

BURNING ISSUES

TRDRP Newsletter



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The series of articles in this newsletter are intended to inform our stakeholders about the issues surrounding tobacco industry funding of research, to lay out many of the arguments made by the different sides for and against accepting such funding, to stimulate debate, and to invite feedback from our readers.

Tobacco Industry Funding Implications for the Scientific Community

Susanne Hildebrand-Zanki

The Philip Morris External Research Program

The reemergence of a tobacco industry-sponsored research program, the Philip Morris External Research Program (PMERP), has raised red flags in the tobacco control and tobacco research communities because of the past use the industry has made of peer-reviewed and, especially, non-peer-reviewed research. As outlined in the tobacco industry documents now available, the industry has systematically engaged in activities designed to throw doubts on research data that showed a connection first between smoking and health, and now between second hand smoke exposure and adverse health effects.⁽¹⁾ The stated mission of PMERP is to "support the highest quality research that contributes to our fundamental scientific knowledge, help address the concerns of the public health community regarding cigarette smoking, and enables Philip Morris to continue its pursuit of product modification(s) or new product design(s) that might reduce the health risk of smoking."⁽²⁾ PMERP is the successor to the Center for Indoor Air Research (CIAR), which was supported by the tobacco industry to fund research related to indoor air quality. The new program is located at

the same address and has the same director as the CIAR. The stated mission of the CIAR was to "create a focal point organization of the highest scientific caliber to sponsor and foster quality, objective research in indoor air issues and to effectively communicate research findings to the broad scientific community".⁽³⁾ With the establishment of the Master Settlement Agreement (MSA), the tobacco industry elected to cease the operation of the CIAR only to restore it as PMERP, albeit with a broader research focus.

Call to Action

TRDRP is part of the Proposition 99-funded tobacco control effort in California along with other programs funded by the Department of Health Services Tobacco Control Section (TCS) and the California Department of Education (CDE). The Tobacco Education and Research Oversight Committee (TEROC), which has oversight responsibility for these programs, has urged UC to prohibit UC investigators from accepting funding from PMERP. Separately, TEROc has also requested that TRDRP adopt a policy similar to that promulgated by TCS in 2000, which stipulates that "any principal investigator who within the last five years from the start date of the grant period, or during the term of the grant, receives funding from, or has an affiliation or contractual relationship with a tobacco company, any of its subsidiaries or parent company, is not eligible for funding..." TEROc specifically requested that TRDRP "should prohibit any funds from being awarded to entities that are currently receiving funding from the Philip Morris (External Research) Program." This narrowing of the focus on the research program was intended to highlight the in-

herent conflict of interest connection between the funding provided by PMERP and that provided by TRDRP, rather than prohibiting any funding from any and all tobacco industry associated businesses.

In his answer to TEROc, UC president Richard Atkinson assured the committee that "the comprehensive policies the University already has in place, which address research funding from private entities, are appropriate and adequate. The University's policies are intended to achieve two broad goals. They protect researchers' academic freedom to investigate issues they believe are important, independently of political, cultural, commercial, or other sources of influence. They also protect the University, the State, and the public by maintaining the highest scholarly standards, administering funds prudently, and controlling potential conflicts of interest. The University's policies ensure that funders cannot censor or otherwise control the nature or outcomes of the research."

To develop a position statement on this issue, TRDRP sought input from the General Counsel's office, the Vice-Provost for Research, and TRDRP's Scientific Advisory Committee (SAC). The intent of any policy implemented by TRDRP would not be to change existing UC policies, but rather to create an independent policy, which reflects a funder's perspective.

Why not tobacco-industry sponsored research?

Industry-sponsored research has been a topic of debate within the scientific community for decades. Several studies investigating the impact of industry sponsorship on reported research outcomes

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Policies and Positions of Other Organizations on the Funding Controversy

Margaret Shield

As part of an examination of the impact of tobacco industry funding on scientific research, TRDRP reviewed how other entities in the research community have dealt with the issue. The egregious behaviors of tobacco companies in denying the addictive nature of nicotine and denying the links between smoking and disease create a dilemma for scientists who also know the industry as a significant source of private funding for research. The debate centers on the benefits of refuting ties to such an industry versus the benefits of industry financing of valuable research. The discussion quickly becomes complicated with issues such as the protection of academic freedom, the free exchange of scientific information regardless of its source, the research community's obligation to promote public health and whether (or how) to enforce morality. Research institutions, professional scientific societies, editorial boards of journals, and research funding organizations have struggled to develop appropriate policies to address this issue.

Research Institutions

Financial ties between tobacco manufacturers and American universities or medical schools include donations for specific projects or for general operating expenses, endowments, scholarships, consulting fees, as well as specific research grants.⁽¹⁾ In the mid 1990's, a handful of U.S. research centers adopted bans on acceptance of tobacco industry dollars for research.⁽²⁾ These institutions include Massachusetts General Hospital, Brigham and Women's Hospital and the M.D. Anderson Cancer Center. Other institutions, notably Harvard's School of Public Health, have debated the issue and decided that an outright ban on this funding source would be a detriment to academic freedom.⁽¹⁾ Similarly, the University of California does not restrict its researchers from obtaining funding from tobacco sources. (see box page 4).

