

Lung Cancer The Case for Research Funding

by M.F. Bowen

*Absent thee from felicity awhile,
And in this harsh world draw thy
breath in pain, To tell my story.*

William Shakespeare [Hamlet, V.ii.360]

Lung Cancer – An Overview

Lung cancer is the uncontrolled proliferation of non-differentiated, non-functional epithelial cells in the airways. There are several different types of lung cancer, depending on the type of epithelial cell which succumbs to carcinogenic damage and the histological appearance of the transformed cells. Smoking is responsible for 87% of all lung cancers⁽¹⁾ and is strongly associated with all histological classes.⁽²⁾ The most common outcome for all types of lung cancer is the same: death due to loss of pulmonary function and/or complications due to metastasis to other sites, most commonly bone, liver, lymph nodes or brain. At initial diagnosis cancer patients most often present clinically with cough, blood expectoration, shortness of breath, chest pain and recurring pneumonia or bronchitis.⁽³⁾ These symptoms are commonly associated with other, less deadly, conditions and by the time a diagnosis of lung cancer is made, it is usually too late: The disease has spread and treatment in such cases is more invasive, more difficult and less effective. If detected early enough, surgery is the treatment of choice. However, because early

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The Tobacco Industry in Sacramento Hasn't Lost a Beat (what is a tobacco research program to do?)

by Phillip Gardiner

While few are talking about it, the tobacco industry has regained much influence in California, the state with the toughest and most widespread anti-smoking laws and ordinances in the country. California Common Cause Executive Director Jim Knox pointed out that "The failure of the legislature and the governor to enact a cigarette tax increase, and the decision to sell off the proceeds of the historic tobacco litigation settlement, were tremendous victories for the tobacco industry that will come at great cost to the public health. These budget actions are a testament to the influence of the tobacco industry at the state capitol."⁽¹⁾ To borrow a phrase from the newly released Tobacco Education Research Oversight Committee (TEROC) Master Plan, to think that the tobacco control community has chased the tobacco industry out of Sacramento is "The Myth of Victory."⁽²⁾ The article below is drawn mainly from California Common Cause*-Tobacco Report, titled: "California: The Campaign Contributions and Lobbying Expenditures of the Tobacco Industry and Its Allies." (<http://www.commoncause.org/>).

*Common Cause is a nonprofit, nonpartisan citizen's lobbying organization promoting open, honest, and accountable government. Supported by the dues and contributions of over 200,000 members and supporters in every state across the nation, Common Cause represents the unified voice of the people against corruption in government, and big money special interests.

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Tobacco Industry is Back in the House

Since 1997, the tobacco industry has spent over \$9 million lobbying the California Legislature. Once considered the hard place to give away money, now the California Assembly and Senate appear to be one of the easiest places where the industry can buy influence. Through June 30th of the 2002 election cycle, the tobacco industry spent over \$2 million lobbying the California Legislature, \$829,306 in 2002 alone. In fact, during the second quarter of last year, the industry spent \$449,755, an 18% increase over the first quarter. This is no small matter since these expenditures came right at the time that legislature was debating the budget and struggling with the tough question of what to do with the projected \$12.5 billion Master Settlement Agreement (MSA) funds.

Between 1997 and 2002, 25 California State Senators and 55 Assemblymembers accepted a total of \$2.36 million in contributions from the tobacco industry. There are currently many Assemblymembers and State Senators that are receiving tens of thousands of dollars from the tobacco industry, some members receiving over \$100,000. These figures are just reflective of direct tobacco industry contributions. It is important to keep in mind that during this same time period (1997 - 2002), two subsidiaries of Philip Morris, Kraft Foods and Miller Brewing, also contributed \$163, 113 to state office holders in California. Please go to Common Cause's website <http://www.commoncause.org/> for a detailed accounting of who is receiving and who is not receiving tobacco industry support.

The tobacco industry, not being one to discount the importance of California's diverse populations,

made sure that key racial/ethnic groups were recipients of their generosity as well. From 1999 to 2002, the Black Leadership Political Action Committee (PAC) together with the California African American PAC

“Only the tobacco industry benefits from less tobacco research”

accepted \$72,000 from the tobacco industry. Similarly, the California Hispanic Chamber of Commerce PAC, California Hispanic Leadership Fund and the California Latino Alliance together received a total of \$38,000 between 1997 and 2002.

Selling the Farm

The securitization of the MSA funds has and will go a long way to undercut the future of the tobacco control and tobacco research programs in the state of California. Governor Davis and the Legislature decided during the first and second quarter of 2002 to securitize \$4.5 billion, nearly all of the state's share of the MSA payments over the next 22 years. As the Common Cause Report points out: “Were California to wait and receive the settlement payments over time, the state would have received a total of \$12.5 billion. The state will now get approximately 36 cents on the dollar it would have received in future MSA payments. Critics have likened this to taking out a second mortgage on your home to pay for groceries.”

California was once the home to the largest tobacco prevention program in the world. However, with the continuing cuts to tobacco control budget coupled with selling off of MSA funds, California dropped to

8th place in the Campaign For Tobacco Free Kids rankings in 2001, and California's ranking has plummeted further to 20th with the continuing cuts to the tobacco control budget. The California Legislature slashed the Tobacco Control Program by 30%, a total of \$46 million in fiscal year 2002. These cuts have dropped the California program well below the \$165 million identified by the Centers for Disease Control and Prevention as the minimum necessary to make a significant reduction in California smoking rates.

These cuts are of no minor consequence. Dr. Wendy Max, tobacco researcher at the University of California, San Francisco, has pointed out in her latest report that smoking costs California \$16 billion annually.⁽⁵⁾ This figure includes \$8.6 billion for hospital care, ambulatory care, nursing home expenses, prescription drug costs and home health care. Another \$5.7 billion is due to lost productivity attributable to premature death and \$1.5 billion to associated illnesses. While the number of smokers has declined over the past decade in California, the costs of health care generally, and caring for smokers particularly, have skyrocketed.

