BURNING Issues
TRDRP Newsletter
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58 Grants Awarded
The 2003 Funding Cycle

TRDRP Launches a New Era

by M.F. Bowen

TRDRP's 12th Funding Cycle

In the 12th annual funding cycle, TRDRP awarded a total of $18.0 million in 58 grants to individual investigators at 25 California institutions. The overall funding pay line decreased from 26.2% last year to 23.8% this year. This can be attributed to the higher number of applications received this year (244) compared to last year (225) as well as less available funds: $18.0 million this year versus $20.4 million last year. Unfortunately, many excellent proposals again fell short of the pay line. The funding rate for Research Project, CARA and SARA proposals was 17.0% compared to 21.7% last year. Funding levels varied due to the different number of applications received for various mechanisms and the different number of applications reviewed across study sections. Funding levels by award mechanism are listed on page 2.

A complete list of all grant recipients and the abstracts describing their research projects will be published in the 2003 Compendium of Awards, which will be available in in August on our website (www.trdrp.org). All currently funded investigators and 12th cycle applicants will receive a copy; other interested parties may obtain copies upon request from TRDRP (trdrp@ucop.edu or 510-987-9870).

ALSO IN THIS ISSUE

The New Funding Decision Process – How it Worked

In the recently completed 12th funding cycle the TRDRP Scientific Advisory Committee used a different procedure than in past years to arrive at funding recommendations. They made this change, which was announced in the Call for Applications, because they believed it would lead to more informed recommendations, which is particularly important

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A New System of Research Prioritization

TRDRP is initiating major changes in research priorities in the 2003-04 grant cycle that warrant careful attention.

For the past several years, TRDRP has had difficulty maintaining a reasonable funding rate of scientifically meritorious grant applications and funding for research on high priority tobacco use issues in California due to insufficient funds. In order to better meet these goals, TRDRP has established a new system to prioritize applications for its most expensive grants. Proposals for Research Project awards will be categorized into Primary and Complementary areas, and proposals in the Primary areas will have a distinct advantage in the funding process (see below). The other types of awards (i.e., research career development awards, IDEAs, and collaborative research awards) will continue to be available in all areas of tobacco use and tobacco-related disease.

How it was Developed

TRDRP developed this system by engaging in a strategic planning process that included an internal program evaluation and assessments of the program and advice about its future from two expert panels, an open forum at the 2002 TRDRP Annual Investigator Meeting, and an email survey of program stakeholders. One expert panel included tobacco use scientists representing a wide array of disciplines from California as well as a number of other states. The other expert panel included representatives of tobacco control professionals and advocates in California. After a thorough review of recommendations, the Scientific Advisory Committee endorsed a new categorization system

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Award Mechanism	# Applications	# Funded	% Funded
Research Project	125	21	16.8
IDEA	35	4	11.4
Community Academic	13	2	15.4
School Academic	3	1	33.3
New Investigator	28	9	32.1
Postdoctoral Fellowship	28	14	50
Dissertation	12	7	58.3

Grants

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in light of the increasingly competitive funding environment described above. For grant proposals that fell near the preliminary funding payline, the committee considered the relevance of the proposed research to TRDRP's research priorities as well as the scientific merit score assigned by peer reviewers. They assessed responsiveness to research priorities from the proposal's "Scientific Abstract," "Lay Abstract," and "Statement of Relevance."

Although the process involved more effort, the committee members felt that it was justified because they had additional substantive information available when they made very difficult recommendations among proposals with indistinguishable scientific merit. This same process will be part of the new system of application prioritization to be initiated in 2004.

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for research priorities that is being initiated in the 2003-04 grant cycle.

Things That Remain the Same

The following award types will be available for research in all areas of tobacco use and tobacco-related disease:

1. Research career development awards, namely, Dissertation Research Awards, Postdoctoral Fellowship Awards, and New Investigator Awards;

2. Innovative Developmental and Exploratory Awards (IDEAs);

3. Collaborative/participatory research awards, namely, Community-Academic Research Awards (CARAs) and School-Academic Research Awards (SARAs).

Things That Have Changed

Research Project applications will be divided into Primary and Complementary areas, with proposals in Primary areas being funded to a more generous funding payline before considering proposals in Complementary areas.

Primary Areas

The Primary areas comprise topics that TRDRP identified through the strategic planning process described above as important health problems or scientific issues. Some factors that went into selecting the Primary areas below include: maintaining a broad scientific portfolio; identifying questions that have been historically understudied; targeting issues that are of particular concern for Californians; focusing on tobacco-related diseases that demand urgent attention; and highlighting areas with limited funding from other tobacco research funders. The Primary areas comprise the specific topics in the following seven groups:

Development of Nicotine Dependence Treatments

Disrupting the nicotine reward mechanism; understanding and developing treatments that can block the uptake of nicotine, either through desensitizing or "vaccinating" tobacco users; and animal or human studies to elucidate interventions that can break the causal chain in nicotine addiction and lead to more effective treatments for nicotine addiction and smoking cessation.

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Lung Cancer

Etiology and pathogenesis; molecular markers of susceptibility, inception, and progression; state-of-the-art methods for early detection and screening; novel and innovative treatments, particularly molecular-targeted therapies and pharmacogenomics; and chemoprevention.

Public Policy and Economics of Tobacco Use

The effectiveness of public policies and programs for tobacco control, including their economic impact, especially among California's diverse populations; the role of anti- and pro-tobacco forces and activities in shaping and affecting California's tobacco control policies, including new strategies employed by the tobacco industry to maintain its political and commercial influence in California; and studies of approaches to enhance the effectiveness of tobacco control efforts in California.

