

**LUNG CANCER**

**AND**

**STATE COMPREHENSIVE CANCER**

**CONTROL PLANS**

*This paper was produced at the request of C-Change by the Lung Cancer Alliance, a member of C-Change since 1998, and the only national organization dedicated solely to patient support and advocacy for lung cancer patients, their caregivers and those at risk for the disease.*

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# White paper for C-Change

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**Executive Summary:** In 1998, the Centers for Disease Control and Prevention (CDC) established the National Comprehensive Cancer Control Program (NCCCCP) which provides seed money, structure, and support for the development and implementation of CCC plans in all 50 states, and in several tribes, U.S. territories and U.S-Associated Pacific Islands. Of the 61 plans developed to date, none include any comprehensive program for addressing lung cancer, even though lung cancer is the leading cause of all cancer deaths nationally and in every state. Just as the National Cancer Institute cannot meet its widely proclaimed goal “to eliminate the suffering and death due to cancer by 2015,”<sup>1</sup> because lung cancer is not being addressed in its entirety or with any sense of urgency, so too will current state CCC plans that ignore lung cancer fail to achieve their overall goals of reducing the impact of cancer on state populations and budgets.

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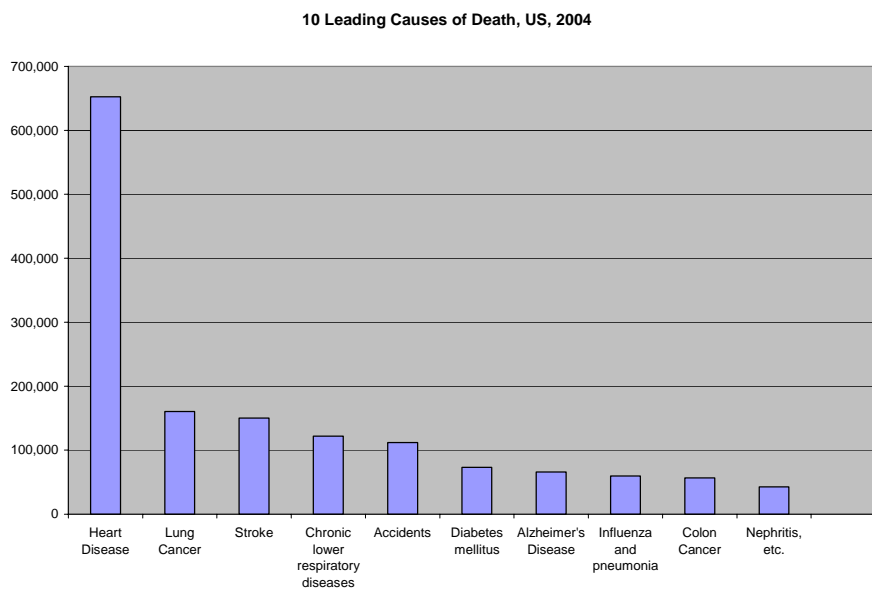
## I. Introduction:

### A. Purpose

The purpose of this document is to provide information to State, Tribe, and Territorial Comprehensive Cancer Control (CCC) planners and other stakeholders on lung cancer and the barriers that now exist to reducing its morbidity and mortality. The goal is to encourage State CCC planners to develop comprehensive policies and proposals, in addition to tobacco control programs, to address lung cancer in its entirety, increase the probability of early stage diagnosis, develop more effective treatments and reduce lung cancer mortality. By comprehensively addressing the biggest cancer killer, state plans can indeed achieve significant reductions in the cancer burden.

### B. Stigma and low survival rates

Lung cancer is the second leading cause of **all** deaths in the United States.<sup>2</sup>



The case for prioritizing lung cancer research and early detection cannot be presented without a frank discussion of discrimination.

People diagnosed with lung cancer, whether they smoked or not, are subject to a higher level of stigma and shame than people with other types of cancers and many other serious illnesses, such as cardio-vascular disease. This “blame-the-victim mentality” is pervasive throughout the medical and public health policy community.<sup>3</sup> Just as significant public health research investment in HIV-AIDS was delayed for years because of its association with behavior deemed “immoral” and “willful,” so too has lung cancer research been under funded and stigmatized by its association with smoking.

Most current and former smokers, however, began smoking before the age of 18, when experts acknowledge their choice was not fully informed or free<sup>4</sup>. Indeed, veterans, whose ever-smoked percentage is nearly double that of civilian populations and whose lung cancer incidence and death rates are substantially higher, were routinely given free cigarettes until 1976. Cigarettes are still readily available at reduced prices at PX stores and military installations. More must be done to help smokers break the powerful addictiveness of nicotine and novel approaches tying cessation to screening are long overdue.

