

Drastic Cut Proposed in TRDRP Budget Implications for the Tobacco-Related Disease Research Program's Future

by Kamlesh Asotra, Ph.D. and Charles L. Gruder, Ph.D.

TRDRP faces drastic budget cuts not seen in a decade

Governor Arnold Schwarzenegger's proposed state budget for 2004-2005 includes a 40% cut to the Tobacco-Related Disease Research Program (TRDRP) from the amount approved by the legislature and signed by Governor Davis in 2003. This reduction was made in two steps: First, the \$23,863,000 approved for 2003-2004 was cut by 9% to \$21,625,000. Then, the appropriation for 2004-2005 was cut 34% more to \$14,253,000. Tobacco control programs funded by the Proposition 99 Health Education Account were also cut, but the TRDRP reductions are disproportionately larger. This is reminiscent of Governor Wilson's proposal to cut TRDRP's budget by 80% in the mid 1990's. That effort was rejected by the courts (see article on page 3, this issue, "The California Cancer Registry: The Whole Enchilada?").

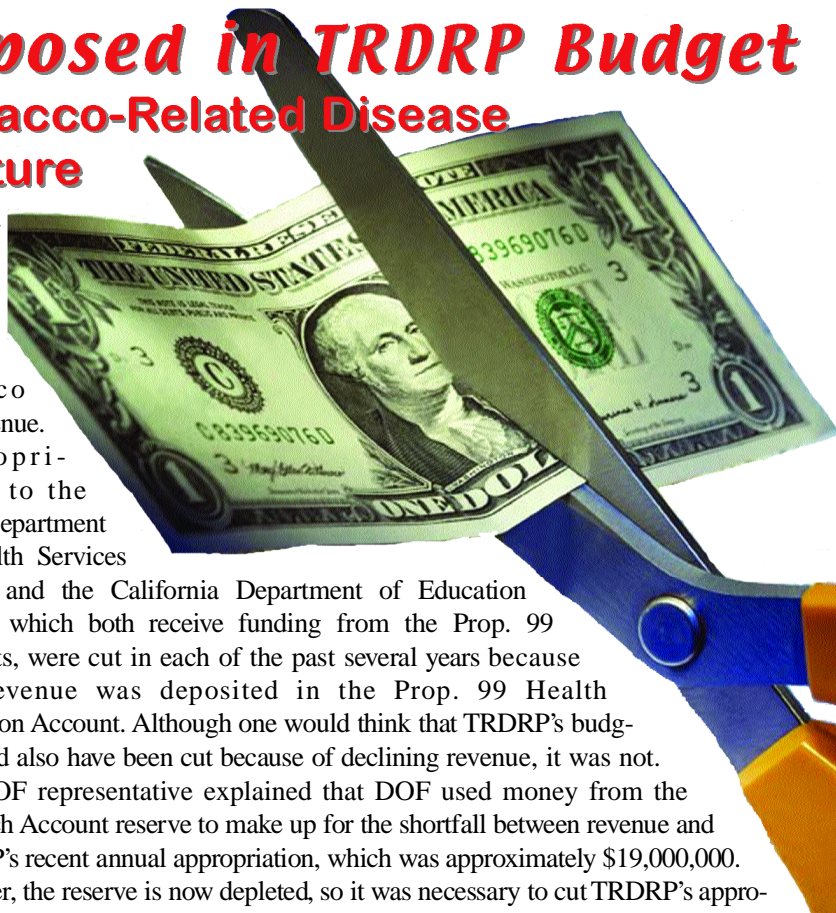
The state Department of Finance (DOF) budget analyst who handles the Prop. 99 accounts reported to the Tobacco Education and Research Oversight Committee (TEROC) in January that the TRDRP cuts were the result of declining

tobacco tax revenue. Appropriations to the state Department of Health Services

(DHS) and the California Department of Education (CDE), which both receive funding from the Prop. 99 accounts, were cut in each of the past several years because less revenue was deposited in the Prop. 99 Health Education Account. Although one would think that TRDRP's budget would also have been cut because of declining revenue, it was not. The DOF representative explained that DOF used money from the Research Account reserve to make up for the shortfall between revenue and TRDRP's recent annual appropriation, which was approximately \$19,000,000. However, the reserve is now depleted, so it was necessary to cut TRDRP's appropriation in the 2004-2005 budget to match projected revenue.

Have tobacco sales in California really declined so much as to require a drastic cut in TRDRP's budget? How do the Board of Equalization and Department of Finance arrive at their figures? To answer these questions, California's major voluntary health organizations (i.e., the American Cancer Society, the American Heart Association, and the American Lung Association) have asked DOF director Donna Arduin for "an accounting of the mid-year and budget year reductions."

Despite the drastic cut to TRDRP's budget, the 2004-2005 state budget includes an inexplicable increase in the appropriation from the Research Account to the state Department of Health Services (see article on page 3 "The California Cancer Registry: The Whole Enchilada?").



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What do the proposed budget cuts mean for tobacco-related research and the health of Californians?

TRDRP faces the challenge of maintaining the integrity and quality of the program with dramatically less resources. The program will find it much harder to fulfill its mission to fund research on the prevention, causes, and treatment of tobacco-related

See "Budget" page 2

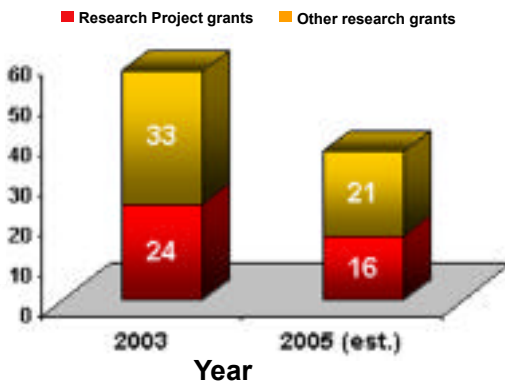
Budget

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disease and the reduction of the human and economic costs of tobacco use in California. There is widespread agreement, both within California and nationwide, that TRDRP has been remarkably successful in its first 15 years of operation.

To give the reader an idea of what the very large budget cut might mean for the number of grants that TRDRP could fund, compare the awards TRDRP made in 2003 with the awards we could make in 2005 after across-the-board cuts. The figure below shows numbers for three-year Research Project Awards and other types of research grants.

Estimated reduction in number of grants



Another consequence of the proposed budget cut for 2004-2005 would be a further decline in the application funding rate. During the last seven years, the success rate has declined from a high of 43% to 25%, and this will drop further unless the number of applications declines or the budget cut is not as deep. In 2003, TRDRP did not have enough money to fund all the research proposals peer reviewers had evaluated as “excellent.” Some of the topics were: gene therapy for lung cancer; novel anti-cancer agents; tobacco use in one of California’s most populous ethnic minorities; smoking and chronic obstructive pulmonary disease (COPD); effects of secondhand smoke on immune response; and a

smoking cessation program for inpatients.

