

EPA's Accuracy, Integrity Questioned Following Tobacco Smoke Report

The Environmental Protection Agency's (EPA) release of a report concerning the alleged effect of environmental tobacco smoke (ETS) on non-smokers was criticized by members of the media and scientific communities, with respect to the integrity and accuracy of the science the EPA relied upon.

A recent report in Investor's Business Daily stated that "many in the scientific and medical community say the data the EPA cites do not bear out its conclusion." (A complete copy of this article is enclosed with this edition of Caucus Notes.)

"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," said Bonner Cohen, senior editor of EPA Watch newsletter, which regularly monitors EPA activities.

Alfred P. Wehner, president of Biomedical Consultants Inc., in Richland, Washington said: "I did work for the EPA in the past and thought of them reasonably well, but when I saw [the ETS] report, I was really embarrassed. It was a bad document."

Such criticism comes on the heels of a recent audit by the Government Accounting Office, which found that the EPA was prone to conducting too little research, managing data poorly and allowing cost overruns in the billions of dollars. [see cover story]

The EPA has also not adequately explained why one of the largest and most recent studies on the subject of ETS, funded by the National Cancer Institute, was not included in its report. This study reported no overall risk for non-smoking women married to smokers.

Questions also remain as to

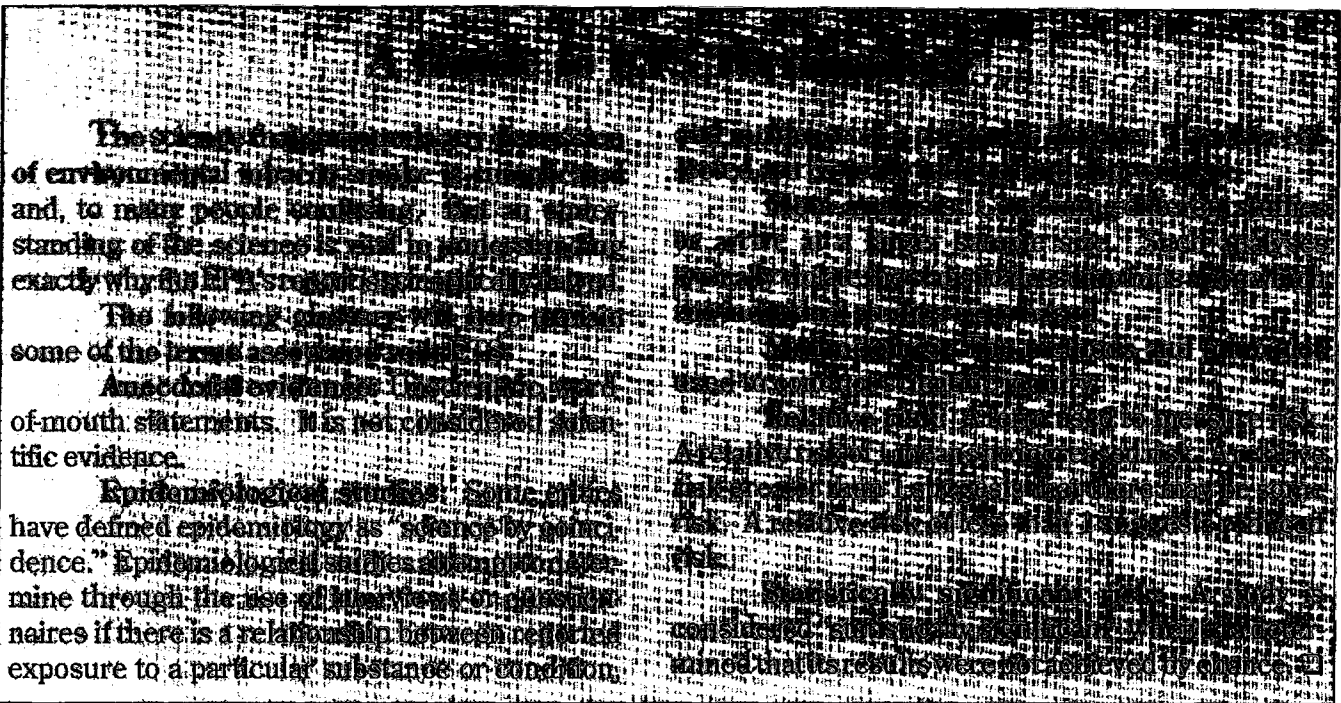
how the EPA reached its conclusion, in light of the fact that 24 of the 30 studies reviewed by the agency found no statistically significant risk of lung cancer in non-smokers based on exposure to ETS. The remaining six studies were conducted in foreign countries, where differences in diet and other lifestyle factors may have affected study results.

EPA Watch's Cohen suggests that the EPA's conclusions about tobacco smoke may have been based more out of a desire by the agency to increase its control of indoor air quality regulation, than in scientific accuracy. "The science of which EPA avails itself is that which happens to fit the political agenda of the moment.... The EPA was not unaware of the fact that the tobacco industry is an extremely appealing target with few allies in the public arena," he said.

The one certainty following the EPA's report on tobacco smoke, is that the available science is inconclusive. Until the EPA responds adequately to the serious charges raised against it, smokers and others who were alarmed by the EPA's report, should be skeptical of the agency's claims.

In the meantime, common courtesy and compromise, along with established smoking and non-smoking areas will remain central to satisfying both smokers and non-smokers. □





Science or Political Science?