At most research institutions, the decision of whether or not to apply for or accept a research grant from a tobacco company or a foundation funded by tobacco companies is in the hands of the individual researcher. To avoid conflicts of interest and protect the rights of their scientists, research institutions typically have policies governing the conditions under which their researchers may accept external funding. However, a recent study of 89 major U.S. research institutions found that the content and enforcement mechanisms of conflict of interest policies vary widely from institution to institution.⁽³⁾ The issue of industry-academic relationships, which have increased dramatically in the last two decades, extends beyond the bounds of any single industry's financial support of research and creates a challenge for research institutions seeking to fund necessary research and activities while maintaining the public trust.⁽⁴⁾

Professional Scientific Societies

Professional societies in the sciences have also been debating the issue of tobacco industry funding. Several societies that focus on health and medical research issues have taken action. The American Medical Association, American Lung Association and American Thoracic Society encourage their members to voluntarily refuse funding from big tobacco and to actively participate in tobacco control initiatives.^(5, 8) The American Public Health Association also enacted a policy in 1994 to "urge organizations working on public health issues to neither solicit nor accept funds from alcohol or tobacco producers or companies and corporations owned or operated by tobacco or alcohol producers for research or program purposes."⁽⁶⁾

Scientific Journals

Peer-reviewed scientific journals typically have policies requiring authors of scientific manuscripts to disclose their affiliations as well as potential conflicts of inter-

est. Such policies are determined and enforced by each journal's editorial board and therefore differ from journal to journal. Even journals with long established policies against publishing articles in which the authors have a financial stake find the rules challenging to enforce in all instances because relationships between researchers and companies can be complex. An example of the problem is found in the situation faced by the New England Journal of Medicine in 1996 when it discovered, post-publication, that the authors of an editorial on the safety of anti-obesity drugs previously served as paid consultants for a prominent manufacturer of these drugs.⁽⁹⁾

Several scientific journals have decided in recent years to adopt policies banning publication of any research study funded by tobacco companies or their affiliates. After heated debate on the topic during the mid-1990's, the American Thoracic Society (ATS) adopted a policy in 1995 of refusing to publish research funded by tobacco monies in the society's two journals – the *American Journal of Respiratory and Critical Care Medicine* and the *American Journal of Respiratory Cell and Molecular Biology*.^(2, 7) Proponents of this action felt that separation from tobacco money was critical to maintain the credibility of the ATS's central mission to prevent and treat lung disease. The *Journal of Health Psychology* and the *British Journal of Cancer* have enacted similar bans. *Nicotine and Tobacco Research*, published by the Society for Research on Nicotine and Tobacco, does not exclude studies funded by tobacco-industry sources, but it does single out those accepting tobacco industry funding for additional scrutiny by requiring that all authors of manuscripts "declare sources of funding, direct or indirect, and any connection with the tobacco or pharmaceutical industries".

The actions of journals that have banned tobacco industry funded studies have come under substantial criticism by the editors of other major journals, notably the *British Medical Journal*⁽⁸⁾, who argue that censorship is not the answer to this problem. A ban on publications solely on the basis of financial sponsorship of the study, rather than on the merits of the scientific hypothesis and the research results, strikes some as a threat to free discussion of ideas. These editors propose that care-

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The Tobacco Industry as a Funder of Scientific Research

Isn't that like leaving the fox in charge of the hen house?

Francisco O. Buchting

The use of science as part of a strategic public relations campaign by the tobacco industry has entailed the systematic manipulation, distortion, and adulteration of the scientific process and record as far back as the 1950's, if not longer. This statement is evident from the chronicle of activities garnered from tobacco industry documents and published scientific studies. Such tactics have proved a worthwhile endeavor for the industry by providing it with the tools to prevail over litigation challenges, impede or delay local, state and national policy changes, and maintain influence over the scientific discourse on health effects associated with tobacco use and environmental tobacco smoke (ETS). The various research programs/centers/councils the tobacco industry has overtly, as well as covertly, created and funded have been multiple fronts for the industry to coordinate and implement its public relations campaign. Through the guise of funding "legitimate" research, the industry was able to conduct its covert campaign while not drawing any significant attention to itself.

Following is a brief account of the tobacco industry's infiltration of the scientific endeavor through its covert activities by positioning itself as a funder of "legitimate" tobacco related studies and steering the scientific discourse. Details of the industry's covert activities and response to the issues of ETS will elucidate how the establishment of the various research programs/centers was part of the industry's strategic campaign to protect itself from legal and legislative action.

The Beginning

By the early 1950's, the tobacco industry was faced with an increase in published independent research linking tobacco use to lung cancer, a questioning of consumer confidence, and threats of litigation. These challenges led to the tobacco companies jointly adopting a strategic campaign put forth by Hill and Knowlton, a public relations firm, that called for the establishment of the Tobacco Industry Research Committee (TIRC), later renamed the Council for Tobacco Research-U.S.A., Inc (CTR).⁽¹⁾

According to the industry's public statement, the intent of the council was to fund independent scientific research on the health effects of smoking; objectivity was to be assured through a peer review process by an independent science advisory committee.⁽²⁾ The true intention of the council was to serve as the industry's front to carry out its campaign to use science for its benefit.



"The most important type of story is that which casts doubt in the cause and effect theory of disease and smoking. Eye-grabbing headlines were needed and should strongly call out the point – Controversy! Contradiction! Other Factors! Unknowns!" (Hill and Knowlton, 1968).⁽³⁾

The activities of the TIRC/CTR were so insidious that its extinction was a crucial part of the Master Settlement Agreement (MSA). Why would the termination of a program purported to fund legitimate scientific research be a condition in a settlement of a legal suit? The reasons for such action are obvious given the real purpose of the council. Bero et al., (1995) provided a comprehensive account of the covert operations of the TIRC/CTR as detailed in industry documents.⁽²⁾ In brief, their find-

ings revealed the existence of a "special projects" division that funded non-peer reviewed projects per the recommendation of industry lawyers. The goals of the special projects were first to develop scientific data to help defend the tobacco industry in litigation, and second to foster relationships with scientists who could later testify on the behalf of the industry. In addition, the special projects were often designed or had their design altered to sidetrack attention from the tobacco-disease causal connection and/or produce results that favored the industry position. These covert activities contradict the public position the industry held for establishing and funding the TIRC/CTR, i.e., to fund, as advised by an independent scientific committee, independent peer reviewed research into the health effects associated with smoking.⁽²⁾

"Let's face it. We are interested in evidence which we believe denies the allegations that cigarette smoking causes disease." (Philip Morris, 1970).⁽⁴⁾

More Smoke and Mirrors - the ETS Machination

Excerpts from a report by the Roper Organization for the US Tobacco Institute highlights the strategy the tobacco industry adopted to address the issue of ETS:

"what the smoker does to himself may be his business, but what the smoker does to the non-smoker is quite a different matter ... This we see as the most dangerous development yet to the viability of the tobacco industry that has yet occurred ... The strategic and long run antidote to the passive smoking issue is, as we see it, developing and widely publicising clear-cut, credible, medical evidence that passive smoking is not harmful to the non-smoker's health." (1978).⁽⁵⁾

The industry's assessment of the potential harm the issue of ETS could bring to its business led the industry to aggressively confront concerns over ETS from different avenues. Once again, like in the health effects area, a public relations campaign to systematically manipulate and distort the study of ETS became a lead strategy for the tobacco industry.