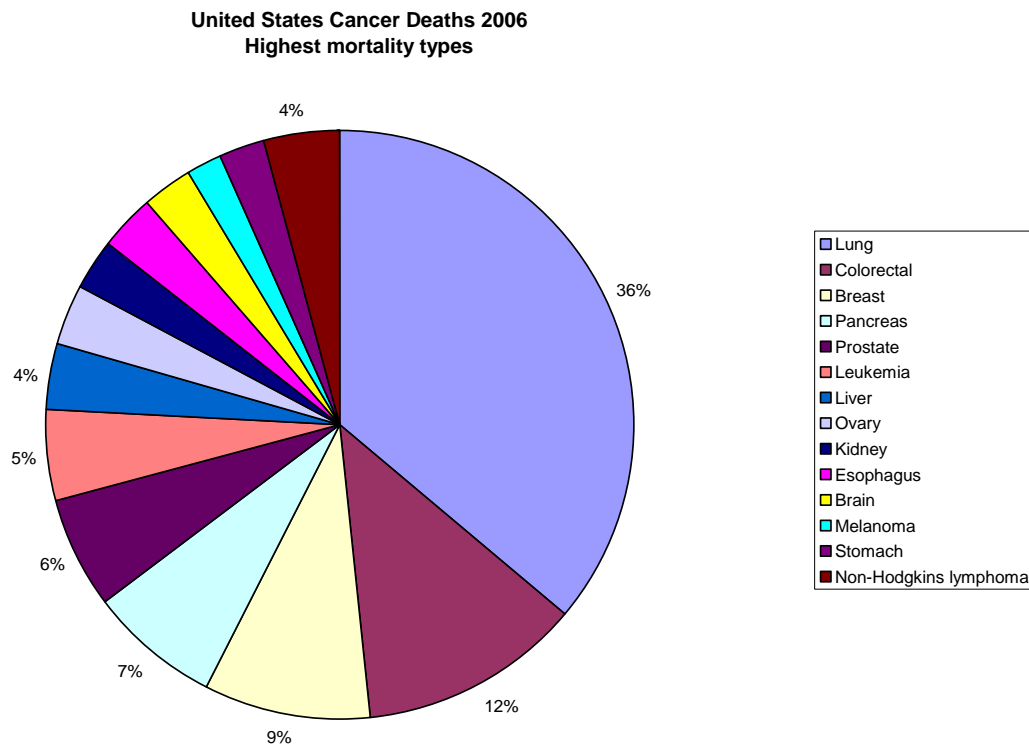
The current, albeit unpublicized, public health policy on lung cancer is that tobacco cessation programs will eventually end lung cancer and thus investments in research and early detection would be a “waste” of shrinking public health resources. No one contests the urgent need for smoking eradication. However, even if all smokers quit today, lung cancer would continue to be a deadly and costly disease. As the Progress Review Group Report on Lung Cancer to the NCI in August of 2001 stated:

*Lung cancer is the leading cause of cancer death for both men and women in the United States, killing more people than breast, prostate, colon, and pancreas cancers combined: Fully 85 percent of patients who develop lung cancer die from it. We are still largely ignorant of the molecular events underlying the development of lung cancer and the mechanisms of resistance to drug and radiation therapy; no agent has been found useful in the prevention of lung cancer; and the benefits of lung cancer screening and early detection are mired in controversy. With half of all lung cancers in the United States now diagnosed in former smokers, it is a sobering reality that tobacco control will ameliorate but not, in the foreseeable future, eliminate the problem of lung cancer. Yet we have funded lung cancer research far below the levels that characterize other common malignancies and far out of proportion to its massive public health impact<sup>5</sup>.*

Approximately 25,000 people who never smoked or were exposed to significant smoke will die of lung cancer in 2006 and the biggest increase has been in non-smoking women under 50. The stigma and blame associated with lung cancer have unfairly worsened the burden on all lung cancer patients, whether they smoked or not, and delayed the investment in research and early detection that must be made to finally reduce mortality in the number one cancer killer.

## II. National Overview

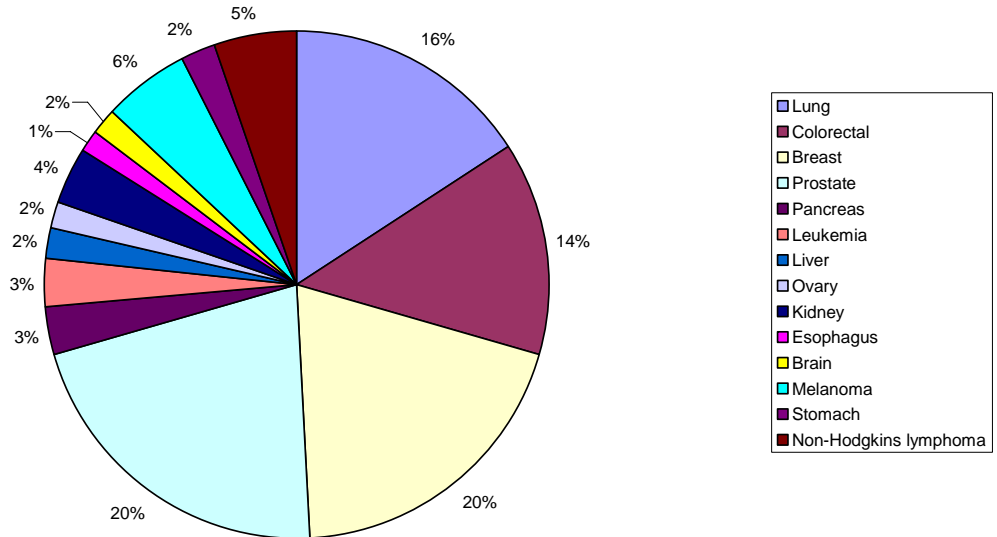
Lung cancer causes 30 percent of all cancer deaths in the United States and is the number one cancer killer of both men and women overall and in every racial and ethnic subgroup, except Hispanic women. In 2006, lung cancer will kill three times as many men as prostate cancer and nearly twice as many women as breast cancer. Yet the public is undereducated on lung cancer statistics. Nor is the public fully aware of the increasing incidence of lung cancer among former smokers and never smokers. A poll taken by the American Legacy Foundation in 2003, entitled “Conspiracy of Silence,” showed that 70% of Americans did not know that more women die of lung cancer than breast cancer. Unfortunately many in the public health establishment fall within that percentage.



### A. Basic statistics

Lung cancer is the leading cause of cancer death worldwide and causes 1.3 million deaths a year worldwide.<sup>6</sup> It is the leading source of cancer death in the U.S. in both men and women. It is the second leading cause of cancer diagnoses in both sexes also. There will be an estimated 213,380 people diagnosed during 2007 and 160,390 will die in 2007, more than the deaths from breast, prostate, colon, liver, kidney and skin (including melanoma) cancers **combined**<sup>7</sup>. Of those diagnosed, 35-40 percent of those diagnosed in the U.S. are current smokers; 50 percent are former smokers,<sup>8</sup> many of whom quit decades ago; and 10-15 percent are never-smokers<sup>9</sup>. The five-year rate survival for lung cancer is only 15 percent<sup>10</sup>. A large factor in poor survival is that 70 percent are diagnosed at late stages<sup>11</sup>.

