MEETING SUMMARY PRESIDENT'S CANCEL PANEL

PROMOTING HEALTHY LIFESTYLES TO REDUCE THE RISK OF CANCER

February 12, 2007 Jackson, MS

OVERVIEW

The President's Cancer Panel (PCP, the Panel) is seeking input to help develop its recommendations to the President of the United States, the U.S. Congress, the Secretary of Health and Human Services, and the broader community of researchers, policy makers, advocates, and others within the cancer community.

This meeting was the fourth in the 2006-2007 series focusing on ways to reduce the risk of cancer incidence and mortality through the promotion of healthy lifestyles. In two of the meetings in this series, the Panel heard reports on factors linking obesity, physical activity, and nutrition to cancer risk. The other two meetings, including this one, focused on the factors linking tobacco use and environmental tobacco smoke to cancer risk.

PARTICIPANTS

President's Cancer Panel

LaSalle D. Leffall, Jr., M.D., F.A.C.S., Chair Margaret Kripke, Ph.D.

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National Cancer Institute (NCI), National Institutes of Health (NIH)

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Speakers

K. Michael Cummings, Ph.D., M.P.H., Chair, Department of Health Behavior, Roswell Park Cancer Institute

Richard Daynard, J.D., Ph.D., Professor of Law, Northeastern University School of Law

Pebbles Fagan, Ph.D., M.P.H., Health Scientist, Tobacco Control Research Branch, National Cancer Institute

Anita Gaillard, Director of Community Programs, Indiana Tobacco Prevention and Cessation Agency

Stanton Glantz, Ph.D., Director, Center for Tobacco Control Research and Education, University of California, San Francisco

Ellen Gritz, Ph.D., Professor and Chair, Department of Behavioral Science, The University of Texas M.D. Anderson Cancer Center

Dorothy Hatsukami, Ph.D., Professor, Tobacco Use Research Center, University of Minnesota Jack Henningfield, Ph.D., Vice President, Research and Health Policy, Pinney Associates Cathy Melvin, Ph.D., M.P.H., Director, National Dissemination Office, Smoke-Free Families

- Thomas Payne, Ph.D., Professor, University of Mississippi School of Dentistry; Associate Director, ACT Center for Tobacco Treatment, Education and Research
- Alexander Prokhorov, M.D., Ph.D., Professor, Department of Behavioral Science, The University of Texas M.D. Anderson Cancer Center
- Douglas Ziedonis, M.D., M.P.H., Professor and Chair, Department of Psychiatry, University of Massachusetts Medical School

OPENING REMARKS—DR. LaSALLE D. LEFFALL, JR.

On behalf of the PCP, Dr. Leffall welcomed invited participants and the public. He provided a brief overview of the history and purpose of the Panel and the aims of the current series of meetings on reducing the risk of cancer incidence and mortality through the promotion of healthy lifestyles. Dr. Leffall explained that the focus of this meeting, the final one in this year's series, would be the impact of tobacco use and exposure on cancer risk and community programs relevant to promoting cancer risk reduction. Dr. Leffall thanked all of the panelists and attendees for participating in the meeting and introduced the hosts, Drs. Daniel Jones and Joe Files.

WELCOME—DR. DANIEL W. JONES

Background

Dr. Jones is Vice Chancellor for Health Affairs and Dean of the School of Medicine at the University of Mississippi Medical Center. He received a degree in chemistry in 1971 from Mississippi College and earned his medical degree from the University of Mississippi Medical Center, where he also completed a residency in internal medicine. After serving as Director of the Community Health Department and Hypertension Clinic in Pusan, South Korea, for 7 years, Dr. Jones returned to the University of Mississippi Medical Center in 1992 where he built an active research program on hypertension. Dr. Jones is a fellow of the American College of Physicians and has repeatedly been identified as one of the "Best Doctors in America" by Best Doctors, Inc. He has served in numerous positions within the American Heart Association (AHA) and will begin a term as President of AHA in 2007.

Key Points

- < Dr. Jones welcomed the meeting participants on behalf of the University of Mississippi Medical Center.
- < Mississippians have some of the unhealthiest lifestyles in the United States. This is the result of both cultural heritage and a history of unequal rights.
- < Working in the state with the worst health measures, including those related to cancer, presents serious challenges, but it can also be viewed as an opportunity. Mississippi has the opportunity to create solutions for health disparities that can be modeled in the rest of the world.
- The Partnership for a Healthy Mississippi was created with funds from the tobacco settlement and has been helpful in reducing tobacco use in the state. Although there is some dissent about how to best use tobacco settlement funds, there is a strong will in Mississippi to continue to make investments in tobacco prevention and cessation.

PANEL I

DR. K. MICHAEL CUMMINGS: Policies to Promote Tobacco Harm Minimization

Background

Dr. K. Michael Cummings joined the staff of Roswell Park Cancer Institute in 1981, and was appointed Chair of the Department of Health Behavior in the Division of Cancer Prevention and Population Sciences in 1999. Dr. Cummings also holds the rank of Senior Research Scientist at Roswell Park and Professor in the Department of Social and Preventive Medicine at the University at Buffalo. He earned a master's degree in public health and a doctorate in health

behavior from the University of Michigan. He has authored over 200 scientific papers on topics related to tobacco control and contributed to several U.S. Surgeon General's Reports on Smoking and Health. Dr. Cummings is also the Director of the New York State Smoker's Quitline and Principal Investigator of the Roswell Park NCI-supported Transdisciplinary Tobacco Use Research Center (TTURC). Dr. Cummings spearheaded efforts to provide public access to the previously confidential tobacco industry documents that were released as part of the 1998 Master Settlement Agreement (MSA). He is widely acknowledged as one of the leading public health experts in the field of tobacco control and has testified as an expert witness in over a dozen court cases against the tobacco industry. Dr. Cummings is a member of many professional organizations, including the American Association of Cancer Research, the American Society of Preventive Oncology (ASPO), the American Public Health Association (APHA), and the Society for Research on Nicotine and Tobacco (SRNT).

- < More Americans will die in the next 3 years from tobacco-related causes than have died in all previous wars combined. Smoking is responsible for approximately one-third of all cancer deaths, yet there is no national campaign that advises people to stop smoking.
- The tobacco settlement provided funds for Mississippi to create a world-class tobacco control program, but this effort is in jeopardy because of tobacco companies and politicians that are more concerned about money than about the people's well-being.
- Despite some progress, the tobacco problem has not been solved and is poised to get worse in the future. Health concerns and excise taxes have led to a decrease in tobacco sales in the United States and other wealthy nations, but this decline has been offset by growing sales in other countries. The largest increase in tobacco-related deaths over the next 15 years will be in countries such as China and India and other parts of the developing world.
- Sig tobacco companies are beginning to move the manufacturing of their products to locations in the developing world where they benefit from inexpensive labor and limited government oversight. These types of business decisions will ensure that the tobacco business remains very profitable; this continued profitability provides little incentive for change.
- In 2003, the World Health Organization created the Framework Convention on Tobacco Control (FCTC), which identified policies that attempt to address the global epidemic of tobacco. Thus far, 143 countries have ratified this document; however, the United States has not yet done so. Delays in ratification will delay the reduction of tobacco-related deaths; thus, the U.S. and other countries should be encouraged to adopt the policies outlined in the FCTC as soon as possible. The President's Cancer Panel should urge the President to recommend ratification of the FCTC.
- The pending implementation of FCTC policies provides a unique opportunity for studying the effects of these national-level policies. The information gained will inform the antitobacco efforts of other countries.
- The Roswell Park TTURC, which is supported by NIH, has created an international study involving 13 countries and more than 50 scientists from around the world to monitor the effects of FCTC policies.
- One study examines the effectiveness of warning labels on cigarette packages. The U.S. warning label was last updated in 1984; in contrast, Canadian warning labels were updated in 2001 and are much larger and more eye-catching. Research has shown that people are more likely to notice bigger warning labels and labels with graphics. Labels should be educational; for example, most people already know that smoking causes lung cancer and heart disease, but many don't realize that it is also associated with other health problems, such as

- impotence. Providing information that is new to users may be more effective at attracting their attention and result in higher rates of tobacco cessation.
- While FCTC policies and other programs are somewhat effective at reducing tobacco use rates, widespread change will not occur until the tobacco industry is no longer profitable. Although it may seem farfetched, one option would be for state and Federal governments to buy out the shareholders of the tobacco companies. The Government would have to prioritize health over profits, which would dramatically change the landscape of the tobacco issue.