Although \$14.3 million may seem like a large amount, it won’t go very far in supporting research on cancer, heart and lung disease, nicotine dependence, and tobacco control. For this reason, TRDRP is facing the daunting task of modifying the program further to adjust to the new budget reality while ensuring that we continue to fund research that has significant impact on tobacco control and the detection, prevention, and treatment of tobacco-related disease in California.

We have accepted our Scientific Advisory Committee’s recommendation to take the following immediate step. Instead of spending the full amount available for new grants this year – approximately \$19.5 million – we will carry forward approximately \$2.5 million into 2004-2005. This will increase the amount we can award next year from \$12.7 million to \$15.2 million. This “soft landing” option will produce a smoother transition from the budgets of the past three years to the new much smaller amount. This action will only help for one year, however, and the Scientific Advisory Committee is prepared to consider additional program changes.

We will start by reviewing the changes we implemented as the result of the strategic planning process completed last year. We initiated this process to prepare for the anticipated decline in tobacco tax funds over the next five years. We identified Primary research topics for Research Project Awards and will give them priority over Complementary research topics in this year’s funding process. Most applications for Research Project Awards did address Primary topics; and the number of all applications submitted this year declined by a quarter. Although we believe the Primary/Complementary dichotomy was a positive step in adjusting to the

anticipated gradual decline in funds, other changes may now be necessary because the budget cuts have been accelerated.

We have also decided to cancel this year’s Annual Investigator Meeting (AIM 2004). We believe, and the Scientific Advisory Committee agrees, that the time and money that would be spent on AIM 2004 would be better devoted to planning and to additional research grants. We have already begun planning for AIM 2005 and details will be announced in a future issue of this newsletter.

What can you do as a TRDRP stakeholder?

We want to thank TRDRP’s stakeholders who contacted us when they heard about the budget cut and asked how they could help. We would like to hear from anyone who has questions or suggestions. Please contact us at either (510) 987-9870 or trdrp@ucop.edu.

You can also contact the voluntary health organizations that have already requested further information and explanations from DOF: The American Cancer Society (Theresa Renken, Legislative Advocate, theresa.renken@cancer.org), the American Heart Association (Jamie Morgan, Legislative Director, jamie.morgan@heart.org), or the American Lung Association (Paul Knepprath, V.P. Government Relations, pknepprath@alac.org). Another valuable resource person is the Chair of the state Tobacco Education and Research Oversight Committee, Kirk Kleinschmidt (kpk326@aol.com). See the article next page, “The California Cancer Registry: The Whole Enchilada?,” for additional suggested action.

1. February 17, 2004 letter from Theresa Renken (American Cancer Society), Paul Knepprath (American Lung Association) and Jamie Morgan (American Heart Association) to Donna Arduin, Director of Finance.

The California Cancer Registry: The Whole Enchilada?

by Phillip Gardiner, Dr.P.H.

The continued increase in the proportion of Proposition 99 Research Account funds going to the California Cancer Registry (CCR) is serving to severely undermine the mission of the Tobacco-Related Disease Research Program (TRDRP): funding groundbreaking tobacco-related disease research. Indeed, the CCR portion of the Research Account has risen to the point that in the next fiscal year, 26.1% of all Prop 99 Research Account monies will go to the CCR. While the CCR plays an important role in cancer surveillance, it isn't clear whether any of the Research Account funds they receive actually support tobacco-related disease investigations. Moreover, the CCR mission is quite distinct from that of the TRDRP (see "Differing Missions" page 7).

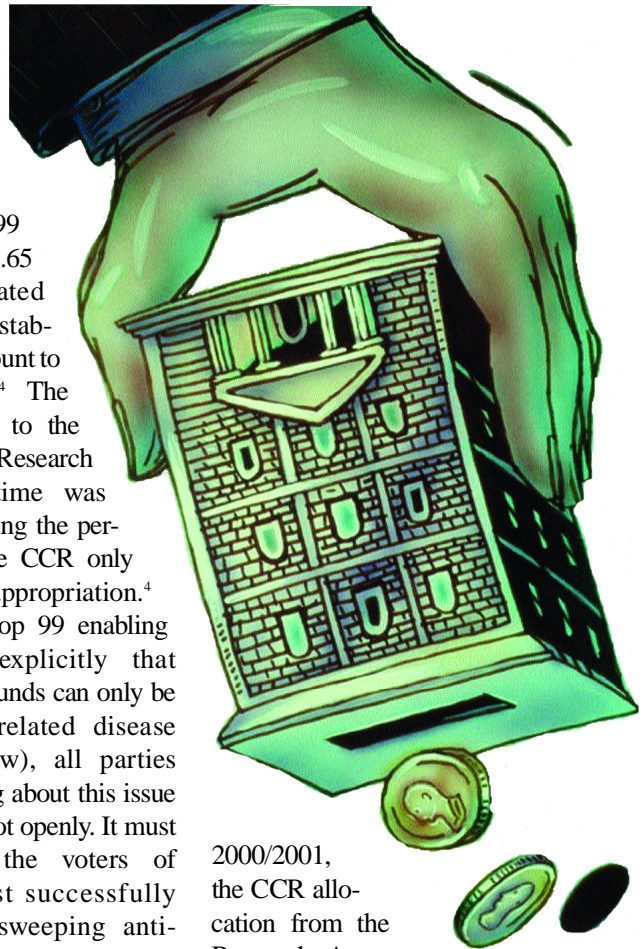
The TRDRP has voiced its concerns about this misallocation before in numerous Burning Issues articles.^{1,2,3} However, with the current precipitous decline in the TRDRP's budget (see: Drastic Cut Proposed in TRDRP Budget: Implications for the Tobacco-Related Disease Research Program's Future, in this issue), it is increasingly important that this misallocation be corrected, and that all the Research Account monies be allocated to the TRDRP. This is necessary so that the integrity of the Research Account can be maintained and tobacco-related disease research bolstered in the state of California. In order to take action to remedy this situation, it is first necessary to retrace the history of the ever-growing allocation to the CCR and review the language of the Prop 99 enabling legislation, including the legal precedents outlawing the diversion of Prop 99 Research Account funds. To conclude, a number of concrete, new, and hopefully creative remedies are suggested that could lead

to solving this seemingly intractable situation.

A Disturbing Trend

In 1989, when Prop 99 was implemented, \$1.65 million was allocated from the newly established Research Account to the Cancer Registry.⁴ The money appropriated to the TRDRP from the Research Account at that time was \$40.92 million, making the percentage going to the CCR only 4% of the total appropriation.⁴ Even though the Prop 99 enabling legislation states explicitly that Research Account funds can only be used for tobacco-related disease research (see below), all parties involved said nothing about this issue at the time, at least not openly. It must be recalled that the voters of California had just successfully passed the most sweeping anti-tobacco legislation anywhere in the country (indeed, in the world), hence, there was not much sense in quibbling about a mere 4% misallocation.