What is a Tobacco Research Program to do?

The Tobacco Related Disease Research Program (TRDRP) has avoided the brunt of the California budget crisis. However, with declining revenues from smokers, our funds have been continually dropping. Ironically, a tax on tobacco products that has been so good for the public's health, and indeed the font of the TRDRP's existence, may inadvertently play a role in shortening the life of TRDRP. It has been well established that a rise in cigarette prices will result in a decline in tobacco purchases. While this is immediately beneficial to the health of those smokers and potential smokers who may,

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indeed, be deterred by the tax, and while the mission of the TRDRP is absolutely that of improving the public health, one must not overlook the fact that a decline in tobacco purchases means a direct loss of revenues for the TRDRP. The proposed cigarette tax increases, absent new revenue sources, may prove the undoing of arguably one of the top tobacco research programs in the nation.

It is important to note that it would be short-sighted to think that as smoking rates drop, there will be less of a need for tobacco-related disease research. On the contrary, even if every smoker in California quit today, many people would still develop cancers and other maladies from past smoking habits. Indeed, continued research is imperative to address and hopefully blunt the progression of smoking related disease.

The repeated siphoning off of research account revenues to support the California Cancer Registry continues to inhibit TRDRP's ability to fund a broad range of excellent

research. As we have often pointed out in this newsletter, the nearly \$5 million a year redirected to the Cancer Registry could fund at least nine, three-year awards at an average cost of \$170,000 per year. We will have to work with the Cancer Registry and others to remedy this situation. Only the tobacco industry's benefits from less tobacco research.

However, apart from supporting back-fills to off-set the impact of increased taxation, haggling over allocations to the Cancer Registry, or exposing the tobacco industry's intrigues in Sacramento, the TRDRP needs to strike out in bold new directions. At recent meetings of both tobacco researchers and tobacco control advocates, from around the country and here in California, it was pointed out that the TRDRP needs to do a better job at publicizing the importance and impact of the research we fund. The tobacco control community and the public generally need to be made aware of significant research findings, their use in the development of public policy and research's contributions to prevention and cessation efforts. One participant stated, "Your program has funded critical research on second-hand smoke, California's burgeoning racial and ethnic communities, and maternal and child health to name a few, and these stories aren't getting out; no one hears about your successes."

It would be programmatically and fiscally naïve to think that in the near future, the California Legislature is going to significantly augment tobacco research funding (let alone replace the funds taken away from the tobacco control program over the last few years). The tobacco research commu-

nity has to be, indeed needs to be, forward thinking and begin to explore additional avenues of funding apart from the Prop 99 account. Innovative fund raising strategies need to be pursued forthwith. Partnering with other funding agencies to tackle large research programs, aggressively seeking funds from foundations, establishing tobacco-related disease support group(s) and hiring a fund raising firm, can all lead to augmented funding. Greater funds means more research on critical tobacco use issues facing Californians. The use of fund raising experts by our sister program, the California Breast Cancer Research Program, which is also reliant on tobacco tax dollars, is proving to be successful.

TRDRP needs to construct a far-sighted plan that incorporates public relations, publicity and fund raising, to augment and support our research mission. While we are exposing the tobacco industry machinations in Sacramento, we must be creative, innovative, proactive and not depend solely on tobacco taxes nor the vagaries of the up-and-down political process in California to secure our future.

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Lung Cancer

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diagnosis is so problematic, radiation and chemotherapy are usually required in conjunction with surgery. The survival rate is 49% in those cases where the tumor is detected early but only 15% of lung cancers are detected early enough for patients to qualify for this relatively sanguine prognosis. The 5-year survival rate for all stages of lung cancer progression combined is only 14%.⁽⁴⁾

Lung cancer is now the leading cause of cancer mortality in both men and women in the US. An estimated 157,400 people died of lung cancer in the US in 2001, a figure which represents 28% of all cancer deaths that year.⁽⁴⁾ Lung cancer annually kills more women than breast cancer and more men than prostate cancer. In California, for example, an estimated 13,200 people died of cancer of the lung or bronchus in 2001, 25.8% of all cancers in California; 2,800 died of prostate cancer or 5.5% and 3,900 of breast cancer or 7.6% of all cancers.⁽⁴⁾

There are at least two bright spots in this otherwise gloomy picture. For one thing, lung cancer rates between 1988 and 1997 dropped twice as rapidly in California as in the rest of the country,⁽⁵⁾ due at least in part to California's aggressive anti-smoking campaign initiated in 1988.

Secondly, long-term lung cancer survivors have recently been found to have a better quality of life than expected.⁽⁶⁾ Nonetheless, recent incidence and mortality statistics remain dismal.

Lung cancer incidence and mortality rates display striking and largely unexplained racial/ethnic differences.⁽⁴⁾ Among men reported lung cancer incidence rates (per 100,000) are highest in African Americans (117), followed by Caucasians (71.9), Asian/Pacific Islanders (51.9), Hispanic (38.0) and American Indians (25.1). Mortality rates follow this same trends. The underlying causes of these discrepancies are likely complex but at least part of the reason for the disparities in mortality may reside in the fact that race and ethnicity influence access to appropriate and aggressive cancer care and treatment post-diagnosis.⁽⁷⁾ Biologic differences may also play a role as susceptibility to certain, possibly more deadly, histological types of lung cancer are higher in African Americans as compared to Caucasians even after adjustment for smoking.⁽⁸⁾ Racial/ethnic differences in the metabolism and detoxification of tobacco smoke components, including carcinogens, may be another factor for the higher incidence of lung cancer in African American men.^(9,10,11) The preference of African-American smokers for mentholated cigarettes⁽¹²⁾ may be yet

another factor in the increased cancer incidence seen in this population: Menthol may enhance exposure to carcinogenic smoke components, possibly through its action as a bronchial dilator.⁽¹²⁾ Lung cancer rates among men are 2-3 times higher than those in women in all ethnic categories; however, there is compelling evidence that women are more susceptible to lung cancer given the same amount of smoke exposure.⁽¹³⁾ As in the case of ethnic differences, the reasons for this disparity are largely unexplored and unexplained.