DR. ELLEN GRITZ: Impact of Continued Smoking on Cancer Survivorship Background

Dr. Gritz is Professor and Chair of the Department of Behavioral Science and Olla S. Stribling Distinguished Chair for Cancer Research at The University of Texas M.D. Anderson Cancer Center. Dr. Gritz has published extensively on cigarette smoking behavior, including prevention, cessation, pharmacologic mechanisms, effects on weight, and special issues of concern to women and high-risk groups, including ethnic minorities, youth, and cancer patients. Dr. Gritz has served on the National Cancer Policy Board and the Board on Population Health and Public Health Practice and is a past president of ASPO. She is currently Vice Chairman of the American Legacy Foundation Board of Directors as well as President of SRNT. Dr. Gritz was the first recipient of the ASPO Joseph W. Cullen Memorial Award for outstanding research in smoking, and received the ASPO Distinguished Achievement Award in 2001. In 2002, she received The Margaret and James A. Elkins, Jr., Faculty Achievement Award in Cancer Prevention from M.D. Anderson. In 2006, Dr. Gritz was the recipient of the annual Business and Professional Women's Clubs Texas Award. Dr. Gritz is a fellow of the Society of Behavioral Medicine and the American Psychological Association, and is Senior Editor for Behavioral Sciences of Cancer Epidemiology, Biomarkers, and Prevention.

- The nationwide National Health Information Survey has provided data for two population-based surveys on smoking behavior in cancer patients. The first study revealed that approximately 20% of long-term cancer survivors smoke, which is similar to the rate among people who have no history of cancer diagnosis. However, the second study, which stratified the data based on age, showed that smoking prevalence is much higher in young adult cancer survivors (42.6%) than their age-matched counterparts who have never had cancer (26.5%).
- Initial smoking quit rates after cancer diagnosis are relatively high (approximately 50%), but the risk of smoking relapse remains high for the 1-2 years following diagnosis and treatment. The time immediately following cancer diagnosis and treatment should be viewed as a "teachable moment," an opportunity to help patients understand the dangers of smoking and benefits of quitting.
- A recent study monitored the smoking behavior of 150 non-small cell lung cancer patients, all of whom were smokers or recent quitters (within 3 months). Sadly, 43% of these patients smoked at some point during the first year after their surgery and 37% were current smokers at 1 year postsurgery. The majority of patients who resumed smoking did so within 2 months of their surgery. Smoking relapse is correlated with a shorter quit time before surgery, more nicotine dependence, and lower income. Interestingly, a correlation was also found with increased education level; one potential explanation for this is that educated individuals who continue smoking may be more likely to be highly addicted to nicotine, making it more difficult for them to quit smoking. The results of this study emphasize the need for interventions to prevent smoking relapse immediately following surgery.

- There is a growing volume of literature regarding the harmful effects of smoking during cancer treatment. With regards to surgery, smoking can contribute to general anesthesia complications, increase the risk of infection and other complications, and impede wound healing. Smoking also reduces the efficacy of radiation therapy and causes increased toxicity and side effects. There are less data regarding the effect of smoking on chemotherapy, but it is generally thought that tobacco use may contribute to immune suppression, increased drug toxicity, and other negative outcomes. Overall, data indicate that smoking cessation at the time of cancer diagnosis will decrease the risk of treatment complications, decrease the risk of second primary tumors, improve overall survival rates, and improve quality of life.
- Most cancer clinical trials do not collect data on smoking history and status unless the focus of the trial is a malignancy that is highly associated with tobacco use, such as lung or head and neck cancers. Because smoking can influence the efficacy of various treatment modalities, it is critical that all cancer clinical trials collect data on smoking behavior, not only upon entry into the trial, but throughout treatment and into remission/survivorship. This information will be crucial for developing a better understanding of how smoking affects different types of therapies. Data should also be collected on whether smoking influences the effectiveness of cancer treatment differently in men and women. Also, information is needed on how smoking affects patients' quality of life and cancer-related symptoms.
- When tailoring smoking cessation interventions for cancer patients, it is important to help them understand the links between smoking and their current cancer as well as the risk for future disease. It is also important to take into consideration special circumstances related to their cancer treatment; for example, patients who have recently undergone surgery for head and neck cancer should not be given nicotine gum. Other psychological issues that often accompany a cancer diagnosis, such as guilt, depression, and anxiety, must also be compassionately and appropriately addressed.
- < Smoking cessation interventions coupled with clinical trials have exhibited variable efficiency. The highest quit rates in these studies are usually among patients with smoking-related cancers.
- In one study conducted by researchers at the University of California Los Angeles, a continuous abstinence rate of 70% at 1-year follow-up was achieved in head and neck cancer patients who were repeatedly advised by a physician or dentist for 6 months following surgery to quit smoking and remain tobacco free. This intervention reveals that advice given in the context of medical care can be a very powerful tool.
- < A study of nicotine-dependent individuals revealed that, overall, cancer patients were no more likely to quit smoking than their counterparts without cancer. Patients closer to their cancer diagnosis and treatment, however, were more likely to quit.
- < A study of young adult survivors of pediatric cancer who participated in either a peer-based telephone counseling program or a self-help intervention found that patients who received counseling had significantly higher quit rates at 8 and 12 months following the initial intervention.
- The M.D. Anderson Cancer Center has developed a new state-of-the-art comprehensive tobacco cessation and relapse prevention program called the Tobacco Treatment Program, and has made it available to all M.D. Anderson cancer patients who smoke. The program offers in-person behavioral counseling, nicotine replacement, or other appropriate prescription medications and is carried out by a multidisciplinary team, including a psychiatrist, psychologists, nurses, and social workers. The program is completely free for patients and is supported by funding from the State of Texas Tobacco Settlement Funds. The program is currently in its first year of operation; 4,335 patients were seen by the team in 2006.

- When a patient enters the program, extensive information is collected, including information about his/her tobacco history, cancer, and comorbid disorders. The information collected becomes part of the patient's medical record and there is a high level of communication between program staff and physicians providing the patient's cancer care. Patients participate in two to six counseling sessions and are followed up via telephone; some patients receive pharmacological intervention.
- In the second year of the program, electronic medical records will be used to identify all patients who smoke at the time of registration at M.D. Anderson. These patients will receive an automatic referral to the tobacco cessation program. M.D. Anderson will also be implementing "assessment of tobacco use" as a vital sign, making it a component of every patient visit.
- It is necessary to develop and disseminate effective smoking cessation interventions for all cancer patients, including those who have tumor types that are not closely tied to tobacco use. Attention must also be paid to comorbid behaviors that may make cessation more difficult, including depression and alcohol use. More data are needed on the influence of smoking on treatment efficacy, long-term survival, and the occurrence of second cancers.

DR. ALEXANDER PROKHOROV: Smoking Cessation and Prevention in Youth

Background

Dr. Prokhorov is a Professor in the Department of Behavioral Science at The University of Texas M.D. Anderson Cancer Center. During his tenure at M.D. Anderson, Dr. Prokhorov has established a strong record of state and federally funded research projects, and authored numerous peer-reviewed publications. Dr. Prokhorov chairs the Tobacco Special Interest Group of ASPO and also serves on the Scientific Program Committee of SRNT. In July 1990, Dr. Prokhorov received a World Health Organization Medal and Certificate for his outstanding research contributions involving studies on smoking epidemiology and control among children and adolescents. Since 2000, Dr. Prokhorov has directed the Tobacco Outreach Education Program, which was created to increase awareness of the tobacco risks among the general public and enhance smoking cessation counseling skills among thousands of health care providers in Texas and beyond. In 2003, Dr. Prokhorov was among the distinguished recipients of the George and Barbara Bush Endowment for Innovative Cancer Research and was also named the September 2003 M.D. Anderson Educator of the Month.

- < There are over 45 million adult smokers in the United States. The younger people are when they begin smoking, the more likely they are to become adult smokers. Over 80% of adult smokers became addicted to tobacco at the age of 18 or younger.
- Youth smoking is a major public health concern. A 1994 Surgeon General's report concluded that many adolescents are addicted to cigarettes and experience withdrawal symptoms similar to those experienced by adults. In addition to posing a risk for cancer, smoking also causes respiratory illness, reduced physical fitness, poor lung growth and function, and poor overall health.
- There has been a decline in smoking prevalence in youth, although the rate of decline has decelerated in the past 3 years. It is important to note, however, that smokeless tobacco use has increased among older high school students.
- < Flavored tobacco products and tobacco products from other countries (e.g., bidis, kreteks, hookahs) are often popular among young people; these products are sometimes more

- palatable to this population than traditional cigarettes. In one study, 5% of teens reported having tried flavored cigarettes and one-quarter of these found them better tasting than regular cigarettes. Efforts are needed to debunk myths that these "new" tobacco products are safer than conventional cigarettes.
- < A number of factors are known to influence the likelihood of smoking initiation. These include sociodemographic factors, environmental factors, behavioral and personality factors, propensity to risk taking, exposure to smoking in the movies, and depression. Children who witness smoking in movies are 2.7 times more likely to start smoking. To reduce the likelihood that children will be exposed to images of smoking, smoking should be prohibited in movie trailers that will be shown on television and movies portraying characters who smoke should be R-rated.</p>
- Tobacco education programs targeted to young people should take advantage of modern multimedia computer technology, since most U.S. households have personal computers and Internet access and virtually all schools expose children to these technologies.
- The ASPIRE (<u>A Smoking Prevention Interactive Experience</u>) antismoking curriculum was developed by Dr. Prokhorov. The program addresses myriad issues, including socializing without smoking and both short- and long-term health consequences of smoking. In a Houston-based clinical trial, youth who were exposed to the ASPIRE curriculum, including those with multiple known risk factors, were less likely to start smoking.
- The next generation of the program will be more interactive—similar to a video game—and, hopefully, even more effective. The updated program will be tailored to the age, ethnicity, and gender of the user.
- < In order for tobacco education programs to prevent smoking in young people, they need to be appealing to young people, in addition to being based in theory.

