Burning Issues

Tobacco's Hottest Topics Online

Tobacco-Related Disease Research Program Newsletter Volume 10, Number 3 A

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Congress Grants FDA Oversight of Tobacco Products

Guess who's Coming to Dinner?

by: Phillip Gardiner, Dr. P.H.

In a much anticipated and often criticized move the United States Senate on a vote of 79 to 17, turned a deaf ear to the pleas for mercy from North Carolinian Senators, and passed the Kennedy sponsored bill, S 982, on Thursday June 11, 2009 giving the Food and Drug Administration (FDA) oversight of tobacco products. The very next day, the House followed suit and passed the same legislation, by-passing the usual Senate/House conference committee negotiations, sending the bill directly to the desk of President Barack Obama, who in an elaborate Rose Garden ceremony signed this bill into law on June 22nd, 2009. The drama of FDA oversight of tobacco products has riveted the tobacco control movement for over a year now. There are those who argue that it is a complete sellout (1). On the other hand, there are others who argue that it is the best that we could do at this time (2). Burning Issues has devoted much ink to this issue in voicing our own concerns about the legislation. In October of 2007 we reviewed the Bill in detail: *FDA at the Crossroads*, by M.F. Bowen, which identified the many benefits in the legislation for Philip Morris' (3).

Then again in October 2008 we ran an article: *Menthol Moves Center Stage*, by Phillip Gardiner, which exposed the weakness of the bill on the question of Menthol and detailed the hard work that was necessary to get the House Bill amended, moving the question of menthol to the very top of the of the FDA's Scientific Advisory Committee's agenda (4). For this issue we want to focus on The Scientific Advisory Committee itself and what may be one of the more egregious problems with this legislation: the invitation to the tobacco industry to participate and sit on the Scientific Advisory Committee. How is it that the tobacco industry was allowed to be part of the oversight for tobacco control? Why are they invited to dinner? What can be done to mitigate this unseemly situation?

Who's driving this bus anyway?

This new legislation allows the FDA to establish a Center for Tobacco Products within the FDA. In turn this new center would be overseen by a 12-member Scientific Advisory Committee that would be appointed by Kathleen Sebelius, Secretary of Health and Human Services. Astonishing, though is the fact that 3 of the 12 seats are "reserved" for representatives from the tobacco industry (yikes!). Talk about the fox being put in charge of the hen house. Mincing no words, the legislation states: The committee shall be composed of—

> "(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;
>
> (ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;
>
> (iii) 1 individual as a representative of the general public;
>
> (iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;
>
> (v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and
>
> (vi) 1 individual as a representative of the interests of the tobacco growers." (5)

And while the legislation makes it clear that this gaggle of industry representatives will not be voting members, having the fox in on the discussions of the hens is extremely problematic. While the above representation methodology is generally used in appointing FDA Scientific Advisory committees, there are some significant differences when we consider the tobacco industry.

In the first place, the tobacco industry are convicted racketeers! In August of 2006, a Federal Court found the tobacco industry guilty of racketeering and corrupt business practices, or said another way, guilty of being themselves (6). As expected the tobacco industry appealed this ruling, buying time and space to continue their anti-health machinations. But, even the 9th District Court of Appeals saw through the industry's deceptions and has upheld the ruling (7). It is unfortunate that the both the United States Senate and House of Representatives didn't follow the lead of the judiciary branch and just kick these gangsters to the curb.

However, even more problematic, by placing members of the tobacco industry on this Scientific Advisory Committee, the United States finds itself in violation of the Framework Convention on Tobacco control (FCTC), the singular agreement of the international tobacco control movement. Article 5.3 of the FCTC states clearly that: "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law" (8). Indeed, the world tobacco control movement felt so strongly about article 5.3 that they wrote guidelines for its implementation, a 12 page long pamphlet (9). While not

reviewing each and every suggestion, the following guideline goes right to the heart of the matter:

"Principle 1: There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.

13. The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible (9)."

If the United States actually gets around to signing the FCTC, it would automatically be in violation of article 5.3; a terrible precedent for tobacco control in the United States and worldwide. Allowing the tobacco industry to have a voice on the scientific advisory committee would allow them to continue to obfuscate and muddy the issue. It is unfortunate that the crafters of the legislation didn't take the advice of the FCTC, because placing the tobacco industry on the key scientific oversight committee will not protect the formulation and implementation of public health policy, it will produce just the opposite.