The Debate That Shouldn't Have Been

That lung cancer is caused by smoking is a fact so well-known, established, and incontrovertible that it is difficult to imagine a time when it was a subject of debate. Nonetheless it was. The controversy was fueled by the tobacco industry, which spent a considerable amount of time and money disputing the facts and clouding the issue.

Before the invention of cigarettes lung cancer was extremely rare. People started smoking in large numbers during World War I when tobacco companies distributed free cigarettes to members of the armed services.⁽¹⁴⁾ By the 1930's the health effects of this largesse were evident. Physicians noticed a large number of lung cancer cases in men and lung cancer rates in this group rose rapidly thereafter from approximately 10 (per 100,000) in 1940 to approximately 75 in the mid-1980's.⁽²⁾ Lung cancer incidence in women lagged behind that in men, but, following a steep increase beginning in the early 1960's, lung cancer surpassed breast cancer as the leading cause of cancer mortality in women in 1987. These

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patterns closely tracked trends in cigarette smoking. In fact the epidemiological association between smoking and lung cancer was so pronounced, so strong, and so consistent and the association between lung cancer and smoking history in patients so compelling, that the Royal College of Physicians in Britain issued a report in 1962 on the health hazards of smoking⁽¹⁵⁾ which was followed shortly thereafter by the US Surgeon General's report on the same topic in 1964.⁽¹⁶⁾ Nonetheless, smoking was so inculcated into American culture that the American Medical Association itself refused to endorse the Surgeon General's report. In fact, many medical doctors themselves were addicted to cigarettes. More ominously, the AMA continued to accept contributions from the tobacco industry.

In such an atmosphere, the tobacco industry found it advantageous to mount a two-pronged attack on its public relations problem. On the one hand, it denied the association between lung cancer and smoking and on the other it began to market cigarettes with implied reduced health risks.

In 1954 the tobacco industry set the tone of the debate by publishing, under the dubious auspices of the Tobacco Industry Research Committee, the now-infamous "Frank Statement to Cigarette Smokers," which claimed that there were many possible causes of lung cancer and that there was no agreement among authorities that cigarette smoking was one of the causes. Thus began decades of refusal by the tobacco industry to recognize a cause and effect relationship between smoking and lung cancer. At the same time the tobacco industry capitalized on the growing public awareness that smoking was dangerous by promoting first filter then low-tar cigarettes starting in the 1950's and 1960's. Advertising

"tar wars" ensued between competing tobacco companies (the tar derby), which fueled the consumers' misperception that these products were low-risk.⁽¹⁷⁾ By the 1970s and 1980s the tobacco industry had introduced numerous low tar, "light" cigarette brands. However, subsequent research has shown that these products are anything but safe for human consumption and have not appreciably reduced the risk of lung cancer. This may be due to the fact that smokers compensate for reduced nicotine levels by inhaling more deeply and because levels of carcinogenic nitrosamines in such products have actually increased over time.⁽¹⁸⁾

The cause and effect relationship between cigarette smoke and lung cancer has of course, since been abundantly and irrefutably demonstrated. The first evidence that a

tobacco compound directly interacts with a DNA site known to be involved in cancer initiation was produced by a TRDRP-funded researcher.⁽¹⁹⁾ As early as 1986 it was recognized that environmental tobacco smoke can cause lung cancer in adult non-smokers (20, 21). It is no surprise that in 1993 the U.S. Environmental Protection Agency declared environmental tobacco smoke to be a Class A, or known, human carcinogen. Moreover, smoking has now been linked to many other types of cancer beside lung cancer.⁽²²⁾

Chronic Underfunding

With lung cancer the leading cause of cancer mortality in the US, it is surprising that it is grossly underfunded

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Did you know that:

Nat King Cole
Carl Wilson
Joe DiMaggio
Roger Maris
Jimmy Dorsey
Susan Hayward
Betty Grable
Joe Higgs
Gary Cooper
Cal Ripken Sr.
Walt Disney
George Peppard
Spencer Tracy
Harry Reasoner
Melina Mercouri
Audrey Meadows
Art Blakey
Ed Sullivan
Duke Ellington
Jack Benny

Lon Chaney
Wayne McLaren
(The Marlboro Man)
Eddie Rabbit
Lee Remick
Doug McClure
Edward R. Murrow
Larry Linville
Chet Huntley
Franchot Tone
Yul Brynner
Sarah Vaughan
Mort Downey, Jr.
Alan J. Lerner
Desi Arnez
Chuck Connors
John Wayne
Leonard Bernstein
Bert Parks
Arthur Godfrey

all died of lung cancer?

(from: Smoke-Free Educational Services, Inc.)

National Meeting on Tobacco Industry Funding of Research

by Francisco O. Buchting

As part of the ongoing campaign to educate investigators on the consequences of accepting money for research from the tobacco industry, the Tobacco-Related Disease Research Program (TRDRP), along with the American Legacy Foundation, the National Cancer Institute, and the Society for Research on Nicotine and Tobacco, have co-sponsored a national meeting to discuss the tobacco industry's recent public ventures into the scientific arena (e.g., funding external research programs). The meeting, "Tobacco Industry Funding and Scientific Research: Ethical, Legal and Policy Issues," provided a framework to help tobacco researchers, private and public academic institutions, and funding organizations make informed deci-

sions before committing to scientific dialogue or funding arrangements with the tobacco industry. Over 150 scientists, research institutions, administrators, representatives from funding agencies, and tobacco control advocates were in attendance. The meeting, which followed the annual conference of the Society of Research on Nicotine and Tobacco, was held on February 22 and 23, 2003 in New Orleans.

