HOUSE COMMITTEE ON ENERGY AND COMMERCE - HEALTH AND ENVIRONMENT SUBCOMMITTEE

STATEMENT OF HON. **THOMAS J. BLILEY, JR.**
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Mr. Chairman - I am testifying today in order to report to the Subcommittee the results of my extensive investigation of the EPA's handling of the controversy surrounding environmental tobacco smoke or "ETS". As you know, in the past the Oversight and Investigations Subcommittee of this Committee has conducted hearings on EPA's abuses of government contracting requirements. So pervasive is the level of abuse that Chairman Dingell has characterized EPA's pattern of contract mismanagement as a "cesspool". EPA's Inspector General recently has confirmed that such abuses also have taken place in connection with a number of EPA contracts involving ETS, and the O and I Subcommittee's own investigation is continuing.

In addition to various contractual improprieties, however, my own investigation suggests that in its consideration of ETS, the Agency has deliberately abused and manipulated the scientific data in order to reach a predetermined, politically motivated result. EPA's risk assessment on ETS released in January of this year claims that ETS exposure is responsible for approximately 3,000 lung cancer cases per year in the United States. Analysis of the risk assessment reveals, however, that EPA was able to reach that conclusion only by ignoring or discounting major studies, and by deviating from generally accepted scientific standards.

EPA's willingness to distort the science in order to justify its classification of ETS as a "Group A" or "known human" carcinogen seems to stem from the Agency's determination early on to advocate smoking bans and restrictions as a socially desirable goal. EPA began promoting such policies in the mid-to late 1980s, ostensibly as part of its efforts to provide information to the public on indoor air quality issues. The Agency then decided to develop the ETS risk assessment to provide a scientific justification for smoking bans. The risk assessment thus was never intended to be a neutral review and analysis of the ETS science. Rather, it was intended from the start to function as a prop for the Agency's predetermined policy.

Not surprisingly, therefore, the process at every turn has been characterized by both scientific and procedural irregularities. In addition to the contracting violations mentioned at the outset, those irregularities include conflicts of interest by both Agency staff involved in preparation of the risk assessment and the members of the Science Advisory Board panel selected to provide a supposedly independent evaluation of the document. I will not itemize each and every one of these improprieties. Instead, I ask consent that a memorandum providing full details of the history of EPA's handling of ETS be included in the record. The memorandum summarizes the results thus far of my investigation into the Agency's handling of ETS and is based on publicly available documents, extensive correspondence between myself and former Administrator Reilly, and interviews conducted by my staff with the responsible EPA officials.

The ETS risk assessment is far from an isolated example of EPA's approach to the use of science in policy making. The Agency's propensity to scare the public first and ask scientific questions later is both notorious and well-documented. Alar, dioxin and the removal of asbestos from schools are other examples. In fact, concern that EPA's pursuit of media headlines rather than good science was undermining the Agency's credibility caused former Administrator Reilly to convene an expert panel in early 1991 to

assess EPA's use of science. The expert panel issued a report in March 1992 entitled "Safeguarding the Future: Credible Science, Credible Decisions." The report states that "[c]urrently, EPA science is of uneven quality and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation." The expert panel also cautioned EPA, in terms that are directly relevant to the Agency's work on ETS, that "science should never by adjusted to fit policy, either consciously or unconsciously." Unfortunately, in the case of ETS there appears to have been a conscious misuse of science and the scientific process to achieve a political agenda that could not otherwise be justified.

EPA betrays its own lack of confidence in its tortured statistics by refusing to incorporate the results of the ETS-lung cancer study by Brownson and coworkers. The Brownson study, one of the largest and best designed studies ever conducted, was funded in part by the National Cancer Institute. The study looked at exposure to ETS in a variety of settings, at home, at work and in social environments. The study reported no significant association between ETS and lung cancer among nonsmokers in spousal or work settings or from childhood. Even using the highly questionable statistical methods adopted by EPA in the ETS risk assessment, inclusion of the Brownson study would show no significant risk of lung cancer from exposure to ETS.

Evidently, publication of the Brownson study caused no small degree of consternation at EPA. In order to avoid incorporation of the Brownson study's results into the risk assessment and invalidating EPA's claim that the epidemiology shows a significant risk, EPA rushed to issue the final report in early January. Mr. Chairman, given this sort of behavior, in my judgment we must be very cautious about allowing scientific pronouncements from EPA to drive public policy decisions.

EPA AND ENVIRONMENTAL TOBACCO SMOKE: SCIENCE OR POLITICS?

I. INTRODUCTION

With almost unprecedented fanfare, the Environmental Protection Agency ("EPA") released at a news conference on January 7, 1993, a risk assessment on tobacco smoke in the air -- often referred to as environmental tobacco smoke ("ETS"). According to the EPA risk assessment, ETS is a "Group A" or "known human" carcinogen that is responsible each year for approximately 3,000 cases of lung cancer among nonsmokers residing in the United States. The risk assessment also claims that ETS is a cause of respiratory problems in infants living in homes in which one or both parents or some other family member smokes.

Not surprisingly, the claims contained in EPA's risk assessment on ETS generated substantial publicity, with most major newspapers, television news program and radio stations devoting substantial attention to EPA's conclusions. The publicity was, in part, a natural and expected response to the rather dramatic claims made in the EPA report. But EPA officials and staff, joined by Secretary Sullivan of the Department of Health snd Human Services ("HHS"), also left no stone unturned to ensure heavy media coverage of the report. The EPA/HHS campaign was seeded by periodic "leaks" of drafts of the report, and those leaks were followed with a heavily promoted press conference and individual interviews.

The EPA/HHS representatives made clear at their January press conference that they hoped that the EPA report would lead to additional

smoking restrictions by private entities as well as by government at all levels. If the conclusions of the report are valid, that hope is certainly understandable. At the same time, however, if the claims made in the report are invalid, as appears to be the case, the likely consequence will be additional unjustified harassment of and discrimination against smokers -- a consequence that received little attention at the January press conference.

The assumption that often is made is that smoking restrictions and other comparable measures are essentially costless. Increasingly, that assumption has been shown to be incorrect. Whether measured in terms of the number of people who are fired or are not hired because they smoke, by unjustified feelings of guilt among smokers or by the erosion of courtesy and tolerance, the campaign against smoking is not the no-lose proposition it often is portrayed as being.

In Washington, D.C., for example, which has adopted workplace smoking restrictions, the consequences of the ETS controversy are unmistakable. At all hours of the working day, people can be seen, even in the middle of winter, huddled near the doorways of office buildings smoking cigarettes. In fact, some employers -- in Washington, D.C., and elsewhere -- have gone so far as to require current and prospective employees to submit to a urine test, looking for the telltale sign of nicotine.

Over the past several years there has been increasing concern about the politicization of science and other problems at EPA. A two-year investigation by the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee has uncovered disturbing evidence encompassing everything from cronyism in the award of government contracts to systematic bias in the collection, review and presentation of scientific data. Instead of evaluating scientific issues objectively and providing balanced information to the public, EPA has been found on a number of occasions to have manipulated or suppressed data in a manner that has resulted in unnecessary alarm and confusion.

Mounting concern about EPA's misuse of science prompted former EPA Administrator William Reilly to convene an expert panel in 1991 to review EPA's handling of scientific issues and to recommend improvements. The expert panel, which was comprised of eminent scientists from leading institutions across the country, issued a report in March 1992 entitled "Safeguarding the Future: Credible Science, Credible Decisions." The report confirmed that, "[c]urrently, EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation" (p. 4).

The expert panel also cautioned EPA that "science should never be adjusted to fit policy, either consciously or unconsciously" (p. 38). Unfortunately, that is precisely what appears to have happened in the case of the risk assessment on ETS -- the abuse of science and the scientific process to further a political agenda. However one views cigarettes and smoking, EPA's misuse of science and disregard for proper legal and scientific procedures should be cause for alarm. In fact, EPA's handling of ETS sets a disturbing precedent for the Agency's consideration of future controversial scientific questions, raising questions about EPA's ability to separate science from politics in carrying out its mission.

As the editor of "EPA Watch" recently observed in response to EPA's release of the ETS report:

> It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week, with the effect that once again, Americans are going to be

> stampeded into fearing a substance for reasons which upon close inspection are scientifically indefensible.(1)

The discussion that follows describes EPA's activities with respect to ETS -- the procedures the Agency has utilized and the problems that have infected the process from the beginning.

II. THE HISTORY OF EPA'S INVOLVEMENT IN THE ETS CONTROVERSY

A. Putting EPA's Role Into Context

In order to understand EPA's role in the ETS controversy, one must understand how the "passive smoking" issue emerged in the first place. According to Richard Daynard, a well-known antismoking activist, the organized movement to eradicate smoking has proceeded in three distinct phases.(2) During the first phase, activists attempted to persuade smokers to stop smoking on the ground that smoking was bad for the smoker. Although many smokers did stop smoking for that reason, others continued. During the second phase, activists attempted to make smokers feel guilty about their enjoyment of smoking. Again, however, many individuals continued to smoke. The third and current phase, according to Daynard, marked a more fundamental strategic shift. In this phase, the movement began to focus on the "development" of "evidence" about ETS. If people can be persuaded to believe that tobacco smoke is harmful to nonsmokers, it becomes easier to persuade both private entities and government authorities to restrict or ban smoking. According to Stanton Glantz, founder of Californians for Nonsmokers' Rights (later christened Americans for Nonsmokers' Rights), the target of such laws is the smoker rather than the nonsmoker. "Although the nonsmokers' rights movement concentrates on protecting the nonsmoker rather than on urging the smoker to quit for his or her own benefit, [antismoking legislation] reduces smoking because it undercuts the social support network for smoking by implicitly defining smoking as an antisocial act."(3)

Neutral and dispassionate scientific inquiry often yields inconvenient results from the perspective of the social activist. So it has been for EPA with Alar, PCBs and dioxin, to cite only a few examples. ETS must now be added to the list.

The scientific data simply do not support EPA's classification of ETS as a "Group A" carcinogen. Of the more than 30 epidemiologic studies of marriage to a smoker and lung cancer among nonsmokers, the overwhelming majority report no statistically significant association. The studies focusing on ETS exposure in the workplace also generally have not reported a statistically significant increased risk. The most recent and largest U.S. case control study, by Brownson and coworkers, confirms the general no-association pattern.(4) Although the Brownson study was published in November 1992, two months before EPA completed its report on ETS, the EPA report failed even to cite the Brownson study. The reason, undoubtedly, is that EPA's conclusions on lung cancer could not survive inclusion of the Brownson data.

Even without the Brownson data, the classification of ETS as a Group A carcinogen required substantial stretching by EPA. To reach that conclusion, the EPA report combined eleven spousal smoking studies from the United States in a so-called "meta-analysis." Of the eleven studies, however, ten reported no statistically significant increase in cancer among nonsmokers purportedly exposed to ETS. To ensure that the meta-analysis would produce the desired results, therefore, EPA had no choice but to manipulate the numbers.

