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Duke Halts Third Trial; Coauthor Disputes Claim That Data Validation Was Blinded

By Paul Goldberg

Duke University has suspended another clinical trial as part of an effort to check the scientific underpinnings of a genomic technology used to assign cancer patients to treatments.

The trial halted earlier this week was co-sponsored by Duke and the Department of Defense. A government-run database of clinical trials states that the trial was suspended on Oct. 19, http://www.clinicaltrials.gov/ct2/show/NCT00636441.

This is the third study to be stopped in connection with allegations that the genomic technology developed at Duke incorporated errors, which included poor handling of data and inaccurate calculations. Two Duke trials

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In the Cancer Centers:

Arizona Cancer Center Receives $5 Million Gift For Research, Largest Ever To Center

ARIZONA CANCER CENTER received a $5 million gift from the estate of **Fenton Maynard** of Phoenix. This is the largest gift for research activities made to the center in its 33-year history. The Margaret E. and Fenton L. Maynard Excellence in Breast Cancer Research Endowment, will be used to support basic and clinical research by Arizona Cancer Center scientists and physicians to achieve improved diagnosis, treatment or prevention of breast cancer. Also at Arizona, **Alfred Cohen**, clinical professor of surgery in the University of Arizona Department of Surgery, has been named surgical director at cancer center and will join the center's leadership team. He joined the center last February. In addition, the **University of Arizona** and the **Translational Genomics Research Institute** received a two-year, $7.5 million grant from NIH to fund a drug discovery and development center that puts renewed focus on the role of medicinal chemistry. The UA College of Pharmacy and TGen Southwest Comprehensive Center for Drug Discovery and Development will assemble a translational medicinal chemistry team capable of designing and selecting bona fide drug candidates quickly. The grant allows TGen to expand its computational chemistry capabilities and high-throughput screening facilities through additional staff and equipment, and UA College of Pharmacy to expand the number of medicinal chemistry investigators and infrastructure, primarily in Tucson. Principal investigators are **Nathalie Meurice**, of TGen; **Christopher Hulme**, of UA; and **Spyro**

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Moffitt Terminates Pilot Study, Says Action Unrelated To Duke

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were suspended on Oct. 6 (The Cancer Letter, Oct. 2, Oct. 9).

The Duke scientists who led the research now being probed—Joseph Nevins and Anil Potti—said they stand by their results and are preparing a paper that would describe how these results were obtained.

In another development, a biostatistician who had collaborated with Nevins and Potti, and who is listed as a co-author on a paper with the Duke team, disputed the claim that Europeans had conducted a blinded confirmatory study of the technology. Nevins had said to The Cancer Letter that the trial was blinded, and a similar assertion had appeared in a scientific journal.

The study was, in fact, not blinded, the former collaborator said. An unblinded study is considered much less reliable than one that is blinded.

The controversy over the Duke technology is important, because the ability to rely on genetic tests to assign patients to therapies is one of the fundamental features of "personalized medicine." The genomic technology in question is being tested outside Duke as well. Cancer and Leukemia Group B and NCI are considering conducting a trial that would use this approach to assign patients to therapies based on their genetic profiles. Another CALGB trial, now underway, conducts the test, but doesn't use it to assign patients to treatments.

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Though an erroneous test can be as dangerous as a bad drug, validation of such technologies is exceedingly difficult. The Duke case came to light only because biostatisticians at M.D. Anderson Cancer Center devoted about 1,500 hours to recreate this work step-by-step. Much of this fact-checking was uncompensated, but it resulted in a paper published in the forthcoming issue of the Annals of Applied Statistics. The paper claims that patients enrolled in Duke trials could be harmed if this technology is used to assign them to treatment. The paper is posted on the journal's website.

In another development in the controversy, a pilot study that appears to be based on the Duke technology was stopped at the Moffitt Cancer Center (http://clinicaltrials.gov/ct2/show/NCT00720096). Unlike the three Duke trials, which were described as being "suspended," the Moffitt study was "terminated," the database indicates.

According to the database, the study was ended because "funds for this project have been spent, and it is thereby terminated." A Moffitt spokesman's description of the reason for closing the trial differed from one cited in the database. "The trial was closed during extension of funding for low accrual," Patricia Kim, a Moffitt spokesman, said in an email. The action, taken on Oct. 8, two days following suspension of the first two Duke trials, was not related to that controversy, Kim said.

