the eight criteria indicated that it is clear that there is no perfect model that scores well in every area. In all cases structure, implementation and periodic oversight will be important. Further, the mission and mandate of the administering body will be key in determining whether priority will be placed on particular areas of research. Although a focus on research that most rapidly reduces the harm from use of tobacco products would be ultimately advantageous for public health, it would be important to also fund some basic science research.

Although the criteria presented were applied in relation to tobacco funding models, they similarly have relevance for discussions of funding originating from other industries, including the pharmaceutical industry, where concerns have also been raised regarding the potential for conflicts of interest or bias.⁴²⁴⁷⁻⁵⁰ Empirical studies of clinical trial agreements between academic institutions and pharmaceutical industry sponsors suggest that there is considerable variation in the content and requirements of such agreements across institutions, though most do share some basic common elements, such as protecting the investigator's freedom to publish results.²⁰⁴⁷ Additionally, while the focus of efforts to address conflicts of interest in biomedical research has been largely on rules for disclosure, disclosure alone may not address all the concerns related to some funding mechanisms.⁵¹ Thus, further attention is needed to assess the potential risks and benefits of different types of funding models within different research contexts.

It is important to note that we evaluated the models assuming that a full range of tobacco control research would be undertaken with the funds. However, it may well be that the type of research conducted would be relevant to the acceptability of the different models. For example, Eissenberg argues that tobacco companies should pay for research that evaluates current and new tobacco products, and that if the public or not-for-profit sector

provided the funds they would essentially be subsidising the tobacco industry.¹⁰ Nonetheless, tobacco company funding of this type of research could still occur—and would be more acceptable according to the criteria outlined above—if it came from voluntary contributions administered through an independent third party, or legally-mandated contributions, rather than from voluntary contributions direct to academic institutions.

We hope that the ideas put forth in this manuscript provide a constructive context for the next phase of discussions regarding acceptable funding models for tobacco control research. There are a number of issues that require further debate. For example, are the identified criteria the right set? Should any of the criteria be dropped, and should any new ones be added to the list? Discussion is also required regarding funding models. For example, are there other funding models that should be evaluated? Are we at a point where a specific model can be recommended as the “best” one, or where a promising model should be the subject of further refinement and a more in depth application of the criteria? Should a specific model be excluded from further consideration? It would also be important to explore in more detail potential implications on the broader tobacco control community of a funding model that uses tobacco industry money; for example, community-based groups may look to the research community for leadership: would such models be appropriate and feasible for funding community-based organisations? All of these questions are just as relevant, if not more so, in regions other than North America. We invite readers from all regions to continue the dialogue on the relevance of our findings and considerations for applicability within their regions.

There are several next steps that could follow from publication and dissemination of this paper. First, the criteria and possible models could be discussed and debated at formal conference gatherings. The criteria could be vetted and new and/or hybrid models identified and explored. Second, funders could convene to evaluate implications from this paper for their possible role going forward. If these activities take place, then a follow-on paper could be envisioned that could reflect broader agreement around the criteria and specific models worthy of serious consideration. We look forward to refining these ideas and to moving toward a model or models that can facilitate and not obstruct progress toward reducing tobacco-caused death and disability.

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What this paper adds

- ▶ Much has been discussed, debated and written about the purposes, outcomes and ethics related to tobacco industry funding of research. These concerns raise the question of whether there could be a model of funding that would be acceptable to the tobacco control research community.
- ▶ This paper goes beyond previous discussions, editorials and debates by proposing shared criteria that could be used to evaluate any possible funding model that includes financial support from the tobacco industry, and applying them to assess four diverse funding models.