The two-day meeting provided an opportunity for participants to dialogue about this emotionally charged and complex issue. The meeting began early Saturday evening with introductory remarks from Cheryl Heaton, Ph.D., American Legacy Foundation and a co-keynote address from Mitch Zeller, J.D., Pinney Associates and Ron Bayer, Ph.D.,

Columbia University. These speakers that framed the issue of the tobacco industry's funding of research and provided a historical background on the tobacco industry's use of science and the scientific discourse. Scott Leischow, Ph.D., National Cancer Institute moderated the meeting on Sunday over two sessions. The first of session, "Ethical and Legal Perspectives: Is the tobacco industry different?" that looked at how the tobacco industry is different from other industries that fund research. In addition, the issue of whether academic freedom is threatened by policies put into place by funders and/or academic institutions to address tobacco industry funding of research was also discussed. The second session, "Research Funding Practices: Pro and

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New Opportunity for TRDRP Policy

A previous attempt to implement a program policy that would make investigators who have financial ties with the tobacco industry ineligible from receiving an award from TRDRP was unsuccessful due to UC Office of the President's analysis. The proposed policy was a result the TRDRP Scientific Advisory Committee's resolution, passed in June 2001, advising TRDRP to put into place a policy in which any principal investigator who receives current financial support from the tobacco industry should be ineligible for TRDRP awards. This policy would not have been retroactive, but instead would have only focused on an investigator's current or future financial ties with any tobacco industries while holding an active TRDRP award. The definition of financial support in the resolution includes grant support from any tobacco industry research program and any consulting fees or direct financial ties to the tobacco industry or its subsidiaries. In the UC analysis, the TRDRP policy was viewed as being more restrictive than two current UC policies which protect academic freedom for UC researchers and prevent external funders from controlling research outcomes.

A more recent development on this issue has been the vote by the UCSF faculty, in the fall of 2002, approving a resolution for all faculty members to refuse to accept any funding from the tobacco industry and the foundations it supports. The results have been communicated to Chancellor Bishop at UCSF. The matter of putting forth a policy is now being considered by the UCSF University Senate. Some suggest that it is open to debate whether the TRDRP Scientific Advisory Committee's recommended policy is more restrictive or can be considered analogous to the two UC policies mentioned above. TRDRP will continue to monitor developments at UCSF and at the University of California Office of the President.

As always, TRDRP will keep its stakeholders informed of any progress on this issue. The issue of tobacco industry funding of research has not and will not disappear in the near future. More than likely, this issue will continue to play an important role in tobacco research and tobacco sciences as more funding agencies and academic departments put in place policy to address the issues of tobacco industry funding or research.

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con perspectives from scientists about taking tobacco industry money” looked at existing policies and possible future policies at universities and funding agencies. Additionally, pro and con arguments for scientists accepting money from the tobacco industry to conduct research were debated. The afternoon began with the presentation of two case studies on addressing industry funding of research. The first case study, presented by Phillip Gardiner, Dr.P.H., was based on TRDRP’s experience in trying to put a policy in place. The second study, presented by Stanton Glantz, Ph.D., was based on the recent UCSF faculty vote on a resolution for all faculty members to refuse to accept any funding from the tobacco industry, following the case study presentation, a public “Socratic Dialogue,” moderated by Charles Nesson, J.D., Harvard Law School, provided in-depth discussion among a panel of experts in tobacco-related research and tobacco control. Scientists from two tobacco companies participated in the “Socratic Dialogue.” After a lively discussion, meeting attendees divided into small groups to discuss recommendations and future action on the issue of tobacco industry funding of research. The meeting closed with brief reports from the break-out groups. The meeting’s goal of continuing the dialogue on the issue of tobacco industry funding was accomplished. TRDRP will continue to monitor this growing and important issue and will provide updates all of its all stakeholders.

Following is a “briefing” paper written by Joanna Cohen, Ph.D., University of Toronto that was distributed to all meeting attendees. The paper was commissioned by the funders of the meeting. It provides an overview of the main issues discussed throughout the meeting.

Accepting Tobacco Funding for Research:

An Overview of the Issues

by Joanna Cohen, University of Toronto

I. Introduction

Today more than ever, tobacco companies have an interest in portraying a positive corporate image. Funding external research is one strategy this industry has used to counter studies demonstrating the negative effects of tobacco use and to deflect criticisms about its business practices. Although some tobacco industry-funded research has been of high quality, many studies it has sponsored on the risks of active and passive smoking have been shown not to be. Indeed, the higher quality research has focused on substances other than tobacco as a cause of adverse health outcomes; this has been called “distracting research” because it contributes to the playing down of the negative impacts of tobacco use. Further, it has been documented that many grants from tobacco industry research councils were controlled by industry lawyers rather than by scientific advisory boards, and they were awarded specifically to promote research “controversies.”

While the tobacco industry continues to set up external funding programs, several U.S. schools of public health and organizations that fund tobacco-related science have instituted formal policies restricting tobacco industry sponsorship of research. In September 2001, the Society for Research on Nicotine and Tobacco adopted a position statement to encourage its members not to solicit or accept support from the tobacco industry, to continue refusing support from the tobacco industry for Society activities, and to “not endorse the support of its members’ research or their participation in other activities funded by the tobacco industry.” There are legitimate arguments both

for and against accepting tobacco industry funding for research. The purpose of this background paper is to provide an overview of the issues surrounding research sponsorship by the tobacco industry. Seven key issues will be discussed followed by a brief summary of what we know about university, journal and research society practices in this area. A selected bibliography can be found at the end of this document.