And yes, unfortunately the tobacco industry will be the driver of the tobacco control bus. This is nothing new, You guessed it: the industry has a history of doing just this same thing.

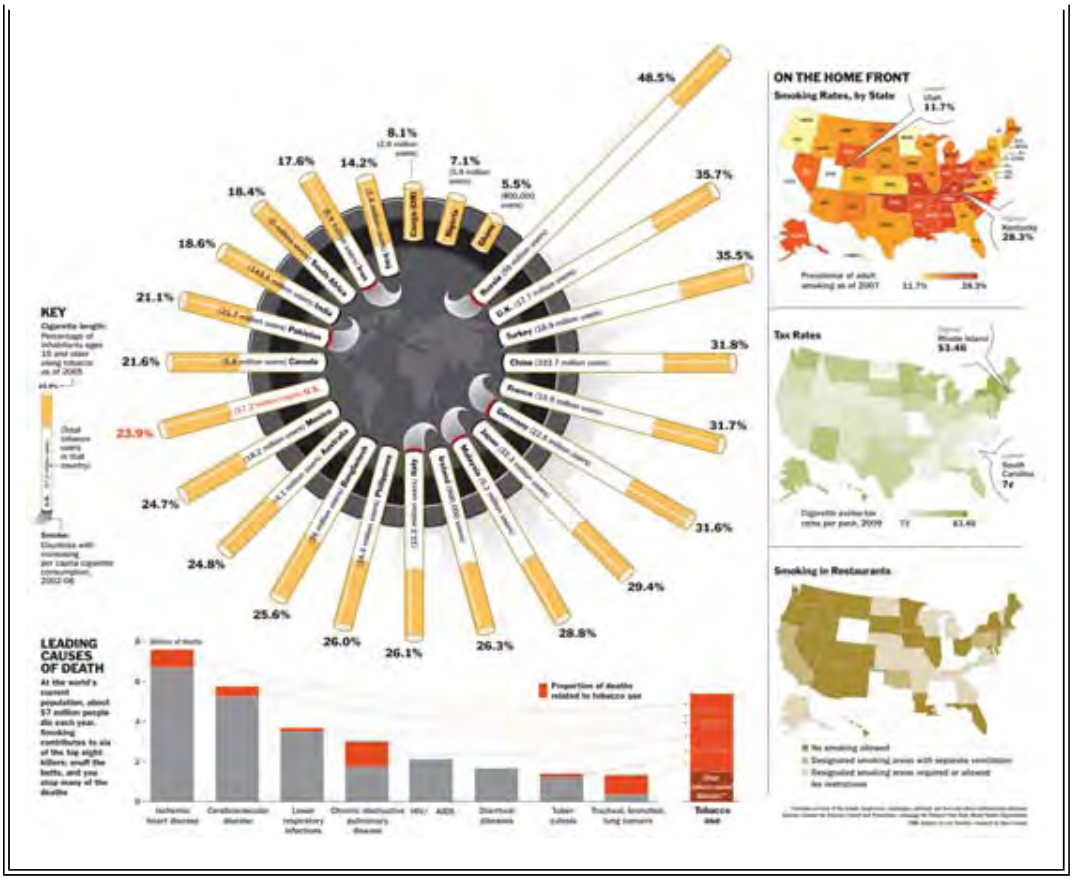
History should be our guide

While industry representatives will participate on the Scientific Advisory Committee as nonvoting members, there is significant negative historical precedent that makes a very strong case for excluding tobacco industry representatives from this committee. In 1968 the National Cancer Institute (NCI) created the Tobacco Working Group (TWG), which included health experts and tobacco industry representatives, to advise its Smoking and Health Program (10), similar to the current FDA authority. Additionally, tobacco industry representatives on that body were non-voting members, again similar to the current requirements of the FDA Scientific Advisory Committee.

Not only did the tobacco industry scientists effectively influence the course of research activities of the NCI, they gave the industry a crucial insider position to keep an eye on the direction in which the NCI's Smoking and Health Program was going. Federal District Judge Gladys Kessler summarized how the industry used its TWG membership in her 2006 ruling that Philip Morris and other elements of the tobacco industry violated the federal Racketeer Influenced and Corrupt Organization (RICO) Act: "Participation by industry representatives proved valuable [to the industry] by allowing Defendants to keep abreast of what the United States Government was doing with respect to smoking and health issues. Their participation also provided a mechanism by which defendants could try to influence the United States Government's activities in the smoking and health area. … The [racketeering] Enterprise engaged in a concerted effort to prevent, curtail, and ultimately to neutralize the TWG's efforts to evaluate cigarettes' [health] effects using an animal bioassay … (6)"

