

BURNING ISSUES

TRDRP Newsletter



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Women, Smoking and Disease

by Margaret Shield

Part II: Putting out the epidemic's fire

Part I of this article, printed in our July issue, surveyed the epidemic of tobacco-related disease impacting women in the U.S., described in great detail in the U.S. Surgeon General's recent report "Women and Smoking."¹ Currently, one of every five U.S. women is a smoker and smoking is the leading known preventable cause of death and disease among women.¹ Part II of this article focuses on necessary subsequent steps in combating this epidemic through improved tobacco control and prevention and treatment of tobacco-related diseases. Continued research is needed to understand smoking behavior issues specific to women and girls so that the most effective interventions can be developed. Some differences between the sexes in susceptibility to smoking-induced diseases are being elucidated, but the extent of these differences and their relevance to devising appropriate therapies are not fully understood.

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Fill this hall with your thoughts at the AIM Town Hall Meeting

The Debate Over Tobacco Industry Funded Research

TRDRP's Scientific Advisory Committee Recommendation and Upcoming Town Meeting - by Margaret Shield

As part of TRDRP's 2001 Annual Investigator Meeting, a Town Hall meeting on Tobacco Industry Funding of Research will be held on Thursday, December 6th from 5:00 to 6:30 p.m. TRDRP invites its investigators and all AIM attendees to participate in this open discussion. Two featured participants will also join us. **Dr. Scott Leischow**, Chief of the NCI's Tobacco Control Research Branch, will discuss the federal government's current role regarding interaction with the tobacco industry, policies on external sources of funding and conversations with other national organizations on this topic. **Dr. Tom Glynn**, Director of Cancer Science and Trends for the American Cancer Society, will discuss the policy recently adopted by the Society for Research on Nicotine and Tobacco (SRNT) that calls

on its members to forego tobacco industry funding. **Dr. Kathy Sanders-Phillips** of TRDRP's Scientific Advisory Committee (SAC) will serve as the moderator of the town hall meeting.

As part of their public relations strategy, tobacco companies have positioned themselves as a significant source of private funding for health research, giving millions of dollars to scientists and research institutions in the U.S. and around the world. Many of these projects have been peer-reviewed and some have produced research that exposes the devastating health impacts of tobacco use. At the same time, the tobacco companies have conducted their own internal research programs and sponsored non-peer reviewed grants, producing reports that deny or misstate the causal

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Town Hall

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relationship between disease and smoking or second-hand smoke. Debate over the ethical dilemma created by the funding of health research by an industry intent on selling a deadly product has been rekindled by the launch of the Philip Morris External Research Program (PMERP) in 2000. In the March 2001 issue of this newsletter (available online at www.ucop.edu/srphome/trdrp/archives.html), TRDRP staff explored the impacts of tobacco industry funding on the research community, as well as the ways in which the tobacco companies have used their research philanthropy to enhance their public images and confound the scientific literature on the health risks of smoking.

In another related development, Brown & Williamson invited researchers to participate in a "Tobacco Science and Health Policy" conference in October, 2001. This conference was advertised as a forum to discuss how the research community can collaborate with the tobacco industry. In response, representatives of a number of organizations – including ACS, AHA, ALA, and AMA- asked their fellow researchers not to attend this conference because the goals of the B&W corporation are incompatible with the subject matter of the conference. These groups believe a national discussion on whether there is a way for research to be appropriately conducted with funding from tobacco companies is warranted, but such a forum should be organized independently without sponsorship by tobacco interests.

At their June 2001 meeting, TRDRP's SAC considered how to respond to the renewed efforts of the tobacco companies to function

as funders of research. Specifically, the committee asked: should researchers who accept

To further foster discussion and gather feedback on this topic, TRDRP invites its investigators and all interested researchers to participate in an open discussion of these issues at the AIM Town Hall Meeting.

PMERP funds be eligible for TRDRP awards? **After substantial debate and a close vote, the SAC passed the following resolution with the full knowledge that the current policies of the University of California prevent TRDRP from imposing this restriction on applicants.**

- Any principal investigator who receives current financial support from the tobacco industry should be ineligible for TRDRP awards; and
- The definition of financial support includes grant support from PMERP and any consulting fees or direct financial ties to the tobacco industry or its subsidiaries; and
- These stipulations should apply to TRDRP reviewers as well.

During the discussion about this recommendation, SAC members expressed a range of opinions. A number of SAC members strongly believe that TRDRP, as a research agency whose mission is to improve public health by reducing the health impacts of smoking, should restrict the eligibility of researchers who are also accepting tobacco industry dollars. This would encourage California researchers to refuse any association with the tobacco com-

panies, who are viewed as using the good names and good reputations of external researchers to legitimize the distorted results of their internal research programs. Other SAC members raised concerns that a restrictive policy on investigator eligibility is a limit to academic freedom and that other checks and balances – such as peer-review of research and institutional policies to prevent external funders from influencing research projects – are already addressing the problem without being so restrictive.

SAC members also asked TRDRP staff to devise a campaign of outreach and education to investigators about this ethical issue to encourage researchers to carefully consider their own choices in accepting or refusing tobacco industry funding. As a first step in its education and outreach campaign, TRDRP devoted an entire issue of its newsletter to this topic (March, 2001). To further foster discussion and gather feedback on this topic, TRDRP invites its investigators and all interested researchers to participate in an open discussion of these issues at the AIM Town Hall Meeting.

TRDRP received a few letters, calls, emails and one manuscript in response to the articles published in our March 2001 newsletter on the topic of Tobacco Industry Funding of Research. Opinions were divided: some researchers would be opposed to any action by TRDRP to make researchers who accept tobacco dollars ineligible for funding, others strongly support such an action. TRDRP hopes to hear from more investigators at the Town Hall Meeting. Two examples of these differing opinions are printed at the right.

