29455
125277


125277

UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

FOR RELEASE ON DELIVERY
EXPECTED AT 10:00 A.M. EDT
October 1, 1984

STATEMENT OF
J. DEXTER PEACH, DIRECTOR
RESOURCES, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE

ON
EPA'S DEVELOPMENT OF THE
CARBON MONOXIDE STANDARDS

Mr. Chairman and members of the Subcommittee:

We are pleased to be here today to discuss our review of the Environmental Protection Agency's (EPA's) development of its carbon monoxide standards.

Concerned about the quality of research supporting these standards, the Chairman, Subcommittee on Oversight and Investigations, asked us to provide information on several aspects of EPA's carbon monoxide research base, including actions taken by several federal agencies concerning a researcher whose studies were key to EPA's proposed standards. We have recently released our report[1] which discusses these issues. Although our report does not contain conclusions and recommendations, at the Chairman's request we have included several observations in this testimony which flow from our work.

[1] Status of EPA's Air Quality Standards for Carbon Monoxide (GAO/RCED-84-201, September 27, 1984).

030205

Perhaps the best way for me to proceed is to discuss the two major questions that we addressed in our review.

--What research is EPA using to support its carbon monoxide standards?

--How did the communication between EPA, the Food and Drug Administration (FDA), and the Veterans Administration (VA) affect the development of EPA's carbon monoxide standards?

Let me first provide a brief background of the actions EPA has taken to date concerning carbon monoxide and conclude with the observations which flow from our work.

BACKGROUND

The Clean Air Act of 1970 required EPA to establish national air quality standards to protect the public health or welfare. In 1977, the Congress amended this act to require EPA to review and, if necessary, revise all air quality standards before the end of 1980 and at 5-year intervals thereafter. Carbon monoxide is one of the pollutants that EPA has regulated under the act. Carbon monoxide is toxic because of its tendency to bind with hemoglobin in the blood to form carboxyhemoglobin, a substance that reduces the blood's capacity to carry oxygen.

EPA initially issued carbon monoxide standards in 1971 and in August 1980 proposed revisions to those standards. After considering various alternatives, EPA was about to issue the revised standards when it learned in 1983 that its primary researcher, Dr. Wilbert S. Aronow, had been investigated by VA and FDA for, among other things, alleged falsification of research results. Dr. Aronow was employed as a cardiologist at the VA

Medical Center in Long Beach, California, from 1964 until he resigned in 1982. From 1973 he served as Chief of the Medical Center's Cardiovascular Section.

The results of the VA and FDA investigations of Dr. Aronow raised doubts about seven of the eight key studies used by EPA to support its proposed revision to the standards. For this and other reasons, EPA has not yet issued the revised standards as called for in the 1977 amendments to the Clean Air Act.

RESEARCH BASE SUPPORTING EPA'S CARBON MONOXIDE STANDARDS

The carbon monoxide standards established in 1971 were based primarily on a study which suggested that low-level carbon monoxide exposure would affect the central nervous system. Subsequent to 1971, several researchers attempted unsuccessfully to replicate this study, raising questions about its reliability. EPA recognized the limitations of its data regarding carbon monoxide's effect on the nervous system, but took no action to change the standards during the 1970's because new studies conducted during this period showed that the standards were still needed to protect people with certain heart conditions. These studies were conducted primarily by Dr. Aronow and showed that low levels of carbon monoxide exposure had an adverse effect on the cardiovascular system, specifically on angina patients.

Based primarily on these studies, EPA was about to issue revised carbon monoxide standards when the Washington Post published an article in March 1983 concerning an FDA investigation of Dr. Aronow's drug-related research. Because of the potential

implications of this investigation for all of Dr. Aronow's research, EPA delayed issuing the standards and assembled a peer review committee of experts in April 1983 to evaluate Dr. Aronow's carbon monoxide research. The committee conducted an audit of his available research data and expressed concern about the validity of results reported. They concluded that EPA could not rely on Dr. Aronow's data and recommended that similar carbon monoxide research be conducted by other independent research groups.

With Dr. Aronow's research in question, EPA was left with one other study (published in 1973 by Dr. Einar Anderson and four coresearchers) that supported its proposed revisions to the carbon monoxide standards. Although this study demonstrates that low levels of carbon monoxide adversely affect the health of angina patients, it has been criticized by various business organizations and state and local governments. Their concerns relate primarily to the methodology used in the study and the fact that it has not been replicated. EPA, therefore, has recently assessed the study and concluded that it does have some flaws and should be replicated, but is, nevertheless, scientifically valid.

Consequently, EPA believes that this study and three other carbon monoxide studies--which show that low levels of carbon monoxide exposure affect the endurance of healthy subjects--provide a sufficient basis to support a proposed revision to the carbon monoxide standards. This assessment is supported by EPA's Clean Air Science Advisory Committee.[2] In May 1984, this

[2]A committee of experts who advise EPA on the scientific bases for air quality standards.

Committee concluded that even without the Aronow studies, there remains a sufficient and scientifically adequate basis on which to issue final carbon monoxide standards. Nevertheless, EPA is sponsoring additional carbon monoxide research that is designed either to further support its research base or replicate and validate the Aronow studies. The results of these additional studies are expected to be available by late 1985 or early 1986.

On August 9, 1984, EPA published a notice in the Federal Register that stated that EPA is inclined to promulgate the revised standards. The notice includes a description of EPA's rationale for believing that the scientific data now available support issuance of the revised standards. It also discusses the uncertainties of the Aronow research but indicates that this research is still being considered along with other uncertain factors in establishing the revised standards so that an adequate margin of safty is provided to protect the public. EPA's decision to request further comments, however, relates directly to the questions raised about EPA's supporting scientific evidence. After receiving the comments, EPA will decide whether to issue the standards as proposed, revise them, or wait until results of the ongoing research are available.