Although in the past EPA and the scientific community have used a 95% confidence interval as a means of ensuring that study results did not occur by chance, EPA adjusted the confidence interval downward -- to 90% -- in its report on ETS. As James Enstrom, an epidemiology professor at the University of California, Los Angeles, explained, "[t]hat doubles the chance of being wrong."(5) To put it in lay terms, EPA's statistical maneuvering is the equivalent of moving the goal lines at a football game in order to score more touchdowns. The implications of EPA's willingness to lower scientific standards in selected cases are profoundly troubling. As Michael Gough of Congress's Office of Technology Assessment has pointed out, "[y]ou cannot run science with the government changing the rules all the time."(6)

The only claim made in the EPA report for which there is at least statistical support is that ETS can affect the respiratory health of very young children. Most of the studies on that issue are so flawed, however, that it is premature to conclude that the association is causal in nature. In the final analysis, it must be remembered that epidemiologic studies can show only a statistical association. They cannot prove causality. After all, there is a strong association between increased life expectancy and increased consumption ofjunk food in affluent countries but no one contends that one is the cause of the other. In fact, many argue the converse.(7)

In light of the weaknesses in the pertinent data, the procedures that have been utilized in "developing the case against ETS" take on a special significance. As one of the world's leading epidemiologists, Dr. Alvan Feinstein of Yale University Medical School, put it in a recent article:

> In the investigations of [ETS], * * * the various studies are contradictory, some going in positive directions and others not. The inconvenient failure of the evidence to comply with a prime requisite of scientific reasoning for causality, however, has not inhibited the causal accusations. The "prosecution" has simply ignored the inconvenient results and emphasized those that are (in a memorable term) "helpful."(8)

A report produced by the Advocacy Institute, a major antismoking organization, entitled "Media Strategies for Smoking Control: Guidelines" (NIH 1989), provides a striking illustration of this strategy. Behind every story detailing the "risks" of ETS, the report stated, could be found "[a] scientist wise in the way of 'creative epidemiology,' i.e., the presentation of data -- both scientifically sound and artful -- so as to catch the glint of media attention * * *" (NIH Report at 7). The report describes "creative epidemiology" as follows:

> Michael Daube, who coined the term, defines creative epidemiology as "the ability of the good epidemiologist to rework data so that what is essentially the same information can be presented in a new and interesting form." Thus creative epidemiology marries the science of the researcher with the art and creativity of the media advocate (id. at 21-22).

Similarly, Jonathan Samet of the University of New Mexico

recently acknowledged that there is much that we do not know and indeed may never know about whether ETS poses a health risk. Notwithstanding those evidentiary deficiencies, however, Dr. Samet made clear that "[i]n the case of environmental tobacco smoke, it would be unfortunate if potentially irresolvable scientific uncertainties thwarted control."(9)

As a result of this strategy, there is enormous pressure on researchers and scientific bodies investigating ETS to come up with the "right" conclusion. The Brownson study, for example, apparently caused considerable dismay because it produced the "wrong" results. Defending his decision to publish the study, Dr. Brownson lamented, "I wish our findings had gone in the exact pattern the public health community would like * * *. But one of the criticisms of medical research is that the only thing findings ever show is some kind of health risk. I feel it's important to publish findings, no matter what they show."(10) Dr. Brownson's eagerness to please the public health community is widely shared. His willingness to release data not in accord with the political objectives of that community unfortunately is not.

Again, Dr. Feinstein of Yale has offered a revealing insight. According to Dr. Feinstein:

> [I]n the current fervor of anti-smoking evangelism, what young scientists would want to risk their career and what older scientists would want to risk their reputation by doing anything that might be construed as support for the "bad guys" of the tobacco industry? What governmental agency would fund research in which the established "accepted" anti-smoking doctrines were threatened by a study proposed by someone -- an obviously deranged skeptic -- who wanted to do an unbiased, objective investigation? (p. 304).

In the same article, Dr. Feinstein revealed that he "recently [had] heard an authoritative leader in the world of public health epidemiology make the following statement: "Yes, it's rotten science, but it's in a worthy cause. It will help us get rid of cigarettes and become a smoke-free society" (p. 303).

Because the debate over ETS has been caught up in the larger, highly emotional controversy about active smoking, the role of EPA in collecting, evaluating and disseminating scientific information about ETS becomes even more important. The Superfund Amendments and Reauthorization Act of 1986 ("SARA") gave EPA the role of "providing information and guidance" to the public on indoor air and radon. 42 U.S.C. Sec. 7401 note. SARA required EPA's research agenda to be reviewed by the Agency's independent Science Advisory Board ("SAB"). The SAB consists of scientists from outside EPA whose role is to assess the factual and theoretical bases for EPA's research and reports. The SAB is supposed to operate as a check on the Agency's use of science in the formulation of regulatory policy -- to ensure that objective scientific inquiry is not subverted to serve political rather than scientific ends. Unfortunately, the SAB has not operated as intended in the case of ETS. As a result, there has been little or no brake on the antismoking proclivities of individual EPA staff members.

B. Early EPA Staff Initiatives Concerning ETS

EPA's policy of promoting restrictions on smoking seems to

have begun with James L. Repace, an "environmental protection specialist" in EPA's Indoor Air Division. In 1980, even before the first major ETS health claims appeared in the scientific literature, Repace wrote with A.H. Lowrey an article reporting on particulate matter in the air of various environments such as bars, restaurants and bingo parlors, without distinguishing whether those particulates were from ETS or some other substance or activity.(11) The only "office" measurements made by Repace were in an experimental, enclosed room in which thirty-two cigarettes were smoked in less than one hour, generating ETS levels grossly in excess of those encountered in the real world. Subsequent research has discredited both the methodology and concluslons of the 1980 Repace study.(12) On the basis of these observations, however, the article claimed that "indoor air pollution from tobacco smoke presents a serious risk to the health of nonsmokers * * * [that] deserves as much attention as outdoor air pollution."(13)

A few years later, Repace published (again with A.H. Lowrey) an article purporting to show that ETS was riskier than "all regulated industrial emissions combined."(14) This second article by Repace and Lowrey, which represented a crude attempt at quantitative risk assessment, has been roundly criticized by both government and private sector scientists.(15)

Repace's extensive work with political advocacy organizations such as the Group Against Smoke Pollution ("GASP") and Action on Smoking and Health ("ASH") and his private and professional focus on smoking raise questions about Mr. Repace's ability to evaluate indoor air issues in a balanced manner. Since the 1970s, Mr. Repace also has been appearing as a paid witness in numerous lawsuits and testifying before various legislative bodies to support governmental restrictions on smoking. Consider in this regard Mr. Repace's statements to the press in reaction to the defeat of an antismoking legislative proposal in Maryland:

> People aren't going to stand for this. Now that the facts are clear, you're going to start seeing nonsmokers becoming a lot more violent. You're going to see fights breaking out all over. Washington Star, April 5, 1980, p. D-l.

Based on my own experiences with Mr. Repace, I do not find these accounts surprising. In 1991, at the invitation of EPA Administrator Reilly, my staff interviewed several EPA employees as part of my and the Oversight Committee's efforts to gather the facts about EPA's procedures in preparing ETS-related documents. When he presented himself in my office, however, Mr. Repace categorically refused to answer any questions. He was accompanied by John Banzhaf, ASH's Executive Director, and Mr. Nantkes of the EPA General Counsel's office. Both were said to be serving as Mr. Repace's attorneys. Within minutes after Mr. Repace left my office, my staff received inquiries from the media characterizing my efforts as "intimidation."

During the late 1980s, Mr. Repace became the driving force behind EPA's push to classify ETS as a "Group A" carcinogen. He began by outlining plans for two reports designed to promote the elimination of ETS. Although his plans personally to draft a "handbook" on the subject were not realized, Repace assumed primary responsibility for two longterm projects -- an "ETS literature compendium" and an "ETS workplace smoking policy guide," as well as a smaller project, an "ETS fact sheet." These projects were meant to further the agenda first announced in Repace's 1980 article.

Even as Mr. Repace expanded his activities within the Indoor Air Division, he was traveling around the world, at the invitation and expense of smoking organizations, to appear at various conferences and media

events to promote antismoking restrictions. For example, Mr. Repace traveled to New Zealand in 1990 to support antismoking legislation in that country. Press coverage of his activities there was typical of Mr. Repace's media appearances, including the identification of Mr. Repace as an EPA employee unaccompanied by the required disclaimer that his views did not then reflect an official EPA position.

In numerous media interviews, Mr. Repace has made the baseless assertion that 50,000 people in the U.S. die each year from exposure to ETS and has left the clear impression that these views reflect EPA's official position rather than his personal views. Such demonstrated bias would create a serious conflict of interest issue at any regulatory agency, apparently with the exception of EPA, most likely leading to the official's recusal from further involvement in the issue in question. In fact, Mr. Repace continued to play a key role in the preparation of documents for the public that were represented as neutral and dispassionate analyses of the facts pertaining to ETS despite the advocacy role he was playing in his "private capacity."

C. How EPA Used Its Role In Indoor Air Research To Further An Antismoking Agenda

1. The ETS "Fact Sheet"

In 1989, Repace prompted the Agency's publication of a "Fact Sheet" on ETS. Despite its name, "Indoor Air Facts Number 5" made extravagant health claims about ETS, going far beyond the conclusions of the 1986 reports of the National Academy of Science ("NAS") and Surgeon General on the same subject. For example, it claimed that exposure to ETS was linked to heart disease, when both the NAS and Surgeon General had found that the available studies did not support that claim.

The "Fact Sheet" also took certain statements in the 1986 Surgeon General's report out of context in order to claim a consensus that "passive smoking significantly increases the risk of lung cancer in adults" (p. 1). Whereas the Surgeon General and NAS reports had emphasized critical limitations on their findings of a possible connection between exposure to ETS and lung cancer, the "Fact Sheet" ignored those limitations and treated the purported relationship as irrefutable.

The "Fact Sheet" also failed to note that even the limited conclusions of the Surgeon General and NAS reports had been strongly criticized and that other reviewers -- including the World Health Organization's International Agency for Research on Cancer -- had reached different conclusions based upon the same data. See, e.g., "IARC Monograph on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking," vol. 38, p. 308 (1986). Furthermore, a number of other studies and reviews published since 1986 contradicted the findings of the Surgeon General and NAS reports with respect to the purported relationship between ETS and lung cancer.(16) None of these was mentioned in the "Fact Sheet."

Finally, the "Fact Sheet" characterized ETS as "a major contributor of particulate indoor air pollution" (p. 2) while failing to mention the numerous studies showing that inadequate ventilation is the single most important cause of indoor air pollution. Significantly, no SAB panel or expert committee ever reviewed the "Fact Sheet's" claims. Instead, the document was distributed freely to the public as if it contained the official, carefully considered policy of the U.S. government rather than simply the personal opinions of Mr. Repace.