P. I. Feedback

Fool me once, Shame on you. Fool me twice, Shame on me. - Chinese proverb

Frederic Grannis, Jr., M.D.

Head, Thoracic Surgery, City of Hope National Medical Center

Burning Issues has performed an important service by raising the ethical and scientific questions involved when biomedical researchers take tobacco industry money. There is good evidence that such funding for research has done enormous damage to the public health in the recent past....The very fact of the performance of the research, the eminence and prestige of the researchers involved, as well as any favorable information obtained, is then used to influence legislation, court decisions, and public opinion in favor of the tobacco industry, regardless of the consequent damage to the health of our citizens....Industry attempts to exploit research are not just ancient history. A striking recent example of the motivation of tobacco companies in funding medical research can be found in the executive summary of a grant for lung cancer early detection by breath analysis, in which Philip Morris contributed \$33,485 to the Clifton F. Mountain Research Project on 8/26/1991. Why? In the section "Benefits to the Sponsor" is the following statement: "It is anticipated that the Sponsor (Philip Morris) of the proposed work will enjoy favorable publicity as a corporate benefactor, reduced litigation by genetically susceptible smokers and possible reduced settlements costs associated with the historical litigation in progress." Mountain, a prominent thoracic surgeon at MD Anderson, reported on his research to the Philip Morris/Quadrivium Meeting on April 15, 1998.

In recent months, there have been a number of articles by epidemiologists recommending a cautious approach toward lung cancer screening. All of these articles prominently cite evidence from Council for Tobacco Research (CTR)-funded research carried out by A.L. Feinstein at Yale University between 1968 and the present, intended to show that lung cancer is frequently not found during life, but can be detected on post-mortem examination in patients dying of other diseases...This research has proven to be deleterious to the public health by fostering a pessimistic attitude toward lung cancer early detection research by inaccurately suggesting that overdiagnosis may be a prominent source of bias.

Whether these surgeons actually believed that tobacco is not a carcinogen or a public health threat will never be known. What is clear to me is that, in either case, their prestige was such that when cynically manipulated by a killer industry, they caused great damage to our society. The tobacco industry has been involved in a systematic effort to bamboozle our elected officials, doctors, scientists, public health officials, educators, lawyers, jurors and ordinary citizens, young and old, for almost fifty years. If we get fooled again into accepting PMERP funding, then shame on us.

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Tobacco Industry Funding: a second opinion

Gaylord Ellison - Professor, Dept of Psychology, UCLA

After thinking about it for some time, I find that I think most of the arguments in your March 2001 newsletter are specious, polemic, and political. I find it insulting that my integrity as a scientific investigator would be questioned were I to accept a grant from Phillip Morris. In your newsletter, there was much discussion of previous funding by Phillip Morris and Big Tobacco, especially some special, non-reviewed projects, which were designed to cast a favorable light on tobacco research emphasized. As a responsible scientist, I had previously investigated the current Phillip Morris grant program. It is entirely peer-reviewed, there are no "special projects", and there are no restrictions on what can be published, other than that the funding source should be cited. I can see no differences between their policies that those of TRDRP, or NIMH, or NSF, or any other funding source I have used.

But also, is this the way science should be conducted--as a war? The TRDRP is funded by tobacco taxes from California, and administered by the University of California. I cannot imagine that anti-tobacco attitudes are written into these laws, or would such be supported by the Chancellor.

Another argument I read in your newsletter was that it would be bad if "Big Tobacco" could list well-known scientists as being supported by them. I would think that if a Philip Morris executive stated that they were supporting research on brain degeneration induced by nicotine the anti-tobacco forces would be overjoyed, rather than punitive.

And it is possible that there are components of tobacco which are beneficial--smokers have a lower incidence of Parkinson's disease, and schizophrenics are very heavy smokers, perhaps as a self-medication. I would not like to think that I could not pursue these kinds of issues with a TRDRP grant. Tobacco-related does not mean Tobacco-inducing Disease.

However, I do find this whole issue distracting from my efforts to discover what parts of brain are especially neurotoxic to nicotine. I think it is commendable that Phillip Morris is funding research into degeneration in brain induced by chronic nicotine. As an impartial scientific observer, I just want to determine the degenerative effects on brain of various drugs of abuse. I cannot imagine that the TRDRP would not support this endeavor. I don't think it is the best interests of tobacco research to draw ideological lines, rather than get on with the research.



Women

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Encouraging women to never start or to kick the habit

The only good news in the smoking picture is that the risks of developing diseases and dying prematurely decline significantly for women who quit smoking, just as they do for men. And most smokers want to quit: 74% or more of women aged 18 to 64 who smoke every day want to quit the habit and 40 to 65% have tried to quit in the past year, with younger women most likely attempting to stop.² The desire to quit is similar for women of all racial and ethnic groups. Smoking cessation evaluation studies thus far show that women and men exhibit similar success rates in their efforts to quit;¹ however, research to determine whether gender-targeted interventions improve the effectiveness of smoking prevention or cessation programs would be valuable.

Design of these interventions can be informed by what is already known about the demographics of women's

smoking behavior and smoking cessation success. The Surgeon General's report summarizes several decades of work in this area. Women are more likely than men to try to quit smoking by reducing the number of cigarettes they smoke rather than by going cold-turkey.¹ Some women do smoke only intermittently, not every day, and these women are most likely to be younger, Black, Hispanic or college-educated.¹ Two large surveys conducted in the late 1990's showed racial and ethnic distinctions in the success women have in quitting the habit: a higher percentage of White women than Black women successfully quit smoking, even when adjusted for

daily smoking rate and socioeconomic factors.³ Groups with low success in quitting smoking were women with only 9 to 11 years of education and women living below the poverty level. The Surgeon General's report notes that most smoking cessation efforts have focused on middle-aged smokers because their risk of developing related illnesses is high. More effort, therefore, is warranted for targeting interventions towards girls and young women to assist them with quitting before they reach this point.