**United States Cancer Diagnoses 2006  
Most diagnosed types**



About half of all current lung cancer diagnoses are in women. Lung cancer kills nearly twice as many women as breast cancer and is the leading cancer killer, more than breast and all gynecological cancers combined. Research suggests significant differences in lung tumors between women and men in tumor development and on a molecular level.<sup>12</sup> There are now more former (46 million) than current (45 million) smokers in the U.S.<sup>13</sup>.

This ratio of former to current will continue to increase<sup>14</sup>. In order to protect these 46 million former smokers, as well as those whose cancer results from other exposures, interventions for lung cancer need to be broader than tobacco control.

## **B. Etiology**

85 percent of lung cancer is associated with tobacco exposure. The second leading cause is radon exposure.<sup>15</sup> In addition, lung cancer can result from the approximately one dozen known lung carcinogens to which workers have been exposed<sup>16</sup>. There are additive effects between radon and cigarettes, also between these industrial/occupational carcinogens and cigarettes. Science has not yet identified a specific gene or genes antecedents to lung cancer, though epidemiology and genetic linkage studies suggests family history<sup>17</sup>. There are likely gene/environment interactions leading to lung cancer, as evidenced by the fact that only 20% of smokers develop lung cancer despite the repeated assaults to the lungs from regular intake of cigarette smoke. Research, however, has lagged in understanding heritable elements in comparison with cancers such as breast and colon.

Although lung cancer risk does decline after smoking cessation, there is no significant decline in risk until twenty years after cessation and the damage to lung tissue from cigarette exposure is not fully reversible. A person's risk of lung cancer never returns to zero following cessation<sup>18</sup>. Therefore, public health education on all risk factors for lung cancer and public health's use of early detection protocols are vital for those with known environmental exposures, as well as heritable risk factors.

### **C. Risk factors**

Even after smoking cessation a person's risk never goes down to zero<sup>19</sup>. 10-15 percent of people diagnosed never smoked or had exposure to secondhand smoke<sup>20</sup>. Therefore, using current evidence to increase the awareness of risk factors for those at high risk and increasing research to better understand risk factors such as family history is important. Risk factors for lung cancer include not only a history of tobacco exposure, but exposure to radon, to other known environmental carcinogens, to battlefield toxins and family history of lung cancer in young immediate family member(s). Research, including epidemiology provides evidence on these risk factors acting both in concert with and independently of tobacco exposure. Comorbidities such as COPD and other inflammatory lung diseases are also risk factors.

### **D. High-risk groups – selected demographics**

#### **1. Racial disparities**

The highest death rate from lung cancer is in African-American men, killing more African-American men than prostate and colon cancers combined<sup>21</sup>. The death rate in this group is 35% higher than white men, who have the next highest death rate.<sup>22</sup> The prevalence of smoking among African American men is similar to that of white men, but they smoke fewer cigarettes. Notwithstanding, African American men have a 50% higher incidence rate of lung cancer than white men and a 35% higher mortality rate. The startling disparity in incidence is unexplained. African American women and white women have similar incidence and death rates<sup>23</sup>, although only 17% of African American women smoke versus 20% of white women. Some papers published to date indicate a greater susceptibility in African-American never-smokers, particularly those with a family history of early lung cancer.<sup>24</sup> More research is urgently needed.

#### **2. Veterans**

Veterans have higher lung cancer prevalence than the general U.S. population. Up until 1976 cigarettes were distributed free of charge in K rations and sundries packets and are still readily available at significantly reduced prices on military bases. Estimates suggest that smoking prevalence among veterans in the Department of Veterans Affairs health care system is approximately 43 percent higher than that of the comparable U.S. population.<sup>25</sup> A recent survey found that 77% of military veterans were current or former smokers, compared to 49% of the non-veteran population.<sup>26</sup> In 2003, the VA provided care for 4.8 million of the 26 million veterans in the United States and

approximately 1.5 million were smokers. State CCC plans should take special note that while the induction to smoking and exposure to other carcinogens occurs during active duty, the burden of care for treating the lung cancer when it becomes manifest decades later falls primarily on the VA, Medicare and state Medicaid.

### ***E. The impact of early detection on survival and costs***

Cancers diagnosed at early localized stages can be treated and cured and incur less than half the cost of treating late stage cancer. Routine population based screening for breast, prostate and colon cancers has increased survival rates and reduced costs. Early detection is directly related to longer survival rates. National Cancer Institute SEER statistics indicate that 61% of breast cancers are diagnosed at stage 1, 91% of prostate cancers and 39% of colon cancers. According to SEER's most recent confirmed figures (1996-2002), the five year survival rates for breast, prostate and colon cancers are now 88.5%, 99.9% and 64.1%.<sup>27</sup> Only 16% of lung cancer is being diagnosed at Stage 1. Consequently, Medicare costs for lung cancer exceed those for breast and prostate cancers.<sup>28</sup>

The overall cost of cancer in the United States was \$9.6 billion in 2004. Lung cancer represented 13% of these costs<sup>29</sup>. These costs and the actual number of lung cancer cases will soar as the baby boomers enter their sixties, the decade of the highest incidence of lung cancer. Without an increase in the percentage of early stage diagnoses, the only alternative will be costly late stage treatment, including in-hospital care, with limited panoply of increasingly costly drugs that to date can only increase survival by a few months.