The Environmental Protection Agency (EPA) has a poor track record for assessing risk. Over the years, the agency has claimed associations between serious disease and controversial products such as dioxin, radon and Alar. The EPA has also raised speculation about the safety of the water Americans use in their showers. These claims have later proven to be exaggerated or unproven.

Last year an independent panel of experts was commissioned by former EPA Administrator William Reilly to study the role of science at the agency. In its report, *"Safeguarding the Future: Credible Science, Credible Decisions,"* the panel posed the question, does the EPA present "the extremes of scientific opinion" because it "needs science to support its legal activities?"

For example, in 1986 the EPA estimated that thousands of Americans were likely to die from radon-induced lung cancer each year. And while the resulting scare spawned a booming industry for radon inspectors and radon detection kits, the mortality figures have not been substantiated. As Leonard Larsen wrote in *The Washington Times*, "All those Americans dead from radon

can't be found except in EPA statistics."

In 1982, 2,400 residents of Times Beach, Missouri were forced to evacuate their homes because the EPA concluded that their community had been contaminated by unacceptable levels of dioxin.

Only years later did the EPA admit to the 800 relocated families that the concentration levels of dioxin were not harmful. In an article for *Human Events* magazine, Richard Minter reports that the EPA regulates levels of radon at 15 parts per quadrillion, which is "the equivalent of a few drops of vermouth in a martini the size of Lake Erie."

The EPA has also stirred up health scares about Alar, a chemical often applied to apples. Apple growers suffered severe financial losses before the EPA's Science Advisory Board found that concerns about Alar had no scientific basis.

In April 1992, the EPA prepared a draft document on the alleged health risks of taking showers. The EPA also plans to make an assessment of the alleged dangers posed by power lawnmowers.

As the independent panel said in its final report, the "EPA has not always ensured that contrasting, reputable scientific views are well-explored and well-documented." □

Designated Areas Key to Public Smoking

When anti-smokers come armed with the latest EPA report on the alleged effects of ETS on non-smokers, separate accommodations for smokers and non-smokers take on a new urgency.

It is important to recognize that some non-smokers would prefer not to be around tobacco smoke, and these preferences must be acknowledged. On the other hand, when approximately one-third of all adults in the U.S. choose to smoke, the preferences of smokers must also be considered.

The Accommodation Program was developed by Philip Morris U.S.A. to help businesses satisfy the



**NON-SMOKERS
AND SMOKERS
WELCOME**

needs of smoking and non-smoking customers. The Program offers guidance for achieving acceptable indoor air quality in both smoking and non-smoking areas. The basic premise of The Accommodation Program is that properly designated smoking areas can help maximize

customer satisfaction.

Businesses participating in The Accommodation Program are easily identified by a bright red and green decal that informs customers that "Non-smokers and Smokers are Welcome." This message immediately lets customers know that whether or not they smoke, they will be accommodated in that establishment.

Any business owner is welcome to become a member of The Accommodation Program. Participating members are provided with extensive materials on how to maximize customer satisfaction by providing arrangements for smokers and non-smokers. For more information, interested business owners can write to:

The Accommodation Program
P.O. Box 8795
Kankakee, IL 60901-8795

As more and more businesses enroll in The Accommodation Program, legislators will hopefully realize that there is no need to pass laws to regulate public smoking. □

Anti-Smokers Likely to Use EPA Report to Push for Smoking Bans

Although the EPA's report on environmental tobacco smoke is based on questionable science, it is likely to result in increased pressure on elected officials, regulators and employers to toughen restrictions on smoking.

While the EPA has no authority to regulate workplace smoking, its report is already being cited by anti-smokers, members of the media and some elected officials as justification for broad smoking bans. The authority to regulate workplace smoking belongs to the Occupational Safety and Health Administration (OSHA). OSHA is currently conducting its own investigation into indoor air quality, and the impact of the EPA's report on that investigation remains to be seen.

Anti-smokers are hurriedly trying to persuade OSHA to issue a regulation prohibiting smoking from many workplaces, before the serious flaws in the EPA's report become widely known. Perhaps anti-smokers assume that the more doubt that is cast on the EPA's report, the less likely OSHA will be to regulate workplace smoking.

Smokers and others who are skeptical of the EPA's conclusions may want to write their elected officials and local newspaper editors to point out that the report on ETS is flawed. You may want to ask your legislators, before taking a position on the workplace smoking issue, to insist that the EPA address the serious deficiencies noted by the Government Accounting Office, that it manages data poorly and conducts too little research. □

HOTLINE

Let Us
Hear From You!

Please call our toll-free hotline
Monday through Friday from 9 a.m. until
6 p.m., EDT, to let us know about smok-
ing-related activities in your area.

1-800-231-1438

IS EPA BLOWING ITS OWN SMOKE?

How Much Science Is Behind Its Tobacco Finding?

By Michael Fumento
 In Los Angeles

"Taken together, the total weight of evidence is conclusive that environmental tobacco smoke increases the risk of lung cancer in nonsmokers."

So declared Environmental Protection Agency Administrator William Reilly at a news conference earlier this month, announcing the impending release of an EPA report attributing approximately 3,000 deaths a year to passive smoking, or environmental tobacco smoke.

Yet many in the scientific and medical community say the data the EPA cites does not bear out its conclusion.

While virtually all scientists agree that smoking is unhealthy — both for smokers and those around them — it's the degree to which smoking is unhealthy, and the way the government musters its scientific case, that raises questions.