Policies

ful peer review should be utilized instead.

Research Funding Organizations

Agencies of the U.S. federal government that fund biomedical research, such as the National Institutes of Health and the Centers for Disease Control, do not restrict funding on the basis of any sources of industry income that researchers concurrently accept. U.S. non-profit organizations and foundations that fund medical research, such as the American Cancer Society and the American Lung Association, also do not currently deny funding to researchers who concurrently accept tobacco-industry support. The only prominent examples of funders that are attempting to divorce themselves from researchers accepting tobacco funds come from the U.K. where the charitable Cancer Research Campaign (CRC) and the Wellcome Trust both have policies against funding researchers who accept tobacco industry funding.⁽¹⁰⁾

The CRC, which provides about one-third of all funds for cancer research in the U.K., enacted a policy in April 1999 that denies funding to any researcher who accepts tobacco money directly, as well as to any researcher who works with or shares resources with those who are funded by the tobacco industry. This policy resulted from the CRC's concern over Cambridge University's decision in 1997 to accept £1.5 million (which eventually went towards funding a chair in international relations) from British American Tobacco. Initially the CRC proposed cutting off an entire institution if any member accepted tobacco industry funds for any purpose; however, after a stand-off with universities followed by intense negotiations, the CRC softened its ban to cover only researchers within the department accepting the tobacco dollars. Because tracking tobacco industry contributions to institutions is complicated, the CRC admits that policing this policy is difficult and it may need to enlist the assistance of tobacco control advocates to enforce the ban.⁽¹⁰⁾

This quick review of policies and positions shows that there will be differences of opinion in the scientific community on the best course of action. The landscape

of tobacco control has changed significantly with the events surrounding the 1998 Master Settlement Agreement. However, Philip Morris's decision to launch a new External Research Program shows much still remains the same on the topic of funding for research projects and research institutions by tobacco manufacturers. Thus the debate over the scientific community's response to this funding source will not, and should not, fade away.

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University of California Positions on Tobacco Industry External Funding and Investments

The University of California administers the Tobacco-Related Disease Research Program, part of the state of California's tobacco control efforts; however, at the same time, it does not prohibit UC faculty from obtaining research funding from tobacco companies. In a recent letter to Jennie Cook, chair of the state's Tobacco Education and Research Oversight Committee, UC President Atkinson recognized the committee's concerns about tobacco industry support of university research, but restated the university's position that UC researchers may obtain funding from any private source as long as university policies are met. In addition to policies requiring "intellectual honesty and integrity in research", UC policy mandates that researchers funded by external sources retain the "freedom to interpret and publish or otherwise disseminate research results in order to support the transfer of knowledge to others", as well as the right to "utilize the results of their research to perform future research".⁽¹⁾ The intent of these policies is to simultaneously protect the academic freedom of UC researchers and prevent external funders from controlling research outcomes.

However, in another area, the university has taken a significant step in distancing itself from the tobacco industry. The University of California Regents recently reaffirmed the exclusion of tobacco stocks from the UC investment portfolio. This issue, which has been dormant for many years because UC's portfolio did not contain tobacco-related holdings, received renewed scrutiny when index funds that include tobacco stocks came under consideration as investment possibilities. At a January 18th meeting, the UC Regents approved a measure to exclude tobacco stocks from UC investments, currently a \$52 billion portfolio. This decision was based on concerns about the social responsibility of investment in tobacco companies, as well as the determination that UC investment goals could be well-met by selection of alternative index funds that exclude tobacco stocks.

With this action, UC joins a growing list of universities - both public (Universities of Washington, Michigan and Wisconsin) and private (Stanford, Harvard, Johns Hopkins and Tufts) - that have permanently divested from tobacco stocks. Other California state funds that have recently banned tobacco investments are California's Pooled Money Investment Account and the California State Teachers Retirement System.

I. Principles Regarding Rights to Future Research Results In University Agreements with External Parties, University of California, Office of the President, 8/26/99 (<http://www.ucop.edu/ott/principles.html>)

Funding

provide evidence that these studies more often report a positive outcome for the industry than similar research funded by other sources.⁽⁴⁾ The fears of conflicts of interest arising from research sponsorship are real. Research institutions have responded by implementing policies aimed at minimizing conflicts of interest of their investigators. And it is these policies that President Atkinson referred to in his response to TERO. However, the scope of these policies and their enforcement vary widely among institutions. As research institutions receive increased funding from private sources, the debate of how to properly safeguard research integrity continues. Tobacco industry funding adds another wrinkle to this debate since many don't see it as just another industry sponsoring research for its own use. Research projects are not aimed at improving existing prod-

ucts or devising improved and safer cigarettes. In fact, the strategy of the industry is to NOT fund research related to its product¹, but to diseases, with the clear understanding that studying the causes of diseases *other than tobacco* is a long term proposition that will take the focus off the immediate problem – legal and legislative actions that will curb the availability of a product that, when used as intended, will ultimately kill the consumer. In addition, the industry has skillfully mixed credible, peer-reviewed research conducted by eminent independent scientists with non-peer reviewed studies, which it uses as evidence in testimony before legislators and juries.

What next?