### ***F. Myth versus facts on lung cancer screening***

By the time symptoms, such as a cough or bloody sputum, become evident, lung cancer has already progressed beyond the early, treatable stage. With over 46 million former smokers, as well as veterans and workers exposed to known lung cancer carcinogens, the need for screening within these high risk populations is urgent, especially given the demographics of the population. The best screening tool at hand is low dose spiral computed tomography scanning (LDCT). Studies published over the past five years, and most recently in the New England Journal of Medicine, clearly demonstrate that LDCT scans can detect lung cancer at the earliest stage 85% of the time. If those diagnosed early are treated immediately, the estimated 10-year survival rate is 92%.<sup>30</sup>

The opportunity offered by LDCT to make a profound reduction in late stage diagnosis cannot be ignored. Opponents have argued that LDCT will lead to overdiagnosis, excess radiation, unnecessary surgeries and undue anxiety. Similar and equally disingenuous attacks were made regarding mammography in the 70's and 80's, and like those arguments, are being countered by the overwhelming evidence of the studies and by the increasing number of proponents in the medical field.

One of the myths is that lung cancer screening is not recommended by the U.S. Preventive Services Task Force (USPSTF). The fact is the USPSTF gave lung cancer

<sup>1</sup> In addition, the USPSTF has raised many questions about colonoscopy.<sup>2</sup>

Another myth is that screening should not be made available to the public until randomized controlled trials have been completed. To date, no randomized controlled trials have been completed on PAP smears, PSA testing or colonoscopy. Yet, they have been widely promoted, subsidized by federal programs and covered by federal, state and private insurers.

Other opponents argue that LDCT screening, even in a high-risk population, should not be done until the National Cancer Institute's National Lung Cancer Screening Trial is completed and reported in 2010 or 2011. No other cancer screening method was held to sequential rather than concurrent trials and no one trial is expected to definitively answer all questions. Indeed, over eight major randomized controlled trials have been carried out on mammography screening and its utility for women under 50 is still the subject of debate.

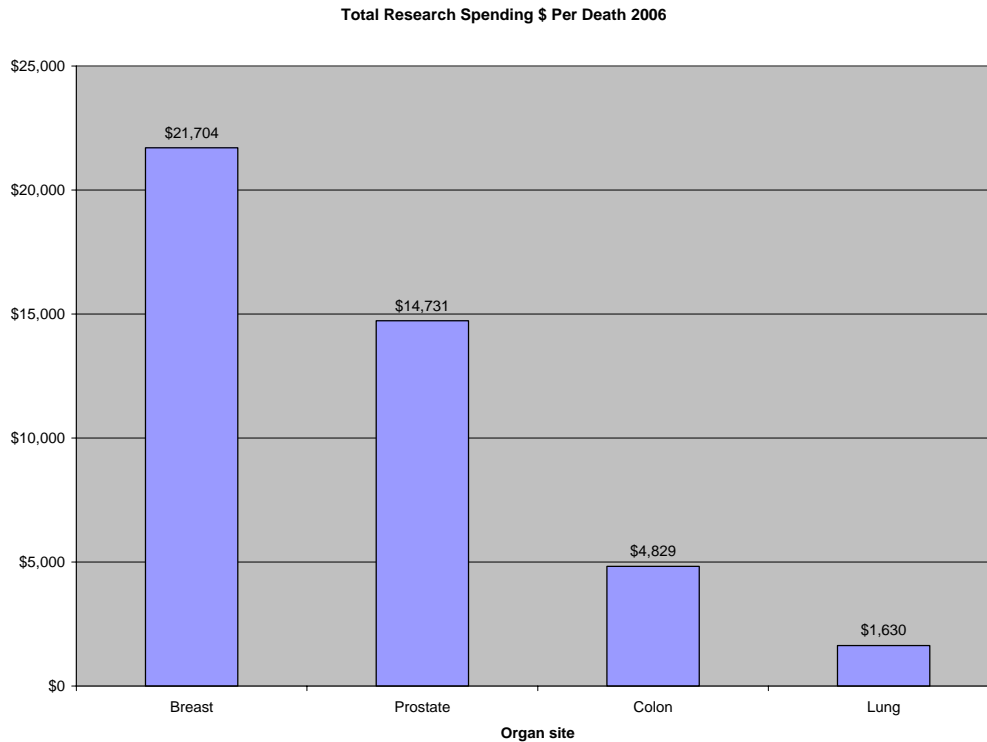
As the arguments and myths are peeled away, the underlying discrimination against the expenditure of public health resources, other than tobacco cessation funding, on lung cancer becomes more apparent. The question for public health policy makers is: will former smokers and veterans and workers at high risk for lung cancer be told about the ability of LDCT scans to diagnose lung cancer at an early treatable stage? This question cannot be legitimately or ethically answered in the negative.

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<sup>1</sup>The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to recommend for or against routine screening for prostate cancer using prostate specific antigen (PSA) testing or digital rectal examination (DRE). Rating: [I recommendation](#). (Source: U.S. Preventive Services Task Force, "Screening for Prostate Cancer," 2002, Available at <http://www.ahrq.gov/clinic/uspstf/uspsprca.htm>.)

<sup>2</sup> "The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality" and "The effectiveness of colonoscopy to prevent colorectal cancer or mortality has not been tested in a randomized clinical trial." (Source: U.S. Preventive Services Task Force, "Screening for Colorectal Cancer," 2002, Available at <http://www.ahrq.gov/clinic/uspstf/uspscoco.htm>.)

