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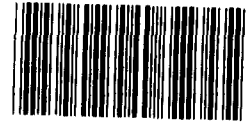
GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-251445

February 8, 1993



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The Honorable John D. Dingell
Chairman, Subcommittee
on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

In response to your request, we reviewed the public release by the Environmental Protection Agency (EPA) of three draft documents dealing with environmental tobacco smoke (or "passive smoking"). The three documents included (1) a compendium of existing scientific and technical information on passive smoking; (2) a risk assessment of the health effects of passive smoking; and (3) a guide to workplace smoking policies. You were concerned that the three documents prepared by EPA and contractors were made public before EPA's review of them was completed. This letter discusses the circumstances surrounding when and how these documents were made available to the public.

In summary, the technical compendium was prematurely released to an Associated Press reporter by an external reviewer before EPA completed its review. The risk assessment and the policy guide were not prematurely released and were made available for public comment when they were forwarded to EPA's Science Advisory Board for its peer review.¹

In April 1991 the EPA project manager responsible for the compendium sent a draft, without EPA management's approval,

¹The Science Advisory Board is an independent group of nonfederal government scientists and engineers who provide advice to the EPA Administrator on technical aspects of issues confronting the agency.

RESTRICTED--Not to be released outside the
General Accounting Office unless specifically
approved by the Office of Congressional
Relations.
RELEASED

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to several external reviewers for review. Subsequently the external reviewer who wrote the chapter on heart disease released the compendium to the Associated Press without EPA's approval. The author said he did this because EPA had already released an earlier version of the compendium to the Associated Press under the Freedom of Information Act and he did not believe he was releasing any new information.

According to EPA's Office of Air and Radiation and the Department of Health and Human Services (HHS) representatives who helped develop the document, EPA does not plan to publish or perform any additional work on the compendium. The Director of EPA's Indoor Air Division told us that additional work will not be performed because some of the compendium's data have become outdated and much of the remaining information was presented in EPA's risk assessment of the health effects of passive smoking that was released on January 7, 1993. As of January 7, 1993, the policy guide was scheduled to be reviewed by the Office of Management and Budget within a few weeks, and the new EPA administration will decide whether it will be issued.

BACKGROUND

In 1986 a report by the Surgeon General and a separate report by the National Research Council concluded that environmental tobacco smoke can cause lung cancer in nonsmokers, as well as an increase in respiratory infections and symptoms of irritation in children whose parents smoke. Following these two reports, in 1987 EPA and offices within HHS² embarked on an effort to produce a handbook on environmental tobacco smoke, compiling existing technical and scientific information. This handbook subsequently became known as a technical compendium and was originally planned to serve as the basis for policy documents. The Indoor Air Division within EPA's Office of Air and Radiation in 1988 asked EPA's Office of Research and Development to prepare an assessment of the risk of passive smoking for respiratory health. About the same time, EPA also contracted for support in developing a guide that would assist in establishing workplace smoking policies.

²Centers for Disease Control; The National Heart, Lung and Blood Institute; and the National Cancer Institute.

TECHNICAL COMPENDIUM
PREMATURELY RELEASED

In 1987 EPA and HHS decided to produce a handbook on environmental tobacco smoke, which became known as Environmental Tobacco Smoke: A Compendium of Technical Information. It was intended to be a compilation of existing scientific and technical information to be used by scientists, policy makers, and other technically trained persons in recommending health policies and smoking restrictions. It was not intended as an official document presenting EPA's position. From 1987 to 1989 authors suggested by EPA and HHS used existing scientific and technical information to write chapters presenting their personal views on a range of issues related to passive smoking, such as economics, policies, and exposure.

In 1989 EPA's Indoor Air Division sent 21 individuals the 10-chapter compendium and asked them to peer-review selected chapters; 3 additional individuals were asked to review the entire document. All 24 reviewers were selected by EPA and HHS representatives on the basis of their knowledge, expertise, or involvement in the particular area. One reviewer, a university professor and member of the school's cardiology division, suggested a chapter on the effects of passive smoking on heart disease. According to the project manager, because the reviewer was on the staff of a highly respected division of cardiology at the University of California at San Francisco and had worked on a number of smoking-related issues, EPA agreed to let him draft a chapter.

In May and November 1990 EPA approved two Freedom of Information Act requests for copies of the technical compendium, including one from the Associated Press. According to the Director of the Indoor Air Division, neither of these draft documents contained the chapter discussing heart disease.

