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Old ways, new means: Tobacco industry funding of academic and private sector scientists since the Master Settlement Agreement

Short title: Post-MSA funding of academic scientists

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ABSTRACT

Background: When, as a condition of the Master Settlement Agreement in 1998, US tobacco companies disbanded the Council for Tobacco Research and the Center for Indoor Air Research, they lost a vital connection to scientists in academia and the private sector.

Objective: To investigate two new research projects funded by US tobacco companies.

Methods: Analysis of internal tobacco industry documents now available at the University of California San Francisco Legacy tobacco documents library, other websites and to the open scientific literature.

Results: Since the MSA, individual US tobacco companies have replaced their industry-wide collaborative granting organizations with new, individual research programs. Philip Morris has funded a directed research project through the nonprofit Life Sciences Research Office, and British American Tobacco and its US subsidiary Brown and Williamson have funded the nonprofit Institute for Science and Health. Both of these organizations have downplayed or concealed their true level of involvement with the tobacco industry. Both organizations have key members with significant and long-standing financial relationships with the tobacco industry.

Conclusion: Regulatory officials and policy makers need to be aware that the studies these groups publish may not be as "independent" as they seem.

INTRODUCTION

Many individuals and institutions, particularly in the scientific community, choose not to accept funding from the tobacco industry [1-4]. Historically the industry's reasons for funding publishable external scientific research have included building public credibility[5-7], developing industry-friendly experts to represent them in litigation and the regulatory process [8-11] and creating controversy about the health risks of active and passive smoking [7, 9-14]. Until 1998, almost all tobacco industry funding for academic scientists came through the industry's Council for Tobacco Research (CTR) and the Center for Indoor Air Research (CIAR). These two organizations played a central role in the fraud alleged by the lawsuits brought against the tobacco industry in the 1990's. In the Master Settlement Agreement (MSA) in 1998, the tobacco companies agreed to disband the CTR and CIAR and cease sponsoring research through industry-wide groups [15].

When the MSA forced the US tobacco companies to act independently of one another, they were left with three alternative strategies, listed in a memo to Philip Morris Vice President Denise Keane by consultant Jim Tozzi [16]:

1. establish a new program within the individual company;
2. join the efforts of an existing group;
3. establish a new organizational structure outside of the company.

The Philip Morris External Research Program (PMERP) [17, 18] is an example of a new organizational structure established outside of the company. The symposium series on inhalation toxicology funded through the International Life Sciences Institute (ILSI) by Philip Morris and RJ Reynolds [19] is an example of joining the efforts of an existing

group. We describe two new industry-funded research projects: Phillip Morris' research projects on cigarette additives and reduced-risk products through the Life Sciences Research Office (LSRO) and the Institute for Science and Health (IFSH).

METHODS

We located the documents cited in this paper by searching the 45 million pages of tobacco industry documents made public as a result of litigation against the tobacco companies. Between May 2005 and October 2006, we searched the UCSF Legacy Tobacco Documents Library http://www.legacy.library.ucsf.edu and Tobacco Documents Online http://www.tobaccodocuments.org, using standard strategies, [20] starting with keywords such as "IFSH", "LSRO", and "external research". The initial searches yielded names of projects, research institutions and researchers, which were then searched. We also read the websites of the Life Sciences Research Office http://www.lsro.org and the Institute for Science and Health http://www.ifsh.org and contacted these organizations to ask questions that were not answered on the websites. We found the IFSH Internal Revenue Service 990 forms on http://www.guidestar.org.