Robert Wenham, a gynecologic oncologist and the principal investigator on the Moffitt study, a collaboration with the Department of Defense, had trained at Duke and is listed among authors on several of that group's publications. A sub-investigator on the study, Jonathan Lancaster, also a gynecologic oncologist at Moffitt, had been a part of the Duke team, and his name is listed on Duke patents and publications.

The pilot study used microarray technology to examine cancer genes to predict how individual women with recurrent ovarian cancer will respond to either liposomal doxorubicin or topotecan.

Validation Study Not Blinded, Coauthor Says

In an interview with The Cancer Letter earlier this month, Nevins said that researchers affiliated with the European Organization for Research and Treatment of Cancer had conducted a blinded validation of the Duke technology:

"Data was made available to us, blinded. All we got was the gene expression data. We ran the predictions and sent it back to the EORTC investigators, including the statisticians in the EORTC group. They took the results, analyzed it in the context of the clinical

responses in that study, and did further analyses with respect to evaluating developing combined probability measures." (The Cancer Letter, Oct. 2).

The study resulted in a publication in the December 2007 issue of The Lancet Oncology. Nevins and Potti made similar claims in published correspondence with Nature Medicine.

Nevins, a basic scientist, is the Barbara Levine Professor of Breast Cancer Genomics and Director of the Center for Applied Genomics and Technology at the Duke Institute for Genome Science and Policy. Potti, an oncologist, is an assistant professor at the Duke Department of Medicine.

Their claim that the study was blinded was challenged by M.D. Anderson biostatistician Keith Baggerly, who had been examining the Duke group's data over the past three years.

"The fact that the data supplied to the Duke group were non-blinded doesn't prove that their analysis used the response information in generating predictions," Baggerly wrote in a letter to the editor of The Cancer Letter. "However, given the errors already acknowledged, we would find it more reassuring if an independent group had either reproduced their results or had successfully applied their algorithm to an independent data set."

Baggerly cites one of the Lancet Oncology paper's coauthors stating that the Europeans "would not be able to reproduce the reported probabilities with the information we have about how they were obtained."

The researcher quoted by Baggerly, Mauro Delorenzi, head of the Bioinformatics Core Facility at the University Hospital Vaud and Swiss Institute of Bioinformatics, confirmed this statement in an email to The Cancer Letter. Delorenzi is a coauthor on the Lancet Oncology paper.

Nevins and Potti were invited to respond to Baggerly's letter, but didn't address the question of blinding in their response. "We stand by our previous statements and the results of our studies," they said in an email. "We do recognize that it is important to address questions regarding our scientific findings, which will be done in the near future in the context of further scientific publication in peer-reviewed journals."

Doug Stokke, a spokesman for Duke, said the decision to suspend the three trials was made by the investigators.

"After being made aware of the questions raised in Annals of Applied Statistics, the principal investigators… trials elected to put a hold on the enrollment of new patients pending greater clarity of the scientific questions," Stokke said in an email. The three trials were the only ones at Duke to rely on the technology in question.

"Blinded External Confirmation Not Demonstrated"

The text of Baggerly's letter to The Cancer Letter follows:

In the Oct.2 Cancer Letter, Joseph Nevins responded to questions about reproducibility of the chemosensitivity signatures that he and Anil Potti had developed by stating that the signature results had been confirmed by researchers at the European Organization for Research and Treatment of Cancer (EORTC) as described in a paper published by Lancet Oncology in December 2007.

"Data was made available to us, blinded," Nevins said. "All we got was the gene expression data. We ran the predictions and sent it back to the EORTC investigators, including the statisticians in the EORTC group. They took the results, analyzed it in the context of the clinical responses in that study, and did further analyses with respect to evaluating developing combined probability measures."