Some scientists and policy analysts who say they couldn't care less about tobacco company profits or even the rights of smokers are worrying aloud that the EPA report is paving the way for justifying new health-based government regulations and programs without any real science behind them.

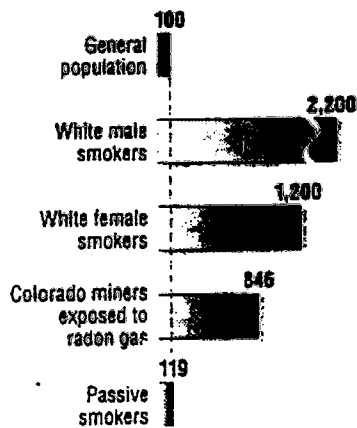
Said Bonner Cohen, editor of EPA Watch based in Chantilly, Va., "It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week, with the effect that once again, Americans are going to be stampeded into fearing a substance for reasons which upon close inspection are scientifically indefensible."

Yale University epidemiologist Alvan Feinstein, writing in the journal *Toxicological Pathology*, said he recently heard a prominent leader in epidemiology admit of the EPA's work on passive smoking: "Yes, it's rotten science, but it's in a worthy cause. It will help us to get rid of cigarettes and to become a smoke-free society."

Another critic, Alfred P. Wehner, president of Biomedical and Environmental Consultants Inc., in Richland, Wash., said: "I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

Smoking Gun?

Relative risk of lung cancer



Sources: EPA, National Research Council, American Cancer Society

One thing both sides agree on is that the direct policy ramifications of the EPA report could be tremendous.

"You can bet your next paycheck that OSHA (the Occupational Safety and Health Administration) will ban all smoking in the workplace," said John Shanahan, the environmental policy analyst at the Heritage Foundation.

Although, in unveiling the report, Reilly expressly referred to cancer in children and in the workplace, the statistical analysis in the EPA report actually ignored the studies that looked for such links.

Rather, the EPA survey is based on 11 American studies of spouses of smokers. The report discussed, but did not put into its statistical analysis, the results of 19 other studies done outside the U.S.

In its analysis of those 11 studies, the EPA found that there was a "statistically significant" difference in the number of lung cancers suffered by non-smoking spouses of smokers, equal to 119 such cancers in nonsmoking spouses of smokers compared to 100 lung cancers in nonsmoking spouses of non-smokers.

This finding of statistical significance allowed it to rank passive smoking as a Class A carcinogen, the highest risk ranking possible.

Statistical significance, while sounding like arcane academic talk, is actually quite important. It is used to account for the possibility that something happened

— in this case the 19 additional lung cancers — by chance.

But critics say that, using its own previous statistical standards, the EPA report shows no such significance.

"Frankly, I was embarrassed as a scientist with what they came up with. The main problem was the statistical handling of the data," said Wehner, who headed a panel of scientists and doctors that analyzed the draft version of the EPA report for the tobacco industry.

'Meta-Analysis'

One aspect of this problem, say critics, involves the combination of the 11 studies into one big group — what the EPA called a "meta-analysis."

The EPA has never before done this. Critics say such combinations may be valid, but if the studies weren't done in the same way, the results will be like comparing apples and oranges and pears.

Not everyone agrees.

"Meta-analysis is totally fair," said Stanton Glantz of the Institute of Health Policy Studies at the University of California, San Francisco. "I review reports like that for the State of California, and the work the EPA did is absolutely first rate, one of the best pieces of science I've seen about anything."

But Wehner said the study was faulty.

"To 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," he said.

'Confidence Intervals'

The 11 studies together actually reflected 10 studies that showed no statistically significant increases in cancer and only one that did. When the EPA says that the weight of 11 studies showed harm from passive smoking, it really meant one positive combined with 10 neutrals.

More important than the use of the meta-analysis, say critics, is the EPA's use, also for the first time, of a less rigorous statistical analysis.

Epidemiologists — those who study disease and accident patterns to establish why they occur — calculate "confidence intervals" to express the likelihood that a result could have happened strictly by chance.

A 95% confidence interval means that there is a 95% possibility that the result didn't happen from chance, or a 5% possibility that it did.

Until the passive smoking report, the EPA has always used a 95% confidence interval, as have most researchers doing epidemiological studies. Indeed, all of the individual ETS studies were published with 95% confidence intervals.

Yet, in its averaging of those ETS studies, the EPA decided to go with a 90% confidence interval.

"That doubles the chance of being wrong," explained James Enstrom, a professor of epidemiology at the University of California, Los Angeles.

Reilly said simply: "With respect to the confidence interval, we have here a 90% confidence level. And that was, in

fact, what was recommended to us by the scientific community as appropriate to this data." Repeated calls to the EPA to find out who in the scientific community had done so went unanswered.

'Hairsplitting' Factor

Glantz said the criticism of the change in the confidence level is a kind of "hairsplitting that only professors care about."

Many epidemiologists, however, disagree.

"In most cases, a scientist would never do this sort of thing," Enstrom said. "It's surprising that they would try to get away with it."

The bottom line is that such "hairsplitting" allowed the EPA to come to a totally different conclusion than it would have using its normal method.

It could now declare that the results of the American studies, when lumped together, were "statistically significant," a term of great importance to the medical community. At a 95% confidence interval, the result would not have been statistically significant and the EPA could not have labeled passive smoking a type A carcinogen.

