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Statement of

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16. Abstract (Limit: 200 words) This testimony concerned the report of the General Accounting Office (GAO) on how NIOSH and OSHA have met their responsibilities for setting new health standards for workers in the United States. GAO concluded that faster standards development was needed to protect workers exposed to toxic substances. Four major areas of concern have been raised from the GAO report and were responded to in this testimony. These four included criteria document publication, priority setting, carcinogen policy, and general research. Criteria Documents contained recommended environmental limits for workers exposed to a particular substance, group of substances, or physical agents; they also contained the rationale for that limit and other relevant information. Since 1972, 62 Criteria Documents have been transmitted to the Department of Labor. There were difficulties in synchronizing efforts between NIOSH and OSHA. The setting of priorities for research was constantly being revised, based on new information as it is received. NIOSH supported the recommendation from GAO that a uniform policy be established for identifying and regulating cancer causing chemicals. Scientific opinion on the kind of evidence used in classifying a substance as a human carcinogen has been changing over the years and NIOSH policy has reflected these changes. A statement of progress in analyzing the adequacy of the material safety data sheets as collected by the General Services Administration was included. ←					
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Madam Chairman and Members of the Subcommittee:

I am Dr. John F. Finklea, Director of the National Institute for Occupational Safety and Health (NIOSH), administered by the Center for Disease Control within the Department of Health, Education, and Welfare. Accompanying me today are Mr. Ronald F. Coene, Director of the NIOSH Office of Program Planning and Evaluation, and Mr. David S. Sundin, Chief of the Hazard Section of the Division of Surveillance, Hazard Evaluations, and Field Studies. We welcome the interest this Committee has shown in our program, particularly in the area of reducing chemical hazards in the workplace.

When the Occupational Safety and Health Act was passed in 1970, NIOSH and OSHA were given Federal responsibility for assuring safe and healthful workplaces for American men and women. The Senate Report on that act recognized the complexity of the task we had been assigned: "Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with.... New processes and new sources of energy present occupational health problems of unprecedented complexity." Congress intended that NIOSH and OSHA work cooperatively toward the same goal, yet gave them separate and distinct responsibilities. OSHA is the regulatory agency, charged with setting and enforcing occupational safety and health standards. NIOSH is the research agency responsible for developing new occupational safety and health information, recommending standards, and providing technical assistance in evaluating employee exposures. The agencies share manpower and training responsibilities.

We are pleased to appear before you today to discuss the report of the General Accounting Office (GAO) on how NIOSH and OSHA have met their

responsibilities for setting new health standards. GAO concluded that faster standards development is needed to protect workers exposed to toxic substances. We carefully reviewed the draft report and provided extensive comments to GAO, some of which were reflected in the final report. We will discuss the four major topics in the report that relate to NIOSH: criteria document production, priority setting, carcinogen policy, and general research.

Criteria Document Production

NIOSH's recommendations for occupational safety and health standards are generally transmitted to the Department of Labor in the form of a criteria document. This document contains the recommended environmental limit for worker exposure to a particular substance, group of substances, or physical agent. In addition to an environmental limit, the document contains the rationale for that limit as well as other relevant information on medical monitoring, labeling and posting, personal protective equipment and clothing, work practices and engineering controls, sampling and analytical methods, and recordkeeping requirements.

Since 1972, we have transmitted 62 criteria documents to the Department of Labor. In developing a criteria document we attempt to review all information relevant to substances covered by the document and conduct thorough internal and external reviews. Consultants from industry, other Federal agencies, State and local governments, organized labor, universities, and professional societies often participate in external review of our documents. NIOSH has made dramatic progress in reducing the average time it takes to produce a criteria document to the present 13 months per document. For fiscal years 1972 to 1975, NIOSH only transmitted from 5 to 7 criteria documents a year to the Department of Labor. In

fiscal year 1976, we transmitted 29 criteria documents. Our current schedule calls for 24 documents a year.

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Increasingly, we are developing single documents covering groups of substances with similar chemical, toxicological or pharmacological characteristics. We are also developing documents on industrial processes such as coal gasification, coal liquefaction, roofing, and welding. These process documents will be based on a number of single hazard criteria documents which we will update and relate to specific industrial processes.