TRDRP is now faced with the decision of what position to take on the issue of tobacco industry funding of investigators applying to TRDRP. Options range from remaining silent on the issue, educating our

applicants and reviewers about the strategies employed by the tobacco industry, urging them to forego tobacco industry funding, or not inviting reviewers who have industry ties. We would like to encourage our readers to give us their opinions on this issue. Our contact information is on the back of this newsletter.

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Fox

By the mid to late 1980s, the tobacco industry was faced with increasing scientific evidence of the harmful effects of ETS. A number of industry documents provide details as to the extent of the industry's (in particular, that of Philip Morris') implementation of a public relations campaign. An industry document from British American Tobacco summarizes the details of a 1988 meeting in which Philip Morris's plans to deal with the ETS issue in the United Kingdom were laid out.⁽⁶⁾ The UK tobacco industry was informed of the Philip Morris plan to covertly recruit research scientists who would dispute the risks of ETS on an international level, thus keeping the controversy alive. This endeavor was code-named the "Whitecoat" project and referred to as such in the industry documents.⁽⁷⁾ The global coordination of the "Whitecoat" project, as well as the screening of proposals for areas of sensitivity, was to be done by the Convington and Burling law firm hired by Philip Morris. Subsequent industry documents clearly outline the creation and funding of the International Center for Indoor Air Research (ICIAR) as the agency under which this global campaign was managed and carried out by lawyers.⁽⁸⁾ In addition, these docu-

ments detailed the progress and success of the "Whitecoat" project and of the Witness Development Programme located within the ICIAR in achieving its surreptitious aims.

About the same time, the Center of Indoor Air Research (CIAR) was created in the U.S. in 1988. The CIAR, like the TIRC/CTR, also emphasized that the funding of research projects be done in a "scientifically rigorous and objective manner" based on peer review by independent scientists and thus this process "ensures that only high quality research . . . is recommended for funding".⁽⁹⁾ Similar to the TIRC/CTR and the ICIAR, the CIAR also funded "special projects". The focus of the CIAR was more narrowly defined than the TIRC/CTR, i.e., focused on indoor-air-quality research. Given the industry's pattern to fund studies that did not question the casual relationships between mainstream smoking and disease, or in this case ETS, it is of no surprise that the CIAR focus was constricted, thus diverting the argument from ETS to other pollutants/carcinogens present in indoor environments. Furthermore, CIAR projects were funded as contracts rather than grants. The significant difference between a contract vs. a grant award is that contractual agreements generally provide less latitude for the investigator and allows the funder (CIAR) greater

control over the research conducted.

A comprehensive look into the CIAR can be found in Barnes & Bero (1996).⁽⁹⁾ Their findings demonstrate the existence of what was known at the TIRC/CTR as "special projects". Besides funding independent peer-reviewed studies, the CIAR also funded special projects it categorized as "applied" and "other". These goal oriented "applied" and "other" studies were directly funded by the board of directors without undergoing peer review. The CIAR board of director membership consisted mainly of tobacco industry executives from the charter tobacco companies who funded the CIAR (Philip Morris USA, R. J. Reynolds Tobacco Company, and Lorillard Corporations, and Svenska Tobaks A.B. (a Swedish tobacco company later added in 1994). Moreover, in publications referring to the studies that were funded, the CIAR did not mention that some of the projects were funded through a process that was exempt from the peer-review process. An analysis of the projects funded by the CIAR found that special projects were more likely to focus on ETS than peer-reviewed studies, that the special reviewed projects tend to support the industry's position, and that special reviewed projects tend to be used by the industry to argue against ETS regulations.⁽⁹⁾

Exclusionary Policies: Simplistic Approaches to Complex Issues?

Jeffrey Cheek

At first glance, it seems prudent for TRDRP to avoid all appearances of any association with individuals and/or institutions receiving funding from the tobacco industry. However, a fundamental principle for any research program is to ensure that the science it supports is both rigorous and impartial. TRDRP should indeed seek to minimize the risk of conflicts of interest between its researchers and the tobacco industry – and do so in a fair, unbiased manner so that the Program remains beyond reproach. Unfortunately, implementation of the policy recommended to TRDRP by the California Tobacco Education and Research Oversight Committee (TEROC) would fall short of these goals, as the recommended policy is not comprehensive and could promote distrust between health effects researchers and tobacco control professionals.

If TRDRP were to adopt a policy restricting eligibility for funding, what are the consequences for the Program or its stakeholders? The following details several concerns with the recommended policy and seeks to redress those issues that are excessively punitive and/or discriminatory.

A rose by any other name – it's still money from the tobacco industry

There are always potential conflicts of interest when any industry funnels money towards research focused on its commercial products. The example of pharmaceutical industry funding that either discourages or prevents publication of negative data illustrates just one of many concerns regarding commercial support of public health research⁽¹⁾, also see *Policies and Positions of Other Organizations on the Controversy* in this newsletter). However, given the broad implications of industry funding and the influence it may buy the tobacco companies, a major limitation of the policy recommended to TRDRP is the sole focus on researchers who receive funding from the Phillip Morris External Research Program (PMERP). Essentially, this policy would target a select group of researchers with expertise in either pulmonary health effects

of indoor air pollutants or environmental engineering/indoor air quality specialists. On the other hand, other individuals or entities receiving other (and often more controversial) support from the tobacco industry would be exempt from this ban. For example, there are TRDRP investigators who have served as expert witnesses for the tobacco industry; certainly this constitutes a direct (and potentially far more insidious) conflict of interest.

The rationale behind the limits of the recommended policy is that, by focusing on researchers directly supported by Phillip Morris (i.e. PMERP), TRDRP would not have to address the more subtle issues of secondary or privately arranged financial ties between the tobacco industry and TRDRP awardees. However, this spotlight on PMERP contrasts with the model for the proposed ban (i.e. the policy imposed by the California Tobacco Control Section (TCS) on its applicants), which specifies a far broader set of guidelines that discourages, for example, community-based organizations from accepting any form of support from the tobacco companies or their subsidiaries. Conversely, if TRDRP adopted the recommended policy, those receiving tobacco industry money from sources other than PMERP would be exempt from restrictions on TRDRP funding. At best, the proposed ban discriminates against health effects researchers and indoor air quality specialists; at worst, by casting suspicion on the validity of PMERP-sponsored research without proving it invalid, it is both unscientific and anti-democratic. It follows that an effective strategy to counter “influence peddling” by the tobacco industry must necessarily be comprehensive, particularly in recognition of past strategies employed by the industry’s multiple fronts.