2. What EPA Doesn't Know

Paradoxically, EPA elsewhere was quite candid in acknowledging the gaps in its knowledge about ETS. EPA's 1987 report to Congress, for example, recognized that indoor air quality is not only a matter of specific pollution sources but also of the ways in which buildings are designed, operated and used. EPA's indoor air quality program purportedly was designed to "address the problem from both perspectives" (P. 8).

In its 1989 report to Congress, EPA indicated that it had "moved to establish a research program to remove the scientific uncertainties" identified in the 1986 NAS report on ETS (vol. I, p. 42). In the same report EPA acknowledged that "[a]ctual human exposure to many of these [indoor air] pollutants is at this time not well understood" (vol. III, p. 11). The 1989 report also emphasized the need for ventilation research, noting that the "entire building system is implicated in issues of indoor air quality" (vol. III, p. 39) and that much more research is needed concerning the numerous variables that determine indoor air quality (id. at 36-39).

At this point, I, among others, expressed concern that there appeared to be a contradiction between EPA's conclusions on ETS in the "Fact Sheet" and the Agency's recognition elsewhere that there were large gaps in its knowledge about ETS. In response, EPA's Assistant Administrator for Air and Radiation, William Rosenberg, denied that there was any scientific doubt. In a June 1989 letter to Senator Warner of Virginia, Mr. Rosenberg stated that "[t]he evidence, in our view, is conclusive for lung cancer and for respiratory symptoms in children" and that "ETS has been shown to cause cancer and other health effects in healthy nonsmokers."

The "Fact Sheet" and Mr. Rosenberg's letter make clear that the Agency had reached firm conclusions concerning ETS without the benefit of either SAB review or public comment. Aside from the question of whether this position was scientifically justified, it is unclear why the Agency then decided to spend millions of dollars to conduct a formal "risk assessment" on ETS for the ostensible purpose of determining whether ETS does indeed pose a risk to health.

3. The ETS Technical Compendium

In November 1989, EPA released a draft ETS "technical compendium," the second of the Agency's documents concerning ETS. Conceived originally as a reference document, the compendium consisted of ten (later eleven) chapters on a variety of subjects not always directly related to ETS. With the exception of a draft chapter on "Exposure Assessment of Passive Smoking" by Mr. Repace, the compendium articles were solicited from scientists and consultants outside the Agency.

Although ostensibly a collection of scientific information about ETS, the first chapter, written by Thomas E. Novotny, claimed, based on public opinion polls, that the public increasingly believes that ETS is harmful to health and therefore supports smoking restrictions. But public opinion and acceptance of smoking restrictions are obviously irrelevant to the scientific and technical issues of whether the restrictions are justified in the first place. In addition, public opinion on scientific issues often is shaped by dramatic reporting, not by familiarity with the science itself. EPA scientists should have recognized that using public opinion to support a scientific hypothesis -- and ultimately, new regulations -- was irresponsible. That is particularly so when individual agency employees had played such a pivotal role in forming the very public opinion upon which they now were proposing to rely.

In addition to the chapter on trends in public attitudes, the compendium contained other articles on active smoking and on economic issues

surrounding workplace smoking. The only unifying theme of the compendium is that, in the Agency's view, smoking and ETS are "bad." Like most of the Agency's outside contractors on ETS, many chapter authors for the compendium, including Stanton Glantz, Jonathan Samet, and, of course, James Repace -- had long been active in the antismoking movement.

Although styled (and later defended by the Agency) as a scientific reference document, the compendium was in fact designed as an advocacy document for smoking restrictions. The preface to the compendium indicated that it was intended to be distributed to scientists, public officials, legislators and those in the private sector who are or may be concerned about ETS. The overall purpose was to "provide information necessary to allow the public, government agencies, and the building industry to make well-informed choices regarding exposure to ETS" (p. 2). The letter accompanying the draft compendium indicated that the compendium was an "integral component of [EPA's] ETS strategy," which was to include a separate "policy-maker's guide" that in turn would be a simplified version of the compendium.

It is hard to see how policymakers could make "well informed" choices on the basis of the information contained in the compendium or the simplified version known as the "policy guide." Both the compendium and the policy guide were initiated and drafted long before the Agency had prepared a formal risk assessment on ETS. By these actions, EPA violated the public trust in three ways. First, EPA conducted an end run around the statute creating the SAB review mechanism. In doing so, it not only threatened the integrity of the SAB review process but ran the risk of alarming the public for no good reason. In addition, EPA deliberately permitted policy to drive science rather than the other way around. As the "Fact Sheet" demonstrated, EPA started with the restrictive policy it wanted to promote and then worked backward to "develop" the scientific conclusions necessary to justify that policy. Finally, even though it has no statutory authority to regulate smoking, EPA's Indoor Air Division sought to become the de facto federal ETS regulatory authority by using the "Fact Sheet," the compendium, the policy guide and the ETS risk assessment to frighten employers and state and local regulators into imposing additional restrictions on smoking.

4. Bias In Preparing The Compendium

Although still in draft form and not reviewed by the SAB, the compendium received widespread media attention. Robert Axelrad, Director of the Indoor Air Division, had asserted unequivocally in a May 8, 1990, letter to The Tobacco Institute's counsel that EPA was "not interested in promoting any media attention to the documents while they are in draft form and will do everything possible to assure that they are not construed as EPA policy." Notwithstanding Mr. Axelrad's assurances, the compendium was leaked to the press and its more sensational claims openly publicized prior to any scientific review of the document's contents. According to a February 1993 report by the General Accounting Office ("GAO"), EPA staff in April 1991, before EPA had completed its own internal review of the document, improperly sent a draft of the compendium to several external reviewers, including Stanton Glantz. Glantz, an outspoken antismoking activist since the 1960s, immediately proceeded to provide a copy to an Associated Press reporter. According to the GAO, Glantz claims that his release of the report was simply a "mistake."

Most disturbing was the public dissemination of the chapter on cardiovascular disease. Glantz, one of the authors of that chapter, appeared in Boston -- again with James Repace -- at the World Conference on Lung Health in late May 1990 and gave both a presentation and news interviews on that chapter. Dr. Glantz used the occasion to repeat and underscore the unsupported claim that more than 30,000 nonsmoking Americans die of heart

disease each year as a result of exposure to ETS.

This activity made a mockery of EPA's procedures for ensuring that its policy documents receive a full and fair review before they are finalized. Glantz has a long record of public statements demonstrating his commitment to that political agenda, notwithstanding the lack of scientific support for his claims concerning ETS. While his training is in mechanical engineering rather than medicine or some other relevant discipline, he has pontificated on every conceivable smoking-related topic, such as advertising and economic issues, about which he plainly can make no claim to professional competence.

To cite one example, Dr. Glantz's organization stated in its 1983 annual report that "irrefutable medical and scientific evidence has confirmed what millions of nonsmokers have intuitively known for a long time: Tobacco smoke * * * poses a serious health risk for nonsmokers who breathe secondhand smoke." Thus, Dr. Glantz's mind was closed on the ETS/cardiovascular disease issue three years before the 1986 reports of the Surgeon General and National Academy of Sciences both determined that there was insufficient evidence to support the claim that exposure to ETS presents any increased risk of heart disease.

At an April 1990 antismoking conference in Perth, Australia, Glantz made a series of revealing comments. First, he noted that "it's very nice to see that the same ideas that a few of us were advocating in 1983 which were viewed as so strange, radical and hopeless have now really become very mainstream." A self-described "lunatic" on the issue, Dr. Glantz then excoriated the American Cancer Society for its alleged decision to terminate an employee for intemperate behavior in connection with a local smoking ordinance. "He [the employee] may be a little impolitic which I of course view as a plus. But you know activists need [to be] rewarded[.] * * * I had no objection to all the people who were given awards on the first day [of the conference], but I did notice that there was not a single lunatic among them * * *." He further confessed that "[t]he main thing the science has done on the issue of ETS, in addition to help people like me pay mortgages, is it has legitimized the concerns that people have that they don't like cigarette smoke. And that is a strong emotional force that needs to be harnessed and used." Glantz concluded by stating that "we are all on a roll and the bastards are on the run and I urge you to keep chasing them."

I expressed my concern to Mr. Reilly that the selection of Dr. Glantz to write part of the ETS compendium was a grave error in judgment. Glantz's involvement, coupled with leaks of information and inadequacies in the review process, led me to conclude that the Agency's procedures had been seriously compromised.

In response, Mr. Reilly assured me that the SAB would be given an opportunity to review the technical compendium and that EPA had not yet decided whether Glantz's chapter would be included in it. Ultimately, however, the technical compendium was not reviewed by the SAB and Mr. Reilly subsequently took the position, contrary to the Agency's prior statements, that the compendium was not a basis for the policy guide or risk assessment.

5. EPA Reneges On Its Pledge To Permit The SAB To Review The Technical Compendium

Despite Mr. Reilly's repeated oral and written assurances, the SAB was never given an opportunity to review the compendium. In early 1991, EPA switched course and began to act as if the compendium had never been written. In a letter to me, Mr, Reilly claimed that SAB review of the compendium was unnecessary since the compendium had "no direct bearing on future agency action." When he was questioned by the House Commerce

Committee's Subcommittee on Health and the Environment in April 1991, EPA's Deputy Administrator Henry Habicht could only say the compendium was "on a separate track."

That the technical compendium got onto "a different track" is curious, considering especially that when the SAB finally did review the policy guide in December 1990, it requested a "supporting document that explicitly states the technical basis for each of [the policy guide's] summary statements on the state of scientific knowledge." As noted above, EPA originally intended the policy guide to be a simplified version of the compendium. When I asked Mr. Reilly "[w]hat led the agency to redefine the role of the technical compendium," the answer was that the media had interpreted its release to the public as EPA endorsement of the draft document's content. As EPA staff had rather disingenuously told the media at the time the compendium was leaked, that interpretation was inappropriate. The Associated Press reported on May 29, 1991 that --

> [m]uch of the controversy over the report has focused on the estimate of 37,000 heart disease deaths attributed to secondhand smoke. That section was written by Stanton Glantz and Dr. William Parmley of the University of California, San Francisco.
>
> "Thirty-seven thousand may be a figment of Stan Glantz's imagination and William Parmley's imagination, or it may be a real estimate," said Axelrad [Director of EPA's Indoor Air Division].
>
> "Any effort or any attempt to imply any kind of endorsement or acceptance by EPA" of the death estimates in the technical compendium "is at this time totally inappropriate," he said.

D. The ETS "Policy Guide"

In June 1990, EPA released formally the first draft of its policy guide, entitled "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies." The guide's stated purpose was to provide government and private sector decision makers with information on the technical basis for controlling exposure to environmental tobacco smoke and to describe a variety of technical and policy options for instituting effective smoking restrictions.