A good place to start with improving smoking cessation efforts is still in the doctor's office. Given the magnitude of the health risks associated with smoking, the question "Do you ever smoke?" should be an essential part of any health care exam, followed by referral to appropriate resources and assistance. Among smokers over the age of 18 who had visited a physician within the past year, just 39% of women smokers and 35% of male smokers had been encouraged to stop smoking by a health care professional.¹ Only 26% of girls and young women from ages 10 to 22 recalled that a

health care professional had ever suggested that they try to quit smoking.¹

Smoking and Weight Control

A key issue in tobacco control for women, and especially for girls and young women, is the interplay between smoking and staying thin. The use of cigarettes to control weight possesses some mythical qualities as it has been such a large part of the tobacco industry's pitch to the female market for so many decades. Cigarette ads have either directly stated such claims in slogans (for example: "You can't hide fat clumsy ankles. When tempted to over-indulge reach for a Lucky instead") or have indirectly linked thinness to smoking by the models selected for ads and by brand names (for example: "Superslims" from Virginia Slims).¹

Research has shown that there is a relationship between body weight and smoking, although it is not as dramatic or as entirely positive as many women may believe.¹ More research is needed on smoking initiation and body weight in adolescent girls because this group has not been adequately studied and is very likely to make choices about smoking based on body image concerns. However, body image perceptions are not shared equally by all women. Many studies have shown that there are distinct cultural differences about optimal body image associated with racial and ethnic groups that impact the emphasis women are likely to place on this issue in their smoking decisions. These distinctions further emphasize the need to tailor smoking prevention or cessation interventions to specific target populations of women.

The Surgeon General's report notes that much of the data on weight and smoking has come from studies of White women and this group may be the most likely to have a link between their smoking behavior and worries about weight.¹ When women of nor-

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mal or lower than normal weight, judged by a body mass index measurement, were asked about their self-perception of their weight. White women who are current smokers and former smokers were more likely to say that they were overweight than nonsmokers.⁴ This relationship did not hold true for Black or Hispanic women. Regardless of smoking status, Black women were less likely to perceive themselves as overweight than Hispanic or White women.

Studies performed thus far have not confirmed the commonly held belief that a woman will lose weight if she starts to smoke.¹ Overall the relationship between smoking and weight is not linear: moderate smokers (10-20 cigarettes per day) weigh less on average than light smokers (<10 cigarettes per day), but heavy smokers (>20 cigarettes per day) weigh more than either group. Studies also show that smoking influences body fat deposition patterns in women, with deposition of fat in the abdominal rather than the gluteal region. This leads to new health risks as abdominal obesity has been linked to greater incidence of type II diabetes, cardiovascular disease and other health problems.

Most challengingly, many current smokers are concerned that quitting smoking will cause them to gain weight. This worry can even override fears about the health risks of continuing to smoke. The Surgeon General's report concludes from many conflicting studies that women typically gain 6 to 12 pounds in the year after they stop

smoking, but that this rate of weight gain slows in subsequent years. Programs that combine smoking cessation with weight control may be a way to overcome this problem, but altering perception of body image may be more effective than providing actual weight loss assistance. Women smokers in a smoking cessation program who received cognitive-behavior therapy to reduce concerns about their



weight were more successful at quitting smoking than groups that participated in a weight control program alone or standard counseling alone.⁵

Reproductive Effects of Smoking

Tobacco use has numerous detrimental effects on the female reproductive system¹, resulting in risk of estrogen-deficiency disorders, infertility and ectopic pregnancy. Smoking during pregnancy is also associated with greater incidence of placental damage, spontaneous abortion, stillbirth, low-birth weight babies and SIDS. More research in this area is needed to understand the molecular and cellular mechanisms that lead to the development of these disorders and to identify the components of tobacco smoke that are most damaging. This knowledge would serve both as further evidence to convince women of the dangers of smoking and as a means to develop

therapies that might mitigate the impact of smoking for women, especially pregnant women, who are unable to quit.

Efforts to encourage pregnant women not to smoke are working: during the 1990s, smoking during pregnancy dropped dramatically from 18% to 12% in the U.S.⁶ However 12% in real numbers means that about half a million expectant mothers continue to

smoke during their pregnancies. Pregnant White teenagers had the highest smoking rate of any group of women at 30% and more pregnant teens reported smoking during the last part of the '90s. A major concern is that many women plan to stop smoking only during the time they are pregnant. Most wo-

men who quit during pregnancy take up the habit again within six months of having their baby, and 70% are smoking again within one year.¹ Concerns about the impact of smoking on the fetus, not themselves, are the main reason that women stop smoking during pregnancy. More needs to be done to explain that exposure to secondhand smoke (SHS) is also a serious health risk for infants and young children. A TRDRP funded study provided evidence that SHS is linked to an increased risk of SIDS⁷ and there appear to be links between childhood exposure to SHS and development or exacerbation of lung ailments later in life.¹ Importantly, interventions should also address the woman's addiction and emphasize the improvements in the mother's own health resulting from smoking cessation.

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Disease Treatment and Research

For most tobacco-related diseases, further research is needed to identify mechanisms of disease initiation and progression; for all smoking-related diseases, further research is needed to develop better treatments. Coronary heart disease (CHD) is the overall leading cause of death of middle-aged and older women in the U.S. Smoking greatly increases the risk of this disease for women of all racial and ethnic groups and is implicated in as many as two-thirds of all CHD cases in women younger than 50.¹ Although the correlation is clear, epidemiologic studies attempting to determine relative risk of CHD in smoking vs nonsmoking women have produced differing results, possibly due to shifts in women's smoking patterns that have resulted in increasing relative risk in recent years. Once women quit smoking their risk of CHD decreases rapidly and dramatically by mechanisms that are not well understood; however, it may take 10 years or more before their risk is similar to that of nonsmokers.