COMMUNICATION BETWEEN EPA, VA, AND FDA REGARDING CARBON MONOXIDE RESEARCH

While employed at VA, Dr. Aronow also conducted research on certain new drugs for pharmaceutical companies. VA normally allows this type of research if it is approved in advance by the VA medical center where the research is to be conducted. In June

1979 while reviewing an application to approve the use of certain drugs, FDA began an inspection of some of Dr. Aronow's drug research. This inspection disclosed a number of problems, including incorrect patient selection, conflicting data, and possible falsification of records. In October 1979 FDA provided the VA Inspector General's office with a report of its inspection. A subsequent VA review of Dr. Aronow's research resulted in VA directing him to discontinue all research activities. In addition, FDA and Dr. Aronow signed a consent agreement in October 1982 limiting Dr. Aronow's access to certain new drugs and his right to serve as a clinical investigator of those drugs. FDA also placed Dr. Aronow's name on a list of those who have agreed to restrict or cease their role as investigator of these drugs for pharmaceutical firms.

During the 1979-80 time frame, EPA was attempting to establish an interagency agreement with VA under which Dr. Aronow would conduct carbon monoxide exposure research. EPA signed the interagency agreement on October 9, 1979, and sent it to VA for approval in January 1980. Dr. Aronow conducted the research between November 1979 and January 1980.

In August 1980 there were written and telephone contacts between VA and EPA regarding the proposed interagency agreement. For example, a letter dated August 7, 1980, from an EPA project officer to VA's Assistant Chief Medical Director for Research and Development requested that VA sign the interagency agreement. The letter expressed appreciation for Dr. Aronow's efforts and stated that Dr. Aronow's research was of extreme importance to EPA in its

regulatory decision-making process. At that time VA declined to approve the agreement because Dr. Aronow had already completed the research using VA funding. In reviewing these contacts we could find no indication that anyone in VA notified EPA of problems with Dr. Aronow's research. In explaining this lack of notification, VA told us that it considered the problems concerning Dr. Aronow to be an internal personnel matter and that VA had no reason to doubt the quality of Dr. Aronow's carbon monoxide research. Therefore, unaware of the VA and FDA investigations, EPA began using the results of Dr. Aronow's studies to develop the revised carbon monoxide standards.

FDA, however, did send a letter to EPA in July 1982 concerning its inspection of Dr. Aronow's drug research. The letter was sent after an FDA official read an EPA Federal Register notice requesting comments on Dr. Aronow's carbon monoxide research. However, because of a series of apparent miscommunications within EPA, officials in the office responsible for developing the carbon monoxide standards told us that they never received the letter. These officials told us that, if they had received the FDA letter or had any earlier indication of Dr. Aronow's research problems, they would have begun at that time to audit his research data and reexamine the data base supporting the proposed standards.

Observations

Based on our review of the events surrounding EPA's development of its carbon monoxide standards, we have some general observations about how EPA might avoid this type of problem in the future and on VA's decision not to inform EPA about Dr. Aronow's research problems.

Part of EPA's difficulties in developing the revised carbon monoxide standards resulted from its decision not to replicate or otherwise verify the key research supporting the revised standards. This is particularly important since most of the research was conducted by one individual. EPA officials and various researchers have stressed the importance of replicating key studies to further validate the results, particularly when these studies are used in establishing standards. However, because of Dr. Aronow's reputation as a renowned cardiologist, EPA did not have other independent researchers replicate those studies.

Because our review focused only on EPA's carbon monoxide standards, we do not know how widespread these data reliance problems are. However, in those instances where EPA can identify a key study or studies that demonstrate results that are critical for setting standards, the EPA Administrator should consider using a data audit--like that conducted on the Aronow studies--to verify the quality of the key study's results. Where he deems it appropriate, the Administrator should also, as an option, consider sponsoring additional studies to replicate the key study in question.

The Administrator also needs to evaluate carefully the public comments he receives on the adequacy of the scientific information now available to support the carbon monoxide standards in the form currently proposed. Given the serious questions raised about the Aronow research and what appear to be legitimate questions about the applicability of other available research to

the standard-setting process, careful consideration and resolution of issues that may be raised by public comment is essential to deciding whether to issue the standards as proposed or to select another alternative.

Concerning VA's communications with EPA, we believe that VA officials clearly erred in judgment by not informing EPA of the circumstances concerning Dr. Aronow. The information we have included in our report shows that VA had knowledge of potential problems with Dr. Aronow's research as early as October 1979, when FDA transmitted its inspection findings to VA. Also, by late 1980, VA had completed its own investigations of Dr. Aronow's research and had restricted his research privileges. During this time VA officials also knew of Dr. Aronow's carbon monoxide research and its importance to EPA. Yet, they decided not to notify EPA because they considered the situation an internal personnel matter.

On the other hand, FDA notified EPA of its concerns as soon as it learned that EPA was relying on Dr. Aronow's research to establish carbon monoxide standards. Although, this notification never found its way to the appropriate EPA office, FDA at least believed it had an obligation to share the information with EPA and acted on that belief.

While it is difficult for us to make specific suggestions that agencies use sound judgment, we believe that VA's

Administrator, at a minimum, should review any VA guidelines or instructions that could either be reemphasized or clarified to help prevent a similar situation from occurring in the future.

- - - - -

Mr. Chairman, this concludes my prepared statement. We would be glad to respond to your questions.