Only one major newspaper or television news show covering the EPA announcement made any reference to this sudden change of policy:

Critics say this statistical maneuvering amounts to little other than moving the goal posts to ensure that a football that landed on the two-yard line would count as a touchdown.

"They're using it so they can get an effect," Enstrom said. "They're going all out to get something they can call significant."

Glantz responds, "There is nothing magical about (the 95%). I know that scientifically it's widely used, but there is a strong body of thought that people are too slavishly tied to 95%."

But critics say that noting that the original selection of 95% was arbitrary misses the point. It was arbitrary to make a football field 100 yards long, but once that's the standard, you can't change the length in the middle of a game.

"You cannot run science with the government changing the rules all the time," said Michael Gough, program manager for biological applications for the congressional Office of Technology Assessment.

'One-Tailed' Analysis

Glantz said that another statistical reporting change, using what is known as a "one-tailed" analysis as opposed to a two-tailed one, compensates for lowering the statistical confidence.

In fact, it actually reduces the confidence level even further, providing a greater chance of labeling something carcinogenic when it isn't.

Said Joel Hay, a health economist at the University of Southern California who teaches statistics, "In essence, that's more like going to an 85% level, which would triple the chance of a mistake due to chance.

"If they've done both, then they're obviously reaching for results," he said.

The tobacco industry charged that the EPA left out of its analysis a recent major study, released in the November American Journal of Public Health, which, if combined with the other 11 American studies, would have resulted in no statistically significant findings even using the moved goalposts.

Reilly responded to the charge by saying that the EPA report was too far along to include these latest findings.

But, "When one new study can throw it from nonsignificant to significant and another can throw it back again, you're not demonstrating a clear trend," said

Alan Gross, a professor of biostatistics at the Medical University of South Carolina in Charleston.

Enstrom notes that substances previously labeled carcinogens normally have been found to have a much greater difference between levels of cancer in those exposed and in those not exposed.

With lung cancer caused by direct or active cigarette smoking, for example, there may be 1,000 cancers compared to 100 for nonsmokers, as compared to the 119 per passive smoker the EPA found per 100 for nonsmokers.

Enstrom said, "For a heavy smoker exposed to asbestos, you can get up in the range of a relative risk of a hundred or more," meaning that for every 100 unexposed persons with lung cancer you find 10,000 exposed ones.

"With a disease like lung cancer and finding excess risk of only two or less, you really have to think about what you're doing with the data," he said. "To me, it's frightening that they could make such a case out of such a small risk factor when you've got so many variables."

Inexact Science

One problem with slicing the data so thinly as the EPA passive smoke study does is that epidemiology is not an exact science. A single variable unaccounted for can destroy a whole study.

According to Gary Huber, a doctor with the University of Texas Health Center in Tyler, "At least 20 confounding factors have been identified as important to the development of lung cancer. These include nutrition and dietary prevention, exposure to occupational carcinogens, exposure to various air pollution contaminants, genetic predisposition and family prevalence," among other factors.

"You're going to see huge lifestyle differences between (families with smokers and families with no smokers) generally," said Gross.

One of the 19 non-U.S. epidemiological studies that the EPA did not put into its data base, conducted by American and Chinese researchers in China, actually found a statistically significant

decrease in risk.

"When you change just one of the assumptions EPA made," said Wehner, "just one parameter, you can prove ETS saves lives — and, of course, that's just nonsense. But it demonstrates how easily results can vary when assumptions are changed only slightly."

EPA Watch's Cohen and other EPA critics think that the passive smoking report is just the latest in a litany of EPA abuses of science to achieve political ends — most prominently that of enlarging its own authority, especially to gain more control over indoor air regulation.

Cohen notes that while the EPA has attributed 5,000 lung cancer deaths a year to radioactive radon gas seeping up from the earth into houses, the epidemiological studies on household radon tend to show that houses with higher levels of the gas have lower levels of lung cancer.

Outside EPA Report's Warning

"The science of which EPA argues itself is that which happens to fit the political agenda of the moment," Cohen said. "Epidemiology didn't support its position on radon, so they ignored it."

Cohen notes that an outside report commissioned by the EPA released last year found that there was a wide perception that the agency's science was "adjusted to fit policy." He says that clearly, the EPA did not heed the report's warning.

"The EPA was not unaware of the fact that the tobacco industry is an extremely appealing target with few allies in the public arena," Cohen said.

"Further, the tobacco industry has cried wolf so many times that it doesn't have any credibility anymore."

But Enstrom says that "politically correct" science isn't science at all, and that regardless of how one feels about smoking and passive smoking, the EPA's tack is simply wrong.

"I don't think it bodes well for the field," Enstrom said. It's going to make it hard to distinguish a real (problem) from a manufactured one using statistical manipulation."



William Reilly

THE AMERICAN SPECTATOR

M
CC: RVPS
P. A. A. A. A.
with holding to
Fred Bond
Darryl McKim
John Perry
Chadwick
F. H. I.
W. Woodrum
7/15

April 1993

Hillary Polluted

“A foolish consistency is the hobgoblin of little minds.” Ralph Waldo Emerson observed, and it certainly has brought grief to the reformist couple now resident at 1600 Pennsylvania Avenue.

Just the other day Hillary Rodham Clinton (known as just Hillary Clinton on the campaign trail) promised to introduce organic foods into the White House and to ban tobacco from the premises, saying that neither she nor President Clinton smokes. Alas, the little minds of the Washington press corps produced recent pictures of Mr. Clinton majestically chomping down on a cigar of Churchillian immensity. Apparently he resorted to the dratted stogie repeatedly on his campaign plane. And so, to banish Emerson's hobgoblins, the White House rushed out deputy press secretary Lorraine Voles to explain: “He never smokes it—he kind of chews it.” Leave it to our youthful president to devise “safe smoking.”