Chronic Obstructive Pulmonary Disease

Inception and pathogenesis of chronic bronchitis and emphysema (collectively referred to as "chronic obstructive pulmonary disease" or COPD); the molecular genetic mechanisms underlying differences in COPD susceptibility and progression, including differences between genders; and research on more effective diagnostic and therapeutic options.

Tobacco-Related Health Disparities among California's Diverse Populations

Tobacco use and tobacco-related disease in racial and ethnic groups, youth and young adults, women and girls, low SES and rural populations, and LGBT smokers; prevention, cessation, and differential distribution of tobacco-related cardiovascular and pulmonary disease and cancer in California's diverse populations; and tobacco use habits, traditions, and patterns of understudied populations.

Cardiovascular and Cerebrovascular Disease

Mechanisms by which tobacco use promotes development or complications of cardiovascular disease and stroke, e.g., by pathologic effects on vascular function, inflammation, oxidation, thrombosis or metabolism.

Secondhand Smoke and Outdoor Tobacco Smoke

Assessment of exposure to secondhand smoke (SHS) and outdoor tobacco smoke (OTS), especially measures or models of exposure to SHS/OTS in non-laboratory settings (e.g., residences such as apartments or houses, outdoor dining areas, and buildings' entrances and ventilation areas); the relationship of exposure to SHS/OTS and tobacco-related disease or reproductive health effects; and program interventions, public policy, and economic studies to blunt the spread of SHS/OTS.

Complementary Areas

Research areas not listed above that are relevant to TRDRP's mission will be categorized as Complementary. The Scientific Advisory Committee will recommend funding of proposals in the Complementary areas only after they have recommended proposals in the Primary areas. Thus a more stringent payline will be used in the Complementary areas than in the Primary areas. In other words, TRDRP expects to fund a smaller percentage of applications in the Complementary areas than in the Primary areas. TRDRP has not set *a priori* amounts to be allocated to the Primary and Complementary areas.

Implications for the Funding Decision Process

Principal Investigators will indicate whether their research topic is in a Primary or Complementary area. If the topic is in a Primary area, the application will include an explanation of how it is responsive to the particular Primary area. During the peer review and Scientific Advisory Committee evaluation processes, TRDRP will examine applications for appropriate categorization into Primary and Complementary areas. TRDRP reserves the right to make the final decision as to whether a topic is in a Primary or Complementary area.

As in 2003, the scientific merit of applications will be determined by peer review and the Scientific Advisory Committee will recommend applications for funding based on the scientific merit scores assigned by the peer reviewers together with their judgment of the degree to which proposals are responsive to TRDRP's mission. The committee will use separate

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paylines for Primary and Complementary areas.

Impact on Our Investigators

The objective of realigning TRDRP's research priorities was to allow the program to exist within the fiscal constraints which it is currently experiencing and will continue to experience in the future, while at the same time to enable the program to fulfill its legislative mandate to "support research efforts related to the prevention, causes, and treatment of tobacco-related diseases." We realize that the research interests of many of our Research Project investigators who are currently funded and many of those who have received funding from us in the past will not fall into one of the Primary research topics. We regret any difficulties this may cause and wish that we could fund all the topics that we have funded in the past – however, fiscal realities dictate that we make these painful changes and we hope that our investigators will be understanding of our predicament. We encourage all of our Research Project investigators to seriously consider focusing at least part of their research efforts in one of our Primary topic areas. Please remember that researchers interested in all topics germane to tobacco-related disease are still welcome to apply for career development, IDEA awards and community/participatory research awards.

The newly-established Primary and Complementary topics will be contained in the 2004 Call for Applications, to be released in September.

TRDRP Grant Application Workshops

TRDRP staff will host information meetings to explain these changes to the research community and answer questions. The dates, locations and times, of these TRDRP Application Workshops are listed below.

TRDRP
Tobacco-Related Disease Research Program

Application Workshops
New Priority Meetings

DATE	LOCATION	TIME
September 26, 2003	Oakland 300 Lakeside Drive 12th Floor, Room 1217	9:00am – 12:00pm
October 1, 2003	University of California San Diego*	9:00am – 12:00pm
October 2, 2003	University of California Los Angeles*	9:00am – 12:00pm

* Specific locations will be emailed to all TRDRP Investigators

HIPAA: The Sequel

by Francisco O. Buchting

This is a follow-up to the "Do You HIPAA" article that appeared in the July 2002 issue. At the time that the newsletter was printed, the final HIPAA regulations had not been published, and the Privacy Rule (the section of HIPAA that addresses research) had not gone into effect. But, as of April 14, 2003, the Privacy Rule is in effect, thus HIPAA has changed the environment in which researchers may find themselves if they need to access protected health information[1] (PHI).

This article will limit itself to how the HIPAA Privacy Rule impacts research and how it is being interpreted by the University of California; it is not meant to be a comprehensive overview of HIPAA. All researchers are encouraged to inquire within their organizations, especially the Institutional Review Board (IRB) or Privacy Board at their institution, as to how the Privacy Rule is being interpreted for the purpose of research at their institutions.