It has never been clear why EPA prepared and released a risk management document like the policy guide and before that, the "Fact Sheet" and compendium, in advance of any final scientific assessment of the supposed "risk" to be managed. Ordinarily, an agency concerned with public health responds to allegations that a particular substance presents a risk to health by conducting a formal analysis of the scientific data called a "risk assessment." This assumes, of course, that the agency has statutory authority to regulate that substance. If the risk assessment justifies the conclusion that a significant risk exists, the next step is to develop policies or regulations to mitigate that risk. As the National Academy of Sciences/National Research Council has recognized, risk assessment is concerned with defining the health effects of exposure to hazards, while risk management is the process of selecting the most appropriate policy alternative by integrating risk assessment results with engineering data and social, economic and political concerns.(17)

Obviously, if the risk from ETS at levels typically encountered in the workplace was found to be minimal, there would be no justification for recommending, as did the "Fact Sheet" and policy guide, that smoking be prohibited except in separately ventilated areas. Even Administrator Reilly recently conceded in a letter to me that "beginning the development of an Agency risk assessment after the commencement of work on the draft policy guide gave the appearance of the very situation -- i.e., policy leading science -- that I am committed to avoid."

Equally troubling is the fact that the guide even went so far as to encourage ETS-based lawsuits by employees against their employers. In doing so, the policy guide grossly overstated the legal significance and precedential value of the handful of cases favorable to the policy guide's viewpoint while understating the significance of the vast majority of others, which were not.

The perception that the EPA policy guide on workplace smoking crosses the line from information into advocacy is not mine alone. ICF Incorporated, which functioned as the nominal prime contractor for preparation of the policy guide, recently provided me with a marked-up copy of the guide purporting to reflect ICF's own handwritten editorial comments. I discovered that my concerns about the tone and emphasis of the legal discussion in the policy guide were shared by ICF's own internal reviewers. Marginal comments on this section included such observations as "it seems really weird to have a much lengthier discussion on litigation than on the effectiveness of various mitigation alternatives" and "this discussion is too rah-rah -- this chapter should be more objective in tone." For reasons that have never been explained fully, however, ICF apparently was not asked to comment on the draft prior to its public release in June 1990, even though ICF supposedly supervised the preparation of this document by its subcontractor, the Smoking Policy Institute. As will be discussed later, many questions remain about the Smoking Policy Institute's role in preparing the policy guide.

The SAB's eventual review of the scientific conclusions in the policy guide was incomplete at best. Prior to the guide's release, EPA had decided to limit the SAB's review to those parts that referred to the risk assessment, to ensure that the latter was "properly characterized." Since the SAB had not yet seen a risk assessment draft it could approve, one must question how it could make sure that the policy guide properly characterized it. Moreover, the policy guide covered a much broader range of issues than the risk assessment. The policy guide had been drafted based on the technical compendium, which, as I have explained, EPA has never given to the SAB to review, and which makes many more health claims than does the ETS risk assessment. These include unsupported assertions that ETS has been shown to cause cardiovascular disease and suggestions that ETS has been associated with brain cancer.

Such extravagant claims are at odds with EPA's private admissions to other government officials that "[w]e know very little about ETS exposure in the workplace, and cannot estimate the relative significance of workplace vs. home vs. all other sources of exposure; nor can we clarify the significance/role/impact of exposure to other pollutants (e.g., radon and other air carcinogens) in addition/conjunction with ETS exposure."(18) If EPA knows "very little" about ETS exposure in the workplace, it is difficult to understand why it would decide to issue a workplace policy guide. EPA cannot assert, as it did repeatedly in the policy guide, that only smoking bans or separately ventilated smoking lounges are appropriate without occupational exposure data. In the absence of such data, the policy guide's recommendations necessarily reflect only the personal preferences of the guide's authors. I expressed these concerns many times in writing to EPA

Administrator Reilly and received noncommittal replies.

E. Irregularities In Contract Award Procedures

The selection of the policy guide's author, Robert Rosner of the Smoking Policy Institute ("SPI"), raises further questions about the document's objectivity and reliability. SPI is in the business of counselling employers on the implementation of smoking policies and operating smoking cessation clinics. This organization therefore had a vested financial interest in conveying the impression in the policy guide that employers without smoking policies or cessation programs were at risk of lawsuits or worse.

In addition, Mr. Rosner had no technical background in any of the areas on which the policy guide purported to reach definitive conclusions.(19) These include the possible health effects of exposure to ETS (and other indoor air components), the legal ramifications of workplace smoking policies, public attitudes toward smoking, and the claimed economic consequences of permitting smoking in the workplace.

Apart from this obvious conflict of interest and lack of necessary qualifications, the award of the SPI subcontract appears to have violated federal procurement regulations, an impropriety EPA has recognized only grudgingly. As ranking minority member of the Subcommittee on Oversight and Investigations of the House Committee on Energy & Commerce, I uncovered evidence that SPI was improperly sole sourced on the subcontract, and that the choice was made by Indoor Air Division officials at EPA rather than by the prime contractor, ICF Incorporated. This abuse of the contracting process, as well as the conflict of interest noted above, has been brought to the attention of the EPA Inspector General.

Under federal regulations, an agency may not specify the use of a certain subcontractor without competitive bidding. In the case of the policy guide, EPA staff first solicited the Smoking Policy Institute for the job and then sought to funnel the work through the main contractor, ICF Incorporated. In fact, Robert Axelrad telephoned SPI's Rosner in mid-1988, before getting ICF involved, and told Rosner that EPA had $30,000 to spend on the project for that fiscal year and also would provide funding the following year. On July 23, 1988, Mr. Axelrad followed up with a bid solicitation letter to Mr. Rosner:

> The attached stack of material represents the current status of the technical manual on environmental tobacco smoke which we discussed in our telephone conversation on the 11th.
>
> As you will see from a review of this material, substantial portions of the manuscript are still to be written/ assigned/edited. What I am looking for is someone who can take the lead role at this stage in ensuring that the document is: a) conceptually sound; [and] b) a useful addition to the body of knowledge available on environmental tobacco smoke at a reasonable cost. This would entail managing the entire process from this point to completion of a camera-ready manuscript.
>
> If you are interested in taking on the

task, please send me a letter describing:

1. The conceptual changes you would make, and a revised outline reflecting your suggested changes;

2. A brief description of tasks which you perceive to be necessary to get from here to there; and

3. A reasonably detailed all-inclusiue budget for accomplishing the above.

As I mentioned to you on the phone, I have approximately $30K to begin the project this fiscal year and am prepared to put limited funds into the effort next year.

An arrangement was made in August 1988 that SPI would be paid by making SPI a subcontractor to ICF.(20) The "justification" memo that ICF wrote to support the sole-source subcontract stated that SPI was uniquely qualified. There was no support for that claim, however, nor any indication that ICF had made any evaluation of SPI. The drafts of the policy guide written by SPI were not even copied to ICF but went straight to Mr. Axelrad at EPA.

The only copy of the policy guide commented upon by ICF was the draft released publicly in June 1990. This raises questions about Mr. Reilly's statement to me in March 1992 that "ICF's role was, and is, more than simply a conduit for payments to the Smoking Policy Institute. In addition to providing comments on the various drafts prepared, ICF managed much of the external review process * * *." The documents from ICF's files recently turned over to me suggest that, far from commenting on "various drafts," ICF's first opportunity to comment on the policy guide occurred when the document was released for public comment. In sum, ICF file documents confirm that its involvement began only after the policy guide was released publicly -- and after I had begun to raise questions about the propriety of the SPI contract.

The situation with SPI further underscores the fact that a risk assessment was crafted to justify a policy that had been adopted long before. The record clearly shows, first, that EPA staff hand-picked SPI to prepare documents that would advocate workplace smoking restrictions long before any assessment of the science had been completed; second, that EPA arranged for SPI to be signed up as a subcontractor to ICF to circumvent applicable federal procurement requirements; and finally that, in this way, taxpayer funds helped produce what is essentially a marketing and promotion aid for SPI's business.

Unfortunately, the SPI contract appears to be but one example of a more general pattern of contractual problems at EPA. In light of widespread revelations about EPA's contracting practices, on July 8, 1992, Chairman Dingell convened the House Commerce Committee's Subcommittee on Oversight and Investigations to conduct hearings on "The Collapse of Contract Management at the U.S. Environmental Protection Agency." The majority of the hearing was devoted to a number of instances of contractual abuse and mismanagement at EPA that had been identified by the GAO and the EPA Inspector General.

Whether the problems with the SPI subcontract would have come to light absent a congressional investigation is an open question. The replies that I received to my inquiries to Mr. Reilly as late as March 1992

were less than forthcoming. In a letter to me dated March 24, 1992, for example, Mr. Reilly unequivocally stated that --

> [w]e do not agree that the subcontract issued to the Smoking Policy Institute (SPI) was issued in violation of Federal procurement law. * * * These contracts were competitively awarded in full compliance with all Federal contract laws. The smoking policy guide was well within the scope of the [ongoing EPA/ICF] contracts and ICF's selection of the Smoking Policy Institute was proper based on their determination that the SPI had unique or specialized experience in this area.

Mr. Reilly also stated without qualification that "[t]he Smoking Policy Institute was not selected by EPA staff but by ICF," even though Mr. Axelrad had told my staff six months earlier that EPA staff had selected SPI.

Even more curiously, at the Oversight hearing on July 8, 1992, Mr. Reilly repeatedly claimed that he lacked knowledge about how SPI was selected, the nature of SPI's supposed "specialized experience," the fact that SPI was in the business of promoting workplace smoking restrictions, or any other information pertinent to the unqualified statements he had made in his March 24, 1992, letter to me. It is impossible to square these oral statements with the prior and quite detailed assurances Mr. Reilly had provided to me in writing.

Since then, EPA has reversed its earlier public position that the SPI contract was awarded properly. At the July 8 hearing, the Agency's own Chief Financial Officer acknowledged that "this might very well be an improper contracting practice. It may be a pass-through and the designating of the $30,000 may also be improper." Mr. Reilly's most recent letter to me dated July 31, 1992, attaches a memorandum from Mr. Axelrad to his supervisor at EPA, Eileen Claussen. Mr. Axelrad's memorandum acknowledges that his decision to contact SPI outside normal procurement procedures was inappropriate and that his recommendation "probably" caused ICF to select SPI as the subcontractor. Mr. Reilly indicated at the July 8 hearing that he had requested an investigation by EPA's Inspector General of the apparent conflict of interest and other improprieties in the award of the SPI contract. Congressmen Dingell and I made a similar request and asked that the Inspector General report his findings to the House Subcommittee on Oversight and Investigations.

In March 1993, the Inspector General sent me a letter setting forth his findings. In that letter, the Inspector General states as follows:

> We believe the award [of the contracts to SPI] was tainted in how it was processed. First, there was no attempt by ICF to seek competition. Second, the actions by an EPA program official gave the appearance that he, rather than ICF, selected the subcontractor.

The Inspector General also found that "the EPA believed that "it may have been 'unauthorized action' under the EPAAR [EPA Acquisition Regulations]." The Inspector General also indicated that "the procurement should not have proceeded on a non-competitive basis."