Yet if Mrs. Clinton stands by her edict on organic foods and tobacco, consistency will as a consequence of dubious government findings lead to the banning of apples, cellular telephones, computers, hot showers, chlorinated water. The White House will be a truly restful place. Today the life expectancy of the average American living outside the White House in regions unpatrolled by Mrs. Clinton is, according to the National Center for Health Statistics, greater than ever before. In Mrs. Clinton's White House, peo-

ple may live forever. If she responds as scrupulously to other environmental advocacy groups as she has responded to the advocates of organic foods and the opponents of tobacco, the smokeless, appleless White House—free of pesticides, radon and noxious electromagnetic fields—can be renamed the Green House.

I have no doubt that tobacco is not a health food. But does not dignity and freedom require that we allow adults to decide for themselves what substances they will consume so long as those substances do not threaten public health or safety? Right now there are far greater risks circulating among us than tobacco. Consider AIDS, which is not just dangerous; it is lethal. Or consider the new



strains of tuberculosis now spreading through urban centers. They are contagious, can be spread by a mere cough, and assuredly can kill.

But we are told that tobacco smoke spread through the air by smokers who do not practice our youthful president's “safe smoking” is dangerous. The Environmental Protection Agency has produced a report arguing that a smoker's second-hand smoke increases the risk of lung cancer in nonsmokers and contributes to approximately 3,000 deaths annually. In truth, this report is another example of the EPA shaping scientific findings to support its own pre-conceived policies. The report, with all its shoddy science, will undoubtedly open the way for new health-based government regulations. Remarks Bonner Cohen of *EPA Watch* in Chantilly, Virginia, “It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week.”

To establish second-hand smoke as a killer of 3,000 hypothetical Americans, the EPA had to ignore the antithetical findings of a study sponsored by the National Cancer Institute. William Reilly, head of EPA, claimed his report was too far along to take into account those findings, but had he his report would not have been able to claim second-hand smoke as a carcinogen. Furthermore, the EPA report—in an unprecedented change in its statistical method—lowered the scientific threshold for declaring something a human carcinogen.

This politicization of science is going to keep Mrs. Clinton busy. Now that the EPA has lowered the standard of risk, not only can second-hand smoke be classified as a cancer risk but so can ordinary tap water, whose risk factor is twice that of second-hand smoke. The electromagnetic fields that emit from everyday consumer appliances such as electric blankets, hair dryers, computers, and cellular telephones make them up to four times as dangerous as second-hand smoke. And then there are all those fruits and vegetables seething with chemicals. Obviously, it is only a matter of time before the Clintons shut off the White House's electricity and settle down to growing their own peccas. □

JOHN SHANAHAN

The Environmental Protection Agency (EPA) may soon embark on a politically correct crusade against a popular target: the tobacco industry. If the crusade is successful, the likely result would be a ban on smoking in restaurants and the workplace to protect others from "secondary" smoke.

It is a crusade I well understand. As a nonsmoker who intensely dislikes the smell of other people's fumes, and as the father of a newborn daughter, I have strong personal objections to having my family subjected to secondary smoke. Yet, ironically, I cannot in good conscience condone EPA's crusade.

The Science Advisory Board (SAB) at EPA has recommended that EPA Administrator William Reilly list secondary smoke, bureaucratically known as environmental tobacco smoke (ETS), as a Class "A" carcinogen. The board based its recommendation on a yearlong review of the EPA data on the subject. Unfortunately, the board's recommendation was not based on standard scientific methods. Instead, it was based on methods specifically devised by EPA to yield the desired result: that secondary smoke causes cancer.

The study on ETS has ramifications beyond the smoking controversy. Why? Because this is the first major risk-assessment study conducted by EPA since the agency issued guidelines earlier this year — and already the EPA is ignoring its own guidelines.

This sets the wrong precedent. And the likely result already can be predicted: Other products similarly will be tarred as "carcinogens" using the same politically correct procedures.

For instance, EPA is now looking into the carcinogenic effects of taking showers. The alleged culprit is the small amount of gas released from volatile organic compounds in shower water. Obviously, most people would be concerned, if not horrified, at the prospect of EPA regulating their showers. Yet the methods used for the secondary-smoke assessment will partly determine the likelihood of such a possibility.

There are many basic problems with the Science Advisory Board's "science." The first problem is that

John Shanahan is an environmental and energy policy analyst at the Heritage Foundation.

Smoking under the gun



the EPA used a 90 percent confidence "interval" (which is a measure of scientific certainty) in its statistical analyses. Yet the standard confidence interval used by practically all scientists — including EPA scientists — is 95 percent. While lower confidence intervals theoretically can be used, answers derived from these lower confidence intervals are much less reliable. Consequently, scientists don't tend to use them.

The second problem is that the conclusions of the scientific advisory board may have been derived from incorrectly combining numerous dissimilar studies. In scientific inquiry, large studies are not always available, to provide researchers with accurate, reliable data upon which to form their conclusions. In such cases, scientists sometimes combine the statistical information from smaller studies to form a more reliable statistical picture. This process is known as meta-analysis. However, meta-analysis is not an appropriate analytical tool unless the smaller studies are all similarly structured.