In essence, the tobacco industry's racketeering conviction stemmed in part from abusing their position on the TWG. This is exactly the same thing that they are attempting to do by being placed on the FDA Scientific Advisory Committee. Sharon Eubanks, the lead prosecutor for the government in the RICO case along with tobacco control expert and UCSF professor Stanton Glantz have suggested that language quoted above and other parts of/ from Judge Kessler's ruling should have been added to the FDA Bill. Moreover, Judge Kessler found that not only had the industry engaged in these illegal practices in the past, but that they were continuing to do so and likely to continue to do so in the future (6). This finding has now been upheld on appeal giving the industry no leg to stand on. Hence, given the past, current and probable future practice, there should be no question; the tobacco industry should definitely not have a seat at the table.

Leading Cause of Death Chart
At the world's current population, about 57 million people die each year. Smoking contributes to six of the top eight killers; snuff the butts, and you stop many of the deaths.
http://www.time.com/time/interactive/0,31813,1911060,00.html



Tobacco Industry Representation: By any means necessary

Then as if to add insult to injury, a representative of tobacco growers is slated to become a member of the FDA Scientific Advisory Committee (5). Why this is so outlandish is that the FDA authority that was passed explicitly states that the FDA will not have any jurisdiction over tobacco farming, tobacco growing and tobacco production! The proposed law specifically excludes regulation of tobacco leaf not in the possession of a manufacturer of tobacco products. The language is specific:

"(2) LIMITATION OF AUTHORITY-

IN GENERAL- The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer"(11).

Clearly, the industry's influence was so great in the crafting of this legislation that they were able to get seats at the table for tobacco farmers, who were unambiguously excluded for FDA oversight; talk about inviting uninvited guests to dinner.

A cautionary note as we move forward

Denunciations and recriminations have been voiced by many in the tobacco control movement concerning the many weaknesses in the FDA Bill. The tobacco control movement must admit having representatives of the tobacco industry as part of the FDA's scientific oversight of tobacco is clearly problematic. If it was necessary in 2006 under the pro-tobacco Bush administration to include these scoundrels in the legislation, that's one thing. But it is a whole other thing to maintain this arrangement and other parts of the legislation

given the regime change in Washington. On the other hand, the tobacco industry's placement on the scientific oversight committee is a testament to their considerable political strength and the relative weakness of the tobacco control movement. While those negotiating this deal certainly could have fought harder, the fact remains that the tobacco control movement lacked the political acumen and/or clout to restrict the participation of the tobacco industry. There are many advances for the tobacco control movement contained in the FDA legislation, still it is quite sobering to realize that the tobacco industry- even after their racketeering conviction – squarely in opposition to the FCTC – and we all have knowledge of their past practices, that this industry was again invited to dinner and allowed a seat at the table.

But let's not wring our hands. There is a bold proposal out there put forward by the National African American Tobacco Prevention Network (NAATPN) that says that the tobacco control movement should come together and form a committee to oversee the work of the FDA Scientific Advisory Committee. Instead of just a few select groups determining what happens, as was the case in the crafting of this legislation, let's gather representatives from across all sectors of the tobacco control movement to monitor the work of this scientific advisory committee and the broader tobacco work of the FDA. Yes, if the foxes are at the table then, someone (none dare call us dogs) must oversee what exactly what the foxes are doing.

The NAATPN proposal grew out of discussions between tobacco control advocates and researchers around the country who were concerned (to put it mildly) about the legislation. Specifically, following the all the hard work around getting the menthol amendment (See Burning Issues, Menthol moves Center Stage, 2008) it was determined that oversight of the FDA process around menthol could not be left to the proposed tobacco industry tinged Scientific Advisory Committee. With language that states in part that the first order of business for the scientific advisory committee is to determine "the impact of the use of menthol in cigarettes on the public health including such use among African Americans, Hispanics, and other racial and ethnic minorities" (12.), there was no confidence by NAATPN and others that this committee would carry out its task.

While the tobacco control movement might not be able to alter the current make up of the FDA Scientific Advisory Committee, we can not only demand representation on the committee itself, but establish a broad coalition of forces to serve as watch-dogs over the process itself. This whole episode highlights that as a movement we are still not strong enough to keep the tobacco industry from coming to dinner. But we must remain vigilant, for when we take up the next major fight, possibly about FCTC ratification or banning menthol, we may find ourselves in a position to thwart the machinations of the tobacco industry and deny them a seat at the table.