RESULTS

Life Sciences Research Office (LSRO)

The Life Sciences Research Office (LSRO) was established in 1962 by the Federation of American Societies for Experimental Biology (FASEB) to provide expert opinion on by medical issues for the US Army[21] and incorporated as an independent nonprofit research organization in 2001[22]. Philip Morris contracted with the Life Sciences Research Office, to conduct reviews of and public meetings on cigarette additives and of the methods necessary to assess "potential reduced risk tobacco

products" [23]. Tobacco industry scientists are invited speakers and observers at many of the meetings [24-30]. The end product of this process, a series of book-length reports, the first two of which ("Evaluation of Cigarette Ingredients: Feasibility" [31] and "Evaluation of Cigarette Ingredients: Scientific Criteria" [32]), were available for sale on the LSRO web site as of September 2006 [33]. Philip Morris Worldwide Scientific Affairs' intention for this project was to "Provide a framework for cigarette ingredient review that can become a model for regulatory bodies" [34]. In general, Phillip Morris intended the projects with LSRO to meet the goals of the 2002 Institute of Medicine Report "Clearing the Smoke: Assessing the Science Based for Tobacco Harm Reduction"[35].

In their descriptions of these projects on their website (accessed in 2006) [23, 36] the LSRO states, "In order to preserve the third-party independence of the review, PM will have no role in the design, conduct, deliberations, or the conclusions of the committees/panels. … All private communications between PM and LSRO will be restricted to authorized individuals and will be logged. Private communication between PM and members of the expert panels/expert committees is prohibited." However, Philip Morris appears to have had more input into the LSRO process than LSRO's web site description would suggest.

In his initial letter to Philip Morris, outlining the way in which the LSRO would do the proposed cigarette additives project, LSRO director Michael Falk stated that "Expert Review Panel members will be selected for their scientific credentials, absence of bias and conflict of interest, active participation in the field, open mindedness, and willingness to devote the necessary time.[37]" The LSRO received and even solicited input from Philip Morris to determine the membership of the panel. A memo from PM

scientist Edward Carmines to fellow members of the Worldwide Scientific Affairs Department states:

> Attached please find a list of people LSRO is talking to for the SAB [probably the expert panel, since there was no additional scientific advisory board]. They are now evaluating potential conflicts of interest on each of these individuals. Let me know if you have any specific concerns about any of the candidates. I need documentation to provide LSRO with if we feel an individual is not qualified or is biased against the industry.[38]

Later the LSRO appears to have asked PM to suggest an epidemiologist and a cardiovascular toxicologist[39]. This level of involvement in choosing the membership of the expert panel on cigarette additives stands in clear contrast to the LSRO's public statement that Phillip Morris would have no role in the design of the committees.

The prohibition of private communication between Phillip Morris and members of the expert panels also appears to have been interpreted in a way that would benefit Philip Morris. In a series of e-mails in December 2001, PM scientist George Patskan asked what the sentence "Private communication between PM and members of the expert panels will be prohibited" [40] meant, Carmines replied "I spoke to the LSRO and they do not see a need for clarification. We are restricted from discussing issues with the Board relating only to the charge of the committee. We can use them for other issues.[41]"

The cigarette additives project had a single expert panel. The reduced risk project had a "core committee" that integrated the findings of smaller, topic-specific expert panels. The membership of the cigarette additives expert panel and the reduced risk core committee included many individuals who have financial ties to the US tobacco industry, including Phillip Morris (Table 1). Seven of the 15 panel and committee members have documented direct financial relationships with the tobacco industry and two more have

indirect or non-financial relationships. Thomas Slaga was awarded a PMERP grant in May 2001[42] and Emmanuel Rubin was an expert witness for Philip Morris on at least 2 occasions (Table1).