Just the Facts

HIPAA is the Health Insurance Portability and Accountability Act of 1996. It represents Federal efforts to standardize health information and protect the privacy of individuals' medical records. The HIPAA Privacy Rule directs a covered entity[2] (CE) to implement policies and procedures that provide security and privacy to an individual's heath information, PHI. The Privacy Rule applies to three types of CEs: health care providers, health plans, and health care clearinghouses. The Privacy Rule allows CEs to use or disclose PHI for certain activities, such as treatment and billing, without a patient's HIPAA authorization (Authorization), but requires Authorization for most other activities requiring access to PHI, including research. Section 164.508 of the Privacy Rule addresses access to PHI for the purpose of research, as well as research creating *de novo* PHI. The Privacy Rule has identified IRBs or Privacy Boards as entities that should review and approve access of PHI for research. What this means for research is that access to any patient data will be restricted and only allowed after approval has been granted by an IRB/Privacy Board and subsequently accepted by the covered entity.

Following is an interpretation of the final Privacy Rule and how its implementation and practice can affect research.

Are researchers considered CEs?

No, researchers are not covered entities, thus they are not permitted to access PHI held by a CE unless HIPAA requirements are met. A researcher must demonstrate to a CE that he/she has met the Privacy Rule requirements for disclosure of PHI by a CE in one of the following ways: the research subject has authorized release of PHI by signing an Authorization form; the PHI has been Deidentified or consists of a Limited Data Set; or a Waiver of Authorization has been obtained (see box). The body to determine if the Privacy Rule requirements have been met by the researcher is the IRB/Privacy Board.

I work at a CE as a health care provider and I can access PHI. Does that mean that I can also access PHI when I am in my researcher capacity at the same CE?

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Options to obtain PHI from a CE

A scientist who needs to access PHI for the purpose of research must submit a HIPAA application to the IRB/Privacy Board at his/her institution and once approved provide the following information to a CE in order to gain access to PHI:

- A copy of IRB's approval for consented research and a signed Authorization form for each subject; or
- A copy of HIPAA certification that the research meets the elements of a Waiver of Authorization; or
- A copy of HIPAA certification for research using a Limited Data Set (LDS). The LDS may include zip code, full dates of birth or death, full date(s) of service, or geographical subdivision (at the city level). LDS may not include other personal identifiers of subject, relatives, employer, or household members; or
- An approval letter that allows research using a de-identified data set. Two methods through which a data set is considered de-identified are by removing all 18 personal identifiers of subject, relatives, employees, and households members (for full a full list of all 18 identifiers see Burning Issues, July 2002) or by having a biostatistician confirm that individuals cannot be identified; or
- Evidence that the requirement for work preparatory to research or for decedent research have been met.

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No. In this case, a researcher who is also a health care provider has dual roles and responsibilities. As a treatment provider, the PHI that is used or disclosed is protected by HIPAA, it resides in the medical record and the patient has HIPAA rights to his/her PHI. As a researcher, he/she has to obtain Authorization to access PHI because researchers are not considered CEs.

Is the information collected for a study considered PHI, and does it fall under HIPAA requirements?

Technically the information obtained for a study is not PHI. The information created as part of research may have similar characteristics to PHI, but it is not PHI since it was obtained as part of research. Also, remember that a researcher is not considered to be a CE.

An exception to the above is when the research information is also part of treatment/health care and also resides in the medical record at a CE. In this instance, the individual's health care record may be used, added to, or produced in the course of doing research. When the research information and PHI are admixed in a research project to the point that it becomes impossible to determine the source of information, the research record falls under the HIPAA Privacy Rule and PHI Privacy Standards should be applied to the entire research record, not just part of it. The researcher must also assure that the *de novo* PHI is also maintained in the HIPAA-defined Designated Record Set.

Note that all research records are subject to the Common Rule,[3] irregardless of whether they are or are not HIPAA protected.

Can I incorporate the research subject's HIPAA Authorization language into the Informed Consent form so the subject only has to sign one form?

Yes, you can embed Authorization language in the Informed Consent form, but only if you adhere to California Law, i.e., the Authorization language must be "clearly separate from any other language present on the same page and . . . executed by a signature which serves no other purpose than to execute the Authorization". Thus, if the researcher decides to insert Authorization language into the informed consent form, then the subject signs the embedded Authorization language and the Informed Consent form, but separate signatures are required for each section of the "compound" form. Furthermore, the information regarding the use and disclosure of PHI must be clearly separate from all other

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Informed Consent elements.

When in doubt, the simplest way to obtain HIPAA Authorization and satisfy California Law may be to have the research subject sign an Authorization form that has been amended, not embedded, to the Informed Consent form. Remember to have the subject sign both forms.

I have an ongoing protocol that was approved before April 14, 2003. What do I do when I enroll new subjects?

Even if the protocol was approved and ongoing before April 14, 2003, a researcher will have to obtain HIPAA Authorization from all subjects enrolled after April 14, 2003. Subjects that were enrolled in an active project before April 14, 2003 do not have to sign a HIPAA Authorization and they do not have to be re-consented (grandfather clause). Note one exception: if a study is modified after April 14, 2003, subjects must then be asked to sign a HIPAA Authorization addendum to the consent form.

So when it's all said and done, how does the HIPAA Privacy Rule affect my research?

It is important to remember that HIPAA is not a set of regulations to address how research should be conducted. Technically, research is neither prevented nor hindered by HIPAA. The Privacy Rule allows an individual to determine when his/her health information may be used for research. In addition, the Privacy Rule places the responsibility on IRBs or Privacy Boards to provide CEs with assurances that PHI will be protected. It is very important to remember that HIPAA does not override the Common Rule or the FDA's human subject protection regulations. Likewise, HIPAA does not override California Law that provides greater protection of the privacy of health information. In fact, California Law has the same and in most instances greater restriction than HIPAA (for example, California's Confidentiality of Medical Information Act, codified in California Civil Code Section 56).

So maybe HIPAA will never be your best friend, but it does not have to be your foe.