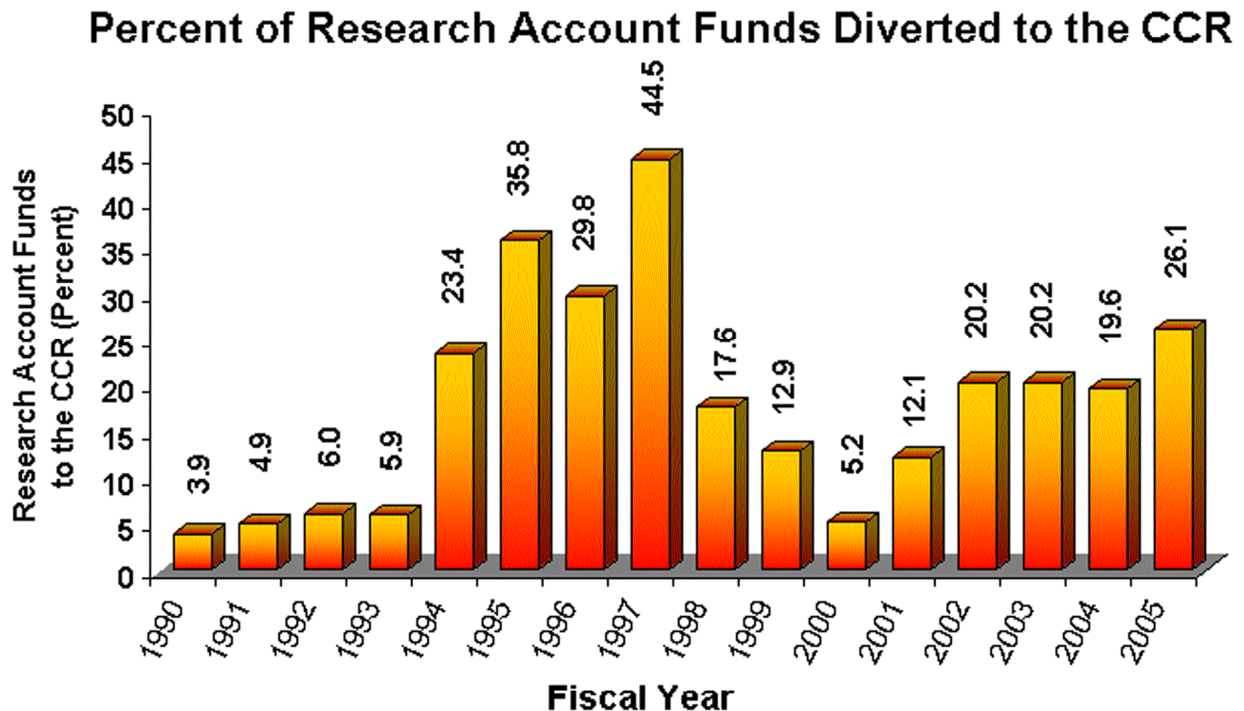
In the early part of the 1990's, the allocation of Research Account funds to the CCR hovered around \$1.7 million (see figure 1).⁴ Even when the Wilson Administration illegally tried to divert 80% of TRDRP's funding (see below), the CCR continued to receive a portion of the Research Account. In fact, the CCR allocation rose from \$1.6 million in 1993/1994 to \$2.03 million in 1994/1995, just when the Wilson diversion was taking place. When money was restored to the program, allocations to the CCR went up to and stayed around \$3.5 million per year throughout the latter part of the 1990's. Then, in fiscal year



2000/2001, the CCR allocation from the Research Account jumped from \$1.7 million in 1999/2000 to \$5.05 million in 2000/2001, an increase of \$3.35 million or 197% in a single year.⁴ Incredibly, these increases to the CCR have been taking place even while revenues to the Prop 99 Research Account are declining. Alarming, the TRDRP allocation for fiscal year 2004/05 will fall from \$19.43 to \$14.253 million, while the Research Account's contribution to the CCR during this same year will increase from \$4.738 million to \$5.026 million.⁵ The sobering fact is that if the Governor's budget is passed in its current form, 26.1% of the Research Account will go to the CCR.⁵

To add insult to injury, representatives from the Department of Finance

Figure 1



CCR

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recently informed the Tobacco Education Research Oversight Committee (TEROC) that, in addition to monies going to the CCR from the Research Account, an extra \$384,000 will now be going to the Environmental Health Investigation Branch (EHIB) to pay for three salaried positions!⁶ What about the staffing positions in the TRDRP? Who will be next to receive monies from the Research Account, Parks and Recreation?

With \$5 million more annually going to the TRDRP for tobacco-related disease research, many more grants could be funded (see: *Drastic Cut Proposed in TRDRP Budget: Implications for the Tobacco-Related Disease Research Program's Future*). However, now, with over a quarter of all Research Account funds proposed

to go to the CCR and EHIB, coupled with declining tobacco revenues, tobacco-related disease research is clearly in jeopardy.

One might ask, isn't it illegal for Research Account funds to go to agencies that are not mentioned in the Prop 99 enabling legislation?

The Law is on TRDRP's Side
Proposition 99 Enabling Legislation
 All aspects of The Tobacco Tax and Health Protection Act legislation (Prop 99) can't be reviewed here. Those interested in all the sections of the law should go to: www.leginfo.ca.gov. Highlighted below are some of the key tenets of this law. The Prop 99 legislation clearly states that: "The Research Account ...shall only be available for appropriation for tobacco-related disease research."⁷ Moreover the legislation goes on to say that: "Tobacco-related disease research"

includes, but is not limited to, research in the fields of biomedical science, the social and behavioral sciences, public policy, epidemiology, and public health."⁸ "The Legislature hereby declares that public policy research is an area of compelling interest because of its potential to determine the best methods for reducing tobacco use on a wide scale among Californians."⁹

Another provision of the Prop 99 legislation states that California investigators should have equal access to all Research Account funds: "All research funds shall be awarded on the basis of scientific merit as determined by an open, competitive peer review process that assures objectivity, consistency, and high quality. All qualified investigators, regardless of institutional affiliation, shall have equal access and opportunity to compete for the funds in the Research Account."¹⁰

With money being siphoned out of

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the Research Account for non-research activities, California investigators do not have “equal access and opportunity to compete for the funds in the Research Account.” While monies destined for the CCR and EHIR may be going to a good cause, this is not what is called for by the enabling legislation, nor does diverting money from tobacco-related disease research reflect what the voters of California endorsed in 1988.