This statement about blinded validation is consistent with another they have made in print, that "we have applied our methods, as well as several of the original signatures, to predict patient response in additional datasets, some blinded to us, yielding accuracies consistent with our initial results (2,3)" (Potti and Nevins, Nat. Med., 13:1277-8, 2007). Because the outcomes for the clinical samples examined in reference #2 (Hsu et al., J. Clin. Oncol. 2007, ovarian and lung tumor data) were discussed in previous papers from the Duke group (Bild et al., Nature, 2006, Dressman et al, J. Clin Oncol, 2007, Potti et al., NEJM, 2006) and were thus known to the Duke group, the comment about blinding presumably applies to reference #3, which is the Lancet Oncology study noted above.

The assertion of blinding is critical for the Duke group's claim of "confirmation" by an external group, demonstrating that the Duke predictive model works.

In contrast to this claim, however, the Lancet Oncology paper does not mention that any blinding was done. Rather, the paper explicitly states that data were *not* blinded: "MD, PF, AP, CA, SM, JRN, and RDI had full access to the raw data." Four of these authors (Anil Potti, Chaitanya Acharya, Sayan Mukherjee, and Joseph R. Nevins) are at Duke.

To further clarify the blinding issue, we asked some of the European authors of the Lancet Oncology paper if they could supply details of the information that

was sent to the Duke investigators. They kindly sent files that had been supplied before the predictions in the paper were made, including an overall description file. [*Editor's Note: The table is posted at* http://cancerletter.com/special-reports.] The header and first four rows of selected columns from this file—each row is a patient—are listed below.

Arm, Composite label
A, npCR Ep P- T3 N1 HB01
A, npCR En Pn T2 N0 HB02_PF16_B
A, npCR Ep Pp T2 N0 HB03
A, pCR Ep Pp T2 N1 HB04

As can be seen, each patient's response status (pCR or npCR for pathological complete response or no response) is contained in the label used to identify each patient - meaning that a patient's response status was not blinded. This interpretation of labels is stated in an attached legend, which further specifies that patients in Arm A received fluorouracil, epirubicin and cyclophosphamide (FEC); patients in Arm B received epirubicin and taxotere (ET).

The fact that the data supplied to the Duke group were non-blinded doesn't prove that their analysis used the response information in generating predictions. However, given the errors already acknowledged, we would find it more reassuring if an independent group had either reproduced their results or had successfully applied their algorithm to an independent data set.

The European authors were not given the opportunity to do so, because full details of the algorithm were not supplied. Indeed, one author (Mauro Delorenzi) told us "we would not be able to reproduce the reported probabilities with the information we have about how they were obtained." At present, only the Duke group has produced scores that separate patients that responded from those that did not, and they used data that were not blinded.

In sum, (a) the Lancet Oncology paper states that authors were not blinded, (b) treatment and response information were supplied before final predictions were made, and (c) the Duke group's co-authors in Europe cannot independently reproduce their predictions. We believe that blinded external confirmation has not yet been demonstrated.

Capitol Hill:

House Report Seeks $15M For Lung Cancer Screening

By Paul Goldberg

The House version of the appropriations bill for the Department of Defense gives $15 million to lung cancer research, albeit with the caveat that these funds "are primarily for an early detection program for military beneficiaries."

This appears to be a thinly veiled reference to the screening regimen promoted by the International Early Lung Cancer Action Program, a group of doctors headed by the radiologist Claudia Henschke, of Weill Cornell Medical College.

If it survives, the bill language would drastically alter the original program developed in 2009, which aims to promote peer-reviewed research in lung cancer risk assessment, chemoprevention, screening and diagnosis, and interventions for early-stage disease (http://cdmrp.army.mil/funding/lcrp.htm).

Last year, Congress gave $20 million to the DOD lung cancer program. This year, neither the Senate bill nor that chamber's appropriations report mention the lung cancer program specifically.

The House language could end up being omitted from the final conference report, but even if it is, DOD would have to explain its reasons for not using these funds in a manner specified by the House.

Proponents of lung cancer screening—usually performed via low dose spiral computed tomography—regularly insert screening provisions into bills moving through Congress and state legislatures. Usually, these efforts are led by the Lung Cancer Alliance, a lobbying group. A call to LCA President and CEO Laurie Fenton Ambrose was not returned.

A coalition of organizations, lung cancer scientists and physicians recently urged the Senate appropriations leadership to protect the peer-reviewed lung cancer research program .