WHAT WILL TRDRP DO ABOUT HIPAA?

In the near future, TRDRP will be coming out with a policy on HIPAA assurances. A guide for TRDRP in developing this policy has been the work done by the HIPAA Privacy Office at the University of California Office of the President. TRDRP will follow the policy set forth by the Regents of the University of California. In addition, TRDRP historically has patterned itself closely on NIH and thus will continue to monitor what NIH is doing in regards to HIPAA. In the future, HIPAA assurances may be required as a condition to release funding at TRDRP.

Another key issue for TRDRP will be the impact HIPAA may have on the peer review process. During this process, a project's feasibility, given the scope of work and proposed research plan, is taken into account and subsequently reflected in the scientific merit score. The issue of HIPAA may come up during a study section around a proposed project's feasibility. Over the next months, TRDRP will be considering how to factor this issue into our procedures as we prepare for the 2004 study sections. Any changes will be reflected in the TRDRP application CD-ROM due out this fall.

Endnotes

1. Protected Health Information (PHI) is the term given to patient information that resides with a covered entity (CE).
2. A Covered Entity (CE) is a health care provider, health plan, or healthcare clearinghouse that holds patient information.
3. The Common Rule is the set of current federal rules governing the protection of human subjects. The Common Rule was developed by the department of Health and Human Services - Federal Policy for the Protection of Human Subjects - 45CFR 46.

Readers are encouraged to visit the University of California website for the latest update on HIPAA within UC
http://www.universityofcalifornia.edu/hipaa.

Other websites with information about HIPAA are:
Health and Human Services
http://www.hhs.gov/ocr/hipaa

National Institutes of Health
http://privacyruleandresearch.nih.gov

Where Have All th
(. . . gone to reduce

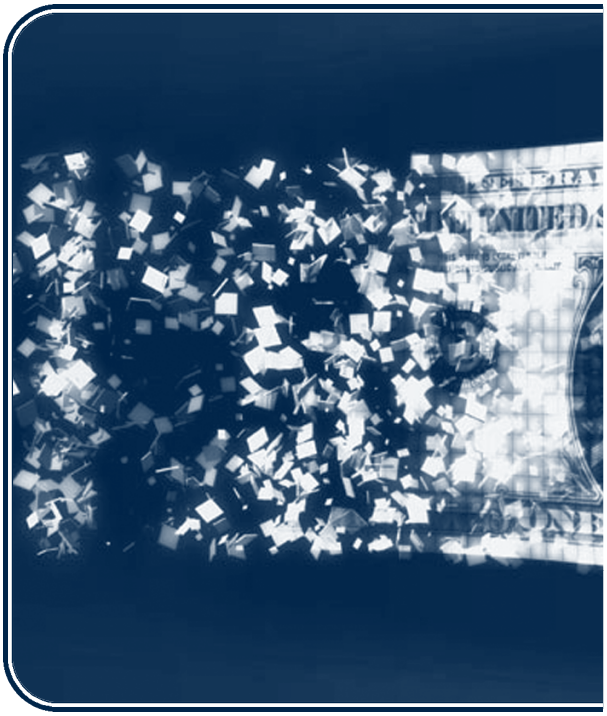
by Phillip Gardiner

Slash & Burn

Increasingly, state governments are cutting back tobacco control and research programs, citing record state budget deficits as the reason[1] (*see box, page 11*). While the huge state budget deficits are real (in California's case a whopping $38 billion), it still seems that tobacco control and research budgets are far too small to be a significant part of the solution. Yet, in several states, programs are facing draconian cuts or being eliminated altogether. One constellation of forces driving the nation-wide onslaught against tobacco control funding is the tobacco industry, its subsidiaries and its allies. As clean indoor air ordinances and legislation sweep the nation,[2] the tobacco industry, not an uninterested bystander, has correspondingly increased its monetary support of both federal and state elected officials throughout the country.[3]

In the March 2003 edition of Burning Issues, I described the influence of the tobacco industry in Sacramento, California's state capitol.[4] However, even with the major cut-backs described in that article and the continuing assault on tobacco programs in this state, the problems we face here in California pale in comparison to the outright gutting of major programs in Oregon, Colorado, Massachusetts and Florida. Furthermore, the positioning of the tobacco industry in some of these states is so great that over 90% of legislators and state-wide elected officials are receiving money from the tobacco industry![5] Below, I highlight some of the more glaring assaults on tobacco control and research programs taking place around the country. For a state-by-state account of the cut-backs being suffered by tobacco programs, please go to the Campaign for Tobacco Free Kids (CTFK) Website: www.tobaccofreekids.org.

The Oregon Trail . . . Littered with Butts



The $11 million Oregon Tobacco Control Program was completely shut down this spring by the state legislature in an attempt to blunt the state's $2.1 billion revenue short fall.[6, 7] Just three years ago, in 2000, Gary Weeks, then Director of the Department of Human Services stated that "cigarette consumption has declined 20% over the three years since Oregon voters approved ballot measure 44."[8] Similarly, when Jean Thorn, the new Director of DHS, delivered the message that the Oregon program had been trashed, it was pointed out that "the number of adults with children in the household who say that smoking occurred in the home in the past 30 days declined from 26 percent in 1996 to 12 percent in 2001."[6] Overall tobacco consumption in Oregon has declined by 23% since the program began in 1997. In fact, between 1996 and 2000, smoking declined by 41% among Oregon 8th graders and by 21% among Oregon 11th graders.[1] How could a program that was this effective be completely closed? One wonders how decimating an $11 million program helps cure a $2 billion budget short fall.