Cigarette smoking is also the leading cause of Chronic Obstructive Pulmonary Disease (COPD).¹ This group of diseases involving airflow obstruction, including emphysema and chronic bronchitis, is now the fourth leading cause of death and impacts over 16 million people in the U.S.⁸ The Mortality rates for women from COPD have been increasing over the past 30 years, following the dramatic increase in the numbers of women who smoke during the 1950's and 1960's. Lung damage that becomes

apparent in adults may also result from maternal smoking during pregnancy or exposure to SHS during childhood or adolescence. Improvements in techniques for diagnosing COPD at early stages and more effective therapies are needed to combat this problem.

Smoking causes cancers of the bladder and oropharynx and is linked with increased risk of cervical, liver and colorectal cancer in women.¹



Other associations – between SHS and breast cancer or between smoking and acute myeloid leukemia – have been suggested by some studies but require further investigation. Lung cancer is currently the leading cancer killer of U.S. women, accounting for 25% of all cancer deaths in women, and roughly 90% of all lung cancers are attributed to smoking. Smoking increases the risk in women for all four main types of lung cancer: squamous cell carcinoma, small cell carcinoma, adenocarcinoma and large cell carcinoma.¹ The risk for dying of lung cancer is 20 times higher for women who smoke two or more packs of cigarettes per day than for non-smoking women, and this risk continues to increase with

greater cigarette use. Non-smoking women who are exposed to SHS, commonly from spouses or family members who smoke, are also at higher risk than individuals without any tobacco smoke exposure of developing lung cancer.⁹

Some data suggest that women may be more susceptible to developing lung cancer with lower exposure to smoke than men, but relative risks determined by different studies vary and this issue is still not well understood. Differences in lung cancer risk between the sexes may result from differences in genetic susceptibility, smoking patterns or in women's brand preferences. Further investigation of all these variables is needed. Virginia Slims, a Philip Morris product that has been very popular with women, contains the highest levels of N'-nitrosonornicotine of 10 major cigarette brands tested, as well as very high levels of other carcinogenic nitrosamines.¹² Women are also one of the groups who choose menthol cigarettes,

exposing them to the still undefined extra risks of this type of cigarette. In addition, a recent study has identified a genetic clue that suggests women have a greater susceptibility to lung cancer. The gastrin releasing peptide receptor (GRPR) gene is located on the X chromosome and is involved with normal lung development, but activation of the gene by smoking in adults may result in abnormal cell proliferation that increases the risk of lung cancer. Analysis of smokers showed that women express significant amounts of GRPR messenger RNA with lower yearly cigarette use than male smokers,¹¹ probably because they have two active copies of this gene.

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Some studies have compared lung cancer incidence and mortality among women of different racial and ethnic groups.¹ Overall, White, Black and Hawaiian women have similar incidence rates, while incidence rates are about 50 percent lower for Hispanic and Asian women. These lung cancer incidence rates mirror the smoking prevalence in these groups. One study showed higher lung cancer incidence among Black women than White women in the 25 to 54 year age range and five year survival rates were also slightly lower for Black women (13.5%) than White women (16.6%).¹ These trends bear further investigation to understand their magnitude and origin; however, these distinctions between groups of women do not appear to be as dramatic as the 50% cent higher incidence of lung cancer seen in Black men compared to White men.

Unfortunately, the prognosis for lung cancer continues to be extremely poor and one-half of all lung cancers in the U.S. are now found in former smokers. Thus the need for lung cancer therapies will persist for decades to come even with strong tobacco control measures. Greater emphasis on research in this field is needed to develop effective early screening methods to detect cancerous nodes while they are localized and more treatable. Development of therapeutic approaches that are more effective than current chemotherapeutic regimes is also needed, but this still requires further understanding of the mechanisms of development of lung malignancies. Lung cancer research has been underfunded and underprioritized by national funding agencies. The National Cancer Institute has devoted only about 3% of its budget for lung cancer research even though

the disease accounts for 30% of all cancer deaths.¹² On a recent positive note, a Lung Cancer Progress Review Group has been formed by the NCI to map out a plan for focusing the agency's efforts and encouraging multi-disciplinary projects. In California, TRDRP will continue to prioritize funding of research projects

A major concern is that many women plan to stop smoking only during the time they are pregnant. Most women who quit during pregnancy take up the habit again within six months of having their baby, and 70% are smoking again within one year.

examining lung cancer, especially those that will lead to development of better techniques for diagnosis and treatment of this devastating disease.

Conclusion

In broader terms for public health, our understanding of human behavior and disease is too often drawn from a body of scientific studies in which women did not proportionally participate or sex-specific differences were not examined. Continued prioritization of the inclusion of women in clinical and field studies, as well as research directed toward understanding sex specific differences in disease progression and treatment, is therefore warranted until this inequality is removed. The Institute of Medicine released a report this spring, "Exploring the biological contributions to human health: does sex matter?"¹³ that makes the case that all research endeavors – from the cellular level to longitudinal studies of individuals – must be designed to consider and analyze sex differences.

Existing data sets may be reanalyzed by gender or new studies may need to be initiated to collect the necessary data. Even in studies at the cellular or molecular level, investigating biological differences between the sexes is important because all cells have a sex-specific genotype, with corresponding differences in gene expression.