### III. Federal Cancer Research Funding and Impact on Mortality

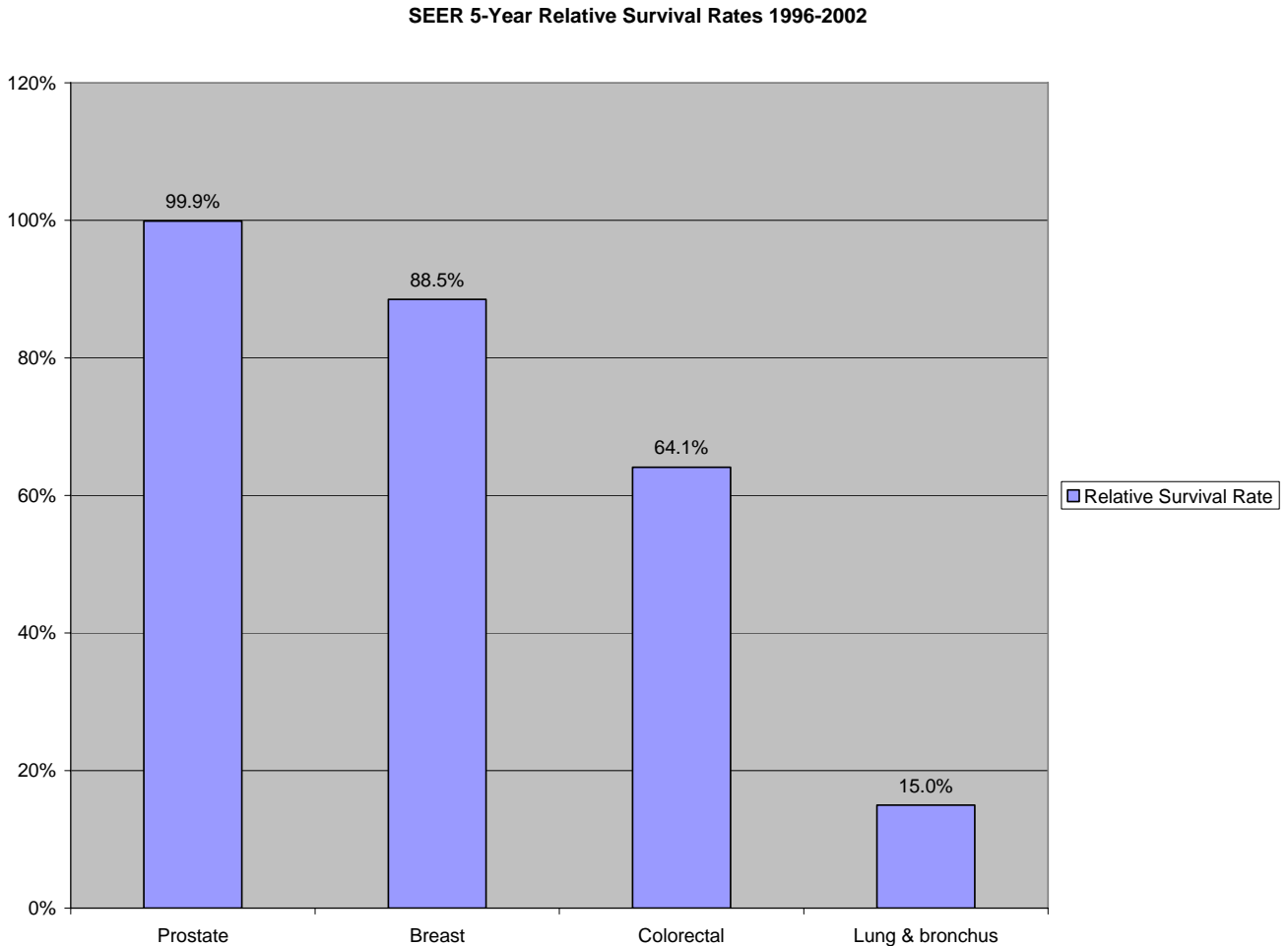


In 1971, Congress passed the National Cancer Act. Funding for the National Cancer Institute (NCI) has risen from \$400,000,000 a year then to \$4.8 billion in FY06. Research grants are awarded competitively but programs and funding allocations are determined internally. Historically, lung cancer has been funded at less than a third to a tenth of the funding levels for other major cancers.

This pattern is also evident at the CDC. Of the \$310 million appropriated in FY06 for Cancer Prevention and Control programs, \$204 million was earmarked for breast and cervical cancer, \$14 million for prostate cancer, \$14 million for colorectal cancer and nothing for lung cancer.

In 1992, Congress began funding research programs through the Department of Defense. Over \$2 billion has been allocated to breast cancer and \$750,000,000 to prostate cancer. Only \$35 million has been allocated to date for lung cancer, despite the fact that service men and women face greater exposure to lung cancer carcinogens (Agent Orange, asbestos, nuclear fuels, etc.) and have higher incidence and mortality rates for lung cancer than the civilian population.

The enormous disparity in FEDERAL funding is reflected in the 5-year survival rates:



Source: National Cancer Institute, SEER Cancer Statistics Review 1975-2003, Table I-A.

## IV. State CCC Plans and Lung Cancer

### A. Overview

In December, 2005 the CDC issued a report on State CCC plans entitled “A Content Review” as part of its continuing effort to “provide guidance and encouragement to states, territories, and tribes to establish broad-based coalitions, assess the burden of cancer, determine priorities for cancer prevention and control, and develop and implement CCC plans.”<sup>31</sup>

They ignore the fact that over 60% of those diagnosed with lung cancer today are former or never smokers. While State CCC plans address tobacco control and cessation programs, they omit critical areas. To address lung cancer in its entirety, CCC plans must include a comprehensive plan including research and support for early detection. None of the plans analyzed offered any comprehensive proposals to address lung cancer in its entirety. Moreover, while 30 of the 31 plans included tobacco cessation programs, none recognized the synergistic opportunity of linking

cessation programs to lung cancer early detection protocols that have been proven to yield voluntary quit rates three times the national average.<sup>32</sup> California is one of the only states to have set up its Tobacco-Related Disease Research Program (TRDRP). Even in that program, which is virtually unique among states, only 14 percent of a \$350 million investment in research over ten years' (since 1995) went to lung cancer research.<sup>33</sup>

## ***B. State CCC plans and stakeholders***

The Center for Disease Prevention and Control's (CDC) guidelines for CCC plans states:

“A comprehensive approach to cancer control is needed because gaps in service delivery and coverage exist. Thus the scope of comprehensive cancer control involves a diverse group of stakeholders who must coordinate their efforts to implement such a plan. For this reason, the partnership of stakeholders involved in developing the comprehensive plan should also be broad and inclusive. These coordinated efforts usually occur in the context of a formal collaboration across multiple disciplines and organizations.”<sup>34</sup>

Despite these urgings and the obvious need for broad based coalitions, no Lung Cancer Alliances advocates were appointed to any state committee until last month when New York became the first to do so. Given lung cancer's enormous impact on public health resources, the failure of public and private cancer organizations to address it appropriately, and the discrimination and stigma associated with the disease, lung cancer advocates must be included as stakeholders in every state CCC committee.