Courts Find Diversion of Research Account Funds Illegal

There is already legal precedent for labeling the misappropriation of Research Account funds as illegal. Both the Superior and Appellate Courts of California found Governor Pete Wilson and the California Legislature in violation of the law for allocating approximately 80% of the Research Account for other state needs.^{11,13} This diversion of funds severely crippled the TRDRP by restricting the funding of new research in 1995 and 1996.¹²

In Superior Court case No. 379450, consolidated with No. 379257 in 1995, the Honorable Roger K. Warren ruled against the appropriation of Research Account funds for purposes other than tobacco-related disease research because these purposes were inconsistent with the state constitution and statutes. In his Statement of Decision, Judge Warren said, “With respect to the other two challenged appropriations out of the research account, the court also concludes that – based on the evidence before the court, that those appropriations are not for the purposes of tobacco-related disease research, and therefore are also in violation of section 30122, subdivision (b).”¹¹

Similarly, in 1996, the California Appellate Court upheld the lower

court’s decision. The Appellate Court, drawing on the same law cited by Judge Warren, was clear and minced no words in its decision to block Governor Wilson and the legislature’s diversion of Prop 99 Research Account funds: “Pursuant to section 30122, subdivision (b)... the research account is available only for appropriation for tobacco-related disease research.”¹³

Moreover, since Prop 99 was a ballot initiative, the Appellate Court further stated that The Tobacco Tax and Health Protection Act were protected by the California State Constitution: “The Act has superior legal status for two independent reasons. First, the Act creates the tobacco tax fund and directs the amounts which may be appropriated from the fund. Second, since the Act was enacted as an initiative statute, which has superior legal status to ordinary legislation, no legislative enactment may conflict with it. (Cal. Const., art. II, § 10, subd. (c).)”¹³

The actual Prop 99 legislation coupled with the California Superior and Appellate Courts’ decisions makes it crystal clear that all monies in the Research Account must go to tobacco-related disease research. It would be unconscionable if the misappropriation of state funds is allowed to continue, since the California Courts found this practice illegal eight years ago. While the current diversion to the CCR is not as dramatic as the Wilson administration’s maneuver, still the piecemeal increases to the CCR from the Research Account are just as damaging to the TRDRP’s research mission and potentially illegal.

My Way or the Highway?

In hindsight, the neglect to register protest and voice concerns about the misallocation of TRDRP funds in 1989, when the diversions to the CCR began, may not have been the best strategy. It is possible that if objections had been raised initially*, the TRDRP

and the California tobacco-related disease research community would not be witnessing the increases to the CCR that are taking place today. Others might argue that since there is now a fifteen-year history of Research Account funds going to support the Cancer Registry, the TRDRP should just accept the way things are and get over it. Yet regardless of the length of the time that the misappropriation of funds has gone on, this diversion remains detrimental to tobacco-related disease research and on the surface is illegal.

All recipients of Prop 99 funds are facing declining allocations, forcing cuts to programs, elimination of projects, and the scaling back of tobacco control and research efforts throughout the state. In this time of shrinking budgets and diminishing tobacco research and control possibilities, it seems incredible that the allocation to the CCR from the Research Account continues to grow; is the California Cancer Registry destined to get the whole enchilada? Is it really the current way or the highway? All hyperbole aside, if we are to successfully put tobacco-related disease research back on its feet, then we must strike off in a new direction. Below are a few suggestions to generate discussion and push the resolution of this problem forward.

Funds for the CCR and EHIR should come from the Prop 99 “Unallocated Account.” In a letter to Governor Schwarzenegger, the Tobacco Education Research Oversight Committee (TEROC) proposed the following solution: “Both TRDRP and the California

**It is important to note that TRDRP staff in the early 1990s did voice concerns about this misappropriation. However, with then Governor Pete Wilson promising to divert the lion’s share of Research Account revenues to other state projects, TRDRP staff increasingly focused on blunting these efforts. Even though the program was saved and the Governor’s diversion was deemed illegal, the allocations to the CCR continued unabated.*

Differing Missions

The TRDRP, CCR and the EHIB all have important roles to play in ensuring that California is a healthy place to live. On the other hand, only the TRDRP's sole and legislatively mandated purpose is to fund tobacco-related disease research.

The Tobacco-Related Disease Research Program Mission

"The mission of TRDRP is to support research that focuses on the prevention, causes, and treatment of tobacco-related disease and the reduction of the human and economic costs of tobacco use in California."¹⁵

The California Cancer Registry Mission

"... data generated from CCR is utilized to:

"Monitor the amount of cancer incidence trends by geographic area and time in order to detect potential cancer problems of public significance in occupational settings and the environment, and to assist in their investigations;

"Provide information to stimulate the development and targeting of resources to benefit local communities, cancer patients and their families;

"Provide high quality research into epidemiology and clinical medicine by enabling population-based studies to be performed to provide better information for cancer control;

"Inform health professionals and educate citizens regarding specific health risks, early detection and treatment for cancers known to be elevated in their communities; and

"Respond to public concerns and questions about cancer."¹⁶

The Environmental Health Investigation Bureau Mission

"identify and work toward controlling harmful environmental factors, and promote those that are healthful.

To accomplish this, the branch . . .

"Conducts health and exposure investigations; "Undertakes health and exposure surveillance

"Provides public health oversight, technical assistance and training; "Facilitates public participation and effective community relations; "Develops policy initiatives and recommendations

"Maintains scientific preparedness"¹⁷

The missions of the CCR and EHIB are broad, indeed, noble mandates to track cancer and perform health exposure investigations in California. And true, both the CCR and the EHIB conduct some tobacco-related research. However, nowhere in either of their mission statements are there any mentions of tobacco-related disease research being the primary focus or intent of the agency.

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Cancer Registry are vital state programs that should receive full support. However, Prop. 99 Research Account funds must be used in accordance with the intent of the voters. TEROC proposes that you can meet these needs by appropriating funds to the DHS programs from the Prop. 99 Unallocated Account, thus freeing funds in the Research Account for appropriation to TRDRP."¹⁴

The TRDRP strongly supports this

initiative of TEROC. Of the six funds established to manage the Tobacco Tax and Health Protection Act (Prop 99), the Unallocated Account is one of the largest, receiving 25% of California's tobacco tax revenues, a projected \$87,000,000 for fiscal 2004/2005.⁵ Given the size of the Unallocated Account and the relatively small need of the CCR, it seems reasonable that this account should be used to shore up short falls, such as those in the CCR budget. The Research Account receives only 5% of tobacco tax revenues; let's not put the burden of supporting the CCR and the EHIB

on the back of the smallest Prop 99 account. The TRDRP will continue its ongoing discussions with representatives of the Department of Health Services in attempts to resolve this matter.

Representatives of the Department of Finance, TEROC, Department of Health Services, and the TRDRP should meet as soon as possible. Since all budgets are being affected by the decline in tobacco tax revenues, it seems prudent, indeed necessary, for the key players in this drama to meet and discuss this matter. The

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Department of Finance should be prepared to justify the allocation of research funds to the CCR; they will need to distinguish their allocations from the diversion of funds under the Wilson Administration in the mid-1990s. On the surface the processes look very similar. In this regard, the TRDRP is preparing a letter to be sent and circulated to the above mentioned parties to secure a meeting time as soon as possible.

TRDRP representatives will meet with the University of California General Counsel. It is clearly time for there to be a meeting with UC lawyers to fully review both the history and the law surrounding the misappropriations of funds from the Prop 99 Research Account. With declining tobacco revenues, coupled with increases in the funds diverted from the Research Account to the CCR, the TRDRP must explore all avenues available to itself to ensure its long-term survival and the survival of the tobacco-related disease research enterprise in California.

Friends of the TRDRP should meet with Legislators to discuss alternative funding for the CCR. Tobacco researchers, voluntary health organizations, health advocates and concerned citizens should target key legislators to meet with to discuss the issue of misallocation of Research Account funds. TRDRP funded investigators are encouraged to talk with their state representatives and send a strong message that tobacco-related disease research is vital to the health of Californians and necessary to combat the “junk” science of the tobacco industry. The TRDRP is developing materials that can be used by our staff and friends to highlight the successes of our program and at the same time tar-

get the misallocation of Research Account funds. Friends of the TRDRP are preparing to meet with Legislators to inform them about our needs and hear their suggestions.