DR. DOUGLAS ZIEDONIS: Tobacco Dependence and Psychiatric Illness Background

Dr. Ziedonis is Professor and Chair of the Department of Psychiatry at the University of Massachusetts Medical School and UMass Memorial Health Care. He has served as Director of the Division of Addiction Psychiatry at the Robert Wood Johnson Medical School, Co-Director of the University of Medicine and Dentistry of New Jersey Tobacco Dependence Program, and Director of the Addiction Research Program at the Cancer Institute of New Jersey. Dr. Ziedonis is an internationally recognized leader in co-occurring mental illness and addiction—tobacco dependence in particular. He is leads and advises several national initiatives in this area, including efforts within the Robert Wood Johnson Foundation, the Veterans Affairs (VA) Health Care System, and the American Psychiatric Association (APA). He has served as an advisor to President Bush's New Freedom Commission on Mental Health and is a Senior Fellow for the Substance Abuse and Mental Health Services Administration (SAMHSA) Co-Occurring Disorders Center for Excellence and the Treatment Improvement Protocols (TIPs) on Co-Occurring Disorders. He has served on the APA Practice Guidelines Work Group on Substance Use Disorders and Council on Addictions. Dr. Ziedonis has written over 100 book chapters and peer-reviewed publications and co-edited three books and five behavioral therapy manuals for cooccurring disorders. He also serves on the editorial boards of The American Journal of Drug and Alcohol Abuse, The Journal of Groups in Addiction & Recovery, and The Journal of Substance Abuse Treatment.

- It is estimated that 60-75% of patients in mental health treatment settings smoke cigarettes. High rates of smoking are observed in patients diagnosed with schizophrenia, bipolar disorder, major depression, panic disorder, and post-traumatic stress disorder. The *Journal of the American Medical Association* recently published data showing that 44% of all cigarettes consumed in the United States are consumed by individuals with a psychiatric disorder. This population suffers disproportionately from tobacco addiction and use, but is not the focus of most smoking cessation interventions; this is likely due in part to the social stigma of mental illness. The result is that smoking rates for this population have not changed in 40 years.
- It has become clear in the past 10 years that people with mental illness are burdened with and die from tobacco-related diseases. This population is at high risk for pulmonary cancers as well as respiratory and cardiac diseases.
- < Individuals with a history of depression or substance abuse disorders do not do as well in tobacco cessation programs. They are in need of more intensive interventions than other sectors of the population.
- < Efforts should be undertaken to raise awareness about the need for smoking cessation interventions in mental health patients. Mental health professionals must be trained about the importance of tobacco cessation, and tobacco control programs must be informed about this underserved population. Smoking cessation must be integrated into mental health treatment rather than dealt with separately.</p>
- There is opportunity for the President and Federal agencies to address this issue. The VA health system could have a large impact on this problem; it treats a large number of patients with behavioral health problems, many of whom smoke. SAMHSA, the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, and the Center for Mental Health Services have not been adequately addressing tobacco issues. The NIH has begun to fund more research on these issues, but there is still opportunity for improvement. The Centers for Disease Control and Prevention (CDC) should also play a lead role.
- There is interest in learning more about the effect of early smoking on psychiatric conditions in adolescents. It is possible that smoking exposes young people to substances that could alter their neural physiology. It is known that individuals who start smoking at a young age are more likely to be diagnosed with psychiatric disorders; however, the relationship between early smoking and psychiatric illness is likely very complex.
- In order for clinicians to adopt evidence-based smoking interventions, it will be necessary to bring about change in both programmatic and infrastructure features of the health care system. Physicians need to be educated about interventions, but they also need to have access to the appropriate tools and infrastructure to implement these interventions. Staff in mental health treatment settings need to be trained with regard to smoking interventions as well. The need for better coordination between those who provide mental health and primary care services is also critical.
- The New Freedom Commission Report on Mental Health states that if co-occurring disorders remain untreated, both disorders will likely worsen.
- There are several challenges associated with implementing smoking cessation programs in mental health patients. Many patients are not motivated to quit smoking. There is also a need to increase awareness about the problem and improve access to treatment. Mental health patients have also emphasized the importance of hearing about other patients with similar disorders who were able to quit smoking.

- Personalized feedback is important for individuals attempting to quit smoking. They should be told about their levels of expired carbon monoxide (a measurement commonly used to indicate smoking behavior and/or exposure to secondhand smoke) and the cost of cigarettes per year. They also need to be made aware of the broad array of health problems for which smoking puts them at risk.
- The President should consider holding a national meeting to discuss integration of mental health and medical services. Participants in the meeting should include SAMHSA, NIH, CDC, and the VA.
- Secause of their disproportionate consumption of tobacco products and the fact that they have been historically underserved, smokers with psychiatric disorders should be considered a special population and given priority status for research and outreach funding. Government publications should specifically address this population as they address other underserved populations.
- < SAMHSA should require funded programs to incorporate tobacco assessment and treatment planning into existing Federal reporting mechanisms. It should also provide funding for staff training.
- < Tobacco advocacy organizations should focus on tobacco control efforts in individuals with psychiatric disorders.
- < Mental health and addiction treatment programs should stop selling tobacco products. This is often a source of revenue for these programs.
- < Research needs to be conducted on how well existing interventions work in populations with mental health disorders.
- The VA health system should create a national best practice committee to develop a strategic plan for dealing with smoking behaviors in their patients.
- Smokers with psychiatric disorders have been historically underserved. It is necessary to raise awareness of this issue and target funding to train mental health staff, primary care providers, and tobacco control staff about the needs of this special population.

DISCUSSION: PANEL I

- The 1969 Public Health Cigarette Smoking Act prohibited cigarette advertising from broadcast television and radio, but it also preempted the ability of states and localities to regulate tobacco marketing, reserving that responsibility for Congress. As a result, many states and localities are unable to pass laws limiting the nature of tobacco advertising even if they want to make this part of their tobacco control program.
- < Cancer patients who continue to smoke exhibit higher rates of recurrence, higher rates of second primary tumors, and shorter overall survival times.
- It is difficult to pinpoint how long it takes to become addicted to smoking, but 100 cigarettes is often used as a benchmark because this number seems sufficient to strongly influence the brain. This is a complex issue and it is evident that some people are more likely than others to become addicted.
- The New York, Massachusetts, and California Departments of Mental Health and the New Jersey Division of Mental Health Services have implemented programs to combat the high rate of smoking among mental health patients; however, much opportunity for improvement remains. It would be beneficial if SAMHSA included tobacco in its State Incentive Grants for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders.

- The 5 A's for tobacco cessation—ask, advise, assess, assist, and arrange—are included in *Treating Tobacco Use and Dependence*, a Public Health Service Clinical Practice Guideline that outlines standard practice for all physicians and health care professionals. However, the approach has not necessarily been widely incorporated into all medical and health care practice.
- The M.D. Anderson Tobacco Treatment Program has not yet encountered any serious barriers to its operation; however, long-term data are needed to determine whether patient follow-up and retention pose difficulty. Similar programs at other institutions may find it difficult to secure funding needed to support the extensive staffing needs of the programs, but the M.D. Anderson program has thus far been sufficiently supported by M.D. Anderson and the State of Texas.
- < The cost of a pack of cigarettes varies depending on the level of state and/or local excise taxes. The cost to manufacture a pack of 20 cigarettes is approximately 5 cents.
- The problems caused by tobacco have not disappeared and are actually poised to worsen. The President could help combat this by ratifying and aggressively implementing the FCTC. Efforts should also be made to diminish the profitability of the tobacco industry. One other possibility would be to subject the tobacco industry to regulation by the Food and Drug Administration (FDA) and mandate the removal of nicotine from tobacco products; this would truly allow people to exercise their free will regarding whether they want to smoke.
- < Smoking and tobacco use by cancer patients have been understudied. Tobacco and smoking cessation programs should be established in all oncology settings, and information about tobacco use should be collected as part of oncology clinical trials.
- < Age- and audience-appropriate antismoking curricula should be developed and implemented throughout the entire educational continuum, from elementary school to high school and college; these curricula should make use of modern technology. Furthermore, additional research is needed on cessation programs for young people and effective strategies need to be more widely disseminated.</p>