## ***C. State CCC plans and disparity***

The CDC report notes that all State CCC plans discuss disparity but states: “Few plans identify specific populations that are to be addressed by each objective; most of the objectives related to the reduction or elimination of disparities use general terms that are targeted to all priority, special, or minority populations.”

The disparity in lung cancer affecting African American men is profound, and cannot be attributed to differences in smoking prevalence. Yet, no state plan discusses this aspect of the disease that is long overdue for concerted efforts in research, earlier detection and follow-up targeting the disproportionate impact of lung cancer on African-American men.

## **V. State Funding Sources for CCC Plan Objectives**

### **A. Master Settlement Agreement (MSA) funds**

The agreement negotiated in 1998 between four tobacco companies and 46 states, the District of Columbia and the territories (Florida, Minnesota, Mississippi, and Texas had reached separate agreements) will distribute approximately \$250 billion over 25 years. Fourteen states, including some of the largest, sold bonds in order to realize as much of their share as possible in an up front lump sum. Consequently their future MSA revenues are in effect frozen to pay off the bonds. The remainder of the states can expect to receive an average of \$5 billion a year in MSA funding, according to the 2005 report issued by the Government Accountability Office.<sup>35</sup>

According to the GAO analysis, the FY04 MSA payments of \$11.4 billion to the states, were allocated by the state as follows:

- 44% for budget shortfalls
- 20% health programs
- 9% for debt services
- 7% education
- 7% infrastructure
- 3% for economic development for tobacco regions
- 2% tobacco control

The MSA placed no restrictions on how the state legislatures and governments could spend these funds. According to a report issued by Tobacco Free Kids, overall state expenditures from MSA funding on tobacco cessation programs in FY07 will be \$597.5 million, up 8.4% over FY 06 levels. Funds set aside for health programs were primarily earmarked for Medicaid, children's health initiatives and community care centers. The few states that included cancer programs usually earmarked funds for breast, prostate and colon cancer programs.

No state legislature specifically earmarked any MSA funding for lung cancer research, early detection or treatment.

However, the state CCC committees have an opportunity to correct this omission. As per the terms of the MSA, starting in FY 08 and continuing through FY 17, the states will receive bonus settlement payments totaling almost a billion dollars per year.

### **B. State excise taxes on tobacco products**

In addition to the MSA funding, in 2004 the states collected a total of \$12.6 billion in state and local tobacco tax revenues.<sup>36</sup> State excise taxes on a pack of cigarettes ranged from a low of \$0.07 in South Carolina to a high of \$2.58 in New Jersey.<sup>37</sup> (The federal excise tax of \$.39 per pack brought in \$7.4 billion revenue to the federal treasury in 2003.)<sup>38</sup> Since 2001, 42 states and the District of Columbia have increased tobacco taxes 75 times.<sup>39</sup>

While tobacco cessation advocates have successfully tied tobacco tax revenues to cessation programs that same public health logic is not carried over to lung cancer research and early detection programs. Consequently the states have ignored this opportunity to correlate tobacco tax money to, for example, screening and early detection programs for former smokers, which would reduce the number of costly late stage diagnoses and the burden on state health care systems and budgets.

## **VI. Future Funding Sources for State CCC Plan Objectives**

### ***A. Future MSA allocations process***

Beginning in 2008 and through 2017, annual MSA payments to state increase substantially, and will remain high after 2017.<sup>40</sup> The Campaign for Tobacco-Free Kids estimates the increase will represent at least \$900 million annually. This is an opportunity for state CCC committees and state legislatures to readjust their cancer plans and funding priorities. If one year's increase alone were devoted to lung cancer, that would equal the cost of developing a new drug<sup>41</sup>. 1/3 of the increase alone would double the amount of federal government spending per lung cancer death on lung cancer research.

### ***B. New state tobacco tax initiatives***

New state tobacco tax initiatives must include lung cancer research and early detection programs in addition to tobacco control and cessation programs and prioritize lung cancer as the leading cigarette-related cancer killer. Not all budgets are complete and now is the opportunity to insert set-asides for lung cancer research and early detection. LCA is asking State CCC Committees and state legislators to set aside no less than 1% of all tobacco tax and MSA revenue on lung cancer research and early detection.

### ***C. State research funding at state institutions***

Most states have excellent well-funded state university systems, including research centers. Some states fund research institutions via public-private partnerships. The funding mechanisms exist to target lung cancer research and early detection through state universities and state-funded research institutions. State CCC Committees should urge that states do this.

## **VII. Recommendations for State CCC Plan Committees**

### ***A. Include lung cancer advocates***

State CCC plan committees must include Lung Cancer Alliance advocates. LCA advocates include lung cancer patients, survivors, caregivers, many of whom have public health, policy, and/or medical backgrounds.

State CCC plan committees must include at least two LCA advocates, at least one of which would sit on the steering and/or policy committee.

## ***B. More targeted tobacco control programs with links to early detection program***

Due to the large contribution of smoking to lung cancer morbidity and mortality, all levels of prevention are enhanced by effective well thought out public health education programs on tobacco use prevention and cessation, especially those targeted at young people. Other methods include public and private payer reimbursement for tobacco cessation programs and regulation policies such as workplace smoke free laws, counter-marketing and disincentives such as tobacco taxes.