II. The Issues

1. Academic Freedom

Academic freedom is a key value in university settings. Some believe that imposing any boundaries on researchers, including prohibiting them from accepting funding from certain sources, is an anathema to the ideals of academia. They argue that any such restriction could lead to a stifling of necessary scientific debate because there would be fewer funding options. If it is perceived that debate is curbed in any way researchers and their institutions may eventually lose some of their credibility. It is important to note, however, that a number of boundaries are already imposed on academic research. For example, institutional review boards are federally mandated in the United States, and academic research must adhere to human subjects and other ethical standards (e.g., scientific integrity, financial conflicts of interest). Further, funding agencies may place particular requirements on the use of their funds, and academic institutions may also have their own rules and regulations about the conduct of research and the use of research funds. In addition to mandated requirements, scientists also have an obligation to society to identify real health problems and promote resolutions, while institutions have an obli-

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Cornelius Hopper Diversity Award Supplement

TRDRP's mission is to mitigate the impact of tobacco-related illness by funding research that is relevant to issues surrounding tobacco use and disease. TRDRP recognizes the value to science and society of increasing the diversity of investigators researching tobacco use and tobacco-related disease and in encouraging researchers to address the specific needs of under-served segments of our society. Differences in training, background, and experience will enrich the capacity of researchers to effectively tackle the issues surrounding tobacco control in California. All TRDRP principal investigators are encouraged to provide training to qualified students, fellows, and community members who are underrepresented. In support of these goals, TRDRP offers the Cornelius Hopper Diversity Award Supplement (CHDAS) and welcomes participation by all qualified individuals, including those from socioeconomic, cultural, ethnic, racial, linguistic, and geographic backgrounds who are under-represented in tobacco research.

The CHDAS is named in honor of Cornelius L. Hopper, M.D., who was the UC Vice President for Health Affairs from 1983 until his retirement in 2000.

Applications are due
April 23, 2003, at 5:00 P.M.
They are available on the TRDRP
website: www.trdrp.org.

Looking to TRDRP's Future

by Charles L. Gruder

The Tobacco-Related Disease Research Program (TRDRP) is in the process of developing a strategic plan for the next five to seven years, which will guide our response to declining research funds. TRDRP's sole source of funds (i.e., the Research Account of the Proposition 99 tobacco surtax fund) has been declining and will continue to decline as tobacco consumption decreases in California. It could possibly drop 25% over the next several years, from \$19.4 million to \$14.4 million. Moreover, for the past three years, an increased amount of Proposition 99 Research Account funds has been appropriated to the California Cancer Registry and, as a result, less has been available to TRDRP. If this trend were to continue, in a few years the registry would receive 25% of the funds in the Research Account, in contrast to 6% in the years before the allocation was dramatically increased.

TRDRP is committed to supporting excellent science that will contribute to improved tobacco control efforts in California and to more effective prevention, detection, diagnosis, and treatment of tobacco-related disease. To be programmatically and fiscally prudent, it is necessary for us to consider how to modify TRDRP to respond effectively to the aforementioned changes. One feature of the plan will be ways to augment funds (e.g., private development).

To date, we have obtained advice, suggestions, insights, and recommendations on the program's future directions from scientists within and outside California who are familiar with the program, from attendees at TRDRP's 2002 Annual Investigator Meeting, California tobacco control experts, and other TRDRP stakeholders. Stakeholders were asked the following questions:

1. Currently, TRDRP offers the following types of awards: Research Project, Innovative Developmental and Exploratory (IDEA), New Investigator, Postdoctoral Fellowship, Dissertation, and Collaborative. These are available in all research priority areas. Should TRDRP maintain, limit or expand the number and type of mechanisms available in different research priority areas?
2. TRDRP funds research across a broad range of scientific disciplines and priority areas. Should the TRDRP prioritize, expand, limit or maintain funding in all or some areas?
3. What research would be most useful to your organization?
4. How can TRDRP and the tobacco control community work more closely with one another?

We are sincerely grateful to those who responded to our inquiries. Suggestions will be summarized for discussion by TRDRP's Scientific Advisory Committee, which will recommend a strategic plan. Changes in the program will be reflected in the next Call for Applications, which will be issued in the fall.

UPDATE

2003-04 Budget

The governor's 2003-04 budget, introduced on January 10, proposes to appropriate the same amount to TRDRP as in past two fiscal years, \$19,434,000. In the current fiscal climate, no budget cut is good news. The state's huge budget problem has been widely reported in the press and readers may reasonably have expected this to result in a reduction in TRDRP's resources. It is important to understand a distinction in the sources of state funds. The state budget shortfall is in the general fund, whereas TRDRP's revenue derives from a special fund, namely, the Research Account in the Cigarette and Tobacco Products Surtax Fund. This fund, which was created by a constitutional amendment (i.e., voter passage of Proposition 99 in 1988) and state statutes, may be spent only on tobacco-related disease research.

Although state statutes prohibit the use of tobacco research funds to reduce the budget shortfall by allocating them to other state programs, there are still risks to TRDRP's 2003-04 budget. The governor's budget proposed to increase the state tobacco excise tax by \$1.10 per pack. As econometric research has demonstrated – some of which was funded by TRDRP – this increase would drive down tobacco sales. Since TRDRP's revenue derives from a different tobacco tax, our budget would fall proportionately. However, the governor's budget proposes to protect TRDRP, along with the other programs funded by Prop. 99 tax revenue, by "backfilling" TRDRP's potential loss of Prop. 99 revenue with revenue from the proposed new tobacco tax increase. In other words, if passed, this backfill provision would protect TRDRP's budget from a dramatic decline.