Further research into the differences between men and women - and between different racial and ethnic groups - in tobacco use, disease incidence and therapeutic strategies should continue to be a priority for national funding agencies, as it will for TRDRP. To reduce the epidemic of disease among women smokers in the U.S., however, what we need to know is already clear: too many women are suffering from smoking-related diseases and, despite this, too many young girls and women are still picking up the habit. The fact that non-smoking is the norm must be promoted as a counterbalance to the tobacco industry's continued targeting of women in their marketing. Magazines for women, apparently silenced by accepting a great deal of tobacco advertising dollars,¹ have given little press to the impact of smoking on women's health and even health magazines rarely mention that the single greatest improvement a woman can make in her health is to stop smoking. Perhaps the most important component in breaking the epidemic's grip will be effective prevention programs targeted at young girls to keep them from taking that first puff. Taking the fire out of this epidemic clearly must continue to be a public health priority for the foreseeable future.

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A REVERSAL OF FORTUNE: THE FRAMEWORK

by Phillip Gardiner

Novotny Quits

In a stunning move, 23-year veteran of the U.S. Public Health Service, Thomas E. Novotny, resigned this past August as the United States chief negotiator for the international Framework Convention on Tobacco Control (FCTC). While Health and Human Services spokesperson William Hall stated that Novotny's departure "had nothing to do with the international tobacco treaty negotiations," others suggest that he was increasingly troubled by the United States' change in position on many key provisions of the World Health Organization's FCTC.¹

The FCTC² (*see box page 12*) has identified numerous issues to be addressed by the 153 member nations of the international working group. Negotiators have been discussing provisions, including, tobacco price and tax policies; passive smoking; protecting women, children and adolescents; smuggling tobacco products; selling duty-free tobacco products; advertising, promoting and sponsoring of

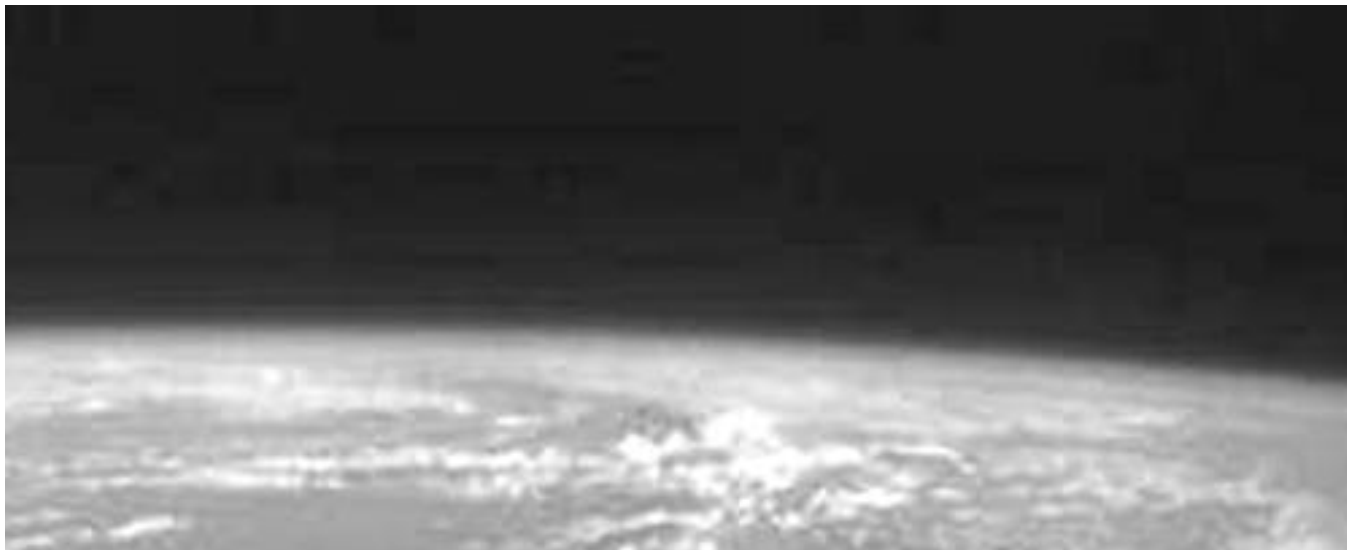
tobacco products; regulating tobacco products, including testing and reporting of tobacco product ingredients and constituents, and the ability to require tobacco product modification; regulating the tobacco industry; information exchange; health education and research; agricultural policies; and tobacco use prevention and cessation.

The United States was considered one of the leading tobacco control advocates among the six elected vice-chairs (Australia, India, Iran, South Africa, Turkey being the others) when formal negotiations were launched in Geneva Switzerland in October 2000. At this first meeting, negotiators had agreed that countries should 1) prohibit the use of deceptive advertising terms like low tar, light and mild; 2) prohibit tax-free and duty-free sales of cigarettes; 3) impose taxes on tobacco products to reduce tobacco consumption; 4) encourage governments to protect non-smokers by banning smoking in workplaces and public buildings; and 5) support the licensing of tobacco retailers. Additionally, during the October meeting negotiators had agreed that

health warnings should be in the language of the country where the cigarettes are sold and there should be restrictions on smoking on public transportation and in enclosed public places.^{1,3}

However, by May of 2001, six months after the election of President George W. Bush, the U.S. negotiators in Geneva had completely abandoned support for all of the positions stated above. Specifically, the U.S. sought to eliminate the provisions calling on nations to prohibit the use of deceptive terms like low tar, light and mild to market tobacco. The U.S. also sought to delete language that would have prohibited tax-free and duty free sales of cigarettes. Incredibly, the U.S. asked that the negotiators reconsider provisions that would protect non-smokers by banning smoking in workplaces and public buildings. Moreover, the U.S. came out against licensing tobacco retailers and argued against health warnings being written in the language of the country where the cigarettes are being sold.^{1,3}