We are presently developing a criteria document that will contain a recommended standard for exposure to pesticides during their manufacture and formulation. This document will provide recommendations covering all 1,800 pesticides listed in the 1976 edition of the NIOSH Registry of Toxic Effects of Chemical Substances. Of the 96 criteria documents planned for fiscal years 1978-1981, 24 will deal with single chemical compounds and the remaining 72 will cover groups of compounds. Based on these estimates, we expect that in addition to the 1,800 pesticides previously mentioned, the NIOSH criteria documents oriented toward groups of hazards, and processes or industries will cover more than 3,000 hazards by 1981. Thus, the Institute will be developing recommended health standards which will apply to over 4,800 chemical and physical agents during this period.

This increase in criteria document production has been made possible, in part, by the NIOSH program progress reporting system. This system has been improved each year to the point where we consider it to be highly effective both in monitoring progress and providing a stimulus for greater effort.

Four "critical" milestones are identified for each criteria document. They are: starting date, completion of first draft, completion of final

draft, and transmission to the Department of Labor. Quarterly progress reports show completed milestones and a rescheduling of missed milestones with a reason for delay. I meet during each quarter with NIOSH office and division directors to discuss these reports and am also advised of major problems as they emerge. A more detailed tracking system is also maintained that identifies more than 40 events, with dates, in the development of each document.

It has always been our policy to invite OSHA to participate during our criteria document reviews. Furthermore, we have offered OSHA our assistance in translating criteria documents into occupational health standards. We have conducted research to answer their specific questions that have arisen during the standards development process for lead, cotton dust, benzene, sulfur dioxide and beryllium. We have also provided experts to testify at OSHA public hearings and assist in the questioning of witnesses.

We would agree with GAO, however, that NIOSH and OSHA have had difficulty synchronizing their efforts in developing standards. We will work closely with the present Assistant Secretary of Labor for Occupational Safety and Health, Dr. Eula Bingham, and her staff to resolve any remaining problems in this area. We have been meeting monthly with OSHA and these meetings at the policy level and at the working level have proven helpful in coordinating our programs. We also have many staff level contacts outside the context of these regular meetings. We believe it is important to coordinate our work in this area so that standards can be established which effectively control workplace exposures. We do not agree, however, that the number of our criteria documents should be limited to the number of standards that OSHA is able to promulgate. Criteria documents have a

value even before being translated into enforceable standards. They are widely distributed and many companies use them as a basis to control hazards even though the documents do not have the force of law. They provide a thorough review of the existing literature and state of knowledge on a hazard and serve as an impetus for further research by NIOSH and others. They are also being utilized by other government agencies and by international bodies such as the World Health Organization as the basis for setting international permissible limits for occupational exposures.

Priority Setting

When NIOSH began to develop criteria documents we found it necessary to establish priorities to determine which of the thousands of physical and chemical hazards we should focus on first. Originally, our priority system consisted of estimating the number of workers potentially exposed to a hazard and evaluating the severity of its effect. Through this method, criteria for recommended standards were developed for many of the most serious agents, including asbestos, benzene, beryllium, lead, mercury, silica, and noise. The NIOSH priority system has since been revised to also consider new information relating to toxicity or carcinogenicity, new recommendations by professional societies, toxicity reports on substances which have no OSHA standard, and recommendations from government agencies, professional societies, trade associations, and unions. The priority system has been flexible enough to allow us to develop recommended standards for substances that we had not previously recognized as high priority hazards, such as Kepone, vinyl chloride, 2 nitropropane, and phenyl beta naphthylamine.

Because new information is constantly being developed, the substances on our priority list are periodically re-evaluated. This new information

on hazards is obtained through research reports, reports from health professionals, the NIOSH National Occupational Hazard Survey and the Registry of Toxic Effects of Chemical Substances and associated subfiles. We also receive information from the World Health Organization, and from comments on our proposed priorities published in the Federal Register.

NIOSH began the National Occupational Hazard Survey (NOHS) in 1972 in an attempt to determine the extent of worker exposure to chemical substances and physical agents. Visits were made to 4,636 workplaces that had been selected with the assistance of the Bureau of Labor Statistics in the Department of Labor to ensure a representative cross section of industry type and size. The NIOSH teams collected general information about each plant, such as its major product or service, the number of employees, and the availability and kind of medical care. They also recorded the number of workers in each job category potentially exposed to specific chemical and physical agents.