Currently many payers do not cover tobacco cessation even though medical interventions have been shown to increase cessation success by 200 percent<sup>42</sup>. According to one source, “third-party reimbursement for smoking cessation intervention services is low, despite the dramatic health benefits of smoking cessation. Smoking cessation rates would improve significantly with full coverage of existing tobacco cessation treatments<sup>43</sup>. Research suggests that insurance coverage for smoking cessation treatment has a positive effect on reducing smoking rates in insured populations<sup>44</sup>. According to CDC, in 2005 thirty-eight states provided some coverage for all Medicaid beneficiaries, four states for only pregnant women, seven covered all recommended medications, and a form of counseling, and only one state covered all federal government-recommended treatments, all lower than Healthy People 2010 objectives<sup>45</sup>. CT scanning of those at high-risk is a documented intervention point for smoking cessation and increases adherence.<sup>46</sup>

The only clinically utilizable method for the early detection of lung cancer is low-dose CT scanning. According to a recent New England Journal of Medicine publication, it is appropriate to offer low-dose CT scans to those over 40 at high risk for lung cancer due to health histories<sup>47</sup>. This publication of the largest long-term study ever conducted in the early detection of lung cancer found 85 percent of lung cancers at Stage I and demonstrated that if lung cancer is detected and treated early, the estimated ten-year survival would be 92 percent. This a profound contrast to lung cancer’s 15% five-year survival rate in the unscreened population.

CT scanning represents an intervention opportunity for smoking cessation promotion. There is evidence that scanning increases cessation attempts and adherence. “...low-dose helical CT scanning may serve as a strong catalyst for smoking cessation and that delivery of effective smoking cessation interventions along with CT scanning represents a potential opportunity to increase the overall cancer prevention benefit of lung cancer screening.”<sup>48</sup> Another study found that “multiple low-dose, fast spiral chest CT scan screenings for lung carcinoma may represent teachable moments and opportunities to enhance motivation for smoking abstinence.”<sup>49</sup>

### **C. Statewide quality standards for LDCT scanning for lung cancer**

LCA has been urging Congress and the federal government to set quality standards for LDCT scanning based on the protocols developed by the International Early Lung Cancer Action Program. The State CCC planners have the opportunity to take the lead in setting these standards statewide. A proposal is attached in Appendix 1.

### **D. Chemoprevention**

State-funded research could increase knowledge about early detection of pre-cancerous cellular changes, such as those that occur in the cervix and can be detected by Pap smears. Currently, no chemopreventive medications are available for those at high risk of lung cancer, unlike the availability of tamoxifen and raloxifene for breast cancer<sup>50</sup>. Due to the enormous cohort of those at risk (46 million former smokers), developing chemoprevention is an urgent priority for primary prevention, and state-funded research efforts could contribute to advances in this area.

### **E. Access to treatment of lung cancer at all stages**

There are significant problems with access to care for lung cancer. The uninsured and under-insured face forbidding treatment barriers, which seriously affect their survival. One study found that the three-year relative survival proportions were 23 percent for privately insured patients and 13 percent for uninsured patients with lung cancer<sup>51</sup>. Mulligan and colleagues found that racial disparities in lung cancer outcomes disappear when treatment is universal, such as in the Military Health Care System<sup>52</sup>.

Access to specialty care is vital and people can benefit from treatment at all stages of lung cancer. Many with diagnoses of advanced lung cancer, including those with coverage, do not get referred to oncologists<sup>53</sup>. In addition, “chemotherapy prolongs survival in community settings, but is underutilized for persons with advanced NSCLC\*.”<sup>54</sup> [\* NSCLC = non-small cell lung cancer, the most common type.]

### **F. Increasing clinical trial enrollment**

Clinical trial enrollment can increase access to treatment and can increase survival. “Enrollment in lung cancer clinical trials was found to be associated with improved survival at a moderate incremental cost.”<sup>55</sup> Yet less than 10 percent of lung cancer patients participate in clinical trials<sup>56</sup>. The largest barrier is accurate, objective information about the costs and benefits and refuting myths about cancer clinical trials. Public health education could make a large difference in enrollment.

### **G. Pain control and palliative care**

All patients should receive the standard of care pain management if they have pain symptoms<sup>57</sup>. States can work to increase access to palliative care specialty care for people encountering barriers to that type of care. Connecticut’s 2006 plan, for example, intends to “advocate for the adoption of supportive pain statement by....licensing boards.”<sup>58</sup>

## **H. Psychosocial care**

Lung cancer patients experience higher level of psychosocial distress than other cancer patients, e.g. 43 percent of lung cancer patients versus 30 percent of gynecological cancer patients. Meeting the mental health needs of lung cancer patients and their families is of critical importance<sup>59</sup>.

## **I. Recovery - Oxygen**

Many people with lung cancer use oxygen to increase comfort. Oxygen is covered by Medicare<sup>60</sup>. Oxygen is covered under some state's Medicaid, e.g. Idaho, Montana, and Iowa, but clearly wider coverage is necessary<sup>61</sup>.

## **J. End-of-life care and bereavement**

Lung cancer families and their patients deserve evaluation, cultural competency and honest communication in end-of-life care and bereavement. Patients and families need referral to appropriate services for both end of life and bereavement<sup>62</sup>.

Connecticut's Cancer Plan has a goal, for example, of ensuring "a high quality palliative and hospice care services and (sic) and available and accessible to all Connecticut residents."<sup>63</sup>

## **VIII. Conclusion**

Lung Cancer is the nation's biggest cancer killer of both men and women. While survival of the second, third, and fourth major cancer killers has steadily increased over the last 36 years, that of lung cancer has not. 2007 marks a tremendously profound opportunity to impact lung cancer and it is incumbent on State CCC Plan Committees to take corrective measure immediately.

Beginning with the inclusion of Lung Cancer Alliance-affiliated patients and caregivers on State CCC Committees and continuing with other recommendations outlined in this document, State CCC Plans can significantly impact the morbidity and mortality from lung cancer.

## **IX. Lung Cancer Computed Tomography Quality Standards Act of 2007**

**Purpose:** to establish standards and quality controls for CT scans for lung cancer similar to those Congress enacted in The Mammography Quality Standards (MQSA) of 1992 in order to insure uniform high quality through comprehensive regulation, the pooling of data on the scans and outcomes to expedite the development of increasingly accurate and cost effective scans and the establishment of Centers as repositories and research centers for analyzing the data.

