DRAFT PRESS RELEASE

Goal of Industry is Objective Review

Science does not support draft documents scheduled for review by experts

Washington, D.C. -- Major flaws in the scientific foundation and statistical analysis that form the basis of draft Environmental Protection Agency (EPA) documents on environmental tobacco smoke (ETS) will be pointed out tomorrow during a meeting of the EPA's Science Advisory Board.

The draft ETS documents and the composition of the Science Advisory Board panel that has been convened to review them have been the subject of considerable media attention and controversy. "It is ironic that press reports have charged that the current panel is 'slanted' in favor of the tobacco industry," said Brennan Dawson, vice president of The Tobacco Institute. "Such charges are demonstrably wrong," she said, adding that "not one of the panel members has ever demonstrated the slightest bias in the industry's favor with respect to ETS or any other issue."

"Despite the inaccurate media reports, our objective continues to be an open and impartial review of the scientific merits of the draft documents," Dawson said. "An objective review of the these documents will demonstrate that they have no sound scientific basis," she said.

In comments submitted to EPA in advance of the Board's meeting (an annotated list of scientific comments critical of the documents is enclosed), dozens of independent scientists have challenged fundamental and technical aspects of the draft documents.

During the public meeting, the Board will hear from key scientific experts with various areas of expertise. Among those scheduled to attend and present analyses of the draft documents are:

- Dr. Maurice E. LeVois, a highly experienced epidemiologist who has served at the Centers for Disease Control and has designed extensive health effects studies for the U.S. government. Dr. LeVois has detailed a number of important errors and omissions in the draft risk assessment, noting that the draft arbitrarily omits important epidemiological, dosimetric, medical and statistical evidence that conflicts with the conclusions reached by the EPA.

- Peter N. Lee, a British statistician whose work is frequently cited by the EPA in the risk assessment. Mr. Lee explains why the misclassification adjustment made by the EPA is mathematically incorrect, and because of this and other errors in methodology, the risk estimates are incorrect.

- Dr. Joseph Fleiss, head of the division of biostatistics at the Columbia University School of Public Health who has discussed a number of considerations that make meta-analysis an invalid tool for drawing conclusions about ETS.

While many flaws were pointed out during the public comment period -- and will be the topic of oral presentations to the Board -- several key issues demonstrate the lack of scientific justification for claims concerning ETS made in the draft documents and promulgated by anti-smoking activists:

o The draft ETS risk assessment is the first risk assessment ever conducted by EPA that is based entirely on epidemiologic evidence. The studies reviewed in the EPA report do not support the determination that ETS is a cause of lung cancer in nonsmokers. For example:

-- Of the 24 published studies on spousal smoking and nonsmoker lung cancer, the vast majority (19) have reported no statistically significant elevated risk associated with ETS exposure.

-- Even those few studies that have reported a statistically significant association between nonsmoking spouses and lung cancer report risk ratios that are weak at best -- all in the range that epidemiologists consider difficult to interpret because of the problems inherent in design and conduct.

o The draft report applies the procedure of "meta analysis" -- whereby a body of epidemiologic studies are combined to produce a single estimate of relative risk - incorrectly. For example:

-- Several studies -- all reporting no statistically significant association between marriage to a smoker and risk of lung cancer -- were omitted from the calculations.

-- The draft fails to calculate risk for the U.S. studies alone, despite the fact that it purports to estimate risk for the U.S. population. None of the existing nine U.S. studies have reported a statistically significant association between spousal smoking and lung cancer.

-- Combination of the U.S. and non-U.S. studies is unjustified as exposure levels, study bias and other lifestyle factors may vary greatly among cultures. Additionally, the discrepancy between a meta analysis of the U.S. studies (reporting no significant increase in risk) and non-U.S. studies is a serious inconsistency that casts further doubt on the draft documents.

o The reported risk in the draft document is flatly contrary to other evidence. For example:

-- The draft asserts that ETS exposure causes more than one-fourth of all female nonsmoker cancer deaths. If the assertion were correct, female nonsmoker lung cancer rates should have followed trends in cigarette sales and male smoking rates. There has, however, been no substantial increase in female nonsmoker lung cancer rates since 1950.

-- If the standard EPA method of risk estimation were employed (that of extrapolating effects observed at higher exposures to low exposures), a risk estimate is produced that is two to three orders of magnitude lower than the estimate in the draft risk assessment. This further inconsistency undermines confidence in the validity of the epidemiology.

The portions of the EPA's draft workplace policy guide that address health issue are also being reviewed by the Science Advisory Board. Many of the same scientific and broader indoor air quality issues have been raised about this document during the public comment process. The Board will hear from experts who will note that since there is inadequate data on ETS in the workplace, and since the risk assessment document cannot be scientifically supported, workplace guidelines from the EPA are inappropriate.

In sum, an objective and scientifically rigorous review of the evidence and techniques employed reveals that the EPA draft is an uncritical condensation of only selected studies from the scientific literature. The selectively chosen studies were then submitted to a series of highly speculative adjustments.

The fact that this risk analysis has been undertaken at all is surprising when the vast majority of the published studies -- and not a single U.S. study -- has reported a statistically significant association between ETS exposure and nonsmoker lung cancer. Given the inconsistencies and weaknesses in the data, it is not reasonable to infer that ETS exposure causes lung cancer, let alone to attempt to quantify or predict risk.

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