Stanton Glantz has pointed out that the tobacco industry has many friends in the Oregon Legislature.[9] Dr. Glantz documents that key members of Oregon's Ways and Means committee received tobacco industry campaign financing. In a much-used tactic of playing one constituency off another and tugging at the heart strings of all, the vice-president of the Oregon Restaurant Association, a close ally of the tobacco industry and a state senator, rallied senior groups to flood the legislature with letters demanding that legislators choose between "life-saving medicine" for seniors and money for tobacco control. This is the same tactic employed by the tobacco industry here in California in the mid 1990s, when then Governor Pete Wilson redirected Prop 99 funds from tobacco control and research to medical services for needy children and families. Even though some of Oregon tobacco control funds are slated to be restored, the Director of Health Services admits "like everything else in our budget, there's no guarantee that it [the tobacco control program] will be funded . . ."[6]

Programs Gone?
eficits everywhere)

A Mile High and Falling Fast

In April and May of this year, the Colorado State Legislature took the axe to tobacco control efforts in the state and at the same time decimated tobacco research efforts. Senate Bill 282 and SB 192 cut funds for tobacco prevention and cessation programs by $5.8 million and $1.6 million, for fiscal 2002-2003, respectively.[10] SB 282 additionally ordered another $11 million cut in tobacco control programs for fiscal year 2003-2004. These cut-backs, over $18 million spanning two fiscal years, while draconian for tobacco control efforts, are quite an insignificant amount compared to Colorado's estimated budget shortfall of $1.4 billion.[7] These cuts are to programs that had reduced per-capita tobacco consumption by 10% since 2000.[5] The upshot of this budget trimming is that monies allocated to Colorado's tobacco prevention and cessation efforts will total only $3.8 million, 85% below what the Centers for Disease Control and Prevention (CDC) has set for minimum funding for tobacco prevention and cessation in Colorado.[1]

On the research side, the story is even bleaker. The Colorado Tobacco Research Program (CTRP), set up and modeled after the Tobacco-Related Disease Research Program (TRDRP) of California, has all but been eliminated.[10] In 2001, the CTRP was funded at $8 million per year and awarded 15 research grants during its first year of funding. However, with a 50% reduction ($4 million) in 2002 and the program receiving the proverbial "axe" this year, program personnel are only planning to administer the existing funded grants and will not put out a new Call for Applications for fiscal year 2003-2004.[11] To add insult to injury, of the seven Master Settement Agreement (MSA) funded programs, the CTRP and the State Tobacco Education and Prevention Partnership (STEPP) were the only 2 programs whose funding was cut in fiscal 2002/2003.[12] Furthermore, the CTRP was the only MSA funded program totally eliminated for fiscal 2003/2004.[12] Why the disproportionate attacks on both tobacco control and research in Colorado?

Colorado Common Cause reports that the tobacco industry, their subsidiaries, and allies have spent more than $3.5 million on campaign contributions and lobbying between 1996 and November of 2002.[5] Among Colorado's Statewide elected officials, the Governor, Lt. Governor, Attorney General, Secretary of State, and Treasurer have all accepted some of these contributions.[5] Moreover, all six members of the powerful Joint Budget Committee of the Colorado Legislature have received donations from the tobacco industry, their subsidiaries, and their allies.[5] While two-thirds of all tobacco contributions have gone to Republicans, only seven state legislators out of 100 have not received contributions from the tobacco industry.[5] Stated another way, the five top state-wide officers and 93 state legislators in Colorado are all receiving tobacco monies; it is no mystery why tobacco control and research has been decimated in Colorado.

The Bay Colony Throws Tobacco Control Overboard

In a series of stunning moves last fall, then Governor Jane Swift summarily vetoed numerous bills that would have maintained tobacco control funding for Massachusetts.[1] Here is a program that was funded at $48 million as late as 2002, a whopping 136% of the CDC's recommended spending for the state.[1] However, by 2003, even after the state legislature approved funding of $31.3 million for the program, Gov. Swift reduced funding to just $4.8 million through successive budget cuts. Funding levels continue to fall and now a program that, just as recently as March, was promised $2.14 million, is now, in one fell swoop, eliminated.[13] There is a meager $100,000 left to keep some staff on, while other tobacco control administrators receive funds from other accounts. The upshot of all these cuts is the elimination of effective tobacco control programs, the dismantling of the statewide media campaign, and the closure of local community initiatives. For example, the tobacco treatment program at Cooley Dickson Hospital in Northampton was one of the early

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Programs

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casualties of the legislative cutting spree, forced to close its program in August of 2002 due to continued cut backs. In its short two years of existence, it helped some 300 smokers quit.[14] Given the very addictive nature of cigarette use, those who were still in treatment and others on the waiting lists will probably continue to smoke.

The Campaign for Tobacco Free Kids notes: "Prior to the recent cuts, the Massachusetts Tobacco Control Program (MTCP) had achieved considerable success and had been viewed as a national model. Overall cigarette consumption in Massachusetts declined by 36 percent between 1992 and 2000 compared to a decrease of just 16 percent in the rest of the country, excluding California."[1] With a state deficit of over $3.6 billion, the $48 million gained from ending tobacco control in the state of Massachusetts represents only 1% of the debt, a paltry amount.[7] The question is begged: Why are tobacco programs suffering disproportionate cuts (elimination in this case) during these times of fiscal crisis?