EPA's contracting improprieties in connection with the

preparation of the four ETS documents are not confined to the policy guide. In June 1993, the Inspector General reported to me that similar abuses had occurred in connection with several of the ETS risk assessment subcontracts. The most egregious of these appears to be the subcontract between ICF, once again the prime contractor, and Kenneth G. Brown, Inc., which drafted most of the critical sections on lung cancer. The Inspector General states that in the case of the Brown subcontract, "EPA program personnel and ICF simply circumvented the contracting officers" altogether, clearly a violation of proper procedures. Like the SPI subcontract, the Brown subcontract also was awarded on a non-competitive basis, and the only justification for that decision that could be found was an undated and unsigned "sole source justification" file memorandum.

F. The Science Advisory Board's Review Of The Risk Assessment

The first drafts of the ETS risk assessment and the workplace policy guide were released for public comment in June 1990. At the same time, EPA transmitted the drafts to the SAB, requesting formal review. A hearing before a subpanel of the SAB was held in December 1990. The subpanel reported the results of its review to the SAB Executive Committee in April 1991. The risk assessment was sent back to EPA with directions that it be revised extensively. After major rewriting, a second draft was released in June 1992 and a second SAB hearing was held before essentially the same subpanel in July of that year. Following the SAB's report to the SAB Executive Committee in October 1992, the final risk assessment was released on January 7, 1993.

At both the public hearings and in written comments, the validity of most of the risk assessment's assertions was criticized by a number of scientists with expertise in the relevant disciplines. Unfortunately, most of these criticisms were ignored for reasons having nothing to do with science and everything to do with politics. Although the SAB is supposed to function as an independent and unbiased review body, in the case of the ETS risk assessment it became apparent early on that the SAB review process itself had become as intensely politicized as the rest of EPA.

1. How The Panel Was Selected

The EPA Science Advisory Board is intended to serve as an independent review body composed of impartial experts from outside the Agency. Its function is to ensure Agency accountability and integrity in the use of science.(21) In addition to the seven standing members of the SAB's Indoor Air Quality and Total Human Exposure Committee, the decision was made at EPA to select nine scientists to serve in an ad hoc capacity on the panel that was to review the draft ETS risk assessment and policy guide. Because they were to review work that had been developed and put forward by Agency staff and others with vocal antismoking records, their ability to conduct a fully objective critique was essential. Therefore, at the outset I expressed concern to EPA that the selection process be above reproach. I also urged EPA to apply certain -- I thought self-evident -- criteria to ensure objectivity.

My suggestions included that (1) the SAB panel be limited to recognized authorities with relevant specialties; (2) the members should not have participated in the development of the technical compendium, the policy guide, or the risk assessment, or have already provided comments on them, including serving as EPA contractors or grantees; and (3) they should not have become enmeshed in the political controversy surrounding ETS by having testified for or against smoking restrictions, or by having been active members of groups that had taken a position on the broader issues concerning smoking.

EPA squarely rejected the second and third criteria. In his reply to me, Mr. Reilly stated it was EPA's belief that there was merit in having individuals who were previously involved, promising that "the extent of any prior involvement will be publicly disclosed at the meeting." In fact, that was not fully done. Regarding activists' filling SAB positions, Mr. Reilly also promised that "should technical conditions require the presence of such an individual on the panel, he or she would be balanced by the presence of an individual who could represent the opposing point of view."

Unfortunately, the panel ultimately was not balanced in the way Mr. Reilly had suggested. Not one of the candidates suggested by the tobacco industry was even contacted for inclusion on the panel. In contrast, three of six persons suggested by antismoking organizations were chosen, including Dr. David Burns.

The selection of Dr. Burns was especially puzzling, given that Mr. Reilly had assured me shortly before Dr. Burns' selection that "experience has shown that the deliberative process is generally not aided if extreme views are represented on the panel itself." Long before EPA appointed him to evaluate the scientific data on ETS, David Burns was spending by his own reckoning half of his time in the antismoking movement. He had claimed in 1988, for example, that ETS caused 3,000 deaths per year (Nonsmoking Ordinance, So Far, Proves To Be No Hazard To Economic Health, Los Angeles Times, January 8, 1989, sec. 2, p. 1). He also had testified in several cases in favor of local antismoking measures -- including a 1987 initiative in Del Mar, California that would have banned smoking outdoors, on city sidewalks and in beach areas (UCSD Expert is Smoking's Archenemy, Los Angeles Times, August 21, 1989, sec. 2, p. 1). In addition, Dr. Burns had testified in favor of a tobacco advertising ban that a Canadian trial court subsequently held to be a violation of the free speech guarantee of the Canadian Constitution (RJR-MacDonald Inc. v. Le Procureur General du Canada, No. 500-05009755-883 (Superior Court of Quebec, July 26, 1991)).(22) In that testimony, Dr. Burns stated that --

- in the two years he worked for the National Clearinghouse on Smoking and Health, he had helped devise programs to discourage smoking;

- he had served on the American Cancer Society committee responsible for setting policy on tobacco issues;

- he had served as senior scientific advisor for the 1986 Surgeon General's report on ETS and regarded that work as part of his antismoking efforts;

- he is a consultant to plaintiffs' counsel in tobacco product liability cases.

In his Canadian testimony, Dr. Burns acknowledged that his activities are part of an effort to "see smoking behavior disappear from society" (transcript at p. 10470). He acknowledged that "much of the work that [he did] within the university is to teach on * * * the means by which tobacco can be controlled within society" (id. at 4964). Dr. Burns demonstrated his dogmatism when he said that there "is no credible scientist" who would disagree with his views. Finally, Dr. Burns made clear that his single-minded focus is on promoting and supporting restrictions on the use of tobacco in any public place in order to penalize smokers for their decision to smoke.

- [I]n order to modify smoking behavior, one needs to look at * * * changing the public image of tobacco, changing the locations in which tobacco can be used, to create an environment in the larger society that actually discourages rather than encourages the use of this product (id. at 10462).

- [T]he key * * * is not simply providing the information * * * it's also to change the larger environment in which that individual functions to make it less conducive to using cigarettes and more rewarding to not use cigarettes (id. at 10462-463).

- I'm also not particularly inclined to testify to issues relating to the benefits, if you will, of tobacco or to any of the open scientific questions * * * (id. at 4999).

- And to the extent that [the Del Mar smoking ordinance] changes the image of the cigarette smoker and changes the psychological and sociologic rewards of cigarette smoking, then one -- then it contributes to changing the environment in which smoking occurs (id. at 10514-515).

By his own testimony, therefore, Dr. Burns is incapable of even discussing the "open scientific questions" concerning tobacco use, let alone evaluating scientific data relevant to those questions in an objective manner. I would add, by the way, that Dr. Burns himself has not conducted or published any original scientific research on ETS.

Some at EPA recognized, if belatedly, that Dr. Burns' inclusion on the SAB panel would not be appropriate. In addition to the problems previously mentioned, Burns had been involved in reviewing and commenting on earlier versions of the risk assessment and could hardly be expected to be objective in evaluating a report reflecting his own substantial input. On October 22, 1990, the New York Times reported that SAB Staff Director Dr. Donald Barnes had acknowledged that Dr. Burns was not suitable for membership because of his demonstrated bias against smoking. Imagine my surprise when, only two days after the New York Times story appeared, Mr. Reilly informed me that Dr. Burns would be included on the panel after all!

The decision not to include Dr. Burns had been followed immediately by claims in the press by antismoking activists that Dr. Burns had been dropped because of political pressure from the tobacco industry. At the same time, the press also was reporting that some committee members had acted as advisors or peer reviewers for the Council on Indoor Air Research ("CIAR"), a research organization that receives funding from the tobacco industry. Allegations were made that these committee members were biased as a result of their association with CIAR. In fact, the allegations were baseless. Four of the six people with CIAR associations already were standing SAB committee members, and not one had been suggested by the tobacco industry. Regardless of the falseness of the charges, public reporting of them placed pressure on the members not to criticize the Agency's drafts lest they be seen as "biased" in favor of the tobacco industry. As one of these individuals, SAB panel chairman Dr. Lippmann, candidly admitted to the press, "[i]t's not that I'm a tool of industry. I'm a bigger tool of government.

I've been working for the EPA longer. I have more to lose by offending the EPA than industry."(23) Another panelist, James Woods, promised the Associated Press on November 20, 1990 -- well before the SAB hearing -- that "the comments he intends to make on the EPA report will demonstrate that he is not biased toward tobacco companies. 'Wait and see what I say at the hearing.'"

At this point the process had become so deeply enmeshed in controversy that an objective review by the panel was no longer possible. As a consequence, the only responsible course of action would have been to reconstitute the panel. Even the New York Times called for such a move, in an editorial entitled "Objectivity Up in Smoke." In response, the EPA simply proceeded as if no problem existed.

During my investigation, we learned from both Donald Barnes, the SAB staff director, and Robert Flaak, his assistant, that Mr. Flaak deliberately went around his boss, Dr. Barnes, to Dr. Lippmann and enlisted his support in overruling Dr. Barnes' decision not to invite Dr. Burns to join the panel. It would not be unreasonable in these circumstances for a scientist in Dr. Lippmann's position to fear the public consequences of a refusal to give in to the demand of the antismoking lobby on this issue. There also were suggestions that Dr. Lippmann and Mr. Flaak may have met with at least one reporter who had written a series of articles on ETS prior to the December 1990 SAB meeting to discuss the press coverage the meeting might generate based upon the panel's conclusion. Many unanswered questions remain about Mr. Flaak's behind-the-scenes role in conducting off the-record meetings with antismokers and other activities in connection with the panel's composition.

There are questions about the objectivity of other SAB panel members. As mentioned earlier, Jonathan Samet of the University of New Mexico had stated that uncertainties regarding ETS scientific data should not interfere with tobacco control efforts. Like Burns, Samet also had been involved in reviewing earlier drafts of the risk assessment. Before that, he had played a major role in drafting or reviewing portions of the technical compendium and policy guide. In addition, eight of the fifteen panel members were themselves responsible for scientific studies relied upon in the first or second drafts of the risk assessment -- hardly the type of circumstances that ensure independent evaluation.(24)

In response to my written and oral communications of concern about these developments, Mr. Reilly blithely assured me that "the panelists are well qualified to deal with the technical issues that are being directed to them. To the degree that there are differing scientific views on the information under review, the SAB process * * * allow[s] for and mandate[s] a balanced, open discussion of the issues, with ample opportunity for input from and observation by the public." Of course, all the discussion and "input" in the world will not sway a mind already closed on the issue in question. Ultimately, moreover, no such discussion was permitted and input from the public was sharply limited.

When I pressed Mr. Reilly on these points, he replied with a series of non sequiturs. Stating that "it is not easy to select a panel of experts on any 'highly charged emotional and political issue' such as ETS," he then asserted without further explanation that the SAB panel would be capable of providing objective advice and that to delay the process to reconstitute the panel would "not serve the public interest." How the public interest was served by EPA's pressing ahead despite the problems that had arisen has never been explained. Interestingly, Mr. Reilly made no attempt to deny or refute the specific allegations made against Dr. Burns and other panel members.