Yet in the ETS assessment, the SAB did not provide any information

about the underlying studies used in the meta-analysis. There was no way, therefore, for independent researchers to verify whether the smaller studies were similarly structured.

Other problems with the EPA secondary-smoke assessment include: (1) overreliance on exposure data drawn from people's recollection of their exposure to other people's smoke over many decades, (2) bias in the data, due to a failure to properly account for dietary factors that affect cancer rates.

In addition, the EPA "study" already has been overtaken by events that suggest the board's conclusions should be re-evaluated. Within weeks of the Science Advisory Board's report, the National Cancer Institute (NCI) published the results of the largest study ever on secondary smoke. The study of 432 elderly female nonsmokers, which avoids most of the flaws in the EPA assessment, found little or no evidence to support the theory that secondary smoke causes cancer.

Specifically, the NCI study found "no increased risk of lung cancer was associated with childhood passive-smoke exposure," and no

link between cancer and exposure of a spouse to secondary smoke for less than 40 pack years (one pack per day for 40 years or two packs for 20 years). The study did find a statistically insignificant increase in cancer risk for spouses exposed for more than 40 pack years.

Obviously, if EPA declares secondary smoke a Class "A" carcinogen, the contentious debate over this issue will tilt in favor of anti-smokers. Thus, it is important whether EPA's science advisory board based its recommendation on sound science — or whether it was acting politically.

More important than the smoking issue, however, is the dangerous precedent being set. If government scientific findings do not adhere to traditional and rigorous scientific methods, then they will represent nothing more than the political leanings of those wielding a malleable tool.

If science is to be credible and valuable to the public-policy process, it must pass the test of critical scrutiny, whether we like the answers or not. Think about that the next time you're in the shower.

VIEWPOINTS

Cigarettes, politics and the Environmental Protection Agency



WILLIAM MURCHISON

So now there's a Democrat poised to take over the Environmental Protection Agency from Bill Reilly. She's Carol Browner, and the question is: Will anyone be able to tell the difference a year hence?

It's hard to see the Democrats mucking up EPA more thoroughly than the Bush Republicans have done. Though of course they can try. Ms. Browner is Vice Presidential Al Gore's former environmental aide. Mr. Gore sees the environment as seriously underregulated.

However, Mr. Reilly does, too. The transition from Bush Republicans to Clinton Democrats should be as smooth as glass at EPA, where it's hard to see the Clintonites carrying out very many political drive-by shootings from which

George Bush's men would have shrunk Mr. Reilly's regulatory passion shows constantly. What we have at the EPA might be called political science — science you shape and bend to fit a social agenda.

Everybody knows, for instance, that smoking is politically incorrect the environmental equivalent of endorsing Menge Schott's free-speech rights.

Well, the EPA's Science Advisory Board wants Mr. Reilly to lift secondary smoke — called, in bureaucratic circles, environmental tobacco smoke (ETS) — as a class "A" carcinogen; a big-time cancer-causer, that is.

I have discovered over the years that smoking is like gun control: No matter how impressively you marshal the evidence, you never convince the other side. Still, you make an impression by lowering the threshold of proof, as EPA did in assessing the risks attendant on breathing your neighbor's fumes.

Likewise, the EPA lumped together a variety of small studies that may or may not have been structured alike, who can tell. A larger, later-released study by the National Cancer Institute, using 432 nonsmoking women, shows at most a "small" connection between cancer and ETS. Yet Mr. Reilly's EPA wants to point a federal fire extinguisher at lighted cigarettes. A Class "A" carcinogen rating is serious business.

An in-house study last spring by the Expert Panel on the Role of Science at the EPA noted that, outside and inside the agency, EPA science is widely viewed as "adjusted to fit policy." Nothing new here, perhaps: Whenever on a jasmine-scented evening science and politics bed down together, you know the illegitimacy rate is about to jump. Matters are all the worse with the EPA, given the teeth-gritting zeal of the Gore gang, who rarely stop to count the economic cost of their nostrils.

Something else today's EPA has in mind for us is controlling indoor as well as outdoor air. You might have gathered as much from the agency's suspicious interest in environmental smoke. A Senate-passed bill last year, sure to be revived in the coming year, would have set up an Office of Indoor Air Quality, under the EPA's control. Lord help us!

University of Georgia economist Dwight R. Lee, in a paper issued by the National Center for Policy Analysis, says giving the EPA authority over indoor air "would be like giving a machine gun to a child." Most of the time, Mr. Lee says, you can remove toxic chemicals just by improving ventilation. Which is cheaper than certain techniques the EPA has come up with for cleaning the great outdoors. Some EPA regulations, Mr. Lee says, require companies to spend \$6.5 billion — yes, billion — for every life hypothetically — yes, hypothetically — saved.

Comes now, or soon will, Carol

Browner to command this bearding force of federal regulation. Can Democrats outregulate Republicans? Usually, although at the EPA it may be tough.

The curious thing is, Bill Clinton is trying, or says he is, to improve the economy, whose health depends now as ever on the ability of businessmen to invest in jobs and output rather than in the appeasement of regulators. The Clinton administration's mind is divided: Markets and mandates is what the administration appears to want. This could prove in due course the Clinton presidency's undoing. But let's not get too optimistic too soon. Bill Reilly hasn't even cleaned out his desk yet; Carol Browner and Al Gore are still assessing what taxes, what regulations are likeliest to save us from prosperity.

William Murchison's column is distributed by Creators Syndicate.