Table 1: Tobacco industry relationships of LSRO Cigarette Additives Panel and Reduced Risk Core Committee members					
Name	Committee membership	Profession and employers	Relationships with Tobacco Industry	Published with tobacco company personnel?	Pubmed citations on tobacco or cigarette smoke as of Sept 2006
Alwynelle S. Ahl	Cigarette additives (last 2 meetings thru end of project) Reduced risk	Veterinarian Highland Rim Research Organization USDA Tuskegee University	None	No	No
Carroll E. Cross	Cigarette additives Reduced risk	Physician/pulmonologist UC Davis	1970-1977 CTR grant [43-47]	No	28
Donald Gardner	Cigarette additives Reduced risk	Toxicologist US EPA Northrop/Mantech Corp. Editor of journal *Inhalation Toxicology*	2000 Consultant (Lorillard)[48, 49] 1999 Member of Eclipse Report Expert Panel (RJR)[50] 1988 Expert witness (Lorillard)[51] 1987 Applied for position of Executive Director of CIAR[52]	Yes[50]	No
Shayne C. Gad	Cigarette additives Reduced risk	Toxicologist Gad Consulting Services (founder/principal)	None	No	No

		Becton Dickinson Co. G.D. Searle Co. Allied Corp.			
Louis D. Homer	Cigarette additives Reduced risk	Physiologist Legacy Research US Naval Medical Research Institute	None	No	No
Emanuel Rubin	Cigarette additives Reduced risk	Pathologist Thomas Jefferson University Hahnemann University Mt. Sinai Medical School/Hospital	2000 Expert witness (all US tobacco companies except Liggett) [53] 2000 Expert witness (PM) [54] 1997 Expert witness (Lorillard) [55] 1996 Expert witness (Liggett)[56] 1991 Expert witness (PM)[57]	No	No
Rudolph Jaeger	Cigarette additives	Toxicologist Environmental medicine Inc. New York University CH Technologies (founder/principal)	1999 Member of Eclipse Report Expert Panel on CO (RJR)[50] 1995-1996 Consultant (RJR)[58, 59] 1994 Equipment sales (PM)[60] 1987-90 Consultant (RJR)[61]	Yes[50]	No
Robert Orth	Cigarette additives	Chemist Apis Discoveries	None	No	No

		(founder/principal) Monsanto Co. University of Missouri			
Resha Putzrath	Cigarette additives (withdrew from project mid-2003)	Physiologist/biophysicist Georgetown Risk Group (founder/principal) Johns Hopkins University Organization Resources Counselors Inc. Environ Corp. US National Institutes of Health	None	No	1
James L. Schardein	Cigarette additives	Toxicologist WIL Research Labs MPI Research/International Research and Development Corp.	1996 MPI performed animal toxicology tests (Lorillard)[62] 1979-1988 IBD/MPI performed animal toxicology tests (PM)[63-66]	No	No
Thomas J. Slaga	Cigarette Additives	Physiologist/Biophysicist AMC Cancer Research Center, University of Colorado University of Texas Oak Ridge National Laboratories	2001 PMERP research grant[42, 67] 1999 Member of Eclipse Report Expert Panel (RJR)[68] 1987-1994 Consultant (RJR)[69-72] 1978 ORNL had CTR contract[73]	Yes[50]	3
Elizabeth Anderson	Reduced risk	Chemist Exponent Health	2000 SI report on phosphine (RJR) [74, 75] 1998 SI wrote CIAR	No	1

		Sciences International (SI) (founder/principal) US EPA	monograph 1996[76]		
Nancy L. Buc	Reduced risk	Lawyer Buc Levitt and Beardsley US FDA	1995-present Buc Levitt and Beardsley do pro bono work for the Washington Legal Foundation, a nonprofit supported partly by tobacco company donations that litigates against government regulation of tobacco[77]	No	No
Joseph Rodricks	Reduced Risk	Biochemist Environ Corp. (founder/principal)	1986-1989 Consultant (RJR)[78, 79]	No	No
Richard Schwing	Reduced Risk	Risk Analyst General Motors Corp.	1992 Informal (unpaid) consultant (PM)[80, 81]	No	1
Richard Windsor	Reduced Risk	Public Health Educator	None	No	14

Institute for Science and Health (IFSH)

The Institute for Science and Health (IFSH) is a nonprofit organization created in 2001 that "secures and administers grants for under-funded, under-researched health issues affecting at-risk populations, by forging meaningful collaboration with world-class organizations" [82] in eight program areas: tobacco science and health, gastrointestinal disease, neurodegenerative disorders, diseases from airborne contaminants, youth health and development, blood based diseases, degenerative eye diseases and environmental causes of illness [83]. Between October, 2001 and September, 2004, IFSH received $9.5 million and spent $3.0 million on their programs [84-86]. The vast majority of this money went to tobacco-related research.