As early as the mid-1990s the tobacco industry had already focused its attention on the Massachusetts program. Following the successful passage of a 25-cent tax on cigarettes in 1992, ear-marked for tobacco control, the tobacco industry spent nearly $1 million to lobby the legislature in the 1993-1994 election cycle and then increased their lobbying expenditures by 48%, to over $1.3 million, during the 1995-1996 elections.[15] The industry's strategy to undermine the MTCP was simple and straight forward. Dr. Michael Begay documents the industry's tripartite strategy as the following: "Manage the legislative appropriations process; frame the debate as a tax issue rather than a health issue; and limit local damage until passage of a statewide pre-emption bill."[15] Clearly, the industry's strategy has borne fruit, exemplified by the out-

right closure of the Massa-chusetts Tobacco Control Program in 2003. In a personal communication, Dr. Connolly, long time director of the successful and nationally renowned Massachusetts program, stated that he hoped that between $2 and $4 million of the budget cuts will be replaced in fiscal 2004.[13]

The Truth Campaign; Up in Flames, Down in Fla.

The once hard-hitting anti-smoking "Truth" campaign is all but burned out in Florida. In May of 2003, the Florida State Legislature disemboweled this model program by cutting its budget from $37.5 million this year to $1 million for fiscal 2003-2004.[16] What makes this move even that more incredible is that the $37.5 million allocation that was eliminated represented a 21% increase over the $29.8 million spent on tobacco control in fiscal 2002-2003.[1] The "Truth" Campaign, adopted and promoted nationally by the American Legacy Foundation (ALF), had already shown great signs of success in Florida, where youth smoking rates had dropped by 47% since 1998.[1]

The Florida Biomedical Research Program fared only somewhat better. It was initially gobbled up in the Florida's pro-tobacco frenzy in the Florida Legislature; however, in an 11th hour reprieve, Governor Jeb Bush restored $3.5 million of the once $6 million program, but only for one year.[17] Founded in 2001 and endowed with a trust fund of $6 million a year, this program had funded 42 research projects during its first fiscal year.[18] This past year FBRP received over 60 applications and 20 of them were determined to be scientifically meritorious based on peer review. Unfortunately, with the slash in budget funds, these 20 investigators are receiving letters stating that their grants will not be funded. Moreover, just like in Colorado, the FBRP will not be issuing a Call for 2003-2004 applications; it is not even clear whether there will be a staff employed next year to administer the existing grants.[17] So, what happened to tobacco control and research efforts in Florida?

In a now too familiar refrain, State Representative Sandra Murman, (R-Tampa), Chairperson of the House Services Appropriations Subcommittee stated: "On the one hand you take money from the medically needy or fund a marketing campaign."[16] This false dichotomy, perpetuated state after state by the tobacco industry, has essentially closed down the Health Department's Division of Health Awareness and Youth Tobacco Use program. Additionally, the FBRP is on life support. Bill Corr, Executive Vice President of the Campaign for Tobacco-Free Kids, summed up the Florida situation thusly, "The Florida Legislature just put the

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Tobacco Control Cut-Backs in Selected States

	FY2003 (millions)	FY2004 (millions)	Percent Decrease
Florida	$37.0	$ 1.0	-97
Nebraska	$7.0	$ 0.405	-94
Colorado	$15	$3.8	-75
Indiana	$32.5	$10.8	-67
Massachusetts*	$4.8	$ 2.14	-55
Minnesota	$37.55	$18.35	-51
Maryland	$30	$18	-40
Vermont	$5.2	$ 4.5	-13

source: Campaign for Tobacco-Free Kids, Danny McGoldrick, Director of Research; website update 6-2003, *program funding was eliminated, except for $100,000 in 2003

Programs

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future health of kids in the hands of the tobacco companies."[16]

From Sea to Shining Sea: The Cost of Eliminating Tobacco Control is Staggering!

Without factoring in the impact of the closure of their programs, CTFK estimates that the cost of tobacco-related illness and disease in Oregon, Colorado, Massachusetts and Florida is already at $9.5 billion, and this figure does not include the health care costs associated with second-hand smoke.[1] Moreover, total state spending on tobacco prevention (50 states and the District of Columbia) amounts to just 7% of the $9.6 billion a year that the tobacco industry spends to market tobacco products.[1] Today, only 4 states, Maine, Maryland, Minnesota and Mississippi, meet the Centers for Disease Control and Prevention's minimum recommendations for tobacco control in their state, and 18 states, including California, have securitized their MSA funds, basically selling the future of tobacco control in those states.[1]

This summary of recent assaults on tobacco control and research should serve as a sober reminder of how much more work is still needs to be done in order to secure past victories. It seems that elimination of tobacco control and tobacco research funds are just a budget crisis away. Egged on and lavishly funded by the tobacco industry, continuing cuts to these and all other state tobacco control and research programs are a real and present danger. The 4 programs reviewed above had all been successful in reducing smoking in their state. However, with the severe cutbacks to tobacco control and tobacco research, smoking rates will rise again, squandering years of successful public health work.

John R. Seffrin, Ph.D., Chief Executive Officer of the American Cancer Society summed up the matter succinctly: "Gutting tobacco control programs is penny wise and pound foolish. Ultimately, states are going to have to pay the piper in lives lost and spending on health care."[1]

Can Research Help? YES!

Tobacco researchers have an important and crucial role to play in countering the systematic attack on tobacco control and research programs. It is imperative that the successes of these and other programs be researched, documented and popularized among voters in each state. Researchers must show the cost-effectiveness of state tobacco control programs; better to spend a few million dollars up front, as compared to spending billions of dollars to treat tobacco related disease later. Investigators can demonstrate that the long term impact of gutting tobacco control and tobacco research will inevitably lead to

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Programs

Continued from page 11

greater morbidity and mortality from smoking-related diseases. Moreover, it is important for investigators to examine and assess each and every aspect of comprehensive programs and demonstrate that local prevention interventions, state-wide media campaigns, targeted cessation efforts and culturally specific awareness campaigns work, in and of themselves.