Some elected officials did not miss this stunning 180-degree turn



CONVENTION AND FEDERAL TOBACCO POLICY

around. Henry A. Waxman (D.Calif), whose staff has analyzed the World Health Organization (WHO) and HHS documents, was flabbergasted. Waxman accused the Bush Administration of orchestrating "a breathtaking reversal in U.S. policy -- going from global leader on tobacco control to pulling back and advocating the tobacco industry's positions."¹ The U.S. delegation also "opposed restrictions on smoking on public transportation and in "enclosed places" – policies embraced in many US states."¹

Observers were not surprised that, following the dramatic reversal of positions, Dr. Novotny quit his post. A long time tobacco control proponent and public health official, Dr. Novotny was an advocate for the FCTC from its inception. Now, his new bosses, Department of Health and Human Services Secretary, Tommy Thompson, and President Bush, had backed Novotny into a corner; either play ball our way, or don't play ball at all. People in the international tobacco control movement who spoke to Novotny after the May meeting in Geneva, said

that he felt uncomfortable and sometimes distressed, by the positions he had to defend.

The reversal at the FCTC placed the Bush administration at odds with the growing international outcry against tobacco. International tobacco control advocates foreseeing the changes in U.S. policy, with the Bush election, created the Framework Convention Alliance (FCA), in December of 2000, championing the same principals that were to be disparaged by the Bush administration in Geneva in May 2001. The FCA is a "heterogeneous alliance of non-governmental organizations from around the world who are working jointly and separately to support the development of a strong Framework Convention on Tobacco Control, and related protocols."⁴ Member organizations in this global grouping include 24 from Africa, 29 from the Americas, 36 from Asia, 35 from Europe and 16 internationally based initiatives.⁴

This spectacular reversal by the United States on previously agreed upon international tobacco control provisions, highlights the renewed

prominence and influence of the tobacco industry in the Bush administration, which is described below.

The Ties that Bind

George W. Bush's ties to the tobacco industry go back to his days as governor of Texas. During his tenure, Bush assembled around him many operatives of the Philip Morris tobacco company. Most notable in this regard is Karl Rove, considered the leading Republican Party campaign strategist in Texas, at that time. Rove was formally on the payroll of Philip Morris from 1991 to 1996 as a paid political intelligence operative and at the same time, was a close advisor of Governor Bush. Currently, Rove is a senior advisor in the Bush White House and part of the president's inner circle.⁵ Along with Rove, James Francis Jr., originally associated with the industry-funded National Smokers Alliance, was also a close advisor to then Governor Bush. Rounding out Bush's main tobacco affiliations while Texas Governor was Haley Barbour. Barbour, past chairman of the National Republican Party and

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arguably one of the main lobbyists for Philip Morris was also a key player in Bush's 2000 race for the Presidency. As Robert Dreyfuss, a Virginia-based independent journalist, pointed out in 1999: "Just how much influence these men have had on Bush is impossible to measure. But Bush's record on tobacco certainly doesn't displease the industry: opposition to the federal lawsuit against Big Tobacco and to increase taxes on cigarettes, plus vigorous support for tort reform that limits consumer's right to sue makers of dangerous products-like tobacco."⁵

Along with the political advisers identified above, other administration officials in agencies instrumental to tobacco control also bear the stamp of the tobacco industry.

With the selection of Tommy Thompson for Health and Human Services Secretary, Bush reaffirmed his strong ties with the tobacco industry. As governor of Wisconsin, Thompson became friendly and supportive of Kraft Foods and Miller Brewing, both Philip Morris companies and both based in the state. During Thompson's time in politics, he has collected more than \$100,000 in contributions from the tobacco industry, affiliated firms and their executives.⁶ It was widely reported that Philip Morris substantially financed three political junkets, to three different continents, for then Governor Thompson. Thompson made it plain that he appreciated the tobacco giant's help in a letter to Andrew Whist, a Philip Morris senior vice president: "I value your loyalty and friendship."⁶ In all fairness, Thompson signed four separate tobacco tax increases. However, he also signed a smokers' bill of rights, which

gives smokers in Wisconsin similar protected status as minorities, women, and the disabled. Moreover, he vetoed a smoking ban in general seating for the Milwaukee Brewers' new baseball stadium, which is owned by the Miller Brewing Company. And following the lead of the tobacco industry on preemption, Thompson vetoed a bill that would have permitted cities to adopt stronger anti-

This spectacular reversal by the United States on previously agreed upon international tobacco control provisions, highlights the renewed prominence and influence of the tobacco industry in the Bush administration, which is described below.

smoking rules than those implemented by the state.⁶

Adding credence to the appearance that the Bush Administration is soft on tobacco control, Thompson has proposed cutting the budget of the CDC's Office on Smoking and Health (OSH) by 5%. The OSH cuts strike at the heart of smoking prevention programs at the state level.⁷

At the Justice Department, John Ashcroft, the new Attorney General will be the primary person making the decision whether the United States continues its lawsuit against the tobacco industry. Ashcroft claimed in his confirmation hearing that he was "no friend to the tobacco industry." He further stated that he had "no predisposition" regarding the lawsuit against the tobacco industry.⁶ However, in writing to a constituent, as then senator from

Missouri, Ashcroft stated that he was concerned "that the DOJ lawsuit could set an unwise precedent leading to the federal government filing lawsuits against countless other legal industries."⁶ Moreover, Ashcroft has been lukewarm at best to the federal lawsuit against the tobacco industry. The Justice Department lawsuit, filed in 1999 during the Clinton Administration, alleges that the tobacco industry engaged in "fraudulent marketing practices" and seeks more than \$100 billion in damages.⁸ Justice Department lawyers, who are prosecuting the case, estimate that they need at least \$57 million in the next fiscal year for staffing and fact-finding work. Ashcroft has answered this budget request by proposing only a \$1.8 million allocation for pursuing the lawsuit, which will prevent effective prosecution of the lawsuit!