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TRDRP *UPDATE*

by Bart Aoki, Ph.D. and George Lemp, Dr. P.H.

High proportion of meritorious proposals funded

A total of 196 applications were received in the 18th Cycle and due to high levels of merit, a revision of the grant mechanisms, and the identification of additional funds, 71 (36%) will be funded. Consistent with the critical need to develop new researchers with an interest in tobacco-related diseases and issues, 36 (51%) of the new grant awards will go to support new investigators, postdoctoral fellows, and dissertation students. And consistent with the program's mandate to support a broad range of innovative research in tobacco-related disease research, TRDRP will award grants to study cancer, particularly lung cancer (20), cardiovascular diseases (12), pulmonary diseases (5), translational biomedical research (11), nicotine dependence (7), policy issues (3), and social and participatory research (13).

The TRDRP had revised its funding mechanisms during the 2008 funding cycle to include a new California Research Award mechanism. This grant mechanism is intended to support research projects that address questions specific to tobacco-related disease or tobacco control issues in California. We are pleased to announce the first two of these California Research Awards to be funded as part of the new TRDRP Cycle 18 Grant Awards.

TRDRP: Strategic priorities in the midst of crises

As the global recession continues and California confronts a fiscal crisis of historic proportions, it is even more critical that vital Prop 99-based resources be invested in a portfolio of research that holds the greatest promise of benefiting both the health and the economy of the state.

Since its inception, TRDRP-funded research has directly resulted in the flow of hundreds of millions of additional federal and other research dollars into the state. Through TRDRP-funded research, California's scientists have been at the forefront of the development of knowledge that will contribute to stemming the adverse affects of smoking, including its related health care costs (previously estimated at $8.6 billion in 1999 in California). TRDRP funds have played a particularly critical role in supporting breakthroughs in nicotine dependence treatments, lung cancer, heart disease and stroke, pulmonary disease, tobacco-related health disparities, secondhand smoke exposure, and the public policy and economics of tobacco use.

Strengthening the impact of policy research

The program is working intensively to further strengthen the direct impact of TRDRP research on the tobacco control priorities of the state. Since December of last year, TRDRP has collaborated with its state partners (the California Tobacco Control Program, the California Department of Education, the American Cancer Society, the American Heart Association, the American Lung Association, local community-based tobacco control programs, and the Tobacco Education and Research Oversight Committee) to develop a new Policy Research Initiative. As a result, TRDRP recently issued its first Request for

Qualifications (RFQ) for teams of researchers who will work in close collaboration with the program and its partners to plan, conduct, and disseminate research to determine the impact of declining tobacco surtax revenue on the ability of the state to work effectively to control tobacco use. This research will include an economic analysis of the cost to the state in terms of increased morbidity/mortality and increased health care costs if smoking prevalence were to rise by various levels. Additionally, analyses will be conducted to determine the impact of various tobacco control strategies and the disparate impact on diverse populations in California should programs be reduced or discontinued.

This new initiative is distinguished by the close collaboration among community, policy makers, and researchers from its inception to the dissemination of its findings. Such close and sustained collaboration is critical to ensuring that policy research has high currency and will effectively inform the future tobacco control policies of the state. In addition, the results should be timely, given that the initiative is geared to produce interim findings within three to five months and final results within six to 18 months. TRDRP is committed to continuing to invest in research that can guide and inform tobacco control efforts in California. We will keep you fully informed as the current research progresses and as findings from these initial studies become available.

Potential new strategic research initiatives

TRDRP recognizes the need to continually examine the program's ability to meet the highest priority tobacco-related research needs of the state. Consequently, in the coming months, TRDRP, in concert with the program's scientific advisors and tobacco control partners, will identify a number of high priority areas of tobacco-related diseases research (e.g., lung cancer early detection, tobacco-related disparities in African Americans in California, secondhand smoke exposure in Indian gaming sites) as targets for potential new strategic research initiatives. It's likely that some of these targeted priorities will be funded through the annual TRDRP Call for Applications, while other funding opportunities may be announced through separate specific Calls for Applications. Please stay tuned and alert for off-cycle announcements in the coming year.