Many researchers will rightfully point out that much of the documentation work has been done by CDC, CTFK and ALF. Still, with the growing cut-back movement, these analyses must be current, specific, and up-to-date. Additionally, investigators must consistently expose the role of the tobacco industry in state legislatures around the country. While there is excellent research reported in this article on the level of influence of the tobacco industry in certain states, I was not able to find documentation on tobacco industry largesse for every state. One director of a state wide program not reviewed in this article, who asked to remain anonymous, was quite frank: "We must go beyond logic; state legislators don't respond to logic; however, they often respond to incentives from the tobacco industries and their representatives."[19] Researchers must turn the glaring bright light of exposure on the tobacco industry; only then can the tobacco control and public health community voices be heard.

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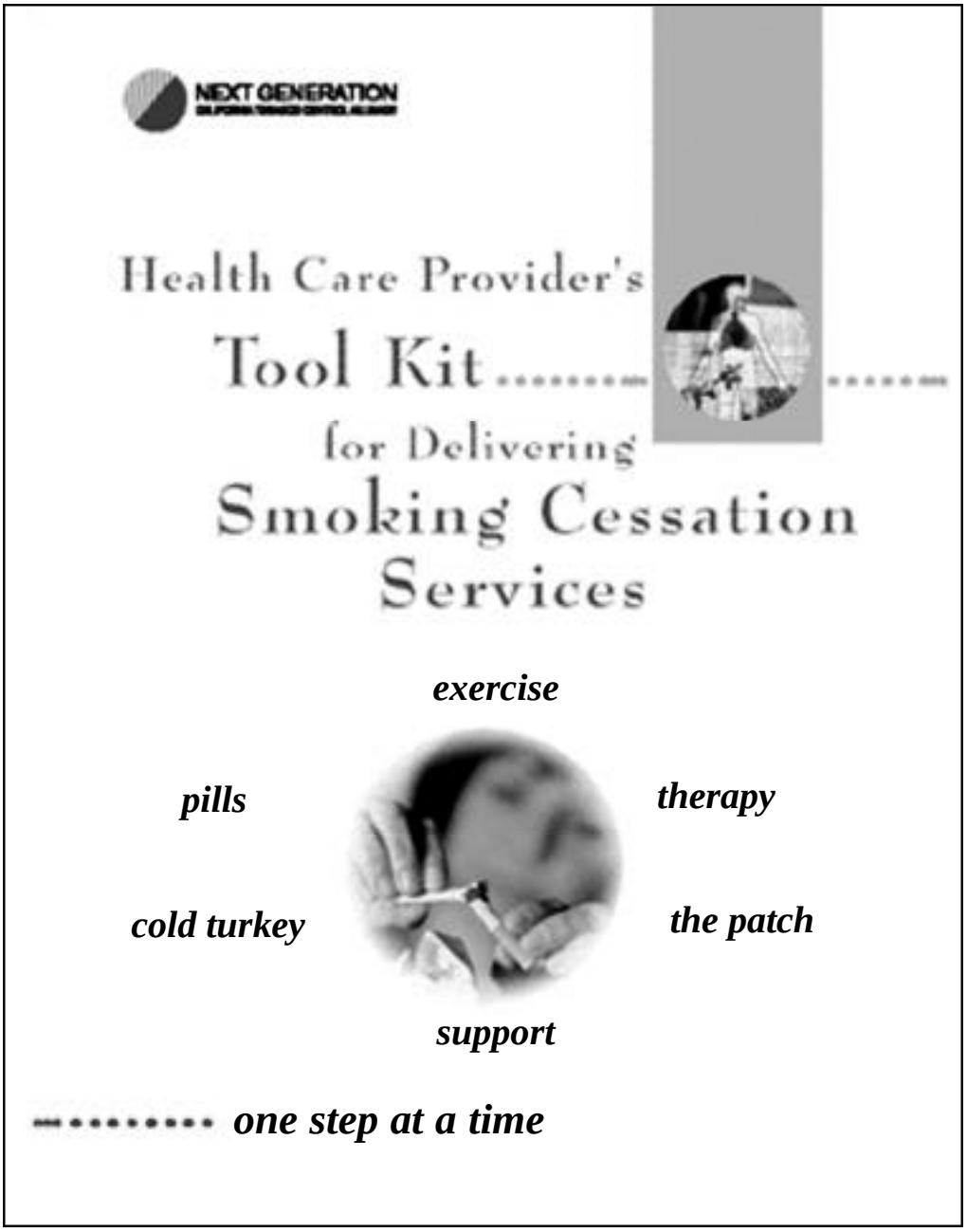
Free Cessation Resource



The Next Generation California Tobacco Control Alliance recently published a Tool Kit to help health professionals conduct effective cessation interventions and deliver services to patients. To order hard copies, call (916)554-0390 or email kirsten.hansen@tobaccofreealliance.org. A PDF version is also available at www.cessationcenter.org.

TRDRP UPDATE

The Fiscal Picture for TRDRP

Charles L. Gruder

Although TRDRP's fiscal picture is looking good for 2003-04, it is clouded by uncertainty about the specific items that will be included in the state's 2003-04 budget and delay in its passage.