Get over it – public health has benefited from some industry-supported research

As noted in previous articles in this newsletter, research on the health effects of to-

bacco use (and particularly on secondhand smoke) have had an authoritative influence on public opinion and legislative and judicial action. What is easily overlooked is that such research has neither traditionally been, nor currently is, well funded by federal agencies. Over the last ten years, relatively few sources (including TRDRP and, yes, Phillip Morris via the CIAR) have provided funding for independent, peer-reviewed research on the health effects of exposure to secondhand smoke. A review of the studies cited in the California EPA report on this topic demonstrates that some of these projects received funding from CIAR.⁽²⁾ The point here is not to justify the continued use of industry-sponsored funding as provided through PMERP. Indeed, the industry has shown that nothing comes free, viz., Phillip Morris used CIAR as a mechanism to collapse their non-peer reviewed research projects – designed to challenge and contradict studies demonstrating any risks of exposure to secondhand smoke – with peer-reviewed studies conducted by reputable scientists focused on tobacco’s health effects. Nevertheless, some of the health effects studies providing evidence in support of regulations that restrict public exposure to secondhand smoke did receive support from the industry.

There is also a discrepancy in TERO’s recommendation to TRDRP, as the committee has specified that TRDRP should prospectively focus on future PMERP grantees, but also should utilize the TCS policy as a model. However, the policy



INTERPOINT >>>

The Philip Morris External Research Program; Fig Leaf Optional

Phillip Gardiner

The newly created Philip Morris External Research Program (PMERP) is nothing more than a not too thinly veiled front for

promoting the interests of Philip Morris (PM) in particular and the tobacco industry generally. PMERP is the latest incarnation of the Center for Indoor Air Research (CIAR), which was explicitly set up to cloud the issues surrounding the harmful nature of environmental tobacco smoke (ETS).⁽¹⁾ The bottom line is that PMERP seeks to surround itself with the best possible scientists to give the public appearance of scientific and corporate responsibility. To strip Phillip Morris of its fig leaf, first I will examine the actual goals of the PMERP, next, examine use of good scientists for bad purposes,

thirdly, locate the creation of the PMERP in the broader post-Master Settlement Agreement (MSA) offensive on the part of the tobacco industry and lastly suggest how scientists and funders can get involved in exposing and isolating Philip Morris.

PMERP: For Health or for Death?

"The Purpose of the Philip Morris External Research Program is to support the highest quality research that contributes to our fundamental scientific knowledge, helps address the concerns of the public health community regarding cigarette smoking, and enables Phillip Morris to continue its pursuit of product modification(s) or new product design(s) that might reduce the health risk of smoking."⁽²⁾

It is somewhat incredible to think that PM is concerned with the "highest quality

that . . . helps address the concerns of the public health community." PM and the tobacco industry generally have spent their entire corporate lives denying, deflecting and obfuscating the deadly truth about their product. Philip Morris has spent years attacking the public health community, so for them to turn around in 2000 and state that they are concerned with helping to address this community's concerns is not entirely believable. It must be borne in mind that, at the same time that the call for the PMERP appeared, PM was leading the fight to block any and all regulatory efforts that would force the tobacco industry to identify and disclose all constituents, chemicals and ingredients that are contained in the various brands of cigarettes. PM's successful blocking of the State of Massachusetts law that required disclosure of ingredients in cigarettes belies their newfound interest in the nation's health.⁽³⁾ The supposed public health concerns that PMERP so boldly trumpets in its stated goals are severely circumscribed when its parent and the other tobacco companies will not even provide the basic information regarding the contents of its products for scientific analysis.

Moreover, Philip Morris has gone out of its way to hinder research that seeks to document the availability of tobacco to minors. The tobacco industry has sponsored legislation in several states making it illegal to conduct test purchases for research purposes (Mississippi House Bill No. 1268, South Dakota Senate Bill 189 as amended, and Official Code of Georgia, Crimes and Offenses, Article 7, 16-12-175).

⁽⁴⁾ How is it possible that PMERP is concerned with "the highest quality research that contributes to our fundamental scientific knowledge" when its parent (PM) is pro-actively blocking tobacco use research among youth? Is PMERP really fit to conduct a research program when its benefactor, Philip Morris, has been and remains the main impediment to tobacco-related disease and tobacco use research?

It is true that some peer-reviewed research funded by the CIAR was helpful in

establishing the case that ETS is a seriously harmful and deadly pollutant.⁽⁵⁾ On the other hand, much of the research sponsored by the CIAR came under the funding of "special projects." It seems highly likely, given the notorious history of tobacco industry funded research that PMERP will continue the "special projects" mechanism (read non-peer-reviewed), like its predecessor the CIAR. These "special projects" were the darlings of the tobacco executives. Tobacco industry documents clearly show that their role was to obfuscate issues surrounding the harmful effects of ETS and ultimately be used as a blunt instrument in Philip Morris' fight with the tobacco control movement.⁽⁶⁾

But probably the most disturbing aspect of PMERP's goals is not so much of what is said, but of what is not said. There is not one word about tobacco use being the number one preventable killer of human beings around the world. No mention that tobacco use is responsible for more than 400,000 deaths per year alone in the United States.⁽⁷⁾ Researchers should question whether the goal of the PMERP to improve the public's health, or whether the goal of this program to advance the economic, political and scientific interests of Phillip Morris, the premier cigarette producer on the planet.