PANEL II

DR. DOROTHY HATSUKAMI: Novel Tobacco Products and the Need for Product Regulation

Background

Dr. Hatsukami is currently Forster Family Professor in Cancer Prevention and Professor of Psychiatry at the University of Minnesota, and Director of the Tobacco Use Research Programs. She is Co-Program Leader for Cancer Prevention and Etiology for the University of Minnesota Comprehensive Cancer Center and Program Leader for Prevention and Epidemiology for the Lillehei Heart Institute. She has conducted extensive research in the areas of nicotine addiction, treatment of nicotine addiction, and smokeless tobacco, and is currently Principal Investigator of one of the seven NIH-funded TTURCs. She is a co-recipient of the Ove Ferno award for her research on tobacco dependence. Dr. Hatsukami has served on a number of national committees, including the National Advisory Council for the Substance Abuse and Mental Health Services Administration; the National Advisory Council on Drug Abuse; the Interagency Committee for Smoking and Health; the Drug Control Research, Data, and Evaluation Committee for the Office of National Drug Control Policy, Institute of Medicine; and the Scientific Board of Counselors for the National Institute on Drug Abuse (NIDA) Intramural Research Program. She has also served on many advisory panels for other United States Federal, non-profit and international

organizations. She is Past President of both SRNT and the College on Problems of Drug Dependence.

- Potential reduced exposure products (PREPs) are tobacco products that can decrease exposure to tobacco toxicants, potentially resulting in reduction of disease risk among those who continue to use tobacco products. The public health community is interested in these products because of the potential benefit for those who will not or cannot quit using tobacco products. Tobacco companies are also interested in PREPs because they are concerned about future litigation and want to maintain consumer demand for tobacco products. However, there is no independent body of literature that examines whether PREPs actually reduce exposure to toxicants and these products are largely unregulated.
- < Cigarettes that are low in tar or nicotine have been manufactured in the past and marketed as light, ultra-light, or mild cigarettes. The reduction of toxicant exposure from these products is primarily caused by the use of filter ventilation rather than the level of toxicants in the tobacco itself. Tobacco companies have implied that these products might reduce the health risk of smoking, and these marketing approaches have been very successful. Approximately one-third of light cigarette smokers believe there is a 50-100% decrease in risk using ultra-light compared with regular cigarettes.</p>
- Studies have shown that exposure to 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), a potent lung carcinogen, is no different between light, ultra-light, and regular cigarettes. Furthermore, epidemiological studies have confirmed that there is no difference in disease risk among individuals who smoke these products.
- < Unlike previous products that attempted to reduce toxicant exposure by utilizing filters, modern PREPs contain tobacco that is modified to reduce specific toxicants. The tobacco is modified through genetic engineering, improved curing processes, or chemical treatment.
- < Advertisements for one of these products, the Omni cigarette, stated that users would reduce their exposure to NNK, benzoate pyrene, and pyrene; however, an independent study showed that exposure reduction was not as much as was claimed. Importantly, exposure to other tobacco-related toxicants, such as polyaromatic hydrocarbons and carbon monoxide, was not reduced at all. These results suggest that use of the Omni cigarette is unlikely to reduce disease risk; however, it also illustrates that the levels of carcinogens can be reduced. Tobacco companies should be required to reduce levels of known toxicants as much as possible.</p>
- < Another type of PREP is a cigarette-like delivery device that heats rather than burns the tobacco. One such product, called Eclipse, was claimed to produce less respiratory inflammation and reduce secondhand smoke by 80%. A survey revealed that most consumers exposed to advertisements for Eclipse believed that the product was associated with significantly lower risk than traditional cigarettes.</p>
- < Oral noncombustible tobacco products represent a third type of PREP. There is evidence that the smokeless tobacco business is expanding more quickly than cigarette sales; this may be in part because of new indoor smoking bans. These products come in different flavors and are "spitless," which distinguishes them from traditional chewing tobacco.</p>
- < Tobacco lozenges have also been developed. Although the levels of toxicants in these products should not be considered safe, the concentrations of carcinogens are lower than in cigarettes.

- Smokeless tobacco products are marketed to a variety of audiences, including young people, travelers, women, and people concerned about exposing those around them to secondhand smoke.
- < Although smokeless tobacco is associated with lower disease risk, these products still have significant health effects, including risk of cancer, diabetes, fetal toxicity, and cardiovascular disease. Furthermore, there is a risk that smokeless tobacco products will not replace cigarettes, but will be used in parallel, possibly resulting in overall increased tobacco consumption. Because of their appeal to young people, they may also result in increased prevalence of overall tobacco use.</p>
- There is extensive variability in the levels of carcinogens contained in different smokeless tobacco products so it is difficult to make generalizations about the relative safety of these products. Also, when assessing the toxicant characteristics of these products it is important to determine the actual uptake of these toxicants into the body of the user, rather than simply the chemical composition of the product.
- Tobacco products should be regulated by the FDA and tobacco companies should be required to disclose information about toxicants in tobacco products. Limits should be placed on the legal levels of toxicants and nicotine in tobacco products. It is unfortunate that medical nicotine products are more highly regulated by the FDA than the PREPs manufactured by tobacco companies.
- < More research is needed on the levels of toxicants in tobacco, smoke chemistry, and human toxicant exposure.
- In order to reach the ultimate goal of reducing tobacco-related morbidity and mortality, a comprehensive tobacco control program is needed to deal with prevention, cessation, and the protection of the public from secondhand smoke. Reduction of toxicant exposure should be a component of this program.

DR. PEBBLES FAGAN: Poverty and Tobacco: Confronting Disparities, Inequalities, and Inequities in America

Background

Dr. Fagan is a Health Scientist in the Tobacco Control Research Branch of the National Cancer Institute. She received her M.P.H. in health education/communications from Tulane University School of Public Health and Tropical Medicine, and her doctorate in health education at Texas A&M University. Her current research and publications focus on youth cessation, young adult tobacco use, and health disparities. Dr. Fagan led efforts to facilitate the publication of the NCI report, Eliminating Tobacco-Related Health Disparities Summary Report, which was published in 2005. Dr. Fagan also organized the National Conference on Tobacco and Health Disparities in 2002, worked with other NCI colleagues to organize the Minority Investigator Career Development Program Planning Meeting in 2003, and the 1st and 2nd Biennial Career Development Workshop to Increase Diversity in Research Funding in 2004 and 2006. Dr. Fagan is collaborating with partners within NCI, the American Legacy Foundation, the University of Kentucky, and extramural researchers to support the activities of the Tobacco Research Network on Disparities (TReND). Dr. Fagan serves as a standing member of NCI Health Disparities Interest Groups, the NCI Tobacco Research Opportunities Team and Surveillance Workgroup, Partners Addressing Disparities in Priority Populations, the Tobacco Control Research Branch Community Policy Team, and the Youth Tobacco Cessation Collaborative. She is a member of APHA, SRNT, and the American Academy of Health Behavior.

- Poverty plagues approximately 37 million people in the United States. There are many areas of "persistent poverty" within the U.S., areas in which 20% or more of the population has been living in poverty for over 30 years. African Americans and Hispanics have substantially higher poverty rates than do Asian Americans and Whites.
- Poor people experience worse health and are more likely to die prematurely than the nonpoor. Tobacco use is epidemic within this population and is a major contributor to premature death due to lung cancer. Men and women in high poverty counties exhibit lung cancer incidence rates that are 12% and 11% higher, respectively, than those in low poverty counties.
- < Although smoking rates among both the poor and nonpoor have decreased in recent years, the disparity in smoking rates has not decreased. Children in low-income areas continue to have higher smoking initiation rates than those in high-income areas. Exposure to environmental tobacco smoke (ETS) is also higher among those of lower socioeconomic status.</p>
- Disparities in tobacco use are mirrored by inequalities in access to and use of quality health care. Many people with a household income of less than \$25,000 per year lack health insurance. Coverage for tobacco dependence treatment by Medicaid is incomplete—and sometimes even nonexistent—in most states (only Oregon offers comprehensive coverage for counseling and medications). Furthermore, many smokers who are eligible for Medicaid coverage of smoking cessation and/or pharmacotherapy are unaware that these services are available to them.
- There are also disparities in scientific practice. A recent report on diffusion and dissemination found that very few systematic reviews have evaluated the effectiveness of behavioral interventions that promote the uptake of cancer control behaviors in minorities and socioeconomically disadvantaged populations. Also, health care providers are less likely to advise hospitalized smokers to quit smoking if the patients are poor.
- There is evidence to suggest that low-income smokers who receive tailored interventions are more likely to quit smoking than those who receive standard care. Motivational interviewing has been effective in increasing abstinence rates and reducing secondhand smoke exposure. Telephone counseling has also helped quit rates.
- Little data exist on the effectiveness of policy-level interventions among poor smokers, although there is evidence that suggests cigarette price increases have reduced tobacco use in this population. However, policies are less effective at protecting poor women than nonpoor women from secondhand smoke.
- Tobacco use is a huge economic burden on the poor. Money spent on tobacco could be better used for food, clothes, or education. Tobacco-related illnesses can also cause loss of income due to unemployment or absenteeism and result in high out-of-pocket expenses (e.g., transportation).
- Partnerships between nationally funded poverty centers and tobacco research centers should be fostered in order to facilitate the development of solutions to reduce disparities in tobacco use and tobacco-related disease among the poor.
- < It is important to monitor the prevalence of smoking among poor young adolescents and assess individual, familial, and community predictors of tobacco use and exposure.
- < Information is also needed about personal and systemic barriers and facilitators to the receipt of cessation treatment.
- < Efforts should be made to ensure that employers comply with workplace smoking bans and poor families should be encouraged to adopt complete home smoking bans.