"The programmatic recommendations made by the FY2910 House Appropriations report are not based on current scientific evidence and would seriously curtail the ability of this program to contribute to fundamental progress against lung cancer," the groups wrote in a recent letter to Sen. Daniel Inouye (D-Hawaii), chairman of the Senate Appropriations Committee.

The controversial pro-screening language of the House report follows:

The Committee has included $15,000,000 for peer-reviewed lung cancer research. Lung cancer continues

to be the most lethal of all cancers, taking more lives annually than all other major cancers combined. The five year survival rate is only 15 percent and a major contributor is that 70 percent of the diagnoses are late stage. Furthermore, military personnel have increased exposure to lung cancer carcinogens and are thus more susceptible to lung cancer than the general population. These funds, in conjunction with the funds provided in fiscal year 2009, are primarily for an early detection program for military beneficiaries. It is expected that this early detection regimen will be initially implemented in Military Medical Treatment facilities in the National Capital Region.

FDA News:

FDA Approves Votrient For Renal Cell Carcinoma

FDA earlier this week approved Votrient (pazopanib) for advanced renal cell carcinoma.

The agency acted on Oct. 19, two weeks after its Oncologic Drugs Advisory Committee unanimously recommended approval for the agent (The Cancer Letter, Oct. 9). Votrient, an oral drug, is sponsored by GlaxoSmithKline (NYSE: GSK). It's the sixth agent approved for this indication over the past four years.

On the same day, ODAC voted 6-4 in favor of approval for PegIntron (pegylated interferon alfa-2b), sponsored by Schering Plough, for the adjuvant treatment of stage III melanoma. FDA approval for that agent is still pending.

Votrient was approved based on a phase III trial showing that Votrient reduced the risk of tumor progression or death by 54 percent compared to placebo, regardless of prior treatment. In the trial, the overall median PFS was 9.2 months with pazopanib and 4.2 months with placebo. Treatment-naive patients who received Votrient experienced 11.1 months of median progression-free survival (PFS) versus 2.8 months with placebo. Patients who had previously received cytokine-based treatment achieved 7.4 months of median PFS with Votrient versus 4.2 months with placebo.

Adverse events occurring in 20% or more of subjects treated with Votrient included diarrhea, hypertension, hair color changes, nausea, anorexia, and vomiting. Grade 3/4 adverse events among these toxicities that differed by greater than or equal to 2% included abnormal liver function, hypertension, diarrhea, asthenia, and abdominal pain. Laboratory abnormalities occurring in >10% of patients and more commonly (greater than or equal to 5%) in the pazopanib arm included increased transaminases, hyperglycemia, leukopenia, hyperbilirubinemia, neutropenia, hypophosphatemia, thrombocytopenia, lymphocytopenia, hyponatremia, hypomagnesemia, and hypoglycemia. Drug-related deaths were observed in 1.4% of 290 patients and included hepatic failure (n=2), stroke (n=1), and perforation (n=1). Hepatic dysfunction is included as a boxed warning in the product label. Other Warnings and Precautions in the label relate to QT prolongation and torsade de pointes, hemorrhagic events, arterial thrombotic events, gastrointestinal perforation and fistula, hypertension, impaired wound healing, hypothyroidism, proteinuria, and pregnancy.

NCI News:

Chemical Biology Consortium Formed With 11 Institutions

NCI has selected 11 institutions to participate in the Chemical Biology Consortium, a major new initiative to facilitate the discovery and development of new agents to treat cancer.

Designed to accelerate the discovery and development of effective, first-in-class targeted therapies, the CBC will choose high-risk targets that are of low interest to the pharmaceutical industry. A unique aspect of the CBC is the NCI's efforts to establish intellectual property rights for investigators and institutions that develop assays or drug candidates.

Sites participating in the CBC are: Vanderbilt-Ingram Cancer Center; The Burnham Institute for Medical Research; Southern Research Institute; University of North Carolina at Chapel Hill; Georgetown University; University of Minnesota; University of Pittsburgh; University of Pittsburgh Drug Discovery Institute; University of California, San Francisco; SRI International, Menlo Park, Calif.; and Emory University.