As noted above, the governor's budget also included, for the fourth consecutive year, a much larger allocation than in the past from the Prop. 99 Research Account to the California Cancer Registry, \$4,738,000. TRDRP will continue to work with California's public health and research communities to identify alternative, stable sources of funding for the registry.

Although TRDRP's budget has remained level for the last two years, it declined over the prior four years and is projected to continue to decline with decreasing tobacco use in the state. In addition to declining revenue, there are other reasons that TRDRP cannot fund as many of the meritorious grant applications as in the past. Research costs have risen. Most grant money is spent on compensation for investigators and technical staff and this cost has increased. Another factor is an increase in the number of grant applications, 9% this year. The percentage of applications funded has dropped, and if this trend continues, it would discourage top investigators from submitting their best projects to TRDRP. These converging trends show why the current TRDRP model cannot be effective and explains our motivation to take a systematic look at the program's future.

Staffing

Recruitment for the TRDRP director opening continues. We had postponed recruitment for the opening of a biomedical research administrator position. We are extremely fortunate that two current staff members agreed to accept additional responsibility to cover this opening. TRDRP research administrator MF Bowen, PhD, is handling the general biomedical science grant applications in addition to her other program responsibilities. A research administrator in the California Breast Cancer Research Program, Larry Fitzgerald, PhD, agreed to manage the cancer grant applications. For those unfamiliar with CBCRP, it is one of the other Special Research Programs administered by the University of California for the state (<http://www.cbcpr.org>).

2003 Grant Applications

TRDRP issued its 2003 Call for Applications in September 2002. The number of applications submitted showed a 9% increase over 2002, from 225 to 245. Peer review of the applications for scientific merit will take place this spring, and awards will be announced in June. It is important for all friends of TRDRP to know that funds for the grants that will be awarded in 2003 do not depend on passage of the 2003-04 state budget.

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gation to undertake research that benefits mankind. Some may contend that because the tobacco industry has deliberately worked to obstruct these responsibilities, arguments claiming the coexistence of academic freedom and tobacco-funded research are moot. It could also be argued that these obligations preclude relationships with an industry that knowingly kills its customers and that has systematically suppressed, manipulated and distorted the scientific record.

2. *Respectability by Association*

It has been argued that recipients of tobacco funding can provide these companies with respectability and legitimacy by association. By supporting research, the tobacco industry can claim it is acting responsibly and in good faith, while at the same time generating good publicity. Indeed, this industry has pointed to the reputable institutions it has funded in an attempt to gain prestige and win the approval of juries. Recipients of tobacco funding may defend the funder's interests; more subtly, they may remain silent on issues that impact negatively on the tobacco industry. These behaviors could help contribute to tobacco company objectives that undermine public health. There are new concerns that the tobacco industry is trying to gain respectability from its associations with universities under the banner of corporate social responsibility. In 2000, British American Tobacco (BAT) donated £3.8 million for an International Center for Corporate Social Responsibility at the University of Nottingham. The following year Imperial Tobacco in Canada, which is owned by BAT, made a contribution to a Toronto university's certificate program in corporate social responsibility.

3. *Tobacco is "Special"*

If universities prohibit the acceptance of tobacco money for research, will, or should, this lead to prohibiting the acceptance of research funds from tobacco sister companies or from other industries? Where should academia draw the line? Tobacco is not the only industry that has demonstrated questionable conduct. Clearly, most industries would have an economic interest in the outcomes of research they fund, resulting in a great potential for conflicts of interest. Pharmaceutical companies have shown some suspect practices vis-à-vis its relationships with academic research. For example, drug companies have "bought" journal editorials, marketing departments rather than medical or scientific departments fund and oversee some studies, and they have been accused of trying to ruin the careers of scientists who have publicized research findings that would be detrimental to these companies. Research has shown that having a financial relationship with a pharmaceutical company is strongly associated with publishing views that are favorable to this industry. The asbestos industry also funded research aimed at quelling fears about the negative health impacts of asbestos. The asbestos companies sponsored little epidemiological research or studies that explored the relationship between asbestos and cancer. The companies dictated the research strategy of the Asbestosis Research Council, vetted publications and sometimes censored publications. Despite potential influence from any corporate funder, some argue that tobacco is "special" and that this industry should be treated differently from other private sector sources. Tobacco is a unique product because it is addictive, toxic and lethal to half of its long-term users; further, the number of people harmed by tobacco worldwide is of epidemic magnitude. Moreover, tobacco industry products are not regulated like other consumer

products; historically they have been exempt from food and drug legislation, consumer product safety legislation and hazardous product legislation. Given the immense harms of tobacco industry products, and the fact that they are not required for subsistence, some argue that the tobacco industry cannot be a legitimate partner in funding scientific research.

4. *Tobacco Products are Legal*

Those who support the acceptance of tobacco industry funds argue that tobacco companies are legal businesses and that their products are legal, thus, there should be no reason for rejecting their money for research purposes. Furthermore, it can be argued that it is preferable to take tobacco money for research (a societal "good") rather than leave it in tobacco company coffers where it can be used for the marketing and promotion of tobacco products. Indeed, university-industry partnerships continue to be strongly encouraged by both government and by universities themselves. However, with revelations that industry sometimes has very strong controls over the conduct of what is supposed to be independent academic research, concerns have been raised about whether science is being driven by a responsibility to contribute to a healthy, productive and just society, or by the market place and stock prices. Some worry that if universities appear to be responding to the profit motive, they will lose credibility and subsequently the public trust. In addition, some believe that the scientific community has a moral and ethical imperative not to collaborate with an industry that is increasing its presence and predatory practices in developing countries where the regulatory climate and public attitudes toward the tobacco industry are more susceptible to abuse by this industry. Although tobacco companies insist that they are better corporate citizens than ever before, at least in developed countries, their actions still do not support their words.