- < State tobacco excise taxes should be increased to discourage initiation and continuation of smoking. It is also necessary to develop Federal and state partnerships to increase complete coverage of tobacco dependence treatments and increase demand for these services among the poor.
- < Health care providers must be encouraged to abide by the Public Health Service Guidelines and advise all patients to quit smoking.
- < Strategies must be developed to disseminate information on cessation treatments to poor persons with low literacy.
- < Data should be collected on how poverty and tobacco differentially affect men and women and racial/ethnic groups across the lifespan to help identify optimal points for intervention in order to reduce cancer, malnutrition, and economic deprivation in the United States.

DR. JACK HENNINGFIELD: Addiction Biology and Tobacco Product Design: Formidable Barriers to Cancer Control

Background

Dr. Henningfield is an Adjunct Professor in the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine, where he directs the Robert Wood Johnson Foundation's Innovators Combating Substance Abuse Awards Program. He is also Vice President for Research and Health Policy at Pinney Associates, a public health issues consulting group in Bethesda, Maryland. Dr. Henningfield was formerly Chief of the Clinical Pharmacology Branch and the Biology of Dependence and Abuse Liability Assessment Laboratory of NIDA. While at NIDA, he frequently served as liaison to the FDA, CDC, Department of Defense, and other agencies concerning tobacco and other drug-related issues. His research focuses on furthering the understanding of the biology of addiction to provide a foundation for more effective treatment and prevention. He was co-editor of the 1988 Surgeon General's Report. Nicotine Addiction, and has contributed to numerous other Surgeon General's Reports on Smoking and Health, and monographs developed by NCI and NIDA, as well as reports by other national and international health organizations. He presently serves on the World Health Organization Study Group on Tobacco Regulation. He has testified on behalf of plaintiffs against the tobacco industry. His current activities focus on the intersection of science, public health, and policy, as related to tobacco, prescription drugs, and illicit drugs of abuse.

- < HIV/AIDS emerged as a serious public health problem in the early 1980s, and eventually became a major focus for Government-funded research. Infection with HIV or diagnosis with AIDS was initially viewed as a death sentence, but treatments began to become available within 10 to 15 years, and the outlook is much more hopeful for patients today. The United States does, however, struggle with getting these treatments to people who cannot afford them</p>
- < Cigarettes are very addictive, even when compared with other drugs such as cocaine, opiods, or alcohol. In the 1980s, NIDA was still trying to determine whether smoking should qualify as an addiction. The tobacco industry had had knowledge to that effect for decades, but it was not made public.</p>
- It is important to recognize that one-half to two-thirds of young people will try some type of tobacco product. The United States should do everything possible to discourage people from becoming addicted and provide comprehensive treatment and support for young smokers.
- There is real incentive to help pregnant women quit smoking. Approximately one-third of women continue to smoke while pregnant. Although disappointing, it is important not to

- make these women feel stigmatized because, as has been seen with other drug addictions, this will only lead them to hide their tobacco use.
- It is important to both prevent and treat smoking addiction; in fact, the two are tightly linked. For example, if parents quit smoking, their children will be half as likely to become smokers themselves.
- It is important to spread the message that all tobacco products are deadly and addictive. Otherwise, people will gravitate toward products they perceive to be safer, such as smokeless tobacco or cigars. Prevention and treatment efforts should be harmonized.
- < Research funded by Philip Morris showed that in animals nicotine has similar neurobiological effects as other addictive drugs. The research program was abolished because of worry that tobacco would be compared to drugs like heroin.
- Rapid delivery of nicotine to the brain maximizes the pleasurable effects of smoking. It can also cause the nausea some first-time smokers experience. Repeated exposure to nicotine results in an upregulation of nicotine receptors in the brain, which results in tolerance and an increased desire for nicotine.
- < Advances in imaging technology have revealed neurological changes associated with craving, which contributes to addiction.
- Tobacco companies have studied nicotine dosing and engineer their products to deliver the addictive chemical in ways that will maximize its addictive properties. Regulation is needed to prevent these types of manipulations that encourage people to continue smoking.
- There are more pharmacological interventions available to treat nicotine addiction now than in the past, but most people do not have access to or utilize these options. There are also behavioral interventions, such as group counseling.
- < Clean air legislation and excise taxes, although not forms of treatment themselves, complement smoking cessation interventions.
- It is necessary to recognize that addiction is a true barrier to smoking cessation that must be addressed. Training and retention of researchers and clinicians in this area are necessary to promote research in the area of tobacco and addiction.
- There is a need for regulatory flexibility on the part of the FDA in order to increase the ability of quality tobacco cessation products to move through the pipeline quickly and be used more creatively. Currently, FDA-approved labeling is not consistent with clinical practice guidelines. Regulatory guidelines should be flexible enough to adapt to future needs.
- < The FDA should regulate tobacco products. This process should be flexible and adaptable. FDA regulation may even lead to the removal of nicotine from tobacco products in the future.

DR. STANTON GLANTZ: Matching Resources with the Problem Background

Dr. Glantz is currently Professor of Medicine and Director of the Center for Tobacco Control Research and Education at the University of California, San Francisco. He has been a leading researcher and activist in the nonsmokers' rights movement since 1978 and is one of the founders of Americans for Nonsmokers' Rights. Dr. Glantz conducts research on a wide range of issues, from the effects of secondhand smoke on the heart and reductions in heart attacks observed when smoke-free policies are enacted to how the tobacco industry fights tobacco control programs. He is author or coauthor of numerous publications related to secondhand smoke and tobacco control, as well as many papers on cardiovascular function and biostatistics. He is now running two educational projects, Smoke Free Movies (smokefreemovies.ucsf.edu), which is working to end

the use of movies to promote tobacco, and Tobacco Scam (tobaccoscam.ucsf.edu), which is countering tobacco industry efforts in the hospitality industry. He served for 10 years as an Associate Editor of the *Journal of the American College of Cardiology* and is a member of the California State Scientific Review Panel on Toxic Air Contaminants. He was also elected to the Institute of Medicine in 2005.

- < There is strong need to match the problem of tobacco use and tobacco-related disease with sufficient resources.
- < There are now approximately 50 million pages of internal tobacco industry documents publicly available on the Internet. A recent search of the peer-reviewed literature revealed that there have been 547 publications regarding these documents.
- In the early 1990s, NCI created ASSIST (American Stop Smoking Intervention Study), a large-scale community-based trial of policy interventions designed to reduce tobacco use. The tobacco industry vigorously opposed this effort; subsequently released documents revealed that the industry was particularly worried about the spread of antismoking infrastructure. Evidence showed that ASSIST did accelerate the decline of smoking prevalence—smoking declined 3% in ASSIST states compared with only 2.1% in other areas. The program also provided the foundation for many state tobacco programs that have since been developed. Despite the success of ASSIST, NCI has not planned a follow-up trial. Such an effort should be planned and implemented.
- The benefits of smoking cessation for heart disease are almost immediately evident. The California tobacco control program prevented 59,000 deaths from heart disease over its first 9 years by reducing tobacco consumption by approximately 2.9 billion packs of cigarettes.
- Reduced cigarette sales as a result of the California tobacco control program resulted in \$4 billion in lost revenue for tobacco companies. The potential for economic losses of this scale motivates tobacco companies to prevent effective tobacco control programs from being established.
- < A comprehensive smoke-free law in Helena, Montana also appeared to reduce the incidence of heart attacks. Local hospital admissions for acute myocardial infarction fell 40% when the law was implemented, but rebounded again when enforcement of the law was suspended as the result of litigation. A meta-analysis of four cities that implemented smoke-free laws revealed a 26% drop in heart attacks.</p>
- < Smoking cessation can also have an effect on lung cancer, even over the short term. Changes in lung pathology can be observed within 6 to 8 weeks of smoking cessation. Lung cancer incidence in California was 14% lower than would be expected 9 years after implementation of the state tobacco control program.</p>
- < Although 30% of all smoking deaths are attributable to tobacco, only 4% of NCI-funded grants have the word "tobacco" in the abstract. Despite the important role of policy in tobacco control programs, only 51 of 9,267 NCI-funded grants include the words "tobacco" and "policy."
- The cancer centers program is the keystone of NCI-funded extramural research; however, the guidelines for this program are not conducive to funding tobacco-related research. NCI-designated cancer centers should be evaluated based on how they are addressing tobacco-related issues, because tobacco is responsible for such a high proportion of cancer deaths.
- < An intramural NCI program devoted to tobacco-related research does not currently exist but should be created.