The program is being developed by NCI's Division of Cancer Treatment and Diagnosis, in conjunction with NCI's Center for Cancer Research and the NCI Director's Office, with guidance from external advisory panels. This effort will be managed by the NCI's Experimental Therapeutics (NExT) Program. SAIC-Frederick Inc. will provide support for the key operational and technical aspects. It is envisioned that the consortium will provide cutting-edge chemical tools for probing complex biochemical signaling pathways and will serve as the starting point for the elaboration of first-in-class targeted therapies. The long-term vision

of the CBC is to bridge the gap between basic scientific findings and NCI-supported clinical research to facilitate the discovery and development of new agents to treat patients with cancer.

SAIC-FREDERICK INC., under its prime contract with the National Cancer Institute, has selected five national centers to conduct cancer experiments using advanced computer simulations.

The "In Silico Research Centers of Excellence" contracts were awarded to the Translational Genomics Research Institute, Columbia University, Emory University, Georgetown University and the Fred Hutchinson Cancer Research Center. The Centers of Excellence will use computer tools developed as part of the NCI Cancer Biomedical Informatics Grid, a data-sharing network for researchers, physicians, and patients.

The Centers of Excellence also are envisioned as ways to promote investigator-initiated in silico research projects, leveraging caBIG tools and data along with a broad range of other tools and data available to the bioinformatics, medical informatics and cancer research communities.

Solicitation for the contracts was open to academic or commercial organizations with "expertise in computational biology, informatics analysis, statistics, genomics, proteomics, or image analysis."

THE CANCER GENOME ATLAS will fund an effort by scientists at The University of Texas M. D. Anderson Cancer Center to siphon meaningful information from an ocean of data about the aberrant genetics that drive human cancers.

The five-year $8.3 million grant from the TCGA will allow the project's lead principal investigator **John Weinstein** and colleagues to put new computational tools to work parsing the multiple genetic pathways that fuel more than 20 types of cancer. The team proposes a more flexible and efficient approach to wringing information from overwhelming quantities of data researchers generate about gene expression and variation in tumors.

Weinstein is professor and chairman of M. D. Anderson's Department of Bioinformatics and Computational Biology, and professor in the Department of Systems Biology.

The M. D. Anderson group is a new Genome Data Analysis Center of the TCGA, which is a joint enterprise of NCI and the National Human Genome Research Institute. The grant is part of the expansion of TCGA, after a pilot project focused on glioblastoma, lung cancer and ovarian cancer.

Co-leaders of the project are **Gordon Mills**, professor and chairman of M. D. Anderson's Department of Systems Biology, and **W.K. Alfred Yung**, professor and chairman of the Department of Neuro-Oncology.

In the Cancer Centers:

City of Hope Wins $4 Million For Research Studies Of DNA

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Mousses, of TGen. . . . **CITY OF HOPE** received NIH grants totaling more than $4 million to for two five-year studies to examine how changes in DNA affect the aging process and to better understand the biological process of how sun exposure can lead to cancer. **Gerd Pfeifer**, the Lester M. and Irene C. Finkelstein Chair in Biology and chairman of the Department of Cancer Biology, is principal investigator for both studies. . . . **EMORY WINSHIP CANCER INSTITUTE** received an anonymous donation of $4.7 million to fund key priorities, said **Walter Curran Jr**, executive director of the institute. The gift will serve as a fund from which institutional research grants will be distributed. Faculty members within Emory will submit grant proposals and an internal review committee will determine which grants will be funded. The priority areas fall into specific categories: Recruitment of faculty researchers; seed grants for scientific research projects; investigator-initiated clinical trials; development of Emory Winship's Survivorship Program; and mentoring opportunities for young physicians and investigators. . . . **OHIO STATE UNIVERSITY COMPREHENSIVE CANCER CENTER** – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute said **John Coffin** of Tufts University has been chosen to receive the Howard Temin Memorial Lectureship. Coffin is professor of molecular biology and microbiology at Tufts University School of Medicine and member of the molecular microbiology and genetics programs at the Sackler School of Gradate Biomedical Sciences at Tufts in Boston. He also is a special advisor to the director of the NCI Center for Cancer Research. He pioneered the use of genomic analysis to understand the biology of retroviruses, elucidating their genetic organization, mechanism of replication, recombination, and transduction. The annual Bertha Bouroncle Lecture at OSUCCC was delivered by **George Canellos** of the Dana-Farber Cancer Institute and Harvard Medical School. Also at OSUCCC, **John Byrd**, the associate