It should be noted that Ashcroft was a member of the Washington Legal Foundation (WLF), which has championed the interests of the tobacco industry on numerous occasions. In fact, an internal Philip Morris memo states, in part that WLF is "A close ally of PM for many years . . . [WLF has] filed amicus briefs against the EPA [and] they have written and promoted our position on the advertising/First Amendment issue."⁶

Another tobacco-friendly appointment is John Graham, the head of the Office of Information and Regulatory Affairs (OIRA) within the White House's Office of Management and Budget (OMB). Graham headed the Harvard Center for Risk Analysis, a corporate-backed center that has championed the idea that citizens are overly fearful of industrial risks including the impact of environ-

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mental tobacco smoke (ETS). Not only do Philip Morris files show that Graham was courted by the industry, but also that, PM applauded Graham for sending letters to the government that argued that the White House should have had greater control over the Environmental Protection Agency's assessment of ETS.⁶

Another tobacco industry advocate is J Howard Beales III, who has been appointed as the Federal Trade Commission's (FTC) new consumer-protection chief. He is an economist who defended a tobacco company's right to advertise Joe Camel to teenagers. Beales, a Reagan era FTC appointee, left the FTC with the advent of the Clinton administration to become a professor at George Washington University and was simultaneously hired as a consultant to the R.J. Reynolds Tobacco Co. It was during his tenure at RJR that the company used his paper to defend their practices of marketing to teenagers. Among other things, Beales asserted that there was "no evidence to support the notion that advertising has an important or powerful effect on teenagers decisions" to smoke.⁶ This conclusion was contradicted by numerous studies since.^{9,10,11} Matthew Myers, president of the Campaign for Tobacco Free Kids, likened Beales' appointment to "putting the wolf in charge of the henhouse," He added: "Someone with those kinds of ties to the tobacco industry, whose position on the impact of advertising, particularly on young people, is so far out of the mainstream, cannot be counted on to protect our kids."¹²

A Hard Row to Hoe

"The prospect of Bill Clinton gone

and a George Bush presidency makes the [tobacco] industry almost giddy." This statement by Martin Feldman, a tobacco industry analyst at Salomon Smith Barney, in September of 1999, rings very prophetic today. If the first 10-months of the Bush administration is any indication, one could argue that the \$8.3 million invested nation-wide by the tobacco industry in the 2000 elections has borne major fruit. During this time President Bush has placed people friendly to the tobacco industry in powerful positions in the government, weakened or outright abandoned a progressive international tobacco control agenda, seriously under-funded the federal lawsuit against big tobacco and cut the CDC's Office on Smoking and Health budget by 5%. As Gary Trudeau's Doonesbury character, Mr. Butts (aka the tobacco industry) pointed out on Sunday October 14, 2001: "So what keeps my spirits up? Just knowing that the Bushies want to settle the federal lawsuit against big tobacco! Are we down with this crew or what?"¹³

And with the nation and the president riveted on the events surrounding the terrorist attack of September 11th, many social and domestic issues along with tobacco will take a back seat. Many will say it is understandable that tobacco control will be neglected, given the current state of affairs. Still, it must be pointed out that enacting strong international tobacco control provisions and going forward with the federal lawsuit are in the public interest. Even as dire as the international situation is, tobacco-related diseases will again this year kill over 400,000 people in the United States alone. Hopefully, the current international crisis is not used as a cover for continued undermining of tobacco control.

With the current officials in the

White House firmly tied to the tobacco industry coupled with the drums of war, the next three years could be very difficult time for tobacco control advocates.

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Framework Convention on Tobacco Control

On 24 May 1999, the World Health Assembly (WHA), the governing body of the World Health Organization (WHO), paved the way for multilateral negotiations to begin on a set of rules and regulations that will govern the global rise and spread of tobacco and tobacco products in the next century. The 191-member WHA unanimously backed a resolution calling for work to begin on the Framework Convention on Tobacco Control (FCTC) - a new legal instrument that could address issues as diverse as tobacco advertising and promotion, agricultural diversification, smuggling, taxes and subsidies. A record 50 nations took the floor to pledge financial and political support for the Convention. The list included the five permanent members of the United Nations Security Council, major tobacco growers and exporters as well as several countries in the developing and developed world which face the brunt of the tobacco industry's marketing and promotion pitch. The European Union and 5 NGOs also made statements in support of the Convention and the Director-General's leadership in global tobacco control.

The Working Group on the WHO Framework Convention on Tobacco Control held its first meeting in Geneva, Switzerland, from 25 to 29 October 1999. The meeting was attended by participants from a wide range of sectors and included representatives of 114 Member States and the European Community, as well as observers from the Holy See, Palestine, organizations of the United Nations system and other intergovernmental organizations and non-governmental organization.

In May 2000, the World Health Assembly unanimously adopted a resolution formally launching the political negotiations, which commenced the 16th of October 2000 in Geneva, Switzerland. At the first session of negotiations, Member States elected Ambassador Amorim of Brazil Chairman of the International Negotiating Body, as well as vice chairs from Australia, India, Iran, South Africa, Turkey, and the United States.