Epilogue

The above suggestions are just a start in the process that will be necessary to solve this dilemma. It can't be nor should it be that the TRDRP must either accept funding the current way or take the highway; there are clearly other options. The TRDRP's mission, put simply, is to support research that focuses on the prevention, causes, and treatment of tobacco-related disease and the reduction of the human and economic costs of tobacco use in California.¹⁵ This mission is in jeopardy with the continued diversion of Research Account funds. We look forward to working with our allies and all stakeholders in solving this problem and putting tobacco-related disease research back on track.

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by Francisco O. Buchting, Ph.D.

The reality is tobacco-related research has been, and will continue to be, a key weapon in the battle against Big Tobacco. This fact was true before the release of the 1964 Surgeon General Report: Reducing the Health Consequences of Smoking, and research became even more prominent in the tobacco battlefield after the release of that report. In fact, research is just as imperative today in the post-MSA environment where the tobacco wars continue. In California, TRDRP has been the leader in funding credible and scientifically sound tobacco-related research that is vital for tobacco control efforts.

This article explains why and how research is a vital part of tobacco control, provides an example of how research has played and continues to play an important role in the issue of second hand smoke (SHS) exposure, and spells out the challenges for the future of TRDRP.

Why do we need a research program?

By the early 1950's, the tobacco industry (TI) was faced with an increase in published independent research linking tobacco use to lung cancer, a questioning of consumer confidence, and threats of litigation. Early research findings were the catalyst for the conversion of tobacco use into a public health issue as well as wake-up call to the TI that business as usual was not going to last forever. According to the TI's internal documents, the tobacco companies' strategy to snuff out this wildfire was to jointly conspire to misuse and manipulate scientific research to severely cripple any public health efforts addressing the effects and damage of tobacco use. Thus research became a very powerful weapon in the tobacco-control battles for over half a century. (See TRDRP Newsletter, March 2001, The Tobacco Industry as a Funder of Scientific Research).¹

The manipulation of data and the creation of "tainted science" have been and continue to be a cornerstone in the TI's strategic public relations efforts to diminish, dismiss, or negate the health effects due to tobacco use and SHS exposure. *"The most important type of story is that which casts doubt in the cause and effect theory of disease and smoking. Eye-grabbing headlines were needed and should strongly call out the point – Controversy! Contradiction! Other Factors! Unknowns!"*² Even to this day, the TI continues to deny or call into question scientific findings and continues to fund and disseminate questionable research findings.³ The production and use of "tainted science" has been an effective tool for the TI to delay and sometimes forestall tobacco control efforts in California, the US, and worldwide.

TRDRP has been an antidote to the TI's "tainted science" strategy by modeling its practices after the National Institutes of Health peer review and by building a distinguished record of funding high quality scientific work by reputable scientists, thus making TRDRP a credible and highly respected funder of research. Research findings from TRDRP-funded projects have been used in key state and national documents to create or support tobacco control policy and legislation, to highlight and discredit the TI's "tainted science", and to support tobacco control efforts.

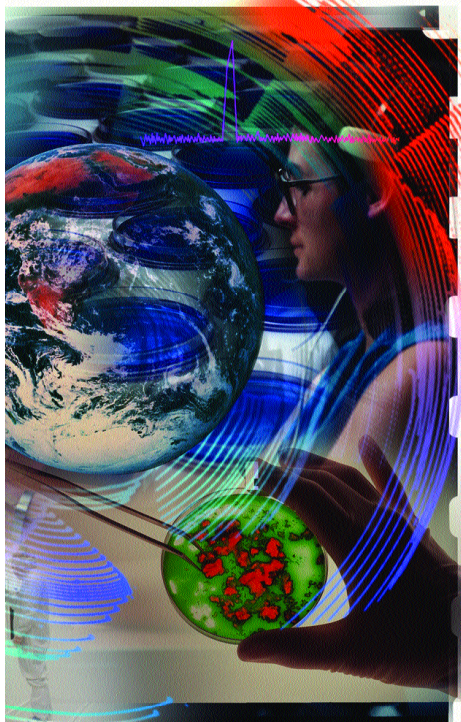
It is of no surprise that the TI had significant concerns when California voters, through the passage of Proposition 99, created a comprehensive tobacco control effort that included an aggressive tobacco control campaign and a tobacco specific research program. A 1989 TI document titled "Project California," and prepared by the State Activities Division of the

Research is Vital



Tobacco Institute proposed an all concerted effort to block the activities from two of the Proposition 99 programs it had classified as unacceptable: *"Industry consultants have completed an initial assessment of proposals offered by the Governor and have identified "acceptable" and "unacceptable" programs listed for funding. Through industry efforts, a significant amount of Prop 99 revenues have been assigned in the Governor's budget, as noted above, to "acceptable" programs. There are two exceptions – University of California Research and Grants and Department of Health Services anti-smoking programs. A sound legislative tactical plan is presently underway to address concerns."*⁴ This document spells out the steps the TI would undertake to undermine or halt the work to be done by both programs. Evidently, the TI recognized and was concerned about the negative impact a legitimate state-specific funder of tobacco-related

r Tobacco Control



research would have on its pro-tobacco activities.

Legitimate science vs. TI “tainted science” in the SHS battles

The TI used the same public relations strategy of systematic manipulation and adulteration of the scientific process and record with the issue of SHS just like they have used with any other tobacco issue that might lead to a tobacco control policy. The use of this strategy by the TI was spelled out very clearly in a 1978 report prepared for the US Tobacco Institute by the Roper Organization: *“what the smoker does to himself may be his business, but what the smoker does to the non-smoker is quite a different matter ... This we see as the most dangerous development yet to the viability of the tobacco industry that has yet occurred ... The strategic and long run antidote to the passive smoking issue is, as we see it, developing and widely publicizing clear-cut, credible, medical evi-*

*dence that passive smoking is not harmful to the non-smoker’s health.”*⁵ Even to this date, this is the strategy still being used by the TI in order to thwart attempts by the tobacco control community and health policy makers to deal with SHS. Why is the tobacco industry wedded to this type of strategy? Because it makes sense and it works, although not as well anymore.

Just as studies linking smoking and lung cancer began to show up in the scientific literature, so did the findings of health effects associated with SHS exposure begin to make a significant presence. The scientific evidence began to confirm what the public health community long suspected: that SHS is more than just an “irritant.” A long battle ensued in the scientific literature and the public health arena over the health effects caused by SHS exposure. While the scientific community and the public health community used legitimate science and public health tools to bring light to the dangers of SHS exposure, the TI continued their public relations campaign of creating controversy and contradiction through “tainted science”. The TI’s need to obfuscate the legitimate scientific findings in the literature was so pressing that they jointly funded the Center of Indoor Air Research to mass produce their SHS “tainted science.”⁶ Never-the-less, epidemiological studies of health consequences due to SHS exposure continued to be published, making the case to create and support tobacco control policy to address SHS exposure.