The IFSH has sponsored four symposia on tobacco: "Forum on Tobacco Science and Health Policy" (St. Louis Missouri, 2001 [83]), "Perceptions and Realities in Funding Health Research Related to Lifestyle Factors Underlying Human Disease in the 21st-century" (Prague, Czechoslovakia, 2004 [83]), "Biomarkers of Harm, Tobacco Toxicity, and Emerging Cancer Patterns and Etiology" (St. Louis, Missouri, 2005[83]) and "Tobacco Harm Reduction and Perception of Risk" (Vienna, Austria, 2006[87]). A symposium on pancreatic cancer is planned for 2006 [88]. Transcripts of the first two tobacco forums and an abstract list from the third were available on the IFSH web site, but as of September 2006, we found no publications from these forums on PubMed, Google or Yahoo, searching the titles of the symposia.

From 2002 to 2004, the IFSH granted $3.9 million to academic scientists studying biomarkers of tobacco smoke exposure and harm, tobacco harm reduction, and tobacco

constituent toxicity [83, 89-91]. (Some of the grants are multi-year, so this figure does not match with program expenditures reported to the Internal Revenue Service.) The IFSH also owns and, until 2006, provided online access to a collection of over 510,000 citations on smoking and health [92]. The cost for managing the citation database was itemized separately in only the 2001 and 2002 reports to the IRS, equaling $670,673 between October 2001 and September 2003 [84, 85]

Of the eight IFSH program initiatives, six (neurodegenerative disorders, diseases from airborne contaminants, youth health and development, blood based diseases, degenerative eye diseases and environmental causes of illness) report no activity. In financial years 2001 and 2002, Gastrointestinal Diseases received 1.4% of the total program services outlay. Program services outlays were not itemized in fiscal year 2003. In 2005 the Gastrointestinal Diseases program initiative made its first research grants for pancreatic cancer: two one-year grants [90] totaling $120,000 [93].

The donor lists for all IFSH program initiatives include "anonymous private donations" and "IFSH General fund." The tobacco science and health initiative lists two additional sources of support: British-American Tobacco (BAT) and Brown and Williamson Tobacco (the former US subsidiary of BAT, which subsequently merged with RJ Reynolds). The gastrointestinal diseases initiative lists eight other sources of support: the Ann E. McEnroe Pancreatic Cancer Research Fund Program (in honor of the IFSH president's late wife), the Debbie Ketterer Memorial Tribute Fund (in honor of a board member's late wife) and six small IFSH fundraisers [82, 94-97] that raised an average of $16,683 each [95-97]. Thus, it appears that the majority of the $9.5 million donated to

IFSH between 2001 and 2004 was earmarked for the tobacco science initiative or general operating expenses.

Of the 17 Tobacco Science and Health grants awarded and documented as of September 2006, 15 funded research on biomarkers, 1 on potential reduced exposure products, and one 1 on chemopreventive agents for esophagageal cancer [89-91]. The chemoprevention research grant was from a fund separate from the other tobacco science grants: the Dietrich Hoffmann Career Development Award, and provided one year of support at $40,000 [94].

Like LSRO, the IFSH presents itself as "independent;" as of 2005 its website stated

> The Institute is independent, a critical factor in maintaining the credibility and integrity of research. A proprietary process is used to manage the overall research process. This process creates a firewall between the Institute's sponsors and the researchers to whom the Institute supplies grant funding. [98]

Likewise, the Request for Applications states:

> The Institute's Board of Directors and the respective Advisory Council consider all offers of support before an offer of support is accepted. The Institute's criteria for accepting grants from a given grantor require that the Institute's credibility can be insured, so that the Institute can function completely independently of the grantor, for example, through unrestricted grants. The Institute, in turn, makes grants to external organizations and individuals [93].