In April 1991 a draft that included the heart disease chapter and a cover letter was sent to representatives of HHS, the author of the heart disease chapter, and two other reviewers. These reviewers were selected on the basis of their expertise related to the added heart disease chapter. According to the Director of the Indoor Air Division, the cover letter improperly characterized the draft as basically complete and ready to go except for final policy review and

clearance by HHS. He said the cover letter should have included a disclaimer, such as:

This document is a preliminary draft. Do not cite or quote. The contents represent only the views of the individual chapter authors. It should not be construed as representing the views or policies of the participating organizations.

According to the author of the chapter on heart disease, an Associated Press reporter who contacted him said that EPA had already provided him with a copy of the initial draft and requested a copy of the compendium that included the heart disease chapter. Although in retrospect the author acknowledges that it was a mistake to have released the compendium, he said his decision to release it was not influenced by the lack of a disclaimer or the cover letter. He cited EPA's release of an earlier version of the compendium to the reporter under the Freedom of Information Act as his primary reason for releasing the document.

In mid-1991 representatives from EPA and HHS met to discuss future plans for the compendium. Although some of the HHS representatives believed the document should have been published, representatives from both offices questioned the value of issuing the document because EPA was preparing to update and present most of the compendium information in its risk assessment. Additionally, representatives from HHS' National Heart, Lung and Blood Institute were not aware that their office would be listed as a sponsor of the compendium and were concerned because they had not reviewed it.

According to HHS representatives, the final decision on the compendium's future was left to EPA. EPA was concerned that, although the document could be issued with a disclaimer stating that it does not represent EPA's views or policies, the public might still consider it as representing EPA policy. In view of these concerns, EPA's Administrator decided in April 1992 not to publish or perform any more work on the technical compendium.

RISK ASSESSMENT AND POLICY GUIDE WERE
PROPERLY RELEASED FOR PUBLIC COMMENT

Two of the three environmental tobacco smoke documents were released for public comment when they were forwarded to the Science Advisory Board for review. One document, entitled Respiratory Health Effects of Passive Smoking: Lung Cancer

and Other Disorders, is intended to be a scientifically objective assessment of the respiratory health effects of passive smoking. Prepared by EPA's Office of Research and Development with contractual assistance, the document states that passive smoking should be classified as a Group A carcinogen,³ in accordance with EPA's risk assessment guidelines. It also estimates the number of annual lung cancer deaths attributable to passive smoking and discusses the connection between passive smoking and respiratory ailments in children.

The other document, entitled Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies, is intended to help policy makers mitigate exposure to passive smoking and is not a debate on its health effects. Developed by EPA's Indoor Air Division with contracted help, the draft describes technical and policy options for fairly instituting effective smoking restrictions.

In November 1990 EPA submitted drafts of the risk assessment and policy guide to its Science Advisory Board for peer review. When this action was taken, the documents also became available for public review and comment. Comments from the public were summarized and provided to the Science Advisory Board for its consideration. The draft assessment was reviewed again by the Science Advisory Board on July 21-22, 1992. The Board concurred that passive smoking was a Group A carcinogen, recommended certain revisions and additions, and stated that EPA had a basis for issuing the document. EPA released the risk assessment in final form on January 7, 1993.

The Science Advisory Board found the draft policy guide's technical content to be correct and appropriate, although the guide needed some revisions. Although the policy guide is still in draft and subject to revision, EPA decided to begin developing a brochure for the general public discussing the findings and implications of the risk assessment. According to EPA, because the brochure and policy guide relate to policy issues, EPA and the Office of Management and Budget will review them before their release.

³A cancer-causing agent in humans.

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We discussed information contained in this letter with EPA officials, including the Director of the Indoor Air Division within EPA's Office of Air and Radiation and the Chief of Staff to the Assistant Administrator of the Office of Research and Development. These officials agreed with the factual content, and we have incorporated their comments where appropriate. As agreed with your office, we did not obtain official agency comments.

Our review focused on EPA documents and correspondence related to passive smoking. In the course of that work, we interviewed personnel and obtained documents from EPA's Office of Air and Radiation, in Washington, D.C., and Office of Research and Development, in Washington, D.C., and Research Triangle Park, North Carolina. We also met with officials from HHS and interviewed the author who released the compendium to the Associated Press. In response to subsequent discussions with your office, we are examining EPA's agencywide peer-review procedures. As part of this examination, we are looking for opportunities that EPA could use to strengthen the peer-review process.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this correspondence until 30 days from the date of this letter. At that time, we will send copies to the Administrator of EPA. We hope that this information will assist you in your continuing effort to monitor EPA's peer-review process. If you have any further questions about this matter, please contact me on (202) 275-6111 or William McGee, Assistant Director, on (919) 829-3500.

Sincerely yours,



Richard L. Hembra
Director, Environmental
Protection Issues

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