**Lung Cancer and Early Detection:** As with most cancers, treating early stage lung cancer costs less than half that of late stage. Yet only 16% of lung cancer is being diagnosed at Stage I when the cancer can be successfully treated. Studies published in the New England Journal of Medicine in October, 2006, demonstrate that screening of high risk populations with low dose Computed Tomography (CT) scanners can successfully diagnose lung cancer at Stage I in 85% of cases and that those who are treated immediately have a 10 year life expectancy of 92%. The announcement of this profound improvement in outcomes, following the highly publicized deaths within months of diagnosis of celebrities who were not screened for lung cancer, has made the public aware of the importance of early detection and the superior efficacy of CT scans over chest x-rays.

While CT scans explicitly for lung cancer screening in asymptomatic people are not currently covered by public or (most) private insurers, scans ordered by a doctor as a diagnostic tool and follow-up scans after diagnosis are covered. Since the cost of a scan has dropped below \$200 retail, if their physician will not write a prescription for a scan, many are opting to pay out of pocket to be screened, particularly former smokers who constitute a large percentage of the boomers.

**Double Standard:** Some in the public health establishment insist that lung cancer screening should not be “allowed” until more randomized controlled trials (RCT’s) have been completed. This insistence on sequential rather than concurrent additional trials is inexplicable, especially given the deadliness of lung cancer and how effective early detection can be. (The limited number of drugs available for late stage lung cancer can only prolong survival by a few months on average.) No other cancer screening protocol was held back for sequential trials before being utilized. Indeed, RTC’s have still not been completed on PSA testing for prostate cancer, the Pap test or colonoscopies. RCT’s on mammographies generated contentious debate for years and as recently as 1997, five years after passage of the MQSA, a National Cancer Institute consensus group opposed mammograms for women under 50 until Congress intervened. The public is viewing this double standard as part of the general prejudice against lung cancer patients. The public is equally skeptical of warnings of overdiagnosis, false positives and radiation exposure, having seen those same arguments used unsuccessfully by opponents to try to delay implementation of breast cancer screening.

**Conclusion:** Given all the variables, an adequate assessment of risk versus benefit on screening for a disease as deadly as lung cancer can only be made on an individual basis through an informed discussion between the patient and his doctor. No one can prohibit people from being screened by CT scans for lung cancer. Millions of patients have already opted to do so. In addition, CT scans have become the preferred method for

diagnosis, staging, treatment, drug development and even concurrent heart disease screening. It is incumbent on Congress to protect the public from potential harm and set quality standards for CT scans for lung cancer as effective as those enacted for mammographies.

### **Mammography Quality Standards Act (MQSA):**

In the 1980's mammography screening for breast cancer became increasingly widespread despite the continuing opposition of many within the public health establishment. Voluntary standards and certification set up by the American College of Radiology (ACR) failed to attract many participants and Congress took action and passed the MQSA in 1993.

The Act sought to insure uniform quality of care by setting standards and a certification process for personnel, equipment and protocols. The FDA was empowered to implement and regulate its provisions. The effectiveness of any screening by imaging depends on the quality of the interpretation and quality is notoriously difficult to legislate. In preparation for reauthorization of the Act in 2007, Congress commissioned a study from the Institute of Medicine (IOM) to determine what additional steps might be taken to enhance quality assurance. That report, "Improving Breast Imaging Quality Standards, 2005" can be accessed at <http://www.iom.edu/Default.aspx?id=27028>.

The MQSA and the IOM recommendations serve as the template for the CT quality standards legislation proposed below. An important aspect of the proposed legislation is the establishment of Imaging Centers of Excellence for the collection and analyses of data from the scans and follow-up data on outcomes. This data will lead to improved accuracy and will expedite the development of Computer Assisted Diagnostic (CAD) tools. CAD tools can drive the price of scans down to that of a blood test and make lung cancer screening available to the entire population. By monitoring outcomes, the quality of the diagnoses made at each institution can be tracked, evaluated and addressed as required. Making this information public would be the most effective quality control measure.

### **Lung Cancer CT Standards legislation:**

The legislation would provide for:

A. standards, certification and accreditation of:

1. facilities (hospital, outpatient department, clinic, radiology practice, mobile unit, physicians' office, a facility of the Department of Veterans Affairs or other facilities as determined by the Commission that conducts computed technology scanning;
2. Personnel involved in the administering of the scan
3. The multi-disciplinary team of medical specialists involved in the interpretation
4. The protocol for interpretation of the scan, diagnosis and confirmation

In general, the quality standards and protocols would be based on those developed over the past 14 years by the International Early Lung Cancer Action Program which cover the qualifications of personnel, equipment standards, diagnostic methods and follow-up procedures. Fees would be set to cover the cost of enforcement and periodic inspections.

B. the establishment of a Lung Cancer CT Quality Assurance Advisory Commission, appointed from the community of physicians, imaging specialists, industry representatives and advocacy organizations, to advise the FDA on appropriate standards and technological advances that may require modification of regulations, and to review analyses of the data collected under this act and make recommendations for appropriate action and to ensure an adequate workforce for scanning and diagnosis.

C. the establishment of Lung Cancer Imaging Centers of Excellence, which shall include the I-ELCAP center at Cornell Weill in New York City and up to four other Centers, designated, and compensated (through HHS) by the Commission to serve as repositories for the data to be collected, processing centers for the data and the issuance of periodic updates on the data collected as well as recommendations for improvements to the imaging protocols and any other additional actions that the data may suggest to enhance the efficacy and accuracy of ct scanning.

D. Require all certified facilities to make print and electronic copies of scans immediately available to its patients and to seek patient permission to share blinded (privacy protected) copies of their scans with the Centers of Excellence.

E. Require all certified facilities to compile and maintain follow-up records on outcomes, which data shall be shared with the Centers of Excellence.

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