IS EPA BLOWING ITS OWN SMOKE?

How Much Science Is Behind Its Tobacco Finding?

By Michael Fumento
in Los Angeles

"Taken together, the total weight of evidence is conclusive that environmental tobacco smoke increases the risk of lung cancer in nonsmokers."

So declared Environmental Protection Agency Administrator William Reilly at a news conference earlier this month, announcing the impending release of an EPA report attributing approximately 3,000 deaths a year to passive smoking, or environmental tobacco smoke.

Yet many in the scientific and medical community say the data the EPA cites does not bear out its conclusion.

While virtually all scientists agree that smoking is unhealthy — both for smokers and those around them — it's the degree to which smoking is unhealthy, and the way the government musters its scientific case, that raises questions.

Some scientists and policy analysts who say they couldn't care less about tobacco company profits or even the rights of smokers are worrying aloud that the EPA report is paving the way for justifying new health-based government regulations and programs without any real science behind them.

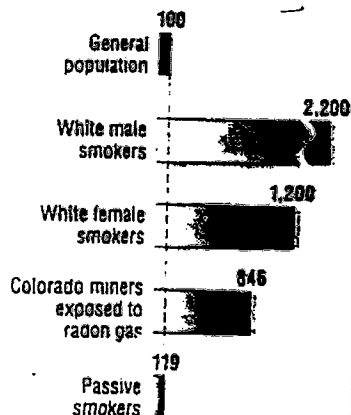
Said Bonner Cohen, editor of EPA Watch based in Chantilly, Va., "It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week, with the effect that once again, Americans are going to be stampeded into fearing a substance for reasons which upon close inspection are scientifically indefensible."

Yale University epidemiologist Alvan Feinstein, writing in the journal *Toxicological Pathology*, said he recently heard a prominent leader in epidemiology admit of the EPA's work on passive smoking: "Yes, it's rotten science, but it's in a worthy cause. It will help us to get rid of cigarettes and to become a smoke-free society."

Another critic, Alfred P. Wehner, president of Biomedical and Environmental Consultants Inc., in Richland, Wash., said: "I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

Smoking Gun?

Relative risk of lung cancer



Sources: EPA, National Research Council, American Cancer Society

One thing both sides agree on is that the direct policy ramifications of the EPA report could be tremendous.

"You can bet your next paycheck that OSHA (the Occupational Safety and Health Administration) will ban all smoking in the workplace," said John Shanahan, the environmental policy analyst at the Heritage Foundation.

Although, in unveiling the report, Reilly expressly referred to cancer in children and in the workplace, the statistical analysis in the EPA report actually ignored the studies that looked for such links.

Rather, the EPA survey is based on 11 American studies of spouses of smokers. The report discussed, but did not put into its statistical analysis, the results of 19 other studies done outside the U.S.

In its analysis of those 11 studies, the EPA found that there was a "statistically significant" difference in the number of lung cancers suffered by non-smoking spouses of smokers, equal to 119 such cancers in nonsmoking spouses of smokers compared to 100 lung cancers in nonsmoking spouses of non-smokers.

This finding of statistical significance allowed it to rank passive smoking as a Class A carcinogen, the highest risk ranking possible.

Statistical significance, while sounding like arcane academic talk, is actually quite important. It is used to account for the possibility that something happened

— in this case the 19 additional lung cancers — by chance.

But critics say that, using its own previous statistical standards, the EPA report shows no such significance.

"Frankly, I was embarrassed as a scientist with what they came up with. The main problem was the statistical handling of the data," said Wehner, who headed a panel of scientists and doctors that analyzed the draft version of the EPA report for the tobacco industry.

'Meta-Analysis'

One aspect of this problem, say critics, involves the combination of the 11 studies into one big group — what the EPA called a "meta-analysis."

The EPA has never before done this. Critics say such combinations may be valid, but if the studies weren't done in the same way, the results will be like comparing apples and oranges and pears.

Not everyone agrees.

"Meta-analysis is totally fair," said Stanton Glantz of the Institute of Health Policy Studies at the University of California, San Francisco. "I review reports like that for the State of California, and the work the EPA did is absolutely first rate, one of the best pieces of science I've seen about anything."

But Wehner said the study was faulty.

"To 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," he said.

'Confidence Intervals'

The 11 studies together actually reflected 10 studies that showed no statistically significant increases in cancer and only one that did. When the EPA says that the weight of 11 studies showed harm from passive smoking, it really meant one positive combined with 10 neutrals.

More important than the use of the meta-analysis, say critics, is the EPA's use, also for the first time, of a less rigorous statistical analysis.

Epidemiologists — those who study disease and accident patterns to establish why they occur — calculate "confidence intervals" to express the likelihood that a result could have happened strictly by chance.

Page 1 of 2

A 95% confidence interval means that there is a 95% possibility that the result didn't happen from chance, or a 5% possibility that it did.

Until the passive smoking report, the EPA has always used a 95% confidence interval, as have most researchers doing epidemiological studies. Indeed, all of the individual ETS studies were published with 95% confidence intervals.

Yet, in its averaging of those ETS studies, the EPA decided to go with a 90% confidence interval.

"That doubles the chance of being wrong," explained James Enstrom, a professor of epidemiology at the University of California, Los Angeles.

Reilly said simply: "With respect to the confidence interval, we have here a 90% confidence level. And that was, in

fact, what was recommended to us by the scientific community as appropriate to this data." Repeated calls to the EPA to find out who in the scientific community had done so went unanswered.