Jack Henningfield, in a personal correspondence, summed up the PMERP this way: "Can a meaningful research program to reduce the known health damage of tobacco be conceived without acknowledging that tobacco causes dependence, disease and death?"⁽⁸⁾

Scientific Legitimacy and Cover, PMERP's Real Goal

The principal reason for the establishment of the PMERP is for Philip Morris to gain scientific legitimacy that serves as a cover for their continued marketing and selling of disease and death around the planet. As an appendix to PMERP's call for applications, there are of over 100 scientists listed as potential peer-reviewers. Many

See "Fig Leaf" page 9

Exclusionary

invoked by TCS is retroactive, as it excludes any applicant who has received funds from the tobacco industry for the past five years. With respect to research on the health effects of tobacco use, such discounting of the contributions of past peer-reviewed studies – and the condemnation of researchers conducting said research based on their association with CIAR – amounts to throwing the baby out with the bathwater. True, based on CIAR's history, it is highly unlikely that the PMERP will be an unbiased or problem-free source of support for future research on tobacco's health effects. Nevertheless, what advantage is gained for tobacco control by taking a punitive (and retroactive) approach against CIAR researchers or peer reviewers who may not have known the extent of manipulative action on the industry's part?

Unfortunately, with respect to the PMERP, researchers who are otherwise strapped for funding may legitimately ask: if Phillip Morris is going to provide money for research (as opposed to advertising or distribution of their products), why shouldn't scientists use it to conduct worthwhile studies on tobacco health effects? It is also clear that there will always be those who, regardless of the source, will accept any funds to maintain their research endeavors. However, there is a distinction between a prospective position designed to inform and encourage divestiture from industry funding and a retrospective, punitive policy that employs condemnation by association – how would you prefer to be approached?

Wedge politics and unforeseen consequences

Even when a position or policy may be clear, the form in which it is communicated ultimately shapes its effectiveness. Recently, a tobacco control group undertook a strategy that serves to illustrate how confrontational approaches can lead to unintended results. This action, initiated by Essential Action's Global Partnership for Tobacco Control (based in Washington, D.C.), was framed as an "educational" telephone and letter writing campaign that targeted those scientists whose names had appeared on a list of potential reviewers for PMERP. Let-

ter writers were requested to be "courteous and polite"; however, they were also instructed to convey how such peer review service was "naïve" and "damaged [the reviewer's] reputation as a researcher." The targeted individuals were also pejoratively referred to as "tobacco industry hires."⁽³⁾ In addition to the letter writing campaign, Essential Action also created a mass email drive by incorporating the email addresses of PMERP reviewers and Scientific Advisory Board members (without their knowledge or consent) into a listserve.

This campaign initiated a wide spectrum of responses from the targeted audience: as of the publication deadline for this article, most had ignored it altogether, but some of those individuals contacted expressed appreciation on being informed about the larger issues involved and agreed to resign as PMERP peer reviewers. However, some of those contacted viewed the campaign as a hate mail drive (or email "spam attack"). (Correspondence between Essential Action and targeted scientists is archived at www.essentialaction.org/tobacco/action/pmpr/phone.html).

This potentially alienated some scientists who might otherwise be allies in the cause. Subsequent to Essential Action's campaign, as TRDRP has inquired with scientists about the possibility of reviewing grants, at least one of the targeted researchers expressed reluctance to work with TRDRP, citing a concern about having any involvement in tobacco health research. Was Essential Action's campaign effective at "raising the consciousness" of PMERP peer reviewers? Perhaps. Unfortunately, it was also perceived by some to be similar to the harassment tactics employed by groups (e.g., animal rights activists) who are opposed to biomedical research in general. Ultimately, the polarizing nature of such political actions can result in an "us vs. them" mentality that neither enables an appreciation of the problem across the broad spectrum of public health researchers, nor addresses the long-term issue of countering the dissemination of "disinformation" by the tobacco industry. Clearly, any policy that TRDRP might impose would have to evaluate the pros and cons of both the immediate outcome and how our stakeholders would perceive such a policy.

What makes for an effective position or policy?

Funding agencies and political action groups have different missions and stakeholders, so strategies that work well for political activism may be contrary for administering public health research. It is the author's opinion that public health programs should avoid the politicization of their funding process; in other words, funding decisions should be based on priorities and scientific merit rather than political considerations. Ultimately, the "double-edged sword" of incorporating a political process into funding research on tobacco control and tobacco-related disease could have repercussions beyond the immediate gains of handicapping the PMERP. Alternatively, the following points should be considered during the debate on whether TRDRP should establish a position or policy on applicants receiving tobacco industry support:

(1) If TRDRP, or any funding agency, is to take either a position that discourages its stakeholders from pursuing tobacco industry funding (or a policy preventing such), it should envelop a broad approach that covers all forms of industry support, either direct or via satellite organizations or subsidiaries. Narrowly focused policies that target one area both ignore the larger problem and serve to further divide the tobacco control movement.

(2) Attempts to educate researchers by addressing the problem from their perspective will be far more effective than campaigns that can be perceived as harassment or as being anti-science. Most researchers who have either received funds from or served as reviewers for the CIAR may be unaware that Phillip Morris used such programs (and will use PMERP) to camouflage non-peer-reviewed research under a patina of legitimacy. An educational campaign to broadcast the deceptive tactics employed by Phillip Morris would be far more encouraging and definitely less polarizing, as opposed to one designed to condemn researchers who, from their perspective, are performing a professional courtesy (much like peer reviewing for journals). Identifying the scientific concerns behind Phillip Morris' attempt to support "legitimate" research (e.g., the simultaneous funding of "special" projects

Fox

Too Bad It Is Not The End - A Leopard Can Not Change Its Spots

For the year 2000, after almost 50 years of tobacco industry's fronts (TIRC/CTR, ICIAR, and CIAR) created to carry out a very successful strategic public relations campaign to help fight its legal and legislative challenges, Philip Morris has established and funded the PMERP. The similarities between the PMERP and its predecessor (CIAR) clearly point to the continued practice by the tobacco industry in abducting the scientific process and dis-course for its benefit. Given the changes in the war on tobacco after the MSA, the creation of the PMERP needs to be looked at from a broader perspective that includes,

but not limited to, a strategic public relations campaign with science as its tool (*see article on Philip Morris, page 7*). In the case of PMERP, it is hard to believe that Philip Morris has changed its spots.