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5. The Need for Funds

An argument in favor of allowing researchers to take tobacco funding is that there are insufficient funds to support all potentially useful research in this area. It is argued that there are no other funders that could (or would) step in to fund the type of research that tobacco companies are willing to support. Further, some believe that just as the pharmaceutical companies are required to support research to evaluate their products, tobacco companies should also be expected to fund research for the evaluation of its own products. Indeed, many are quick to criticize research about new tobacco devices when it is conducted by tobacco industry scientists. Such research may be more credible if conducted by the academic community. Currently, however, even academic scientists who take tobacco money are often suspect. This means that there is very little independent verification of claims being made by the tobacco industry about its products and there is little ability to test these products before they appear on the market. Thus, the status quo suggests that without a shift in attitudes about tobacco industry funding for research, a truly effective and acceptable harm reduction product developed by the tobacco industry, for example, could never receive support from most members of the tobacco control community, at least not in a timely manner. Of course if status quo views about accepting tobacco money for research change, parameters would have to be set up and enforced to ensure that full scientific independence is maintained. It may be that the best scenario for funding studies that evaluate novel tobacco industry products would be through an industry-funded neutral third-party organization responsible for adjudicating research proposals and

administering the funds. Still, many argue that a need for funds is not a sufficient reason to accept sponsorship from an industry with a history of funding research aimed at promoting “controversies” and distracting attention away from tobacco’s adverse health effects.

6. Ethical Guidelines and Disclosure Policies

Ethical guidelines exist to protect research from undue influence on the part of the funder. Further, disclosure of funding sources, the peer review process and some financial conflict-of-interest policies are often thought to be sufficient to ensure scientific impartiality. Nonetheless, industry sponsors may exert influence over the scientific process at multiple points: withholding “negative” findings resulting in publication bias, influencing the study design, limiting investigators’ access to data and having control over publication. In order to address these concerns, the International Committee of Medical Journal Editors (ICMJE) updated its “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.” However, a recent study found that U.S. medical schools failed to include provisions in their agreements with industry sponsors of multi-center clinical trials that adhered to the ICMJE guidelines for accountability, access to data and control of publication. Even if ethical guidelines exist and are adopted, they may not be enforced. A recent study found that potential conflicts-of-interest with private industry are rarely reported. Further, it has been argued that guidelines for industry-sponsored research are not sufficient when dealing with the tobacco industry because they do not address the topics of research (i.e., they would not protect against “distracting research”), nor do they address other possible conflict-of-interest relationships between the industry and researchers or their institutions such

as the acceptance of donations from these companies. There are also ethical issues arising from the source of tobacco industry research funds – researchers who are sponsored by the tobacco industry must accept that these funds originate directly from the sale of cigarettes, including the sale of cigarettes to minors. In addition, some point out that scientists have a professional obligation to consider how their research findings may be used by others. Scientists who willingly conduct research they know will be beneficial to the objectives of the tobacco industry may be taken to task; similarly, some may argue that ignorance or naivety is an unsatisfactory defense for those who enter into research relationships with tobacco companies. At this time it is likely that journal submissions and grant proposals that acknowledge current or past relationships with the tobacco industry will be subject to heightened scrutiny.

7. Funding Eligibility

One development relevant to this debate is that taking tobacco money could jeopardize eligibility for funding from other sources. Cancer funding agencies, in particular, are beginning to take a hard line on tobacco funding. The National Cancer Institute of Canada, the National Heart Foundation of Australia and some members of the Association of European Cancer Leagues will not fund researchers who receive support from the tobacco industry. Cancer Research UK will not fund researchers if their research institute, university faculty or school receives tobacco funds. This organization is currently reviewing its code of practice on Tobacco Industry Funding to Universities with the aim of taking an even stronger stand. Cancer councils in Australia have taken the strongest position to date: they will not fund individuals if anyone in their institution receives tobacco support. The American Legacy Foundation

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as compared to other types of cancer. In 2001 approximately \$900 per death was spent on lung cancer research; by (per death) comparison, \$9,000 was spent on breast cancer research, \$3,500 on prostate cancer, and \$34,000 on HIV/AIDS.⁽²³⁾ All of these diseases richly deserve the funding support they receive. But given the high incidence and mortality of lung cancer and (because of the difficulty of early and accurate diagnosis) the costs of treating it,⁽²⁴⁾ lung cancer deserves much more funding than it presently receives. The fact that lung cancer is not a disease that is sexy or that garners much sympathy or empathy from potential donors does not help the situation. Nor does it help that lung cancer victims, once diagnosed, do not live long enough to become activists for their cause.

TRDRP has tried to rectify this situation for the California research community. Of the 962 grants funded by the TRDRP through 2001, 168 have involved research either directly related to lung cancer or research on basic biological phenomena common to many cancers, including lung cancer. This issue represents 89% of TRDRP's total biomedical portfolio. TRDRP has supported research on etiological mechanisms, new and improved diagnostics and innovative therapies. TRDRP researchers have provided evidence that tobacco smoke damages the p53 tumor suppressor gene,⁽²⁵⁾ developed sensitive tests for the detection of metastases⁽²⁶⁾ and for the early detection of transformed cells,⁽²⁷⁾ demonstrated that environmental tobacco smoke induces tumor development in an animal model,⁽²⁸⁾ developed an anti-angiogenic DNA vaccine⁽²⁹⁾ and developed a blood-test for tobacco-specific carcinogenic nitrosamines.⁽³⁰⁾ These are only a few examples of accomplishments of TRDRP-funded researchers that address the inception, progression and devastating consequences of lung cancer.