In California, the clash of legitimate science and “tainted science” began to be played out in front of town hall meetings, city councils, legislation, and the courts. The success of local action in passing local ordinances to minimize the exposure to SHS rose to state level attention when

AB13 was introduced and subsequently passed and when the California EPA classified environmental tobacco smoke as a Class A carcinogen. In the battles leading up to these two turning-point events, as well as in subsequent battles, the role of scientific evidence has played center stage.

Legitimate research findings, including research funded by TRDRP, produced the evidence needed to overwhelmingly dismiss the claims made by the strategic public relations “tainted science” campaign launched in California by the TI and the unsupported declarations from the TI’s front groups. These legitimate research findings strengthened the arguments for SHS public policies, such as AB13, made by California’s tobacco control community and public health agencies. For example:

Research funded by TRDRP has shown that ventilation does not work when it comes to SHS. In addition, recent research findings are beginning to model how toxins from SHS can be deposited on the furniture and carpet in a room only to be later absorbed through the skin.

TRDRP studies the chemical composition of tobacco smoke have identified a host of toxins and carcinogens associated with a variety of TRD and health effect effects.

At the same time, TRDRP epidemiological studies have reported significant associations between SHS exposure, tobacco related diseases and health effects, while biomedical research has provided the causal evidence by identifying biological mechanisms by which SHS causes disease. For example, different types of cancer, decrease in lung functioning, cardiovascular disease, reproductive and developmental health effects including SIDS and inner ear infection can all be caused by SHS.

Research

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Projects funded by TRDRP that looked at the TI documents revealed that the research funded by the TI in the area of SHS was of consistently lower quality than comparable legitimate research reported in the peer-reviewed literature. The findings from these studies helped bolster the 1996 US EPA findings on the danger of SHS when the industry tried to use its “tainted science” to discredit the report. Results from TRDRP-funded studies also played a role in the California EPA report, in which SHS is classified as a Class A carcinogen.

Ongoing TRDRP research into SHS will continue to produce critical findings that will be important for new public health initiatives in this area. Findings from TRDRP projects looking at home smoking bans across different ethnicities and other priority populations in California and research analyzing the best public health models for increasing success in this area will enhance tobacco control efforts. Likewise, TRDRP studies are also testing different SHS exposure prevention models with children and adolescents in California schools. Currently, TRDRP-funded research is being used by the California Air Resource Board to support their work on classifying SHS as an environmental toxin. TRDRP will continue to make research into SHS a priority, especially when this area is underfunded across all the sciences at the federal level.

What lies ahead?

Imagine a tobacco control effort in California without high quality tobacco-related research. Imagine the TI parading their “tainted science” in front of city councils and state legislature without being challenged by legit-

imate research. Imagine the TI or their front groups using this “tainted science” to overturn or weaken existing tobacco control policy or to stall proposed tobacco control and health policy. The TI’s ability to delay, weaken or overturn tobacco control policy and health policy has been documented numerous times.

Currently, TRDRP funded research is being used by the California Air Resource Board to support their work on classifying SHS as an environmental toxin.

Research funded by the federal government will continue to have a significant role in tobacco control. But in California, a significant amount of the much needed research funded by TRDRP would not be funded by the federal government due to different priorities or political interests. For example, research on lung cancer, COPD, health effects associated with SHS exposure, and California policy specific research has not been historically funded by the federal government at the same level as other research topics. In addition, research that focuses on California’s diverse population and on gender differences will not receive the same amount of attention as it does today, due in part to TRDRP. The synergistic relationship between federal research and California specific targeted research that exists today would also be lost. The reality is that public health policy is influenced by research or is supported by research, and sometimes it is a direct result of research. In the tobacco wars, this has been the case, but even more so now since the TI

continues to manipulate science for its own purposes and not for public health. Thus, more legitimate California specific targeted tobacco-related research is needed.

The TRDRP finds itself at crossroads due to the recent budget reductions and the increasing appropriation to the California Cancer Registry (see article this issue, page 3). The staff at TRDRP is committed to ensuring that the will of the voters of California is carried out and the directions set forth by the legislation for Proposition 99 are followed as closely as possible. The mandate is broad, the challenge is welcome and the need to act is great – 42,000 Californians will die this year of a tobacco related disease. The TI will continue to addict the next generation of replacement smokers in order to maintain their profit margin. “Tainted science” will continue to be funded by the TI to derail tobacco control policy and efforts. The reality is that the science funded by TRDRP does make a difference, it has an impact, and it is one of the powerful weapons we have to combat an industry that knowingly disables and kills the people who use their product and those exposed to SHS.

More research is needed. TRDRP is committed to continue funding the best science and playing a key role in tobacco control in California. TRDRP will have to change in order to maximize the impact of our efforts as the budget situation continues to decline due to a misappropriation of funds from the research account. The minimum amount of funding needed by TRDRP in order for tobacco-related research to, in part, continue to have a significant impact in California is unknown at this time. What is known is that a strong and adequately funded TRDRP equals Research for a Healthier California.

TRDRP's Genesis and Work

The enabling legislation for Proposition 99 provided the framework for research to play a role in California's tobacco control efforts and in mitigating the health effects and diseases associated with tobacco use and SHS exposure. Health & Safety Code, Section 104370 states, "The department (of Health Services) and the California Department of Education shall apply the most current findings and recommendations of research including research funded by the Research Account (TRDRP) of the Cigarette and Tobacco Products Surtax Fund created by Section 30122 of the Revenue and Taxation Code." This tobacco control framework has been a three-pronged approach for California's tobacco control efforts where research (TRDRP), education and intervention (Tobacco Control Section and California Department of Education), and policy (local and state) inform and influence each other. The legislative charge to the University of California, per Health & Safety Code, Section 104530, was to create and manage a comprehensive tobacco-related research program. The scientific charge was broad in scope: "tobacco-related disease research includes, but is not limited to, research in the fields of biomedical science, the social and behavioral sciences, public policy, epidemiology, and public health."⁷

Since 1989, TRDRP has been one of the premier state research programs on tobacco and one of the leading funders of tobacco-related research in the United States. TRDRP's award portfolios are broad in scope of scientific inquiry and numerous in the production of research findings. The research funded by TRDRP has led to groundbreaking discoveries and advances in tobacco-related diseases, nicotine addiction and cessation, and key local and state public health policies. Many of the studies funded by TRDRP focus specifically on California's diverse population, e.g., ethnic groups, socioeconomic status and sexual orientation. At the same time, TRDRP has played a key role in building a tobacco-related research infrastructure in California marked by exceptional researchers who are nationally and internationally recognized as experts in the area of tobacco-related diseases and tobacco control research. TRDRP has created a tobacco-related disease research program that other states look up to as a model and is considered an important partner among the national funders of tobacco-related research. But one of the most important and often judicious roles TRDRP has is in being part of tobacco control in California, nationally, and internationally.

A comprehensive and searchable database of TRDRP research portfolios can be found at www.trdrp.org. In addition, highlights of the first ten years of research funded by TRDRP can also be downloaded from the website.