The grant from BAT and Brown and Williamson is described as "unrestricted" in the Tobacco Science and Health Request for Applications[99]. The Tobacco Science and Health Advisory Council reviews the proposals received, selects proposals to be

reviewed, chooses the 3 outside reviewers each is sent to and then decides which proposals to fund [93, 100]

While there is no obvious direct involvement of the tobacco industry in the granting process at IFSH, 7 of the 10 scientists on the Council had documented direct financial relationships with the tobacco industry. (Table 2) Roger Jenkins, who had been funded almost continuously by the tobacco industry between 1992 and 2006 (the time this paper was written), was a consultant to Brown and Williamson the year before he was appointed to the IFSH Tobacco Science and Health Advisory Board[101-103]. Jenkins was appointed to the IFSH Board of Directors in 2004, and served on both the Board of Directors and the Tobacco Science and Health Advisory Board as of September 2006[104, 105]. (Table 2).

Table 2. Tobacco industry relationships of IFSH Tobacco Science and Health Advisory Council members				
Name	Profession Employers	First financial relationship	Published with tobacco company personnel?	Pubmed citations on tobacco or cigarette smoke as of Sept 2006
Roger Jenkins[a]	Chemist Oak Ridge National Laboratories (ORNL)	2004 PMERP grant to ORNL[106] 2001 Consultant to Brown and Williamson [101, 103] 2000 ETS survey of corp. headquarters (Lorillard)[107] 2000 Instrument validation (PM) [108] 1992-1999 16-Cities study (CIAR/RJR/ORNL)[109, 110] 1994 OSHA presentation (CIAR/ORNL/RJR) 1987-1990 Develop personal air sampler (CIAR)[111-113] 1985 Clove cigarette analysis (RJR)[114] 1976 [115]	No	21
John Gorrod	Chemist University of Essex, UK University of London, UK	1998 Paid visit to PM Research Center[116] 1997 Edited monograph on nicotine metabolism (PM) [117-119] 1993 Grant (PM/FTR)[120] 1992 Paid visit to INBIFO[121] 1989-1994 Postdoctoral fellowships (PM)[122, 123]	No	5

		1987 Paid visit to INBIFO[124] 1975-1978 CTR grant [45, 125, 126]		
Elmar Richter	Veterinarian Ludwig Maximilians Universitaet, Munich	1999 Grant (PM/FTR) [127] 1994 Grant (PM/FTR) [128-130]	Yes [131-135]	31
Dietrich Hoffmann	Chemist American Health Foundation (AHF) Sloane Kettering Inst.	1961-1987 both AHF and the Sloane Kettering Inst received tobacco industry funding for Hoffmann's research[136]	No	203
Karl O. Fagerstrom	Behavioral Psychologist Fagerstrom Consulting (founder/principal) Pharmacia Corp. University of Uppsala, Sweden	2002 Consultant (Swedish Match) [137]	No	44
Stephen Rennard	Pulmonologist University of Nebraska Medical Center	1997-98 Grant to test Eclipse cigarette (RJR)[138]	No	40
Heidi Foth	Toxicologist Halle-Wittenberg University, Germany University of	1991 Speaker at INBIFO [139, 140]	No	40

	Goettingen, Germany			
Marie Stiborova	Biochemist Charles University, Czechoslovakia	None	No	No
Paula Knudson	Certified IRB Professional University of Texas	None	No	No
Alan J. Paine	Toxicologist King's College, London UK Department of Health Toxicology Unit	None	No	No
[a]Roger Jenkins is also a member of the IFSH Board of Directors				