Equally disturbing, I have learned recently that, as the SAB considered the first draft of the risk assessment, Dr. Steven Bayard, the EPA staff member with principal responsibility for the document, was providing "enthusiastic" support to a grant proposal by Dr. Stanton Glantz and his associates in California for a project designed explicitly to discredit any scientist who has consulted on the ETS issue for the tobacco industry and expressed critical views with regard to the risk assessment. As discussed earlier, Dr. Glantz prepared a chapter of the ETS technical compendium and is a well-known and vocal antitobacco activist. The grant proposal seeks to study "[t]he tobacco industry and scientific research." The purpose of the study is to arrive at "[a]n understanding of tobacco industry tactics for influencing research on ETS" by identifying whether particular scientists are "funded by the tobacco industry." That Dr. Bayard's January 10, 1991, letter in support of that application offered to continue to cooperate actively with Glantz and his associates at a time when the risk assessment was still under SAB review raises questions about the EPA staff's approach to resolving legitimate scientific criticisms of their work. Rather than addressing those criticisms on the merits, Dr. Bayard's endorsement of the Glantz proposal creates the impression that he is more interested in silencing his critics.

Dr. Bayard's participation in this effort is even more alarming given his role in the selection of SAB panelists. Mr. Reilly repeatedly shunted aside bias concerns on the ground that the procedures for selecting SAB members are intended to ensure that members "are free from legal and perceived conflict-of-interest." Later on, however, I wrote to EPA asking for an explanation of how the ETS panel was being selected. In response, EPA informed me that the candidates were being selected by Dr. Bayard, with assistance from Robert Axelrad and James Repace.

2. The Initial SAB Hearing

Despite Mr. Reilly's promises, the SAB panel meeting on December 4-5, 1990, was conducted in a manner that effectively prevented scientific viewpoints critical of the two draft ETS documents from being given anything resembling a full and fair hearing. Less than two hours were allowed for presentations by scientists critical of the report. Certain attendees who had personally requested time from the Chairman were foreclosed from speaking under the agenda that had been formulated. The input of several critical points of view was lost, as well as the opportunity for the panel to ask questions and to conduct a dialogue with other scientists. In contrast, twice as much time was given to antismoking organizations. Although there certainly was enough time to accommodate all who had asked to speak, several scientists who had expressed doubts about the risk assessment and policy guide were denied the chance. No explanation was given for the failure to accommodate these speakers or why the SAB hearing was conducted with such rigidity. Most SAB review panels are conducted in an open and collegial manner that encourages vigorous discussion of all competing scientific viewpoints.

Two of the ETS panel members who agreed to review the report did not even attend the first day of the meeting, which was the only time reserved for public comment. Other panel members openly admitted that they had not read any of the written submissions. The panel members did not address or acknowledge the many public comments in their written reviews.

No presentations were permitted on the risk assessment chapter dealing with the respiratory health of children. Without providing any opportunity for public comment, EPA had transmitted to the SAB a new "draft report with a detailed description and analysis of 26 studies" on childhood exposure to ETS. Not surprisingly, the document failed to discuss any studies that did not support EPA's preferred conclusions. By inserting it at the last moment and preventing public discussion of the topic at the

hearing, meaningful public scrutiny of the Agency's conclusion was excluded.

The negative perception created by the SAB was heightened by the Chairman's summary remarks and statements by him and others to the press after the panel adjourned, misleadingly suggesting that the panel had reached a "consensus" on the classification of ETS as a human carcinogen. As the transcript of the meeting shows, there was no such "consensus." Several panel members criticized the draft in key respects. Dr. Jeffrey Kabat, for example, repeatedly questioned important aspects of the methodology used in the draft as well as its treatment of specific studies before concluding that classifying ETS as a Group A carcinogen could be "rash" (II, p. 15). Dr. Kabat stated that "the observations on nonsmokers that have been made so far are compatible with either an increased risk from passive smoking or an absence of risk or I would say that with a risk that's so small that maybe it's not -- you can't measure it with certainty" (ibid). Others on the panel expressed similar reservations about the draft's conclusions.(25)

The advisory panel also did not consider a number of pertinent studies, including a study by one of its own members, Dr. William Blot of the National Cancer Institute. Dr. Blot had served, along with Dr. Wu-Williams, as one of the principal investigators on one of the largest studies ever conducted on ETS and lung cancer among nonsmokers. However, the new study was not discussed by the panel, even though the study had been accepted for publication in the British Journal of Cancer before the panel met. Amazingly, Dr. Blot himself did not mention the study, which reported no health risks from ETS.

After the panel meeting, Dr. Lippmann held a press conference to announce the conclusion that ETS "should be classified as a Class A carcinogen." The impropriety of a supposedly impartial scientific expert attempting to frighten the public on the basis of an incomplete and unsupported document speaks for itself. But Dr. Lippmann compounded this breach by misrepresenting the panel's conclusions concerning the strength of the evidence. Among other remarks, Lippmann stated that "if anything, [the evidence] suggests that it is more potent than we had thought" (Evidence Shows That Tobacco Smoke Causes Cancer, Head of EPA Panel Says, Bureau of National Affairs, Daily Report for Executives, December 7, 1990, p. A8). Perhaps realizing that he had gone too far, Lippmann subsequently tried to qualify his remarks but succeeded only in being inconsistent. "[T]his is a classic case where the evidence is not all that strong." Nonetheless, Lippmann asserted, the "weight of the evidence" supports the risk assessment's conclusions (Passive Smoke A Cause of Cancer, Panel Concludes, The Washington Post, December 6, 1990, p. A9).

3. SAB Executive Committee Meeting, April 1991

Dr. Lippmann presented the SAB panel's report to the SAB's Executive Committee meeting in April 1991. This report was curious for several reasons. First, the SAB concluded that the worldwide epidemiologic data on ETS were too weak and inconclusive to support the draft risk assessment's conclusion that ETS is a cause of lung cancer in nonsmokers. In addition, the panel did not endorse the Agency's quantitative lung cancer analysis, noting that the "real" number "may be greater or less than the number EPA cites."

After concluding that the rationale underlying the EPA staff's conclusions about lung cancer could not be sustained, however, the SAB could not bring itself to take the logical, if politically unpalatable, next step and reject EPA's conclusions regarding ETS and lung cancer among nonsmokers. Instead, the SAB endorsed the conclusion that ETS is a "Group A" carcinogen while taking the extraordinary step of urging the EPA staff to attempt to "make the case" against ETS based on extrapolation from data

concerning active smoking. In essence, the Agency was being encouraged to do the science backwards -- to maintain its conclusion while going about the task of finding support for it.

Not surprisingly, the SAB report did not acknowledge that EPA had largely ignored its own "Guidelines for Carcinogen Risk Assessment," 51 Fed. Reg. 3394 (September 24, 1986), in order to reach its apparently predetermined position. Among many violations of the guidelines, EPA had failed to rule out the possibility of bias and other flaws in the ETS studies and also had failed to consider animal studies and other non-epidemiologic data.

The SAB's report feebly suggested that the panel "had some difficulty in applying the 'Guidelines for Carcinogen Risk Assessment', as they are currently formulated," to the ETS data. Particular attention was given to the report's statement that "[i]f the guidelines for Carcinogen Risk Assessment can be used to cast doubt on a finding that inhalation of tobacco smoke by humans causes an increased risk of lung cancer, the situation suggests a need to revise the guidelines" (SAB Rep. 28). This prompted one member of the SAB Executive Committee to note that it sounded a little like saying "if the data doesn't fit the guidelines, the guidelines should be changed." Nevertheless, the Committee accepted the panel's Group A designation despite the clear failure of the data to satisfy the Agency's own guidelines.

Following the Executive Committee meeting, Dr. Lippmann once again spoke to the press about the SAB's conclusions. This time Dr. Lippmann's statements were considerably more restrained than his remarks at the December 1990 press conference. This time he stated that "occasional, light exposure [to ETS] is not likely to cause any harm" (United Press International, April 19, 1991). Dr. Lippmann also observed that in his view the risk due to ETS exposure is "probably much less than you took to get here through Washington traffic" (Washington Times, April 19, 1991, p. A-3). On three separate occasions my staff asked Dr. Lippmann, "if one were to apply the guidelines as written could you classify ETS as a Class A known human carcinogen?" On all three occasions, Dr. Lippmann failed to respond to the question. The next day, however, Dr. Lippmann stated at a meeting outside the glare of media attention that if the guidelines were applied strictly there was no clear mechanistic basis for calling ETS carcinogenic.

4. The Second Draft Risk Assessment

EPA staff spent the next year and a half attempting to "make a case" against ETS. The revised risk assessment draft was over 600 pages long, finally being issued on the afternoon of June 18, 1992.(26) Incredibly, however, EPA gave the public just nine working days to comment on it even though the report had doubled in length and a whole new set of flaws had been introduced. Even the Science Advisory Board panel had only until July 20 to review the revised draft and consider outside comments before the public review meeting.

The second draft risk assessment was even more curious than the first. As an EPA health scientist who contributed to the draft admitted, the Agency staff had engaged in some "fancy statistical footwork" in the revised risk assessment in order to "fashion [an] indictment" of ETS (Science, vol. 257, p. 607 (July 31, 1992)). In the prior draft, EPA's calculations had showed that the epidemiologic studies based on U.S. populations showed no statistically significant association between ETS and lung cancer among nonsmokers. In order to reach a statistically significant result in the first draft, EPA therefore had included in its calculations all of the studies of ETS conducted worldwide to tilt the balance in the favored direction. Both EPA and the SAB rejected out of hand arguments by critics

that the risk assessment should have considered only the U.S. studies.

When EPA staff was revising the risk assessment, however, it was confronted by the Wu-Williams/Blot study, which had been conducted in China and reported a statistically significant negative association between marriage to a smoker and lung cancer among nonsmokers -- the exposure scenario relied upon in the initial risk assessment draft. Inclusion of the Wu-Williams/Blot study in EPA's analysis would have forced EPA to reverse its conclusions about ETS and lung cancer. At the same time, however, EPA had obtained preliminary data from a large U.S. study that, with some massaging, could be used to support its calculations of risk based exclusively on the U.S. studies.

Accordingly, EPA entirely reversed course and decided in the second draft to disregard the non-U.S. studies. Instead, EPA used the U.S. studies only. The Agency also adopted an entirely new standard of statistical significance, presumably because the one used in the prior draft would not have yielded the desired results, even with the inclusion of the new, if incomplete, U.S. study.(27) Only by manipulating the numbers in a manner that violated well-accepted statistical methods was EPA able to claim in the second draft a barely significant association in the U.S. studies.