(<http://tobacco.who.int/en/fctc>)

The Global Picture for Women and Smoking

Women in the U.S. led the industrialized world in adopting the risky habit of smoking. Now, one of the most critical areas of women's health needs globally is effective interventions in developing countries to discourage women from lighting up that first smoke. Data from the World Health Organization shows the window of opportunity: smoking prevalence among women is 24% in "developed" countries, but only 7% in "developing" countries.¹ Smoking patterns in developing countries are complex and are influenced by many societal factors. The trend is clear, however, that smoking rates are increasing each year, with younger women rapidly picking up the habit.² Some women may still shun cigarettes due to specific cultural standards, but increase their use of smokeless tobacco products. In developing countries with high smoking prevalence among men, women are already exposed to the toxic effects of second-hand tobacco smoke.

Now is the time to take action to prevent tobacco use by women in developing countries according to the U.S. Surgeon General's recent report "Women and Smoking."² Big Tobacco has already launched aggressive campaigns in Asia and other areas, targeting women as a new, profitable market for their deadly product. The ad campaigns utilize culture-specific messages and resurrect the old lies of glamour and independence that worked so well in the U.S. marketplace. While women's equality in these countries should be supported and fostered, it is important to convey the message that smoking is not an essential, or beneficial, component of a women's rights campaign. The dire impact of smoking on women's health in U.S. is a tragedy that is now part of our history; however, if the resources and influence of the U.S. is used constructively and real leadership is exhibited, a global epidemic may be controlled. U.S. support for the Framework for Tobacco must be restored because it is central to these efforts.

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TRDRP Highlights

CARA/SARA workshops

Continuing our efforts to encourage applications for the CARA (Community-Academic Research Award) and SARA (School-Academic Research Award) mechanisms, TRDRP, in collaboration with the California Department of Education (CDE) – Healthy Kids Office, held a series of three workshops in Oakland, Los Angeles, and San Diego during October. These workshops were extremely well attended, with over 100 participants at the three locations. The sessions were aimed at explaining the theoretical approaches to community and school participatory research, learning from the experiences of current CARA/SARA investigators, and explaining the nuts and bolts of submitting proposals to TRDRP. The workshops provided opportunities for participants to network and to begin the process of identifying potential collaborators.

TEROC

TRDRP's Director, Susanne Hildebrand-Zanki, was appointed by the Governor to serve on the Tobacco Education and Research Oversight Committee (TEROC). TEROC is responsible for the oversight of Prop 99 funded programs and is advisory to the California Department of Health Services, the California Department of Education, and the University of California on issues related to tobacco control in California. The committee met on October 12, 2001 in Sacramento. This meeting represented a 'rebirth' of sorts, since 9 of the 12

TEROC members were newly appointed, with one additional appointment still pending. More information on TEROC can be found at <http://www.dhs.ca.gov/ps/cdic/ccb/tcs/html/oversightcom.htm>.

Dr. Diana Bontá, Director, Department of Health Services was at the meeting and voiced her strong support for the work of TEROC and its responsibility to make recommendations to the Department. TRDRP made a presentation to the committee to orient the members to the program's mission, operation, and achievements over the last decade. TRDRP also had the

opportunity to voice its concern about the allocation of an additional \$3,500,000 from the Prop 99 Research Account to the California Cancer Registry rather than to TRDRP.

Compendium

The 2001 Compendium of Awards is now available from TRDRP. It includes all 2001 grant recipients, their affiliate institutions, and the abstracts describing their research projects. You can request a copy from our office or find it on our website.

WARNING: Disparities Are Hazardous to Your Health

The 6th TRDRP Annual Investigator Meeting

Racial and Ethnic Disparities in Tobacco-Related Research

December 6-7, 2001

Los Angeles, The Westin Hotel - LAX
On site registration will be available.



APPLICATION DEADLINE January 17, 2002

TRDRP has issued its 2002 Call for Applications. The Call outlines TRDRP's research priorities and the available funding mechanisms. The 2002 Application packets are available on CD-ROM or our website (www.ucop.edu/srphome/trdrp/). The forms can be downloaded into Microsoft Word for Windows or pdf format. CD-ROMs have been sent to contracts and grants offices of all institutions that have previously applied for funding and to individuals who specifically requested a copy. For copies of the CD-ROM, please contact our office.

We have made several important changes in our new application packet:

Hard Cap on Direct Costs for Research Project and Full CARA/SARA Awards

Due to the decreasing budget allocations, TRDRP is revising the amount available and implementing a hard cap for Research Project and Full CARA/SARA awards. For proposals involving human subjects, average annual direct costs cannot exceed \$170,000. For all other projects the maximum is \$140,000.

Other Support

The Other Support page has been revised to conform to the NIH format. However, TRDRP requires the attachment of the specific aims of other awards that have potential overlap with the TRDRP application.

Human Subjects

Human Subjects, Form 13, has been revised to include more extensive information about the proposed study population.

New Investigator Awards

The instructions for the content to be included in Letter of Support, Form 17, have been revised to give reviewers a clearer understanding of the support provided by the institution.

Dissertation Awards

Graduate school transcripts must be submitted with Dissertation Award applications.



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— November 2001 Newsletter —

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.

HOLD THESE DATES

December 6-7, 2001

TRDRP – AIM 2001
 Los Angeles, CA

January 17, 2002-5PM

TRDRP Applications Due

February 6-10, 2002

Intercultural Cancer Council
 Washington, D.C.

February 14-17, 2002

American Association for
 the Advancement of Science
 Boston, Massachusetts

February 14-15, 2002

1st Latino Conference on
 Tobacco Control
 Washington, D.C.

February 20-23, 2002

Society for Research on
 Nicotine and Tobacco
 Savannah, Georgia

February 20-23, 2002

American Physiology Conference
 on Cardiovascular Disease
 San Francisco, California

March 21-22, 2002

1st Menthol Conference
 Atlanta, GA

April 3-5, 2002

Society for Behavioral Medicine
 Washington, D.C.

April 6-10, 2002

93rd Annual Meeting of the American
 Association of Cancer Research
 San Francisco, California