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Fig Leaf

of the researchers are well published in their respected fields. Additionally, most of these scientists are from well-known universities and research institutions. Harvard, University of California, University of Michigan, John Hopkins, the US EPA, Brookhaven National Laboratory and the NIH along with many others has employees participating in this endeavor.⁽²⁾ Printing the scientists with the names of their institutions is done to give the illusion that the tobacco industry is involved in meaningful scientific collaboration.

While the before-mentioned institutions and many of the identified scientists don't subscribe to the intentions and/or views of the PMERP and the tobacco industry, still their association (however unintentional) lends credibility to these industry's endeavors. The tobacco industry says 'see, we have many of the leading members in the scientific communities working with us, we can not be all that bad'. The problem with this line of argumentation is that while PMERP is portraying itself as an equal partner in the pursuit of science, the reality is that the tobacco industry has historically used scientific research to confuse and distract the public from the underlying negative health consequences of their product. While PMERP is providing a scientific "photo op" for Philip Morris, the tobacco industry con-

tinues to sell products that are addictive, lead to serious disease, and in most cases cause premature death. Frankly, the funding of scientific endeavors to tease out the deadly processes involved in smoking and second hand smoke appears to be the last thing on Philip Morris' mind.

There are other curious issues surrounding the listing of scientists by PMERP. Most funding agencies don't publish their list of reviewers beforehand. Unlike the National Institutes of Health (NIH), where standing study section participants are listed as definite reviewers, PMERP list represents only *potential* reviewers at best. Moreover, some the researchers listed have publicly acknowledged that they were never asked if they would be peer reviewers.⁽⁹⁾ Additionally, as distinct from the TRDRP, where a list of scientists who have actually reviewed the applications are posted for public scrutiny following each grant cycle, PMERP makes no mention of this possibility. The conclusion is inescapable: PMERP is blatantly projecting the good image of renowned scientists and institutions as a front for it's continued marketing and sales of disease and death.

PMERP: Part of the Post-MSA Offensive of the Tobacco Industry

In the hubbub that has surrounded the emergence of the PMERP, a central tenet has been lost. PMERP is but one tactic

within the general offensive of the Master Settlement Agreement (MSA) era to reposition the tobacco industry as a kinder and gently, albeit profitable, conveyor of disease and death.

The MSA gave \$206 billion to the States to end most lawsuits against the industry. With one stroke, the tobacco industry began to right its corporate ship and keep at bay even larger and more damaging lawsuits looming on the horizon. Simultaneously, the industry wrapped itself in a "new and softer" coat. Unfortunately, we have all become much too aware of and perhaps nauseated with the "new" socially responsible tobacco company: "*Working to make a difference. The people at Philip Morris.*" Through an aggressive \$150 million dollar year ad campaign⁽¹⁰⁾, PM and its subsidiaries now want us to believe that they are the champions of battered women, poor African Americans, the homeless, flood victims and the shut-in. Italian love songs? *Give me a break!*

Additionally, the post-MSA Philip Morris wants to promote itself as a fighter against youth smoking. CARD, the youth anti-smoking campaign launched by PM and adopted by some retailers to check the identification of teens before selling them tobacco products, mainly has served the purpose to get Phillip Morris back on television. Moreover, industry marketers know that saying that your product is restricted to adults is a sure-fire way to attract teens.

Fig Leaf

PM and other tobacco companies have established web-sites to make themselves and their product more accessible to the public. In fact, PM has gone so far as to admit that smoking is hazardous to your health. But, clearly, the tobacco industry has drawn a new line in the sand. While they are ready to admit (after 50 years of lying and denial) that smoking can be harmful, the tobacco industry will not admit to the fact that second hand smoke is also a serious health hazard. Rather, they would like the world to believe that side stream smoke from a cigarette is just an irritant. It is within this latter context that we must locate the role of the PMERP.

I suspect that PMERP will fund "special projects" in an attempt to keep alive any and all controversies surrounding the health effects of second hand smoke. Research into "other" air pollutants will be investigated, the lack of causal models will be trumpeted and additional ammunition against indoor smoking restrictions will be sought- the same role-played by its predecessor, the CIAR. This is just speculation; maybe PMERP will prove me wrong.

What is to be Done?

I would strongly encourage funding agencies to adopt a broad-based educational campaign to expose the treachery of the tobacco industry. Through newsletter articles, letters-to-editor, and joining with other groups for common cause funding agencies, including TRDRP, should take the lead in warning researchers and reviewers about the pitfalls of involving themselves with tobacco industry money. They could identify tobacco-related disease scientists and tobacco control advocates who are prepared to speak out against the PMERP. These individuals should be encouraged to write articles, editorials and op-ed pieces. Potentially, TRDRP's *Burning Issues* could sponsor a forum and host a public speak-out on the subject. Minimally, those in the tobacco research arena should discuss this matter with their peers and encourage them to shun tobacco industry funding.

I am of the opinion that following an aggressive educational campaign, like the one outlined above, funding agencies

should restrict support of scientists who maintain funding from the tobacco industry, prospectively as opposed to retrospectively. It is my sense that most researchers will choose the high road and renounce any and all affiliation with the tobacco industry. I believe that most scientists will see through the veneer; the people at Philip Morris are not part of the public health solution, rather they are a large part of the public health problem. The more scientists who refuse to collaborate with PMERP the smaller and smaller their fig leaf becomes.

I recognize that securing funding is always hard, still reliance on tobacco industry funding is not necessary. Biomedical researchers, Epidemiologists, Behavioral Scientists, Health Policy researchers and Community smoking prevention evaluators have other sources to draw on: NIH, NCI, TRDRP, Robert Wood Johnson Foundation, National Science Foundation, American Legacy Foundation, Colorado Tobacco Research Program, Minnesota (MPAAT), National Cancer Society, American Lung Association, American Heart Association, just to mention a few.