As reported in Burning Issues in March, the Governor's 2003-04 budget proposed to appropriate $19,434,000 to TRDRP, which is the same amount as in the past two fiscal years. In his May Revision of the budget, however, the Governor increased TRDRP's appropriation by $4,429,000 to $23,863,000. The increase derives from two sources, the reserve in the Prop. 99 Research Account and the Prop. 10 backfill. The Department of Finance allocated approximately $2.4 million from the excess reserve to TRDRP in direct response to advocacy from the Tobacco Education and Research Oversight Committee, the Next Generation California Tobacco Control Alliance, the American Cancer Society, the American Heart Association, and the American Lung Association. The other source of increased funds is the Prop. 10 backfill. The State Board of Equalization, which determines the impact of the Prop. 10 tobacco excise tax on selected programs funded from designated state tobacco excise taxes, voted to increase the backfill amount over the previous year, resulting in a $2 million budget increase for TRDRP.

Two caveats: First, both of these increases are likely to be one-time only. That is, future year appropriations will be determined only by projected Prop. 99 revenues. TRDRP plans to use the augmentation to fund additional grants in 2003 and 2004. Second, this $4.4 million augmentation is a proposal by the Governor, and appropriation of the funds is contingent on passage of the state budget. As most readers are aware, there is great uncertainty about the final budget because of the record budget deficit confronting elected officials.

Another tobacco tax increase?

The governor proposed a $1.10 per pack tobacco excise tax increase in January and reduced it to 23 cents per pack in the May Revision. He included a provision to backfill all Prop. 99 programs with some of the additional revenue so the budgets of these programs, including TRDRP, would not be adversely impacted by declining Prop. 99 revenue due directly to his proposed new tobacco tax increase.

Tobacco control advocacy organizations (including the Next Generation California Tobacco Control Alliance, the American Cancer Society, the American Heart Association, the American Lung Association, and the Campaign for Tobacco-Free Kids) have joined together in the Coalition for a Healthy Future to lobby California's Governor and legislators to raise the tobacco tax by $1.50 per pack and to earmark 20 cents per pack for tobacco control, including tobacco use research. For information about this effort, please visit the campaign website (www.healthyfuture.net).

Realistic planning

Regardless of the 2003-04 budget that is ultimately passed, the most likely scenario for TRDRP is declining revenue from 2004-05 forward due to decreasing tobacco sales in the state. As reported in recent newsletters, over the past several years TRDRP has been able to fund a declining percentage of scientifically meritorious grant proposals because of increases in research costs and the number of proposals. In an effort to maintain a reasonable funding rate of proposals and to better meet the tobacco research needs in California, TRDRP has made significant changes in its research priorities *(see cover article)*.

Scientific Advisory Committee Update

The following Scientific Advisory Committee members recently completed 3 years of service to the TRDRP: Phillip Gold, M.D. (American Lung Association), Kathy Sanders-Phillips, Ph.D. (Behavioral Sciences), and Lewis J. Rubin, M.D. (University of California, San Diego School of Medicine). Please join us in thanking these research professionals for their time and effort on the TRDRP's behalf.

Cornelius Hopper Diversity Award Supplements

This year marked the fourth year of funding for the Cornelius Hopper Diversity Award Supplements (CHDAS), which are augmentations to TRDRP awards that enable principal investigators to mentor students. The goal of CHDAS is to encourage students who want to pursue research careers in tobacco use and are either from underrepresented groups or who work directly with underrepresented groups that are disproportionately impacted by tobacco use. We are pleased to announce that three currently funded TRDRP investigators will receive supplements to their grants for support of these new personnel on their projects (see below for a list of supplement beneficiaries and PIs).

CHDAS Trainee	Principal Investigator	Institution
Joann Lee, B.S., M.P.H.	Susan I. Woodruff	San Diego State University
Luis Quinones, B.S.	Ricardo F. Munoz	University of California, San Francisco
Naira Serobyan, M.D.	Sophia Khaldoyanidi	La Jolla Institute for Molecular Medicine

TRDRP 8th Annual Investigator Meeting (AIM 2003)

Focus: Research Translation

This year's annual meeting will be held in San Diego at the Sheraton San Diego Hotel and Marina for two full days: Wednesday and Thursday, December 3 & 4, 2003. Meeting events will include a keynote speaker, poster sessions, a plenary session, reception and Town Hall Meeting on "The Nicotine Patch – Does it work?" As in the past, TRDRP will partner with California health voluntaries and the state Tobacco Control Section to conduct a series of workshops.

Abstract submission deadline: October 17, 2003.

The AIM 2003 "Call for Abstracts" will be distributed to our PIs and available on our website in September.

Remembering Janis Jackson

It is with great sadness that we report the death, after a long illness, of Janis H. Jackson, M.D. of the Scripps Research Institute. Dr. Jackson was one of the TRDRP's first awardees, having received 2 grants from the program in its first funding cycle in 1990. She joined our Scientific Advisory Committee in November 2000 and contributed significantly and meaningfully to the SAC's work and decisions. She was a pleasure to work with as well as a warm and gifted individual. Her death is a great loss not only to the TRDRP but to the entire research community. We send our deepest sympathy to her family and friends.

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JULY 2003 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.

UPCOMING CONFERENCES

August 3–8, 2003
12th World Conference on Tobacco or Health
Helsinki, Finland

August 10–14, 2003
10th World Conference on Lung Cancer
Vancouver, Canada

November 15–19, 2003
American Public Health Association Conference
San Francisco, California

HOLD THE DATE

December 3–4, 2003

TRDRP 8th Annual Investigator Meeting
Translational Research

Please mark the date on your calendars and plan to join us for another enjoyable and intellectually stimulating conference at the Sheraton San Diego Hotel and Marina.

San Diego, California