- A national smoking quitline should also be established. The smokefree.gov Web site run by NCI is helpful, but it is underfunded and lacks capacity to serve all those who could benefit from it.
- < Tobacco accounts for 18% of all deaths and an even higher percentage of premature deaths. However, only 1% of the CDC budget goes to the Office on Smoking and Health.
- < Since 1998, the tobacco industry has given \$30 million in campaign contributions to politicians and spent \$230 million for lobbying. Studies have shown that these types of expenditures affect the behavior of politicians. The President and other politicians should be encouraged to refuse campaign contributions from tobacco companies.</p>
- < Budget allocations within Federal agencies that address health issues, such as the NIH and CDC, should correspond to the relative burden of disease.
- With more funding for tobacco-related research, more could be learned about the benefits of policy interventions. A better understanding of the immediate benefits of smoking cessation and reduced exposure to secondhand smoke could also be attained.
- < Efforts must be made to target cessation programs to young adult smokers, many of whom smoke only occasionally or intermittently and do not identify themselves as smokers.
- < The pressing need for tobacco control and tobacco-related research can and should be met with existing resources, even if funding for other types of projects is sacrificed.

DISCUSSION: PANEL II

- < Although current efforts focus on state and local levels, it would be possible to institute a nationwide ban on smoking in public places. This may not be preferable, however, as policy developed on state and local levels may be of higher quality and will likely be implemented more quickly. As of January 2007, 50% of the U.S. population resided in areas where there were complete smoking bans in workplaces and restaurants.</p>
- The dearth of funding for tobacco-related research and activities may be due in part to political pressure. Government agency directors may worry that their budget appropriations will suffer if they provide strong support for these areas. The culture of biomedical science also favors molecular biology over population-based tobacco-related research.
- NIDA has a new intramural smoking cessation program, but it is the only intramural program within NIH devoted to a tobacco-related issue. The National Heart, Lung, and Blood Institute; and the National Institute of Mental Health; and NCI should also develop intramural programs to address this area. Intramural programs are particularly effective, because they often make substantial progress quickly and are sometimes given the opportunity to testify before Congress.
- There are methods available to measure some components of tobacco products; however, it would be desirable to have the ability to perform more comprehensive measurements than are currently possible. For example, there is a need to develop biomarkers that indicate the level of uptake of tobacco constituents. Although a more comprehensive set of assays is warranted, regulation of tobacco products by the FDA can and should be implemented using currently available measurement tools.
- Hispanics have slightly lower rates of smoking than African Americans. Hispanics who immigrate to the U.S. are less likely to be smokers than Hispanics who have begun to assimilate into U.S. culture. However, few data are available stratifying race/ethnicity by poverty status.

- < Institutions or cancer centers that receive money from NIH should be prohibited from accepting research funding from tobacco companies because it poses an inherent conflict of interest.
- There needs to be strong regulatory control of tobacco products by the FDA, including restrictions on nicotine levels. Tobacco regulation must be done in the context of a comprehensive tobacco control plan that includes programs and policies for prevention and treatment of tobacco use as well as prevention of secondhand smoke exposure.
- Efforts must be made to implement tobacco control measures in areas of high and persistent poverty. This should include efforts to increase excise taxes and expand Medicaid coverage of tobacco cessation treatments.
- It is important to recognize that addiction is a biological barrier to cessation. Cigarettes have been designed to effectively package and deliver nicotine to encourage addiction. It is important to target young people in order to prevent addiction to tobacco from occurring in the first place.
- While people can easily obtain tobacco products, tobacco cessation treatments are often less accessible. FDA regulations should be made flexible to promote the development of innovative, effective tobacco treatments, and tobacco cessation should be an area of high priority for the FDA. Furthermore, the tobacco industry should be heavily regulated by the FDA.

PUBLIC COMMENT

Key Points

The fact that Philip Morris supports advertising for a smoking quitline is bothersome to some consumers because of the obvious conflict of interest. Quitlines should be supported by other groups.

PANEL III

DR. THOMAS PAYNE: Intensive Treatment of the Tobacco User Background

Dr. Payne is a clinical health psychologist, holds the rank of Professor of Dentistry, and is Associate Professor of Medicine at the University of Mississippi Medical Center. He is also Associate Director of the ACT (A Comprehensive Tobacco) Center for Tobacco Treatment, Education and Research. Dr. Payne has been involved in clinical, research, and educational aspects of tobacco use and cessation for 25 years. He is widely published in cue reactivity, the genetics of nicotine dependence, applied clinical factors, the health impact of tobacco use, and public health considerations. Dr. Payne has been instrumental in developing clinical treatment programs to help patients quit tobacco use. His contributions have provided the foundation of the ACT Center's clinical services and related ongoing efforts throughout Mississippi and in other states. Dr. Payne provides scholarly reviews for a number of journals and other organizations, and has sat on a number of editorial boards. He was recently elected to the position of Vice President of the Association for the Treatment of Tobacco Use and Dependence (ATTUD), an organization dedicated to the development and adoption of provider standards for providing tobacco cessation services and related activities leading to the promotion of evidence-based practice in this clinical arena.

- The University of Mississippi Medical Center ACT Center, which was initially funded by tobacco settlement funds, developed a comprehensive program to address tobacco issues in the state of Mississippi. In addition to creating intensive treatment programs, the Center works with physicians and other health care professionals to help them target their patients for tobacco cessation. The Center also has an aggressive research program that focuses extensively on dissemination research and also includes investigation of the genetics of nicotine dependence.
- < Tobacco accounts for more deaths in the United States than any other factor and also contributes to high health care costs. One figure suggests that smoking results in \$75.5 billion in direct medical costs and \$92 billion in indirect costs on an annual basis.
- < Some of the benefits of smoking cessation occur quickly. Many patients report an almost immediate improvement in quality of life—they do not tire as quickly and can be more active. Within 3 years of quitting smoking there is a 70-80% reduction in cardiovascular risk; excess risk for cardiovascular disease virtually disappears within 5-15 years. A 50-70% reduction in lung cancer risk is observed within 10 years of quitting. There is also an economic benefit of quitting because money is not being spent on tobacco products. Former smokers also often feel a sense of relief to be free of their nicotine addiction.</p>
- < Some smokers need more than a brief intervention to help them quit smoking. Thought must be given to what kinds of more intensive programs should be developed to help these people stop using tobacco.
- < A whole range of treatment options is needed to address the varying needs of smokers. Programs such as the 5 A's are low intensity, but are valuable because they require minimal training, are easily integrated into ongoing health care activities, and reach high numbers of people. Telephone counseling approaches are slightly more intensive, requiring more training, but often provide users with more attention and access to pharmacological interventions. Site counseling approaches are even more intensive; these types of programs are the best option for managing complex patients and are often associated with the best outcomes. Even the most intensive programs are cost-effective because they result in huge health care cost savings.</p>
- < Medications are an important component of tobacco cessation treatments. Use of pharmacological agents doubles the success rate of all types of counseling-based interventions. Longer-term treatments also increase the likelihood that smokers will quit.
- It is desirable to develop a model for an intensive tobacco cessation program that can be adapted for and easily disseminated to diverse populations. To do this, trained professionals and a supportive infrastructure are needed.
- < ATTUD is dedicated to the promotion and increased access to evidence-based tobacco treatment for tobacco users. ATTUD has developed a set of provider competencies that define the characteristics a tobacco treatment specialist should have. These competencies differ depending on the level of service being provided (i.e., providers working in intensive programs need to have a broader set of competencies than those delivering the 5 A's program in a primary care setting).</p>
- Tobacco treatment specialists who will be involved in intensive interventions require more intensive training. The four programs that currently carry out the most aggressive training on a national level are the ACT Center of the University of Mississippi Medical Center, the Nicotine Dependence Center at the Mayo Clinic, the Tobacco Dependence Program at the University of Medicine and Dentistry of New Jersey, and the Center for Tobacco Prevention and Control at the University of Massachusetts Medical School. There are other programs