Cornelius Hopper Diversity Award Supplements

TRDRP has received 6 applications for the Cornelius Hopper Diversity Award Supplements (CHDAS) and will fund 4. CHDAS provides principal investigators of active TRDRP grants additional funds to mentor young scientists or community members. The goal of the CHDAS mechanism is to increase the diversity of scientists committed to tobacco-related research and is intended for trainees who have experienced barriers to realizing their careers and, if applicable, who are interested in conducting research focused on cultural, societal, health, or educational disparities as they affect underserved segments of our state. Named for Cornelius L. Hopper, M.D., vice president for Health Affairs Emeritus of the University of California, these special supplements enable TRDRP a to continue Dr. Hooper's leadership and commitment to diversity.

TRDRP appropriation in the 2009-2010 state budget

The state's final amended 2009–2010 budget, signed by the Governor on July 28, includes an appropriation of $13,090,000 for TRDRP. This is $1,425,000 less than in 2008–2009, which reflects a reduction in Prop 99 revenue allocated to the Research Account as well as a reduction in University of California research by 10%. We anticipate that the program will fund proposals at a slightly lower rate of funding in the coming year and we will continue to selectively support high priority research initiatives in support of tobacco control and for the advancement of science in tobacco-related diseases.

New TRDRP Scientific Advisory Committee members

Finally, we are pleased to welcome the following four newly appointed members to the TRDRP Scientific Advisory Committee:

Serena Chen, B.A., M.S.
Regional Director, Policy & Tobacco Programs
American Lung Association of California

David Cowling, Ph.D.
Chief, Evaluation Unit
California Tobacco Control Program
California Department of Public Health

Fred Grannis, M.D.
Associate Professor and Staff Surgeon
City of Hope National Medical Center

Statice Wilmore, B.S.
Tobacco Control Program Coordinator
City of Pasadena Public Health Department

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The CT Lung Cancer Screening Controversy

by M.F. Bowen, Ph.D.

Two large-scale trials have been underway in the U.S. to assess the effectiveness of computed tomography (CT) in the early detection of lung cancer: The Early Lung Cancer Action Program (ELCAP) led by investigators at Weill Cornell Medical Center and the National Lung Screening Trial (NLST) sponsored by the NIH. The two trials are set up in different ways and are measuring different outcomes. Their respective supporters had managed to air their differences in relatively civilized debates. As the trials neared completion, however, the gloves came off.

In October 2006, data from the ELCAP trial were published in the New England Journal of Medicine (1). Asymptomatic subjects at high risk for lung cancer were screened annually. According to the report, trial participants found with clinical stage 1 tumors who underwent surgical resection within one month after diagnosis had a 10-year survival rate of 92%. The authors concluded that annual CT screening could detect curable lung cancer, particularly in those participants at highest risk. The words "curable" and "lung cancer" are rarely used together, and the paper was hailed as a breakthrough. Hope and excitement surged amongst lung cancer patients, advocates, and health care professionals. At the behest of lung cancer advocates a provision was

inserted into the National Cancer Act of 2007 (S.1056) that would require the CDC to award at least 10 grants to establish CT scanning programs using the ELCAP protocol. Many in the scientific community, however, were unconvinced by the data; controversy over the effectiveness of CT screening erupted almost immediately. Nearly one year after the latest salvos in the battle, the issue remains unresolved and researchers on both sides of the debate remain at odds.

The issue is of vital importance to the lung cancer community. A diagnosis of lung cancer is one of the most devastating news a patient can receive from his or her physician. The diagnosis is almost invariably made after symptoms have appeared, at which point the cancer is frequently well-advanced and difficult to treat successfully. The overall five-year survival rate is only 15%. If the tumor is caught early enough, the patient's chances rise dramatically to 45%. Early detection is thus key to successful treatment, and lung cancer early detection has been one of the holy grails of cancer research. This article is a retrospective of and perspective on this still-burning issue.

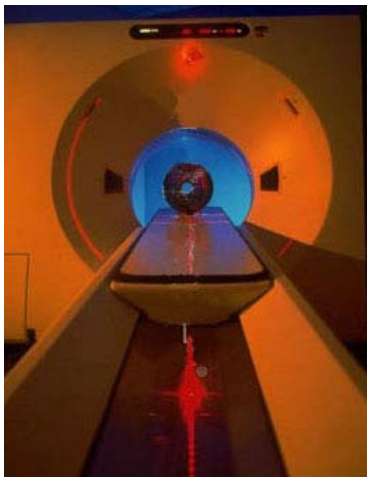
A scientific debate rages

Many clinical trial researchers took issue with four elements of the ELCAP trial: 1) the use of survival as the measure of effectiveness; 2) the lack of a control arm; 3) the risk of false positives; and 4) the statistical model used to estimate expected survival.