Research

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Pulling the Plug on Research Funding: What it Means to the Victims of Chronic Obstructive Pulmonary Disease

by M.F. Bowen, Ph.D.

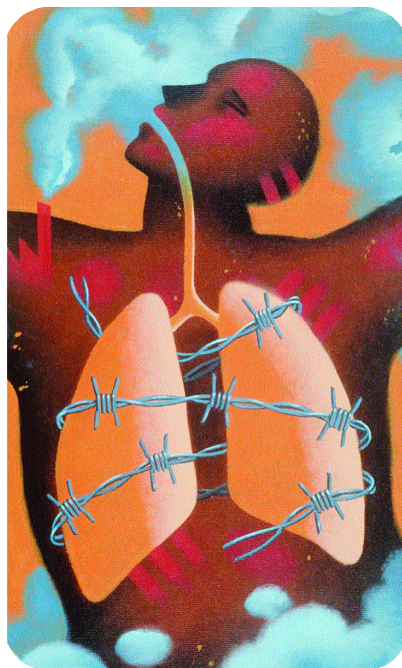
While lung cancer rates have declined in California since 1988¹, mortality due to chronic obstructive pulmonary disease (COPD) is on the rise, with deaths in women and African Americans of both sexes responsible for most of the increase.² COPD is not going away: Smoking rates in 18-24 year-olds are on the upswing in California³ as well as across the country.⁴ Given the difficulty of quitting, many of these smokers will be the COPD patients of the future. Furthermore, management of chronic diseases such as COPD is at a crisis point.⁵ In light of this ominous trend, the decision to cut research funding for tobacco-related disease could very well presage a public health catastrophe. Indeed, the demands on medical services for this disease would seem to call for increased, rather than decreased, funding.

As detailed in other articles in this newsletter^{6,7}, research funds that are more urgently needed for COPD research are being misdirected to the California Cancer Registry and the Environmental Investigations Branch. Given this scenario, it behooves us to ponder the impact that TRDRP's plummeting research dollars will have on those individuals who suffer the most: Californians who will become sick and die as a result of their addiction to nicotine. This article describes the issues surrounding chronic obstructive pulmonary disease (COPD) and why cutting research funding at this point is short-sighted at best and calamitous at worst.

The Breath-Taking Statistics

The percent change in the age-adjusted mortality rate for COPD increased 163% between 1965 and 1998 in the

US. In this regard COPD stands in stark contrast to all other causes of death, including cardiovascular disease, stroke and cancer, all of which have undergone either a decline in mortality rate or maintained a steady rate during that time period.⁸ In the US, approximately 119,000 adults died from COPD in 2000.⁹ Mortality



rates have increased in women and African Americans of both sexes. It is now the 4th leading cause of death in the US (after cardiovascular disease, stroke and cancer) and is expected to move to third place by 2020.⁹ The situation in California mirrors this national trend.² COPD cost the US \$32.1 billion in 2002 – \$18 billion of which was spent on direct health care costs.¹⁰ Globally, COPD currently ranks 12th as a disease burden; by 2020 it is projected to rank 5th.¹¹ What is driving this disturbing trend?

Smoking Takes Your Breath Away

Smoking is the primary risk factor for

COPD, accounting for almost 90% of the COPD cases in the US.¹⁰ A smoker is ten times more likely to die of COPD than a non-smoker.¹⁰ Because COPD does not usually manifest until middle age, the stunning increase in disease prevalence and mortality in the US clearly represents an accumulated disease burden resulting from past smoking prevalence, particularly in women.¹²

Approximately 1.1 billion people in the world smoke; this is expected to increase to 1.6 billion by 2025.¹³ The successful marketing of cigarettes to developing countries by the tobacco industry and changes in age demographics are fueling the increase in COPD throughout the developing world. It is not surprising that COPD is expected to undergo such a dramatic world-wide rise over the next two decades.

Might we expect Big Tobacco to stop selling cigarettes in light of this dismaying epidemic? Don't hold your breath! From 1998 to 2001, Big Tobacco advertising and promotional expenditures within the US increased 66.6% from \$6.73 billion to \$11.22 billion; this included 3.9 billion cigarettes that were given away for free in 2001 alone.¹⁴ In 1998 the combined global revenues of Philip Morris, Japan Tobacco, and British American Tobacco was in excess of \$88 billion. Phillip Morris International's revenues increased 226% between 1989 and 1999.¹⁵ This marketing tsunami and global profiteering has not gone unnoticed by Wall Street: Tobacco stocks still offer an excellent return on investment and are recommended "buys."^{16,17} Unfortunately, what is being "bought" in this case is the health of the public.

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Waiting to Exhale

What is COPD? It is a pathological lung condition characterized by irreversible airflow limitation. COPD sufferers experience shortness of breath, cough and excess sputum. Pockets of dead air accumulate in the dysfunctional air spaces and expiration becomes difficult. Breathlessness may initially be evident only upon exertion but later may be present continuously. The disease is believed to be caused by an abnormally prolonged inflammatory response of the lungs to airborne irritants, which ultimately results in destruction of lung tissue, enlargement of the air spaces and loss of elastic recoil. Airway narrowing due to fibrosis contributes to respiratory impairment in the later stages of the disease. Disability and, in some cases, complete immobility results. COPD patients with advanced disease often require continuous oxygen supplementation and frequent hospitalization. The damage to lung integrity and function caused by smoking cannot be undone. Nonetheless, smoking cessation ameliorates the inflammatory process, decreases cough and sputum production and decelerates the decline in lung function. The take-home message here is that it is never too late to quit: COPD patients should make every effort to do so and should be given the support and guidance they need to make their efforts successful.

The primary pharmacologic treatments for COPD include bronchodilators and glucocorticosteroids. Pulmonary rehabilitation and oxygen therapy are also often prescribed. Lung volume reduction surgery is recommended only in carefully selected patients and the procedure is still considered experimental. Lung transplantation is a treatment of last resort and is limited by a shortage of donor

organs and cost. All of these treatments merely ameliorate the symptoms. There is currently no cure for COPD.

COPD is one of TRDRP's current primary research priorities. Applications are accepted in all areas of research into this disease.

Waiting With Bated Breath - For a Diagnosis

Astonishingly, COPD remains largely unrecognized by the public and is notoriously underdiagnosed by the medical community. It is estimated that over 24 million people in the US have COPD; yet over half of those afflicted do not realize it.⁹ There are several reasons for this. The symptoms – cough, sputum, shortness of breath – are often erroneously thought to be the inevitable consequences of aging. Sufferers don't go to their doctor until breathing is severely impaired. Symptoms are often mistaken for those of asthma or heart disease. Over 75% of cases see a primary care physician; however few such physicians perform spirometry, which is currently the only way to accurately diagnose the condition.^{18,19} Thus less than 50% of estimated cases are accurately diagnosed.