Future Directions

Ongoing work to develop early diagnostics and to design more effective and less damaging treatments for lung cancer needs continued support. We also need to address recently-emerging areas of concern. New and diverse biomarkers are needed to assess lung cancer risk from the new generation of "harm-reduction" tobacco products.⁽³¹⁾ We need to assess the extent of exposure reduction and the impact of these products, if any,



on public health.⁽³²⁾ History tells us that we cannot expect accurate answers from the tobacco industry in response to questions about their new and "improved" products. Such an assessment must be conducted independently. The biological mechanisms underlying ethnic and individual differences in lung cancer susceptibility and mortality need to be defined; in so doing, new ways to approach lung cancer diagnosis and treatment may be revealed. This approach also offers hope that treatment can be pharmaco-genomically designed to fit each patient's specific needs, thus vastly improving clinical outcome.

Conclusion

Like AIDS, lung cancer is a stigmatized disease, with many non-smokers of the opinion that smokers "get what they asked for." This ignores

several salient and incontrovertible facts: That nicotine is one of the most addictive substances known; that as long as it is sold to consumers in the form of cigarettes it is a legal substance; and, perhaps most frightening of all, that the tobacco companies have the financial and, by extension, political, power to influence marketing and legislation to their advantage. Lung cancer will continue to exact a high human toll on its victims and their families, as well as a financial drain on our health service systems. Lung cancer survival rates have changed little over the past 10 years. We have an opportunity to change that. New techniques in molecular biology, biochemistry, synthetic chemistry, and biomedical engineering provide unparalleled opportunities to uncover the mechanisms underlying lung cancer, develop innovative techniques for diagnosis, early detection and treatment, and unravel the mysteries underlying ethnic, sex-based, and individual differences in incidence and survival.

It is not surprising that in most of the great mystic and spiritual literatures of the world, the terms "breath" and "spirit" are synonymous. By finding a cure and by developing therapies and diagnostics that would mitigate the impact of this horrific disease, we would be doing nothing less than saving the victims of a vicious industry - not only in breath, but in spirit.

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New and Integrated Strategies for Prevention, Early Detection and Treatment of Lung Cancer

The 2nd Annual City of Hope Lung Cancer Symposium

Convened on February 21-22 in Long Beach, California by the City of Hope Cancer Center, Department of General and Oncologic Surgery, Section of Thoracic Surgery, this meeting brought together a group of nationally prominent experts to discuss the latest developments in research, prevention, early detection and treatment of lung cancer. The City of Hope forum is unique in that it brings researchers, clinicians and research funding agencies together with public health and tobacco control professionals, the common goal being the reduction of lung cancer morbidity and mortality in the 21st century. Topics discussed included basic biology, the latest early detection technologies, innovative treatments of early, late and advanced lung cancer, prevention, smoking cessation and tobacco control policy. It was a productive, provocative and informative meeting. Collaborative strategies for the prevention, early detection and treatment of lung cancer as well as other tobacco-related diseases were discussed. TRDRP salutes this effort and hopes that it continues into the future. For information regarding future symposia, please contact Frederic W. Grannis Jr., MD, Head, Section of Thoracic Surgery, City of Hope Cancer via email at: FGrannis@coh.org

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(Legacy) will not fund applicants that are “in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity,” and expects that grantees will remain free from tobacco-related contributions for the duration of the grant. In Pennsylvania, institutions receiving tobacco money are ineligible for settlement-based state funding for research and programming. Just as evidence about the negative health impacts of secondhand smoke had a radical effect on the tobacco-control policy debate, the above funding policies also have the potential to quickly lead to changes in university positions about whether individual researchers can choose to accept tobacco industry funds. The academic community will have to address the ethical issues that arise when the actions of one researcher limit the choices of another.

III. Examples of University, Journal and Research Society Policies

There have been no systematic studies exploring the behaviors of individual researchers vis-à-vis accepting research funding from tobacco companies. However, there have been a few studies in which institutions were the unit of analysis. An Australian survey of institutions of higher learning reported that 30% accepted research funds from the tobacco industry in 1991-92, while 2% had institutional policies not to accept research funds from this source. A 1997 study of tobacco associations in the seven New Zealand universities found that five had no formal policies and one had a general policy to disassociate with research that “was not in the public interest.” Based on an analysis of papers published from 1988-94, all UK medical schools but one had accepted tobacco money. An early 1990s survey of U.S. medical

schools reported that 55% had received research funding from the tobacco industry. A recent study of Canadian universities found that 11% received tobacco research funding from 1996-1999, while none had a policy banning such funding; among the faculties of medicine, 25% had received tobacco research funding, and none had a policy to ban acceptance of these funds.

Journals and scientific societies have also debated these issues. The medical section of the American Lung Association, through the American Thoracic Society, has a policy that its two journals will not review papers reporting on research funded by the tobacco industry. The Journal of Health Psychology also will not accept articles arising from tobacco industry-sponsored research. The Society for Research on Nicotine and Tobacco does provide membership to tobacco industry scientists as long as they are willing to sign a statement indicating, among other things, that they will “encourage research on public health efforts for the prevention and treatment of cigarette smoking and tobacco use.” Still, concerns about the presence of tobacco industry scientists at the Society conferences and on its listserv continue to be raised. Some members may feel that these concerns also extend to academic researchers who accept funding from the tobacco industry. Given that university, journal, research society and funding agency policies regarding tobacco industry-sponsored research are on the increase, it is an opportune time for tobacco control researchers to discuss whether there are any conditions under which acceptance of such funds would be acceptable, and if so, what those conditions might be.

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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.

UPCOMING CONFERENCES

April 7–10, 2003

Tobacco Control Section Project Directors Meeting

TCS will host the 2003 Project Directors Meeting. TRDRP will once again be on the program with a session on new directions in research on tobacco use.
Newport Beach, CA

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