The new draft also relied on the argument suggested by the SAB that because active smoking had been associated with increases in risk, ETS exposure also must be a risk factor. The problem with this argument -- that ETS is in many respects a very different substance and is encountered at far lower levels -- was acknowledged in the revised report.(28) At the same time, however, its significance seemed to escape those responsible for the report's conclusions.

Similarly, the second draft risk assessment announced that ETS exposure had been established as a cause of respiratory disease in children. The first draft risk assessment had stated that the data were too inconclusive to draw an inference of causation. No new information became available between the release of the first and second draft risk assessment to support this shift in the Agency's position. Apparently, EPA staff took the SAB's earlier suggestion that it consider "strengthening" the report's conclusions concerning children as a license to sensationalize further the Agency's claims about ETS.

The SAB held public hearings on the revised risk assessment on July 21 and 22, 1992, after having denied requests for more time to submit public comments on these and other problems. The panel submitted its report approving the second risk assessment in October. The panel's conclusions make absolutely clear that it was unconcerned with the scientific soundness of the report's underlying rationale. A brief comparison of the SAB's actions following its first and second review of the risk assessment confirms that the SAB actually disregarded its earlier findings in order to embrace the desired conclusion.

- The SAB concluded in its second review that extrapolation from active smoking data could not, after all, serve as the sole or predominant basis for the conclusion that ETS is a Group A carcinogen.

- The SAB had concluded in its first review that the epidemiologic data were too weak to support the inference that exposure to ETS causes lung cancer in nonsmokers. The SAB reversed its position in its review of the second draft risk assessment once it became clear that active

smoking data could not provide an alternative basis for that conclusion.

- The SAB concluded in its review of the first risk assessment that all studies of ETS and lung cancer conducted worldwide should be included. In the second review, the SAB decided that EPA need only include the U.S. studies. Had the Agency and the SAB adhered to their original decision to use all ETS studies, the meta-analysis would not have shown a statistically significant risk.

- The SAB nonetheless concluded that the Agency had established that ETS is a Group A carcinogen responsible for approximately 3000 lung cancer cases every year in the United States. In the first review, the SAB had concluded that the data were too uncertain for EPA to attach a specific number to the deaths supposedly attributable to exposure to ETS.

Put simply, the SAB concluded that ETS is a Group A carcinogen even though neither of the two rationales advanced by EPA staff to justify such classification is scientifically defensible. The first review determined that the spousal smoking studies were too weak to support an inference of causation. The second review concluded that the active smoking data could not be used as an alternative ground. Nonetheless, the SAB decided that the total "weight of evidence" supported a Group A classification.

Following the SAB's October report, EPA staff rushed to revise and release the final risk assessment. The Agency's haste apparently was motivated in part by the impending change in the Administration. Perhaps of even greater concern to EPA, however, was the release of the Brownson study discussed above. The fact that the largest U.S. case-control study ever conducted reported no statistically significant association between ETS exposure and lung cancer incidence casts further doubt on EPA's claims. Had the Brownson study been included in EPA's analysis, the Agency's calculations would not have shown a significant risk from ETS even using the Agency's highly suspect statistical methodology. Rather than face this embarrassment, EPA rushed to release the report without considering the Brownson study on the pretext that "it had to stop somewhere."(29)

Together, EPA and the SAB have undermined the process by which risk assessments ought to be conducted: first, by ignoring the substantial scientific controversy about what the ETS studies actually show; and, second, by conducting the forum where that controversy should have been thoroughly aired as a mere rubber stamp proceeding. As a result, EPA's preparation and review of the risk assessment have given the appearance of a scientific show trial to legitimize a predetermined policy.

III. CONCLUSIONS

EPA's handling of ETS is a symptom, albeit a very severe one, of larger agency problems. These problems encompass not only widespread abuses in the award and oversight of government contracts but also the Agency's general approach to the use of science in policy making.

In fact, EPA's risk assessment process as a whole has come under fire. In response, top EPA management moved to revamp internal guidelines governing EPA's use of science in risk assessments. In February

1992, Deputy Administrator Henry Habicht issued a document providing agency-wide guidance on science policy in risk assessment and risk characterization. Mr. Habicht noted that significant information often was omitted as assessment documents were passed along in the decision-making process, and that "EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions."

The guidance also drew from principles articulated earlier by the Risk Assessment Council in November 1991, such as the following.

> For users of the assessment and for decision-makers who integrate these assessments into regulatory decisions, the distinction between risk assessment and risk management means refraining from influencing the risk description through consideration of non-scientific factors -- e.g., the regulatory outcome -- and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or serve political purposes. Such management considerations are often legitimate considerations for the overall regulatory decision * * * but they have no role in estimating or describing risk.(30)

In other words, science should drive policy, not the other way around.

In addition to the new risk assessment guidance, as I mentioned at the outset, the EPA Administrator also had convened an expert panel to assess EPA's use of science, which issued an important report in March 1992 entitled "Safeguarding the Future: Credible Science, Credible Decisions." The report confirmed that "[c]urrently, EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation" (p. 4).

The expert panel also cautioned EPA, in terms that are directly relevant to the Agency's work on ETS, that "science should never be adjusted to fit policy, either consciously or unconsciously" (p. 38). Unfortunately, in the case of ETS there appears to have been a conscious use of science and the scientific process to achieve a political agenda that could not otherwise be justified.

While we should applaud the promised willingness of EPA to clean house and revise its methods, we also must question why that was not done in the case of the ETS risk assessment. In his February 1992 policy memorandum, the Deputy Administrator wrote, "we do not expect risk assessment documents that are close to completion to be rewritten" (p. 5). It is difficult to understand why, after acknowledging serious deficiencies in EPA's use of science, the Agency would refuse to correct the flaws in risk assessment projects then under way. Similarly, EPA repeatedly has refused to respond to requests that it reevaluate its handling of the ETS controversy in general and the risk assessment in particular in light of the recommendations contained in "Credible Science." This refusal raises questions about EPA's ability and desire to implement fully the reforms urged by "Credible Science."

It also is deeply disturbing that Administrator Reilly, who professed to be "proud" of "Credible Science," did not choose to abide by its recommendations in his own statements about the ETS risk assessment. As

noted, continuing the pattern of media hype and sensationalism that has marked every aspect of EPA's consideration of ETS, Administrator Reilly and HHS Secretary Sullivan held a joint press conference on January 7, 1993, announcing the finalization of the risk assessment. The press conference proceeded as though the "Credible Science" report and recommendations did not exist.

One of the important conclusions of "Credible Science" is that EPA has done a poor job in communicating with the public about the uncertainties in its determinations. In addition, the Agency's own guidance document emphasizes the importance of explaining fully scientific uncertainties in describing risks. At the January 1993 ETS press conference, however, the Administrator conveyed the clear impression that there is no uncertainty whatsoever so far as ETS is concerned -- that the risk assessment has shown "conclusively" that ETS exposure is responsible for approximately 3,000 cases of lung cancer among U.S. nonsmokers each year and specific numbers of respiratory problems among children.(31) The Administrator also made the ridiculous statement that "the risks associated with environmental tobacco smoke are at least an order of magnitude greater than they are for virtually any chemical or risk that EPA regulates."(32) Among other things, that statement cannot possibly be reconciled with Dr. Lippmann's earlier statement that the risk supposedly associated with ETS is less than the risk of a single trip through Washington traffic.

Finally, the Administrator disingenuously claimed that "[m]y philosophy is, first do the scientific analysis, and only then build the policy, determine the priority and devise the strategy based on a firm scientific foundation. With this report we have laid the firm foundation upon which policy can now be built."(33) The fact that EPA released, several years ago, a "Fact Sheet" and a draft policy guide recommending smoking bans and restrictions renders the Administrator's statement misleading at best.

Some may argue that applying a double standard to ETS is justifiable, or at least understandable, on the ground that the target of EPA's action is tobacco smoking. Regardless of one's personal beliefs about smoking, however, the spectacle of a huge, well-funded government bureaucracy with enormous power engaged in the deliberate manipulation of the public is profoundly disturbing.

Further, if policy decisions are not based on sound science, the integrity of both the political and the scientific processes suffers. As Dr. Feinstein has pointed out --

> [t]he "bad guys" * * * are not always right, but if they are denied a fair and proper scientific hearing, neither society nor science will benefit. Society is entitled to make political decisions based on advocacy. The scientific basis for those decisions however, should depend not on political advocacy, but on scholar-ship -- no matter how it is produced or by whom (p. 305).

These concerns are not limited to ETS. The suspicion that too many scientists and government officials are using "scare of the month" tactics to generate media attention and mobilize public opinion in support ofpersonal political agendas has fueled widespread public cynicism. At some point, people simply stop paying attention. As the public television program "Technopolitics" noted in its June 11, 1991, program on the first draft of the ETS risk assessment --

> [t]he question remains whether the public

> health scare now being created through leaked draft documents and emotional public appeals is real, or is the anti-smoking movement merely using bad science to organize the nonsmoking majority against the smoking minority?
>
> The record of the EPA is not reassuring. On one environmental concern after another, from Alar apples to acid rain to dioxin, the EPA has first put out alarming information and then backed off. Critics charge that the EPA is more interested in being politically correct than scientifically accurate.

In essence, EPA has declared war on smokers. Because of EPA's pursuit of sensational headlines at the expense of objective scientific evaluation, some smokers have lost their jobs and many employers are practicing overt discrimination in hiring and promotion based solely on whether a person smokes. People who think that such interference is unlikely to go beyond smoking should be warned: a report last year on the television show "20/20" indicated that moderate social drinking off the job and participation in employer-defined "dangerous activities" also have become targets of workplace discrimination policies. Can a government-sponsored "technical compendium" or "policy guide" on those subjects be far behind?

EPA's mandate to clean up the nation's air, water, and waste enjoys public support. But conduct by the Agency like its handling of ETS will continue to undermine that support unless the Agency decides to get serious about implementing the recommendations of "Credible Science." If EPA's leaders will not step up to the task of reforming from within, it will become necessary for Congress to do the job for them.

July 1993

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(1) Is EPA Blowing It's Own Smoke? - Investor's Business Daily, January 28, 1993. http://www.fumento.com/smokester.html

(2) Presentation by Richard Daynard, International Council for Coordinating Cancer Research: Conference on Cancer Prevention (February 1991) http://legacy.library.ucsf.edu/tid/qtq72f00/pdf

(3) S. Glantz: Achieving a Smokefree Society - Circulation, vol. 76, 1987 http://circ.ahajournals.org/cgi/reprint/76/4/746.pdf

(4) R.C. Brownson et al., Passive Smoking and Lung Cancer in Nonsmoking Women, Am. J. Pub. Health, vol. 82, pp. 1525-1530 (1992) http://www.ajph.org/cgi/reprint/82/11/1525.pdf

(5) Investor's Business Daily: http://www.fumento.com/smokester.html

(6) In addition to these deficiencies, classification of ETS as a Group A carcinogen cannot be reconciled with EPA's own "Guidelines for Carcinogen Risk Assessment." The Scientific Advisory Board that reviewed the risk assessment acknowledged that the document did not

adhere to the Agency's guidelines, but dismissed such concerns with the suggestion that the guidelines simply be changed. The report also selectively uses data that support its conclusions while omitting evidence that does not. For example, the report completely ignores workplace and male exposure data, which do not show any association between exposure to ETS and lung cancer.