- doing similar work, albeit less systematically and not on a national level. There is a need to encourage communication among programs and increase the standardization of training in this area.
- It is important that physicians be reimbursed for the time they spend performing tobacco cessation interventions, including counseling. The landscape for reimbursement has been slowly improving with efforts by both the Centers for Medicare and Medicaid Services and private insurers.
- The public needs to be educated about the range of treatment options for smoking cessation and given information to help them distinguish between reputable, evidence-based programs and other types of programs.
- The ACT Center has developed a treatment manual and a patient workbook that include evidence-based information about the components of the ACT program. The ACT program has been implemented at 14 sites in the state of Mississippi. A Web-based patient database facilitates program evaluation as well as the organization of medical documents and information.
- The ACT Center training program, which adheres to ATTUD competency standards, is a 4-day curriculum that provides extensive information about various aspects of tobacco treatment. Issues related to program administration and implementation are also discussed. The Center also offers annual 1-day workshops to update people about emerging treatment approaches or medications.
- < Approximately 4,000 individuals have been treated at the ACT Center programs in Mississippi and Arkansas. On average, these individuals have smoked more than one pack of cigarettes per day for 25-27 years. The cost of a single round of treatment is approximately \$420, while the cost for people who require additional treatment rounds or multiple medications is \$500-600.</p>
- < Of the individuals who complete the ACT Center program, 70% have quit smoking at the end of the treatment regimen; 61% and approximately 40% are not using tobacco 3 and 6 months following the end of treatment, respectively.
- < A full range of tobacco cessation treatment options are needed to meet the needs of all tobacco users. Intensive treatments have been widely underutilized despite the fact that they exhibit better outcomes and are more cost-effective. Funding is needed to increase the availability of all types of interventions.</p>

DR. RICHARD DAYNARD: The Impact of Tobacco Litigation on Public Health

Background

Dr. Daynard holds a J.D. from the Harvard Law School, an M.A. in sociology from Columbia University, and a Ph.D. from the Massachusetts Institute of Technology in urban studies and planning (specializing in law and social policy). He is Professor of Law at Northeastern University School of Law, where he has been teaching since 1969. He has been Chair of the Tobacco Products Liability Project since its inception in 1984, presided over more than 20 national and international conferences on tobacco liability issues, and edited the *Tobacco Products Litigation Reporter* from 1985 through 2006. He has written over 80 articles on issues related to tobacco litigation and has spoken about them in over 35 countries. He has been President of the Tobacco Control Resource Center and is currently President of its successor, the Public Health Advocacy Institute, and Chair of the Institute's Law and Obesity Project. He is a Board Member of the Framework Convention Alliance, and worked with the Alliance during the

drafting of the Framework Convention on Tobacco Control to make sure it would include provisions supporting litigation as a tobacco control strategy.

- The reasoning behind increasing the price of tobacco products is that the price of the product should reflect the full cost of the product over time. Increased prices can be accomplished through excise taxes or indirectly through litigation. If companies are forced to pay for lawsuits and settlements, they will increase the price of their products to cover the cost, thereby reducing demand. The \$0.75 average increase in price following the Master Settlement Agreement produced a dramatic drop in smoking, particularly among young people.
- The information that has been released during and as a result of tobacco litigation has diminished the legitimacy of the tobacco companies in the view of many people. The tobacco companies have also been forced to stop claiming that cigarettes do not cause disease. The litigation strategy complements other tobacco control strategies. Past litigation has changed pricing, contributed to the development of consensus policies, increased public awareness, and led to the disclosure of health risks.
- In 1954, The Reader's Digest published an article called "Cancer by the Carton," which was based on recently published scientific articles that suggested that cigarette smoking caused cancer. Some lawsuits were filed against the tobacco companies at that time, but they were not successful because the courts did not think the tobacco companies knew any more about the risks of smoking than the general public did.
- < From the early 1980s through the early 1990s, lawyers who had been involved in asbestos-related lawsuits became interested in targeting tobacco companies and another round of lawsuits ensued. The defense of the tobacco companies was that the plaintiffs had made a personal decision to smoke and, therefore, were responsible for their disease.</p>
- < Since 1994, litigation against tobacco companies has been much more successful. The so-called Global Settlement occurred in 1997 and the MSA was achieved in 1998. The latter put an end to tobacco billboards and highlighted the deception on the part of the tobacco companies about the effects of smoking on health.</p>
- < Many tobacco control programs were funded by the MSA for several years, but the funding levels have dropped substantially. The \$300 million settlement of a class action lawsuit by nonsmoking flight attendants resulted in the formation of the Flight Attendants Medical Research Institute, which funds research on tobacco-related issues.
- In an approximately 1,700-page opinion prepared for a recent Department of Justice case, Judge Gladys Kessler concludes that six or seven instances of fraud were carried out by the tobacco industry. However, the consequences this will have for the tobacco companies is unclear because a U.S. Court of Appeals ruled that remedies can only be sought to prevent the same conduct from happening in the future, not to compensate people who were damaged by past misconduct. It is possible that this decision will be appealed to the Supreme Court.
- There are a series of consumer fraud class action lawsuits against tobacco companies based on the argument that tobacco companies knowingly deceived consumers, leading them to believe that light and low-tar cigarettes were safe. There are also a number of other ongoing cases in various court systems.
- There are currently few lawyers bringing litigation against companies for obesity-related issues because these cases are time-consuming and difficult. Punitive damages would provide incentive for lawyers to become more involved in this area.

- < Obesity litigation has the potential to raise prices of "obesignenic" foods, similar to what tobacco litigation did to tobacco prices. It could also raise the profile of the causal link between certain types of food and obesity as well as damage the legitimacy of defendants. It could also result in companies offering healthier food choices.
- While there are virtually no pending obesity litigation cases, the threat of litigation has already led to changes in the food industry. The food industry does not want to be compared to the tobacco industry. State consumer protection acts that bar deceptive acts, such as marketing unhealthy foods as healthy, are one way to combat the bad practices of the food industry.
- The obstacles to obesity-related lawsuits are similar to those of tobacco-related lawsuits, including personal responsibility arguments and low public awareness of the link between certain foods and obesity.

DR. CATHY MELVIN: Making It Happen—Moving Evidence-Based Interventions into Practice

Background

Dr. Melvin is a Senior Research Fellow and Director of Child Health Services Research at the Cecil G. Sheps Center for Health Services Research, and Research Associate Professor in the Department of Maternal and Child Health at the School of Public Health at the University of North Carolina at Chapel Hill. She also directs the University of North Carolina Lineberger Comprehensive Cancer Center Dissemination Core Facility. Dr. Melvin's research interests include dissemination and dissemination research, translation of research into practice, health systems change and tobacco control and prevention, especially for pregnant and parenting smokers. She is Co-Founder and Chair of the National Partnership to Help Pregnant Smokers Quit (National Partnership), the only national organization working to mobilize the health care system and local communities to help pregnant smokers get the help they want and the support they need to quit smoking and remain tobacco free. Dr. Melvin also serves on a variety of national and state advisory and other groups and is a member of the North Carolina Women and Tobacco Coalition for Health as well as the Scientific Advisory Council for QuitNowNC!

- < Although there is still much to learn, much is already known about effective cancer prevention and control strategies. There should be a commitment to broadly disseminate and implement strategies that have been shown to work. Inadequate dissemination is a formidable problem—the transfer of knowledge gained from research to health care providers is a slow and inefficient process. It is important to rigorously evaluation dissemination strategies and monitor defined goals and outcomes.</p>
- The Smoke-Free Families National Dissemination Office helps more than 60 partners across the country use evidence-based approaches to prevent and treat tobacco use among pregnant and parenting smokers. Since this organization was founded in 1993, the percentage of women who smoke has been halved and the percentage of smokers who report receiving advice from physicians to quit smoking has increased.
- Researchers studying the dissemination of innovations have identified a number of factors that influence the pace of change, including: (1) attributes of the innovation or intervention; (2) ways in which dissemination occurs; and (3) the existence and effectiveness of interorganizational networks and collaborations.
- < New interventions are more likely to be adopted if they are viewed as superior to existing practices, provide timely benefit, and are easy to use. Good dissemination strategies require a