The use of survival as the metric could bias the results in two ways: 1) screening may pick up indolent cancers that would either not be aggressive enough to be fatal or would be eventually neutralized by the immune system; or 2) participants whose cancer was detected through the screening the disease may have lived just as long without the screening; without assessing mortality, it is impossible to say that the screening intervention really prolonged life. Both phenomena would have biased the results in favor of survival. So the validity of the presumed benefit of CT screening, i.e., extending the lifespan of patients diagnosed with lung cancer, cannot be ascertained by using survival as the measured outcome (2).

As a case-control observational study that lacked a control arm, the ELCAP trial does not meet the standards of a randomized controlled trial, the experimental design most commonly used to test the efficacy of a given health care intervention. A randomized controlled design ensures that confounding factors are distributed evenly between test and control arms; as long as sample sizes are sufficient, such a design is considered the gold standard for such trials. A randomized controlled trial using mortality as the end-point was used, for example, to demonstrate the efficacy of mammography screening in older women (3). More to the point of the controversy, it is the same design employed by the competing NLST trial, which will randomly assign high-risk participants to receive either chest X-rays or CT scans and then compare the two groups. The results of that trial will not be available until at least 2010.

More harm than good?



Critics also charge that widespread use of CT screening, particularly in inexpert hands, could result in a plethora of false-positive diagnoses that would do more harm than good. In fact, a recent study has quantified this risk: the risk of a false positive in a CT-scanned group was 21% after one scan and 33%after a second, while those in the X-ray group had a false-positive risk of 9% after one test and 15% after two (4). Furthermore, the increased radiation exposure necessitated by repeated annual screenings could alone promote cancer (5).

A subsequent non-ELCAP study concluded that CT screening may increase the rate of lung cancer diagnosis and treatment but may not reduce the risk of advanced lung cancer and lung cancer mortality (6). However, this study did not end the controversy as it was not a randomized controlled trial either.

"All models are wrong but some are useful"(7)

In response to charges of over-diagnosis and false positives, ELCAP principals responded by pointing out that pathological evaluation of excised tumors identified by CT screening in their study showed that all were cancer-positive and 95% were invasive (8). As the ELCAP lead investigators pointed out, all screening procedures carry some risk of over-diagnosis, but the procedures followed by ELCAP minimized risk, and independent experts agreed that the ELCAP investigators employed a very careful screening regimen accompanied by appropriate follow-up that minimized harm. (9) ELCAP investigators also contended that the statistical model used by Bach et al. was itself flawed and that the Kaplan-Meier curve used to estimate survival in the ELCAP study is used routinely in clinical oncology trials. It is fair to say that no statistical model of estimated survival is without problems and only the control arm of randomized trial can definitively answer the question of whether a procedure really saves lives. Therefore, neither study can be considered conclusive.

Moreover, ELCAP investigators charged that subjecting study participants to chest X-rays, as the NLST study does, is unethical because such imaging was shown a long time ago to be ineffective (10).

In an attempt to determine if early detection leads to treatment of indolent lung cancers, Raz et al examined the natural history of patients with stage 1 non-small cell lung cancer (the most common type) who received no treatment (11). Five-year overall survival was 6% with a median overall survival time of nine months. While supportive of the ELCAP conclusion, the paper did not appease its critics.

Science takes a backseat as things get nasty

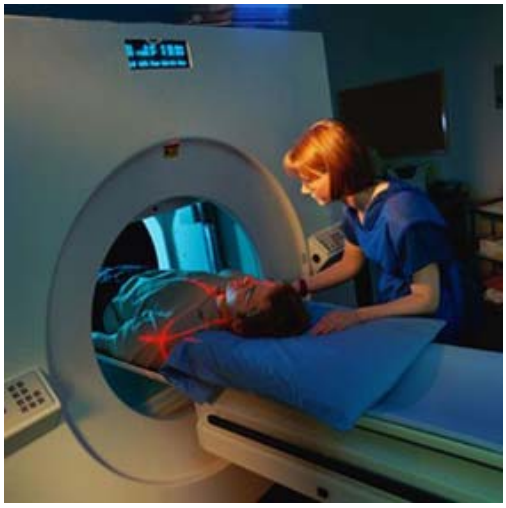
As the melee intensified, Congress, at the behest of lung cancer screening advocates, called for an investigation of two leading NLST investigators on suspicion of conflict-of-interest due to their testimony for the defense in a lawsuit brought against the tobacco industry: Denise Aberle of UCLA, co-principal investigator of the NLST, and William Black, principal NLST investigator at Dartmouth Hitchcock Cancer Center, (12) both lawsuits sought early lung cancer screening for heavy smokers (and in one case for former smokers), a remedy that industry attorneys strenuously opposed. Both investigators testified that the benefits of CT screening are unproven at present and that CT screening for lung cancer could be detrimental to public health. No wrongdoing was found. But the tenor of the debate had taken a nasty turn.