'Hairsplitting' Factor

Glantz said the criticism of the change in the confidence level is a kind of "hairsplitting that only professors care about."

Many epidemiologists, however, disagree.

"In most cases, a scientist would never do this sort of thing," Enstrom said. "It's surprising that they would try to get away with it."

The bottom line is that such "hairsplitting" allowed the EPA to come to a totally different conclusion than it would have using its normal method.

It could now declare that the results of the American studies, when lumped together, were "statistically significant," a term of great importance to the medical community. At a 95% confidence interval, the result would not have been statistically significant and the EPA could not have labeled passive smoking a type A carcinogen.

Only one major newspaper or television news show covering the EPA announcement made any reference to this sudden change of policy.

Critics say this statistical maneuvering amounts to little other than moving the goal posts to ensure that a football that landed on the two-yard line would count as a touchdown.

"They're using it so they can get an effect," Enstrom said. "They're going all out to get something they can call significant."

Glantz responds, "There is nothing magical about (the 95%). I know that scientifically it's widely used, but there is a strong body of thought that people are too slavishly tied to 95%."

But critics say that noting that the original selection of 95% was arbitrary misses the point. It was arbitrary to make a football field 100 yards long, but once that's the standard, you can't change the length in the middle of a game.

"You cannot run science with the government changing the rules all the time," said Michael Gough, program manager for biological applications for the congressional Office of Technology Assessment.

'One-Tailed' Analysis

Glantz said that another statistical reporting change, using what is known as a "one-tailed" analysis as opposed to a two-tailed one, compensates for lowering the statistical confidence.

In fact, it actually reduces the confidence level even further, providing a greater chance of labeling something carcinogenic when it isn't.

Said Joel Hay, a health economist at the University of Southern California who teaches statistics, "In essence, that's more like going to an 85%" level, which would triple the chance of a mistake due to chance.

"If they've done both, then they're obviously reaching for results," he said.

The tobacco industry charged that the EPA left out of its analysis a recent major study, released in the November American Journal of Public Health, which, if combined with the other 11 American studies, would have resulted in no statistically significant findings even using the moved goalposts.

Reilly responded to the charge by saying that the EPA report was too far along to include these latest findings.

But, "When one new study can throw it from nonsignificant to significant and another can throw it back again, you're not demonstrating a clear trend," said

Alan Gross, a professor of biostatistics at the Medical University of South Carolina in Charleston.

Enstrom notes that substances previously labeled carcinogens normally have been found to have a much greater difference between levels of cancer in those exposed and in those not exposed.

With lung cancer caused by direct or active cigarette smoking, for example, there may be 1,000 cancers compared to 100 for nonsmokers, as compared to the 119 per passive smoker the EPA found per 100 for nonsmokers.

Enstrom said, "For a heavy smoker exposed to asbestos, you can get up in the range of a relative risk of a hundred or more," meaning that for every 100 unexposed persons with lung cancer you find 10,000 exposed ones.

"With a disease like lung cancer and finding excess risk of only two or less, you really have to think about what you're doing with the data," he said.

"To me, it's frightening that they could make such a case out of such a small risk factor when you've got so many variables."

Inexact Science

One problem with slicing the data so thinly as the EPA passive smoke study does is that epidemiology is not an exact science. A single variable unaccounted for can destroy a whole study.

According to Gary Huber, a doctor with the University of Texas Health Center in Tyler, "At least 20 confounding factors have been identified as important to the development of lung cancer. These include nutrition and dietary prevention, exposure to occupational carcinogens, exposure to various air pollution contaminants, genetic predisposition and family prevalence," among other factors.

"You're going to see huge lifestyle differences between (families with smokers and families with no smokers) generally," said Gross.

One of the 19 non-U.S. epidemiological studies that the EPA did not put into its data base, conducted by American and Chinese researchers in China, actually found a statistically significant

decrease in risk.

"When you change just one of the assumptions EPA made," said Wehner, "just one parameter, you can prove ETS saves lives — and, of course, that's just nonsense. But it demonstrates how easily results can vary when assumptions are changed only slightly."

EPA Watch's Cohen and other EPA critics think that the passive smoking report is just the latest in a litany of EPA abuses of science to achieve political ends — most prominently that of enlarging its own authority, especially to gain more control over indoor air regulation.

Cohen notes that while the EPA has attributed 5,000 lung cancer deaths a year to radioactive radon gas seeping up from the earth into houses, the epidemiological studies on household radon tend to show that houses with higher levels of the gas have lower levels of lung cancer.

Outside EPA Report's Warning

"The science of which EPA avails itself is that which happens to fit the political agenda of the moment," Cohen said. "Epidemiology didn't support its position on radon, so they ignored it."

Cohen notes that an outside report commissioned by the EPA released last year found that there was a wide perception that the agency's science was "adjusted to fit policy." He says that clearly, the EPA did not heed the report's warning.

"The EPA was not unaware of the fact that the tobacco industry is an extremely appealing target with few allies in the public arena," Cohen said.

"Further, the tobacco industry has cried wolf so many times that it doesn't have any credibility anymore."

But Enstrom says that "politically correct" science isn't science at all, and that regardless of how one feels about smoking and passive smoking, the EPA's tack is simply wrong.

"I don't think it bodes well for the field," Enstrom said. "It's going to make it hard to distinguish a real (problem) from a manufactured one using statistical manipulation."



William Reilly