- strong understanding of the needs of the target audience and also benefit from identifying and using champions to promote the intervention.
- Despite ample evidence of the harm to both the mother and unborn child, more than 20% of pregnant women smoked in the late 1990s. The Robert Wood Johnson Foundation started Smoke-Free Families in 1993 in order to develop effective strategies for preventing and treating tobacco use during pregnancy. Guides developed by the organization identified and described intervention therapies proven to help pregnant smokers quit smoking.
- In 2002, Smoke-Free Families opened its National Dissemination Office, which was charged with making sure evidence-based interventions to reduce tobacco use among pregnant women and parents were put into practice. The Office invited more than 30 national organizations and agencies to come together to determine how to: 1) advance evidence-based science for smoking cessation interventions for pregnant women, 2) build capacity within health care and other systems to deliver evidence-based approaches, and 3) create demand for proven intervention strategies among health care providers and the general public.
- The group decided to form the National Partnership to Help Pregnant Smokers Quit to address these issues. The primary targets of the newly formed partnership were pregnant women and their families, health care providers, policy makers, communities, work sites, and researchers. The group focused on five strategic areas: 1) improving delivery of recommended screening and treatment services, 2) using media to reach pregnant smokers and those who care for them, 3) harnessing community and worksite resources and policies to promote, assist, and support cessation among pregnant women, 4) implementing public and private policies known to increase cessation efforts and successes, and 5) supporting the research needed to develop more effective interventions to improve dissemination efforts and strengthen national surveillance of smoking and pregnancy. The group encouraged input from almost every organization involved in providing services to pregnant women.
- The National Partnership holds monthly working group teleconference calls to achieve various specific agenda items. It tailors its dissemination strategies to specific target audiences and maintains a database to monitor attainment of predefined benchmarks.
- The National Partnership has developed educational plans and electronic and interactive media materials, and sponsored training programs for health care providers across the country. It has also created news releases and advertisements that have been used nationally, and invested in a 3-month Internet media campaign that reached 52% of all pregnant women.
- The National Partnership has worked with Congress to develop measures calling upon state maternal and child health programs to devote attention to smoking during pregnancy. It also gained support in 2003 for the first APHA policy resolution on smoking and pregnancy.
- Working together, the National Partnership has accomplished more than any single organization could have done alone to address the problem of smoking among pregnant women. The time it takes research findings in this area to be implemented has been decreased to only 2 to 3 years. The effort has been successful because its interventions and dissemination strategies are based on solid evidence, and the partnership has been managed in a flexible way.
- Interventions that have been shown to be useful should be disseminated immediately rather than be required to undergo further extensive testing in different settings. Appropriate and effective adaptations to these interventions can be identified after the initial round of implementation. Concerted effort should also be made to sustain effective dissemination strategies.

- There must be more investment in fundamental dissemination research in order to identify more effective ways to accelerate adoption of proven strategies. NCI and NCI-designated cancer centers should support dissemination and implementation research.
- < Networks and collaborative enterprises should be established to facilitate dissemination efforts.

MS. ANITA GAILLARD: Tobacco Use Burden on Indiana

Background

Ms. Gaillard earned a B.A. from Fisk University and a Master of Science in Public Health degree from Meharry Medical College. Since 2001, she has served as the Director of Community Programs at the Indiana Tobacco Prevention and Cessation Agency (ITPC). She is responsible for overseeing the community-based programs funded through ITPC, which are implemented through local community-based partnerships, minority-based partnerships, and state, regional, and pilot partnerships. Prior to joining ITPC, Ms. Gaillard was a marketing representative for St. Francis Hospital and Health Centers, where she focused on tobacco control, government relations, and physician relations. Ms. Gaillard is also a tobacco cessation instructor. She initiated a youth tobacco cessation awareness program and has strongly encouraged youth to participate as advocates in tobacco control.

- < In Indiana, 9,800 citizens die each year from tobacco-related causes. The state spends \$2.08 billion annually on health care directly related to tobacco use.
- < ITPC has several goals. It works to prevent people, particularly youth, from initiating tobacco use. It provides cessation services for those who want to quit using tobacco, and it works to establish policies that reduce exposure to secondhand smoke. ITPC provides funding for community-based programs, a statewide public education campaign, enforcement, evaluation, and administration.</p>
- ITPC is focusing on increasing the tobacco excise tax because it has been shown that a 10% increase in the price of cigarettes results in a 4% decrease in smoking among adults and a 7% decrease in smoking among youth.
- ITPC is also working to increase the number of local smoke-free policies. It does this in part by providing technical assistance to communities working to implement smoke-free ordinances.
- < A study on the economic impact of tobacco by Dr. Patrick Barkey at Ball State University suggested that tobacco use results in 175,000 fewer jobs and depletes personal incomes by a total of \$28.7 billion in Indiana.
- Inconsistent funding is one of the challenges that face state tobacco control programs. Although ITPC was given \$34 million when it was founded in 2001, its budget was cut by 70% within 2 years. This decrease resulted in a 50% reduction in spending on public education and the near elimination of statewide grants. Budgets for enforcement, evaluation, and administration were also reduced. These changes resulted in a loss of momentum because tobacco control was not being comprehensively approached. A trend toward declining smoking rates that was being observed in previous years disappeared when funding for ITPC was reduced.
- < ITPC works hard to address the tobacco prevention and cessation needs of populations in Indiana that experience health disparities, including the poor, less educated, and uninsured.

The rate of smoking among pregnant women in Indiana is 77% higher than the national average.

- < A robust patient education campaign is an important component of a state tobacco control program. The ITPC patient education campaign has successfully reached many Indiana residents—69% of adults and 80% of young people reported having seen at least one ITPC television advertisement</p>
- The tobacco industry tests some of its new products in Indiana, including Taboka, a new smokeless, spitless tobacco product that has been developed by Philip Morris. One consumer reported that when she called the Philip Morris-sponsored smoking quitline, she was put on a mailing list for Taboka.
- < Although the Indiana tobacco control program faces many challenges, it has also had many successes. Adult smoking rates are high, but youth smoking rates are declining. Also, the state has passed many smoke-free air ordinances. Including community coalitions and other programs, there are approximately 2,100 organizations committed to tobacco control in Indiana. A statewide smoking quitline was launched in 2006.</p>
- State programs play an important role in tobacco control. They are well poised to educate providers about clinical practice guidelines and implement projects to develop local programs to help populations experiencing health disparities. For these reasons, it is important to fully fund comprehensive state tobacco control programs.

DISCUSSION: PANEL III

- < There is a need to focus on prevention of tobacco use in youth and other populations in addition to investing in tobacco cessation programs.
- < Many of the core elements of smoking prevention and cessation programs are effective across most or all populations; however, it is important to tailor programs to target audiences because this will increase the likelihood of participation and success. Most tobacco cessation training programs focus on general principles, but there are efforts to modify programs when necessary.
- Pregnant women are an example of a population for which modifications to traditional tobacco cessation efforts should be made. Because of the social stigma associated with smoking while pregnant, many women are reluctant to admit to their health care providers that they smoke. One approach that has successfully been used to address this is to ask different types of questions to pregnant women to allow them to share their smoking behaviors in a less direct way. These types of effective interventions and modifications that have been found to be successful in one population can often be adapted for use in other populations.
- < It would likely be difficult to develop a successful lawsuit against the presence of smoking in the movies because the creation of a movie is a clear First Amendment right.
- Movies such as *Supersize Me* do raise awareness about issues and can drive companies to change their practices. For example, McDonald's announced they would no longer "supersize" meals a short time before *Supersize Me* was released in theaters.
- < It is important to ensure that a broad range of services is made available to those who want to quit smoking.
- < Nicotine medications are regulated by the FDA because they are intended as a treatment for tobacco addiction. However, tobacco products that contain nicotine, including new products

such as lozenges, are largely unregulated by the FDA. This is a double standard that needs to be addressed. Tobacco products should be regulated by the FDA at least as stringently as tobacco cessation products.

- < Tobacco companies should be required to virtually eliminate nicotine from their products.
- Remedies suggested by Judge Kessler as part of a recent Department of Justice case should be enforced.
- < Tobacco control needs to be highlighted as a critical part of cancer prevention and control efforts.
- The allocation of Government resources should be matched to disease burden and focused on supporting interventions known to be effective. The effects of interventions should also be carefully measured.
- The Federal excise tax on tobacco should be increased to supplement the work being done in this area by the states. This should contribute to further declines in smoking rates, particularly in young people, by making it even more expensive.

PUBLIC COMMENT

Key Points

- < Many in the state of Mississippi are working to increase the excise tax on cigarettes and encourage nonsmoking legislation for the entire state. Meetings like those being held by the President's Cancer Panel support these efforts.
- The President should urge the Senate to ratify the World Health Organization Framework Convention on Tobacco Control.
- Despite requiring more time and resources than other tobacco cessation strategies, intensive tobacco cessation interventions require fewer resources than commonly used interventions for other types of addiction, such as alcoholism.
- < It is important to involve professionals from various disciplines in the development of tobacco control programs, because they will be able to help effectively tailor programs for the populations with which they are familiar.
- < Smoking prevention efforts should be emphasized for the 18- to 24-year-old age group because it is during this time that most people who smoke either quit or become addicted. They are also looked to as role models for younger teenagers. General marketing campaigns are also important because they reach a broad range of audiences.</p>

CLOSING REMARKS—DR. LEFFALL

< Dr. Leffall thanked the attendees and panelists for making valuable contributions and assured them that the Panel would carefully consider the information collected at the meeting.

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *Promoting Healthy Lifestyles to Reduce the Risk of Cancer*, held February 12, 2007, is accurate and complete.

Labelle D. Leffally.

Certified by:

Date: June 14, 2007

LaSalle D. Leffall, Jr., M.D. Chair

President's Cancer Panel