Donors and applicants to the other program initiatives at IFSH may not know that the majority of the funds the IFSH administers go to research on tobacco. Brown and Williamson and BAT are not listed on the home page or the IFSH promotional video on the home page. The 10 minute video describes IFSH's mission as "to be involved in orphan diseases" and lists Graves' disease, retinitis pigmentosa, Guillain-Barré Syndrome, torticollis, neurodegenerative disorders, amlyotrophic lateral sclerosis, ADHD, Krabbe disease, pancreatic cancer, cerebral palsy, macular degeneration, multiple sclerosis, lupus, Tourette syndrome tuberculosis, and diseases from airborne contaminants [141]. Two slides, titled "Adult Current Smoking among Women" and "Adult Current Smoking by Age Group & Year" are on the screen for three seconds while a grantee praises the Institute's support for innovative research [141]. The only discussion of tobacco is when the narrator says, "Before Ann McEnroe was even diagnosed [with pancreatic cancer], the Institute was supporting innovative and extremely necessary work to prevent disease: early diagnosis, risk factors, diet, *smoking* (emphasis added), environmental conditions affecting the health and well-being of everyone" [141]. The focus, in their video, on pancreatic cancer and the diseases that IFSH *hopes* to fund, combined with the omission of discussion the significant body of research it already *has* funded, minimizes the role of funding from Brown and Williamson in their affairs.

DISCUSSION

When the US tobacco companies signed the MSA, they lost one of their primary economic and social relationships with scientists in academia. Since the 1930s, the US tobacco industry has recognized the strategic and financial importance of positive relationships with scientists, universities, journals and scientific societies [5]. Funding

academic scientists via the CTR and CIAR allowed the industry to obtain supportive publicity [6, 7], recruit "outside" scientists to serve as industry witnesses in lawsuits and regulatory forums [8-10] and, ultimately, create false controversy about the science that shows smoking and secondhand smoke are dangerous [7-14]. The CTR and CIAR were publicly represented as independent, while in fact both were closely controlled by industry scientists and lawyers [7, 110, 142].

The LSRO and IFSH are not exactly the same as the CTR and CIAR, but they do continue many of their functions. Both provide opportunities for professional and social interaction between industry personnel and academic researchers that may help the industry identify and recruit future witnesses and consultants, the LSRO through its meetings [25, 143, 144] and the IFSH through its conferences[145, 146, 147]. The LSRO's interpretation of the contract to prohibit only private communication between LSRO panel and committee members and tobacco industry employees regarding committee business would permit such recruitment.

Both the IFSH and the LSRO also obscure the true extent of tobacco industry involvement in their affairs. The Philip Morris LSRO project [23] makes explicit claims of independence [148] that are contradicted by the internal tobacco industry correspondence indicating that the LSRO gave Philip Morris a chance to suggest potential panel members[39] and at least to comment on the potential members of the LSRO scientific panels[38]. 54% of the Cigarette Additives Expert Panel and 44% of the Reduced Risk Core Committee have documented direct financial relationships with the US tobacco industry (Table 1). Some of these relationships go back decades and may provide a potential conduit for tobacco industry input into LSRO committee reports.

Although 97% of the funds the IFSH granted 2001-2005 support tobacco research and appear to come from BAT and its former US subsidiary, Brown and Williamson, the IFSH home page and promotional video do not mention these companies or discuss the tobacco research they fund. This obscures the connection between the IFSH and the tobacco industry. The fact that IFSH Tobacco Science and Health Council and Board of Directors member Roger Jenkins was consulting for Brown and Williamson just prior to the time when the IFSH was founded provides a potential conduit for Brown and Williamson input into IFSH granting decisions.

Institutions and individual scientists who do not want to accept industry money [1-4] and members of the public who do not want to donate to organizations funded primarily by the tobacco industry need to be aware of the new organizations the industry is channeling funding through. Regulatory officials and policy makers need to be aware that the studies being published on issues important to the industry such as cigarette additives and "potentially reduced harm products" may not be as independent as they seem.

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