In January 2008, The Cancer Letter published an "exposé" of ELCAP Lead Investigators Claudia Henschke and David Yankelevitz, both of Weill Medical College of Cornell (13). A review of publicly available patent application databases revealed 27 patent applications worldwide between the two researchers that were related to trial methodology, software for interpretation of CT scans, and technology of biopsy needles. One of the inventions had already been licensed by General Electric, a maker of CT scanners. The potential market, and thus profits from screening, is enormous: CT scans cost anywhere from $270 to $4,800, and there are 43.4 million current smokers in the U.S. alone.

Since the Bayh-Dole Act of 1980, which gave U.S. universities and non-profits intellectual property control of their inventions and ideas, most, if not all, investigators and their institutions file for patents for any promising ideas or technologies arising from their research. In fact, TRDRP routinely requires that principal investigators report any patent or license arising from their TRDRP-funded research so that the program can evaluate the impact of the research it funds. However, most journals, conferences, and other sources of scientific and medical information correctly consider patents and licenses to represent potential conflicts of interest and require that such information be disclosed by their authors and experts. This is especially true for information accredited by Continuing Medical Education (CME). CME's purpose is to improve the practice of medicine in an objective fashion; it must remain uninfluenced by commercial interests and its integrity thus depends on proper disclosure of potential conflicts of interest by its experts. The information had been disclosed to the NEJM at the time of the ELCAP manuscript submission, but the editors decided that it was not relevant and it was not published, despite the fact that the article was accredited by CME (14). The ELCAP investigators were inconsistent with the extent of their conflict-of-interest disclosures in other CME-accredited activities as well, and this, along with the failure of the NEJM to publish this information with their original paper, unleashed an avalanche of criticism on Drs. Henschke and Yankelevitz. Many felt that their research was now irrevocably tainted.

As if things weren't bad enough for the two beleaguered investigators, The New York Times in March 2008 revealed that the ELCAP study was funded initially in part by an unrestricted $3.6 million grant from the Vector

Group, the parent company of the Liggett Group, the 6th largest maker of cigarettes in the U.S. According to The New York Times, many, including the NEJM, the American Cancer Society (a source of grants to Dr. Henschke), and Robert Young, chairman of the Board of Scientific Advisors at NCI, expressed surprise (15). The NEJM had never knowingly published work supported by the tobacco industry and ACS disallows grants to investigators funded by the tobacco industry. The Liggett grant was made in 2000 to the Foundation for Lung Cancer: Early Detection, Prevention & Treatment, which was created by investigators. But some suspected that the Foundation was set up expressly to hide the source of the funds. Drs. Henschke and Yankelevitz



strongly denied the allegation pointing out that the gift had been fully disclosed to both grant-funding organizations and initially to the public in both USA Today and BusinessWeek, that it represented only a fraction of the initial cost of setting up the trial, and that the foundation no longer accepts grants from the tobacco industry. Weill Cornell officials also revealed that they joined the foundation shortly after its creation to assure the proper handling of the Liggett grant (16). ELCAP currently receives funds from the Flight Attendant Medical Research Institute and the American Legacy Foundation, both well-known funders of tobacco-related research that are not aligned in any way with the industry.

In this highly charged and competitive atmosphere, some suspected that NLST supporters over-reacted because ELCAP had the temerity to have the answer first. ELCAP lead investigators clearly feel very strongly that CT scanning is the ethical thing to do right now. Their enthusiasm probably led to some questionable decision-making. Nonetheless, no major medical organization has endorsed CT screening for lung cancer, and all are waiting for results from the NLST trial.

The real tragedy

Understanding the CT screening issue benefits from the hindsight provided by the history of mammography screening (17). In 1971, randomized controlled trials showed that regular mammograms detected breast cancer early and saved lives in women over 50 years of age. The results were inconclusive in younger women. But enthusiasm was so high and demand so great that NIH and ACS initiated a massive screening program in women of all ages. By 1990, it was clear that there were problems with over-diagnosis and unnecessary follow-ups and procedures in women under 50 (without affecting breast cancer mortality) while those over 50 were getting fewer exams. Recommendations for breast cancer screening were revised and annual mammograms are now recommended for all women over 40 years of age.