I am sure that some in the research community will think that this suggestion is a bit drastic. I would simply respond that drastic circumstances require drastic measures. The tobacco industry should not be able to buy its way out of responsibility for killing over 400,000 people per year, and that is just in the United States! Let's remove the fig leaf all together and expose the tobacco industry for what they truly are: the largest dealers of deadly drugs in the world. Industry sponsored research has historical been at the service of the industry, nothing more, nothing less. Apart from a fraction of the research funded by the CIAR, the 50 year history of tobacco sponsored research is dismal at best and predatory at worst.

Ultimately, researchers (and all people) have to take responsibility for their actions. Don't give shelter to the tobacco industry by letting them use your good name. Scientists must be aware that accepting funding from the number one killer in the world, regardless of the potential good, essentially promotes the interests of the tobacco industry and helps perpetuate their goal of selling disease and death, pure and simple.

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Exclusionary

under the guise of peer-review; redirecting the focus of indoor air quality away from health concerns directly attributable to secondhand smoke) will be far more effective in accomplishing the objective of minimizing the tobacco industry's influence on health-based research.

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TRDRP Highlights



The TRDRP AIM 2000 Plenary Panel l-r: Susanne Hildebrand-Zanki, Moderator; Greg Connolly, Peggy Reynolds and Theodore Slotkin.

Environmental Tobacco Smoke: Dying Without Trying? - AIM 2000

On November 30–December 1, 2000, TRDRP convened its fifth Annual Investigator Meeting (AIM 2000) with the theme, **Environmental Tobacco Smoke: Dying Without Trying?**. Over 400 attended, a record number. Building on the positive experience of AIM 99, the conference started off with workshops organized this year by the Western States Affiliate of the American Heart Association, the American Cancer Society – California Division, the Tobacco Control Section of California's Department of Health Services, and a number of TRDRP-funded neuroscientists.

The conference continued on the second day with the plenary session addressing the biology, epidemiology, and policy aspects of ETS. **Theodore Slotkin, Ph.D.**, from Duke University reported on his research findings in a presentation entitled "Tobacco, Nicotine, and Fetal Brain Damage: The Smoking gun in ADHD and SIDS", where he discussed some of the probable mechanisms by which exposure to nicotine causes fetal brain damage and the resulting adverse consequences. **Peggy Reynolds, Ph.D.**, of the California Department of Health Services gave a presentation on "ETS and Lung Cancer: The Epidemiologic Evidence" in which she highlighted studies showing the link between ETS and lung cancer in non-smokers. **Greg Connolly, DMD, MPH** of Massachusetts Tobacco Control Program presented information about efforts in Massachusetts to use the link between ETS and adverse health effects for decisive public policy measures, including requiring the listing of ingredients on cigarette packages. Audiotapes of these

plenary speakers are available from TRDRP.

In scientific poster sessions that followed lunch, TRDRP-funded investigators presented their latest findings on many tobacco use issues, including cancer, heart disease, prevention, lung disease, nicotine dependence, policy research, epidemiological studies, health effects on women and infants, and secondhand smoke exposure.

For those of you who attended the conference and were curious about the artwork on the program cover – it was created through a collaboration of two famous poster artists, **Wayne Healy** from the US and **Tomasz Sarnecki** from Poland for an exhibition at the Gene Autry Museum in Los Angeles, CA.

The 2001 Review Cycle

TRDRP has received applications for the 10th funding cycle. During March, April, and May, we will conduct 10 study sections. Funding decisions will be made in early June. Approximately \$21 million is available for new awards. The program's research priorities and award mechanisms have not changed significantly from 2000.

The newly created Colorado Tobacco Research Program (CTRP) has asked TRDRP to conduct the peer review of CTRP's applications. CTRP's first year budget is approximately \$4.5 million and the program must make its first round of awards by June 30, 2001. Since CTRP has adopted TRDRP's research priorities and is using some of TRDRP's award mechanisms, TRDRP

is ideally positioned to conduct the peer review for CTRP. While CTRP applications will be reviewed by TRDRP study sections, they will not be part of the TRDRP funding model and they will not influence funding decisions for California applications.

TRDRP's Budget Declines

The Governor's budget released on January 10, 2001 again contains funding for the DHS Cancer Registry of \$3.2 million above the \$1.7 million appropriated for this agency from the Research Account in the past. This redirection of funds effectively reduces the TRDRP budget from \$23.221 million to \$20.021 million, a 14% decrease. Last year, which marked the first time the Research Account was used to supplement funding for the registry, the additional amount for the registry came to \$3.55 million, which equated to a 16% cut for TRDRP. TRDRP is extremely concerned that its mission is being compromised by these diversions and that alternative funding sources for the registry must be identified.

New Members on the Scientific Advisory Committee (SAC)

Three new members have joined TRDRP's SAC. The new representative from the University of California, San Diego is **Lewis Rubin, M.D.**, Director of the Division of Pulmonary and Critical Care Medicine at the UCSD School of Medicine. **Janis Jackson, M.D.** is an Assistant Professor in the Department of Immunology at The Scripps Research Institute, representing biomedical scientists. **Kathy Sanders-Phillips, Ph.D.**, is a visiting faculty member at the University of California, Berkeley, representing behavioral scientists.

Annual Report 2000

TRDRP's annual report to the legislature for the calendar year 2000 is now available. Breaking our long-standing tradition of mailing the report to the several thousand TRDRP stakeholders, we will make the report available on our website and only send hardcopies upon request.

Note: All TRDRP publications can be found at our website:

www.ucop.edu/srphone/trdrp



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The Tobacco-Related Disease Research Program (TRDRP) supports innovative and creative research that will reduce the human and economic cost of tobacco-related diseases in California and elsewhere.

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92nd Annual Meeting of the American
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New Orleans, LA

MAY 18-23

American Thoracic Society
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MAY 30 -31

Smoke Free Air for Everyone Everywhere
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