Such treatment by both EPA and the SAB is unprecedented. No other substance has been classified as a Group A carcinogen in the face of a clear majority of epidemiologic studies showing no statistically significant association or on an assumed similarity with another substance. Other substances that have been considered for classification as known or probable human carcinogens, including electromagnetic fields and diesel exhaust, have been accompanied by considerably stronger evidence of carcinogenicity in both human and animal studies than ETS. Comparing those risk assessments to the ETS report only reinforces the view that the report is intended to support a policy decision to restrict ETS exposure and not to assess risk objectively.

(7) The risk assessment does not address the data concerning ETS exposure and cardiovascular disease. Two earlier documents prepared by EPA staff, however, an ETS "technical compendium" and a related "workplace policy guide," asserted that ETS exposure is a cause of cardiovascular disease. In fact, exposure to ETS has not been proven to cause or exacerbate cardiovascular disease among nonsmokers. In 1986, the U.S. Surgeon General and the National Academy of Sciences reviewed the data and concluded that there was insufficient evidence even of an association between ETS and cardiovascular disease. U.S. Surgeon General, "The Health Consequences of Involuntary Smoking," U.S. Department of Health and Human Services (1986); National Research Council, "Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects" (1986). No studies have been published since 1986 that would alter their conclusions.

(8) A. Feinstein, Critique of Review Article, Environmental Tobacco Smoke: Current Assessment and Future Directions - Toxicologic Pathology, vol. 20(2), pp. 303-305, 304 (1992) http://legacy.library.ucsf.edu/tid/lsv20a00/pdf

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(11) A.H. Lowrey and J.L. Repace, Indoor Air Pollution, Tobacco Smoke and Public Health - Science, vol. 208, pp. 464-472 (1980) http://legacy.library.ucsf.edu/tid/trd91f00/pdf

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C. Proctor, N. Warren, and M. Bevan, Measurements of ETS in an Air-Conditioned Office Building - Env. Tech. Lett., vol. 10, pp. 1003-1018 (1989) http://legacy.library.ucsf.edu/tid/xaa33e00/pdf

(13) Repace and Lowrey (1980), supra note 11, at 471.

(14) J.L. Repace and A.H. Lowrey, A Quantitative Estimate of Nonsmokers'

Lung Cancer Risk From Passive Smoking - Env. Int., vol. 11, pp. 3-22, at 12 (1985). This study was not funded or sponsored by EPA. Repace apparently undertook the study on his own initiative. The source of his funding has never been revealed.
http://legacy.library.ucsf.edu/tid/try22d00/pdf

(15) Reviews critical of the Repace and Lowrey risk assessment, calling their methodology and conclusions into question, were completed by EPA's Carcinogen Assessment Group prior to publication of the Repace and Lowrey paper:

E. Anderson: Repace and Lowrey's Estimate of the Lung Cancer Risk from Passive Smoking (undated);
H. Gibb: Repace and Lowrey's Estimate of the Nonsmokers' Lung Cancer Risk from Passive Smoking (undated)
http://legacy.library.ucsf.edu/tid/wtt20f00/pdf

In addition, the Repace and Lowrey paper was criticized by the Congressional Office of Technology Assessment in Passive Smoking in the Workplace: Selected Issues, pp. 21-22 (May 1986)

Other scientific articles criticizing the Repace and Lowrey risk assessment as well as their earlier work on ETS include:

A. Gross, Risk Assessment Relating to Environmental Tobacco Smoke, Environmental Tobacco Smoke - Proceedings of the International Symposium at McGill University, D.J. Ecobichon and J.M. Wu, (eds.), Lexington Books, Lexington, Mass., pp. 293-302 (1990)
http://legacy.library.ucsf.edu/tid/zep42d00/pdf

N. Balter et al: Causal Relationship Between Environmental Tobacco Smoke and Lung Cancer in Non-Smokers: A Critical Review of the Literature - Proceedings of the 79th Annual Meeting of the Air Pollution Control Association (1986)
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J.P. Vandenbrocke, Passive Smoking and Lung Cancer: A Publication Bias? - Br. Med. J. pp. 296, 390-391 (1988) http://www.bmj.com/cgi/reprint/296/6619/391.pdf

(17) Committee on the Institutional Means for Assessment of Risks to Public Health, National Academy of Sciences/National Research Council, Risk Assessment in the Federal Government: Managing the Process, p.151 (1983)

(18) This statement was contained in an undated background summary of the risk assessment entitled "Findings in a Nutshell," prepared by EPA sometime in mid-1991. The summary was given to the Occupational Safety and Health Administration, the federal agency that has authority to regulate indoor air quality in the workplace.

(19) According to his resume, Mr. Rosner has a bachelor of science degree in occupational therapy and a master's degree in business administration. His work experience includes jobs as a press intern, restaurant manager, recruitment coordinator of Big Brothers/Big Sisters of Tacoma, radio announcer, founder of an organization "to tackle Seattle's rising crime rate" and as Executive Director of the Smoking Policy Institute. Nothing in Mr. Rosner's education or professional background suggests that he is "uniquely" qualified to assess the "technical and scientific literature on tobacco smoke exposure and health impacts," as was claimed in an undated memorandum purporting to justify the award of the policy guide subcontract to SPI on a sole-source basis.

(20) A June 1991 Report by the House Subcommittee on Oversight and Investigations identifies ICF as one of EPA's ten largest contractors, with active contracts having a potential total value of more than $300 million. The Report notes that audits of ICF's work, performed for EPA by the Defense Contract Audit Agency, had found "numerous problems," including instances in which ICF billed EPA for subcontractor charges before ICF had paid the subcontractors (Report, p. 25). Apparently, EPA also has made it a practice to use ICF as a vehicle to provide subcontracts to consultants selected by EPA. As indicated earlier, EPA's cozy relationship with its contractors and negligent management practices in connection with contracting procedures have been the subject of an ongoing investigation by the Oversight Subcommittee.

(21) United States Environmental Protection Agency, Advisory Committee Charter, Science Advisory Board, November 6, 1987.

(22) The decision subsequently was reversed on legal grounds, although determinations concerning the persuasiveness of the expert testimony and other factual matters were left undisturbed. Le Procureur General du Canada v. RJR-MacDonald. Inc., No. 500-09-001296-912 (Quebec Court of Appeals, January 15, 1993)

(23) Impartial Panel for Smoking Study Proves Hard to Find, Los Angeles

Times, November 24, 1990, p. A-27.

(24) Drs. Benowitz, Blot, Eatough, Hammond, Kabat, Lebowitz, Samet and Weiss had been responsible for scientific studies concerning ETS cited in the first or second drafts of the risk assessment.

(25) Dr. Rockette, for example, observed that "there is this issue of the bias and potentially the systematic bias which the meta-analysis will not control for * * *. [Y]ou are dealing with an estimate of risk [of] about thirty percent * * *. [M]ost epidemiologists, if they did a single study where they got a thirty percent risk, even if it [were] statistically significant, [would] not be very excited about it" (II, p. 19). Even Dr. Samet concluded that "the [lung cancer] chapter falls far short of doing an adequate job of hazard identification and needs to go much further, in light of the Agency's guidelines on hazard identification * * *" (II, p. 30).

With respect to the quantitative risk estimates, the panel voiced even stronger doubts. Dr. Wesolowski stated that he thought "what we're hearing is that we are a little bit weak on exposure, to say the least, and there's going to be a need for a lot of research" (II, p. 82). Dr. Blot agreed, noting that "we're less sure than the chapter presents as to the actual numbers of lung cancer deaths that are due to environmental tobacco smoke * * * " (II, p. 87). He also felt that the inclusion of ex-smokers in the draft's risk estimates was "really poorly justified" (II, p. 94). Dr. Laties, one of the few panelists who actually had read the public comments, strongly recommended that a Japanese study by Dr. Hirayama be dropped based on what he characterized as "devastating" criticism by Dr. Kilpatrick, one of the outside scientists who had reviewed and commented on the draft (II, p. 99). EPA's risk estimates in the first draft depended heavily on this early, extremely controversial study.

(26) The second draft revealed for the first time that the authors of several of the chapters had acted as subcontractors to ICF Incorporated. As noted earlier, the EPA Inspector General has concluded that all of those subcontracts were awarded non-competitively and that at least two violated federal contracting procedures. In addition, as with the technical compendium and policy guide, some of the people who contributed to the revised ETS risk assessment are vocal antismoking activists. Judson Wells, who contributed an important appendix to the revised risk assessment on smoker misclassification rates, is a retired chemist who now devotes most if not all of his time to doing volunteer work for the American Lung Association on the ETS issue. Wells' claims about misclassification rates were of vital importance to the lung cancer conclusions of the revised risk assessment.

(27) Specifically, the revised risk assessment used a 90% confidence interval to judge statistical significance even though (1) a 95% confidence interval had been utilized in all of the underlying studies, (2) a 95% confidence interval is the more accepted measure and (3) EPA had not previously utilized a 90% standard in any previous risk assessment. EPA has never attempted to explain this departure from previous and accepted scientific practice. One commentator noted that "[t]o get scientifically valid data, there are very strict rules and requirements on how and when you can apply meta-analysis, and virtually all of them were violated in the EPA analysis." Investors' Business Daily, supra note 1.

(28) The draft report stated, for example, that "[t]his assumption [comparing MS and ETS to calculate lung cancer risks] may not be

tenable, * * * as MS and SS differ in the relative composition of carcinogens and other components identified in tobacco smoke and in their physicochemical properties in general * * *" (p. 6-6). The draft report also acknowledged that "[t]he concentration of smoke components inhaled by subjects exposed to ETS is small compared with that from active smoking. * * * Breathing patterns for inhalation of mainstream smoke and ETS differ considerably * * *. There are also important differences in the physicochemical properties of ETS and MS (see chapter 3). These have been extensively reviewed earlier by the National Research Council * * * and the Surgeon General * * *" (pp. 7-2; 7-3).

(29) As noted, EPA "stopped" in a most curious place. It fully incorporates data from a still incomplete study by Elizabeth Fontham and coworker while ignoring the much larger, complete and fully reported Brownson study -- which had been funded in part by NCI. In addition to having several years to run, Dr. Fontham and her group have not yet published any data on ETS/lung cancer confounding factors.

(30) Committee on the Institutional Means for Assessment of Risks to Public Health, National Academy of Sciences/National Research Council, Risk Assessment in the Federal Government, pp. 151, 153 (1983)

(31) Statement by William K. Reilly, Administrator, U.S. Environmental Protection Agency, on Environmental Tobacco Smoke, January 7, 1993, p. 1.

(32) Id. at 3.

(33) Id. at 4.