Naturally the hope is for improved detection methods for lung cancer that are non-invasive and definitive. Some of the most exciting areas of research lie in the area of genomic, proteomic, metabolomic, and immunological biomarkers. These hold great promise and some could potentially be coupled with new radiographic techniques such as positron-emission tomography (PET) for even greater efficacy, specificity, and resolution (18). But such molecular biomarkers are not yet ready for prime time. So what are we to do in the meantime for the 43.4 million smokers in the U.S. who are addicted to nicotine and the 47.3 million former smokers, all of whom are at risk for developing lung cancer? And what about those unfortunate individuals who will be told by their physicians that they have a 15% chance of survival?

The real tragedy in this case is not the fact that the public will need to wait until definitive results are available. The real tragedy is that funding for a disease that claims over 160,000 U.S. lives a year has been woefully inadequate in the past and still is; that lung cancer has surpassed breast cancer as the primary cause of cancer mortality in women; that lung cancer was, and still is, considered the fault of the people who are addicted to smoking; that it is still an unmentionable, “dirty” little secret of a disease. Until this changes, many lung cancer researchers and lung cancer victims and advocates will feel they have no choice but to take extraordinary

measures and calculated risks to take back the lives that tobacco has claimed.

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Burning Issues
Tobacco's Hottest Topics Online

Filtered Tips

by Kamlesh Asotra, Ph.D.,

A "virtual"ly harm-free cigarette?

The tobacco industry, always looking out for their customers' welfare, has just introduced the latest in its "harm-reduction" offerings, the electronic cigarette. The product uses a battery-operated heating element or "atomizer" to vaporize nicotine from liquid containing nicotine together with several chemicals and menthol. It's allegedly "the healthiest alternative smoking product you will ever get!" Thus dawns a new era of nicotine addiction courtesy of the ever-innovative tobacco industry.
http://e-cig.com/shopping/shopcontent.asp?type=Home

Where the harm is in harm reduction cigarettes

In the meantime the original "harm reduction" product, "light" cigarettes, long-touted by the tobacco industry as being less harmful than regular cigarettes, are actually as much or more harmful. Just-published research by TRDRP investigator Professor Prue Talbot and her colleagues demonstrates that smoke solutions from so-called "light" cigarettes were "as potent if not more potent" toxicants than that of a traditional brand in their assays on mouse embryonic stem cells.
(Human Reproduction, 1(1): 1-12; 2009).

San Francisco kicks butts

Cigarette butts comprise one fourth of the trash from city sidewalks and gutters, and its removal costs the city a whopping $10.7 million each year. San Francisco Mayor Gavin Newsom would propose a 33-cent-per-pack tax on cigarettes sold in the city to cover the cost of picking up cigarettes butts from city streets. Mayor Newsome may really kick some butt if his proposal is approved by the Board of Supervisors.
http://www.sfgate.com/cgibin/blogs/cityinsider/detail?entry_id=40346)

Nicotine increases cancer risk

A recent study by Dr. Muy-Teck Teh and colleagues from the Queen Mary University of London, UK reported that interaction of a gene called FOXM1 in oral lesions with nicotine from nicotine gum or lozenges increases the risk for developing mouth cancer (PLoS ONE 4(3): e4849. doi:10.1371/journal.pone.0004849). Increased expression of FOXM1 or nicotine exposure alone do not by themselves trigger cancer. This is the first comprehensive study ascribing a cancer-inducing role to nicotine.
http://oralcancernews.org/wp/2009/04/cancer-risk-of-nicotine-gum-and-lozenges-higher-than-thought/

Slideshow: Virginia Slims Purse Packs

Purse packs for women

Philip Morris USA and R.J. Reynolds have initiated an aggressive marketing campaign to lure women and girls to smoking. The Phillip Morris USA announced in October 2008 repackaging of Virginia Slims as “purse packs” of “superslim cigarettes” that have historically appealed to women’s perception as a means of weight control. Correspondingly, R. J. Reynolds launched Camel No. 9 in black boxes with pink and teal borders. A coalition of several public health organizations has issued their own warning: “Deadly in Pink: Big Tobacco Ups Its Targeting of Women and Girls”
http://www.tobaccofreekids.org/reports/women_new/.