director for translational research, received the Michaele C. Christian Oncology Development Lectureship and Award for 2009. The lectureship and award, established in 2007 by the NCI Cancer Therapy Evaluation Program, recognizes the contributions of mid-career scientists involved in the development of cancer therapy agents. Byrd received the award at the annual fall CTEP Early Drug Development Meeting. . . . **INDIANA UNIVERSITY** President **Michael McRobbie** presented Distinguished Professor **Lawrence Einhorn** with a Thomas Hart Benton Mural Medallion in recognition of his prominent achievement and dedicated service. Einhorn is the Lance Armstrong Foundation Professor in Oncology with the IU School of Medicine and a physician/researcher with the Indiana University Melvin and Bren Simon Cancer Center. He is widely recognized for developing in 1974 a chemotherapy regimen for testicular cancer that is responsible for a dramatic improvement in the cure rate. . . . **VIRGINIA COMMONWEALTH UNIVERSITY MASSEY CANCER CENTER** received a five-year, $1.25 million NCI grant to study a novel drug's ability to improve radiation treatment of glioblastoma multiforme in mice as a prelude to human testing. The grant was awarded to **Kristoffer Valerie**, a professor in the VCU School of Medicine's Department of Radiation Oncology and co-leader of the cancer center's Radiation Biology and Oncology research program. . . . **YALE CANCER CENTER** Director **Thomas Lynch Jr.** recently appointed **Chad Ellis** as deputy director for research. Ellis joins Yale from NCI, where he was a program director for the Cancer Centers Program.

Professional Societies:

Caligiuri Succeeds Benz As President Of AACI

ASSOCIATION OF AMERICAN CANCER INSTITUTES installed **Michael Caligiuri** as president, at its annual meeting earlier this week in Washington, D.C. Caligiuri succeeds **Edward Benz Jr**., president and CEO of Dana-Farber Cancer Institute.

Caligiuri is director of the Ohio State University Comprehensive Cancer Center and chief executive officer of The James Cancer Hospital and Solove Research Institute. He is a professor of medicine and a Distinguished University Scholar who holds the John L. Marakas Nationwide Insurance Enterprise Foundation Chair in Cancer Research. Caligiuri's laboratory, which has nearly 40 members, focuses on research in leukemia, lymphoma and the human immune system.

AACI's new vice-president/president-elect is **William Dalton**, president, CEO and director of the H. Lee Moffitt Cancer Center & Research Institute. He will assume the AACI presidency in 2011.

Dalton was the founding director of the Bone Marrow Transplant Program at the University of Arizona and was first hired by Moffitt in 1997 as the Associate Center Director for Clinical Investigations. He was appointed deputy director in 1999. Dalton was professor and founding chairman of the Department of Interdisciplinary Oncology at the University of South Florida until 2001. He served as dean of the College of Medicine at the University of Arizona in Tucson from 2001-2002. Dalton returned to Moffitt in August 2002 in his current leadership role.

Also at the AACI annual meeting, **Janet Rowley** accepted the AACI Distinguished Scientist Award, and **Sen. Arlen Specter** (D-Penn.) received the Distinguished Public Service Award.

CTRC-AACR San Antonio Breast Cancer Symposium will honor two leading breast cancer researchers when it holds its 32nd annual meeting Dec. 9-13, in San Antonio.

The awards will be given by the American Association for Cancer Research, which together with the Cancer Therapy and Research Center at The University of Texas Health Science Center and Baylor College of Medicine, conduct the meeting for nearly 9,000 attendees.

Robert Weinberg, professor of biology at the Massachusetts Institute of Technology, will present the 2009 AACR Distinguished Lectureship in Breast Cancer Research. Weinberg is the author of The Biology of Cancer.

Charles Perou, associate professor of genetics and pathology at the Lineberger Cancer Center at the University of North Carolina, will receive the 2009 AACR Outstanding Investigator Award for Breast Cancer Research, which is funded by Susan G. Komen for the Cure.