Research Funding: Gasping for Breath

COPD has the dubious distinction of being the most under-funded of all the major diseases in the US. Dollars spent on research per COPD death is a mere \$508.²⁰ This stands in stark contrast to 2001 funding levels of HIV/AIDS (\$34,000), breast cancer

(\$9,000), and prostate cancer (\$3500). Even lung cancer, another sadly neglected public health issue, is better funded than COPD: \$900 per death was spent on lung cancer research in the US in 2001.²¹

Like lung cancer, COPD is a stigmatized disease. But whereas lung cancer victims succumb to their disease relatively quickly, COPD patients live a relatively long time, albeit in a debilitated and disabled state. Victims of COPD have begun the long and arduous process of uniting for their common cause and making their voices heard to change health care policy, educate the public, and encourage research to prevent and assuage the ravages of COPD.

A Breath of Fresh Air

A group of health care professionals, researchers, and patient activists are sounding the alarm about the impact of COPD on current and future public health. The US COPD Coalition is a group of professional, government, academic and patient organizations working to reduce the prevalence and mortality of COPD. The coalition organized the first National COPD Conference held on Nov. 14-15, 2003 in Arlington, VA. Issues discussed ranged from causes, epidemiology, pathogenesis, diagnosis and treatment to health care policy and economics. This was an historic moment for COPD, its victims, and the health care professionals who care for them. It was clear from the discussion at this meeting that research is urgently needed in many areas including epidemiology, health care policy, chronic disease management, pathogenesis, diagnosis, education, translation and treatment. For example, the pathogenesis of COPD is still largely a mystery. Understanding the cellular and molecular processes underlying lung inflammation and destruction will enable the development of better treatments and, eventually, prevention or curative

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measures such as lung regeneration. Given the diagnostic problems that have plagued the field for so long, epidemiological studies are needed to assess the true extent of the problem, particularly in California where access to care, ethnic and cultural issues complicate the picture. Health policy research on the costs and benefits of treating this chronic disease is urgently needed. Finally, it is absolutely necessary to continue to investigate, scrutinize and research the tobacco industry – its tactics and the economic toll it exacts on this country and throughout the world. Such research tells the industry that we're watching every breath they take and every move they make. Only by knowing our enemy can we effectively combat the gargantuan marketing, political and legal juggernaut that is Big Tobacco.

COPD has taken a toll on public health and that toll is increasing day by day. It is time to say "Enough!" Through funding, research, activism, and dissemination we can make inroads into the prevention and treatment of this disease. It seems at times that smoking has devolved in the public's mind into a mere faux pas or a minor act of rebellion. Smoking is much more than that. Smoking is increasing the odds of living out the last years of life in a state of debilitation, infirmity and misery. Smoking isn't worth that sacrifice.

When we think about Prop. 99 and how best to allocate its funds in times of fiscal crisis, let's think twice and consider the future medical and public health implications of our decisions. COPD is not only physiologically and emotionally devastating to its victims but, as a long-term chronic condition, fiscally devastating to patients, their families and the California economy. Raiding the Research Account and using these

funds for anything other than tobacco-related disease research is misguided at best. Think twice. It's not alright.

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Initiatives

1. GOLD – Global Initiative for Chronic Obstructive Lung Disease. Objective: To increase awareness of COPD among health professionals, health authorities and the public.
2. NLHEP - National Lung Health Education Program: A nationwide education program aimed at physicians, patients and the public. URL: www.NLHEP.org

New Journals

1. Emphysema/COPD: The Journal of Patient-Centered Care URL: www.lifethreat.org/journal.htm
2. COPD: Journal of Chronic Obstructive Pulmonary Disease www.dekker.com/servlet/product/productid/COPD

Patient Resources

1. Petty TL and Doherty DE. 2003. Save Your Breath, America! Prevent Emphysema Now! National Lung Health Education Program, Denver, CO. URL: www.NLHEP.org.
2. Schacter N. 2003. Life and Breath. 336 pp. Broadway Books, New York.
3. The Pulmonary Research & Education Foundation. Box 1133 Lomita, California 90717-5133. Fax/Tel: (310) 539 – 8390. URL: www.perf2ndwind.org/

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TRDRP UPDATE

TRDRP will not host an Annual Investigator Meeting in 2004.

After much deliberation and input from the Scientific Advisory Committee, we reached the difficult decision not to hold AIM this year. The primary reason is the budget crisis (see “Drastic Cut Proposed in TRDRP Budget” in this issue). The time and money that would be spent on AIM 2004 would be better devoted to planning responses to a reduced budget and funding additional research grants. We have already begun planning AIM 2005 and details will be announced in a future issue.

Research applications down. TRDRP received 24% fewer applications in 2004 (186) than 2003 (244). Although we do not know the reason for this decline, we suspect that it is due at least in part to the initiation of Primary and Complementary research topics for Research Project Awards. Some investigators working in Complementary areas may have decided not to submit applications because of the reduced chance of funding.

Although we will spend less money on new grants this year (see “Drastic Cut Proposed in TRDRP Budget” in this issue), we believe we will be able to maintain a funding rate comparable to last year because there are fewer applications submitted.

Scientific Advisory Committee update. It's a pleasure to introduce three new Scientific Advisory Committee members. **Roshan Bastani, Ph.D.** is Professor and Associate Dean for Research in the Division of Cancer Prevention and Control Research at the UCLA Jonsson Comprehensive Cancer Center. She brings behavioral science expertise to the committee. **Ken Yoneda, M.D.**, Assistant Professor of Medicine at the University of California, Davis, is a pulmonologist and former principal investigator of a TRDRP grant. Dr. Yoneda represents the American Lung Association of California. **Gerd Pfeifer, Ph.D.** is Professor and Chair of the Division of Biology at the Beckman Research Institute of the City of Hope National Medical Center. We welcome Roshan, Ken and Gerd to TRDRP and look forward to working with them.

Staff update. The newest member of the TRDRP senior staff is **Kamlesh Asotra, Ph.D.** Dr. Asotra earned his Ph.D. in biochemistry from Himachal Pradesh University in India. He joined TRDRP from Cedars-Sinai Medical Center where he was a research scientist in the Cardiology Department, as well as Founder and Director of the Confocal Microscopy Facility. Kamlesh is responsible for the research portfolios in cardiovascular disease and general biomedical science. He can be reached at either Kamlesh.Asotra@ucop.edu or 510-287-3366.



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APRIL 2004 NEWSLETTER

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HOLD THE DATES

May 21-26, 2004

AMERICAN THORACIC SOCIETY
100th International Conference
Orlando, Florida

June 1-5, 2004

INTERNATIONAL VASCULAR BIOLOGY MEETING
(<http://www.ivbm2004.ca/>)
Toronto, Canada

June 19, 2004

FIRST ANNUAL WORKSHOP ON USING THE TOBACCO
INDUSTRY DOCUMENTS FOR TOBACCO CONTROL
UCSF - Kalmanovitz Library
San Francisco, California
Contact: Dr. Valerie Yerger, valyer@itsa.ucsf.edu or (415) 476-2784

July 14-18, 2004

1ST ANNUAL SYMPOSIUM ON BASIC CARDIO SCIENCES
AHA's Council on Basic Cardiovascular Sciences
<http://www.americanheart.org/presenter.jhtml?identifier=3014865>
Skamania Lodge, Stevenson, WA