JOHN SEFFRIN, CEO of the American Cancer Society, received the 2009 Distinguished Alumni Award from the College of Applied Health Sciences at the University of Illinois at Urbana-Champaign. He was honored for his outstanding contributions to health promotion and education. Seffrin completed an M.S. in health education at Illinois in 1967.

Prior to joining the American Cancer Society as CEO in 1992, Seffrin was a professor of health education

and chairperson of the Department of Applied Health Science at Indiana University.

AMERICAN SOCIETY OF CLINICAL RADIATION ONCOLOGY has been formed to serve as a professional non-profit organization to the radiation oncology field. ASCRO is primarily dedicated to acquiring a "Provider Status" for clinical radiation oncology physicists.

"ASCRO believes that the quality of patient care will be significantly enhanced when clinical radiation oncology physicists are given Provider Status. Such a status will allow them to make professional decisions based solely on the best interest of cancer patients," said Nabil Adnani, ASCRO president and founding member. "By joining ASCRO in large numbers, clinical radiation oncology physicists will ensure, and for the first time in history, their true place as medical professionals."

"Finally, a long overdue society is born. Clinical Radiation Oncology Physicists now have an organization they can call their own," said Ivan Brezovich, ASCRO chairman and founding member.

ASCRO will work with existing organizations and will seek advice from more established professional societies such as the American Association of Physicists in Medicine and the American Society for Therapeutic Radiation Oncology in its efforts to obtain a "Provider Status" for its members.

Institute of Medicine:
Smoking Bans Are Effective In Cutting Heart Attack Risk

Smoking bans are effective at reducing the risk of heart attacks and heart disease associated with exposure to secondhand smoke, a report from the Institute of Medicine concluded.

The report also confirms there is sufficient evidence that breathing secondhand smoke boosts nonsmokers' risk for heart problems, adding that indirect evidence indicating that even relatively brief exposures could lead to a heart attack is compelling.

"It's clear that smoking bans work," said Lynn Goldman, professor of environmental health sciences, Johns Hopkins Bloomberg School of Public Health, Baltimore, and chair of the committee of experts that wrote the report. "Bans reduce the risks of heart attack in nonsmokers as well as smokers. Further research could explain in greater detail how great the effect is for each of these groups and how secondhand smoke produces its toxic effects. However, there is no question that smoking bans have a positive health effect."

About 43 percent of nonsmoking children and 37 percent of nonsmoking adults are exposed to secondhand smoke in the U.S., according to public health data. Despite significant reductions in the percentages of Americans breathing environmental tobacco smoke over the past several years, roughly 126 million nonsmokers were still being exposed in 2000.

The IOM committee conducted a comprehensive review of published and unpublished data and testimony on the relationship between secondhand smoke and short-term and long-term heart problems. Eleven key studies that evaluated the effects of smoking bans on heart attack rates informed the committee's conclusions about the positive effects of smoke-free policies. The studies calculated that reductions in the incidence of heart attacks range from 6 percent to 47 percent.

Given the variations in how the studies were conducted and what they measured, the committee could not determine more precisely how great the effect is. Only two of the studies distinguished between reductions in heart attacks suffered by smokers versus nonsmokers. However, the repeated finding of decreased heart attack rates overall after bans were implemented conclusively demonstrates that smoke-free policies help protect from the cardiovascular effects of tobacco smoke, the committee said.

The report also provides a detailed discussion of the evidence from animal research and epidemiological studies showing a cause-and-effect relationship between secondhand smoke exposure and heart problems. The committee was not able to determine the exact magnitude of the increased risk presented by breathing environmental tobacco smoke, but noted that studies consistently indicate it increases the risks by 25 percent to 30 percent.

Although there is no direct evidence that a relatively brief exposure to secondhand smoke could precipitate a heart attack, the committee found the indirect evidence compelling. Data on particulate matter in smoke from other pollution sources suggest that a relatively brief exposure to such substances can initiate a heart attack, and particulate matter is a major component of secondhand smoke.

The report was sponsored by the Centers for Disease Control and Prevention.

Copies of "Secondhand-Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence" are available at www.nap.edu.

Further information can be found at www.iom.edu/secondhandsmokecveffects.

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