The field data gathering phase of the study was completed in 1974. Although we have been able to utilize certain aspects of the survey in making rough estimates about specific worker exposures and in our testimony at OSHA and Congressional hearings, we are just now beginning to be able to use the data in establishing priorities and projecting worker exposures to a large number of hazards. A major problem in completing the study, as we testified before this Committee last year, is that companies surveyed often were not aware of the chemical composition of the substances used in their plant. Over 70 percent of the exposures identified were recorded as trade name products for which the chemical composition was not known to the company. Approximately one third of the products we surveyed were designated as trade secret. NIOSH has contacted more than 10,000

manufacturers to identify precisely what chemicals were contained in these trade name products.

Based on our survey, we estimate that more than 7 million workers in the United State are exposed to trade name products containing an OSHA-regulated toxic substance. Even more disturbing, our survey indicates that there may be more than 300,000 workers exposed to trade name products containing one of the 16 carcinogens regulated by OSHA. A single employee may be exposed to more than one regulated hazard or to more than one regulated carcinogen. In these cases, neither the employer nor the employees may have been aware of the ingredients of these products because they were known by trade name rather than by chemical composition. In our survey, the manufacturers designated as trade secret nearly one third (32.5%) of the products containing an OSHA-regulated substance and more than one third (35.4%) of the products containing a cancer-causing agent.

Other information provided by the National Occupational Hazard Survey indicates that ninety-eight percent of small businesses (fewer than 250 employees) and eighty-five percent of larger plants (250 to 500 employees) do not receive industrial hygiene or safety engineering services. The situation is somewhat improved but far from satisfactory with respect to personal protective equipment. Only two-thirds of all plants provided some sort of personal protective equipment.

Carcinogen Policy

NIOSH supports GAO's recommendation that a uniform policy be established for identifying and regulating cancer-causing chemicals. We have always attempted to evaluate all data relevant to establishing a recommended occupational standard and have placed primary importance on any data relating to carcinogenicity in experimental animals or humans.

Criteria documents now contain a separate subsection in which the data pertaining to carcinogenicity is summarized and highlighted.

Scientific opinion on the kind of evidence used in classifying a substance as a human carcinogen has been changing over the past few years, and NIOSH policy has reflected some of those changes. Certain experimental techniques, such as in vitro assays, have only recently been available and the use of individual medical histories is given greater weight than in the past. As new information has become available on carcinogenicity, NIOSH has revised a number of criteria documents. When NIOSH initially developed criteria documents on benzene, beryllium, and chloroform, we presented data giving some indication that the substances might be carcinogens. However, in all three cases we considered the data inconclusive and did not label the substances as suspect human carcinogens. After the documents were transmitted, new information on carcinogenicity became available. As a result we reassessed our earlier position and labeled all three substances as carcinogens and transmitted revised recommended standards to the Department of Labor.

In discussing the cadmium criteria document, GAO noted that there was some difference of opinion within the Institute on the carcinogenicity of cadmium. It is the Institute's position, based on a thorough review of all available evidence on the carcinogenicity of cadmium, that there is not sufficient evidence at this time to label it a suspect human carcinogen. Not everyone within NIOSH agrees with that position. There are other cases of disagreement on substances such as nickel and benzene, in which the Institute has concluded, after examining all available evidence, that these substances should be considered suspect human carcinogens. Not everyone within the Institute agrees with those decisions either. We protect the

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right of individuals to disagree with Institute decisions and express their opinion as individual scientists. We are always ready to examine new evidence as it becomes available and revise an earlier recommendation.

General Research

It is clear from the legislative history of the Occupational Safety and Health Act that Congress intended for NIOSH to conduct some research not directly related to developing criteria for recommended standards. Some examples of this kind of research include behavioral research on how job stress affects health and job performance, development of analytical methods, issues with implications for the energy program such as cold stress, and development of improved personal protective equipment. We also attempt to strike a balance between short-term research, such as developing information needed to assist OSHA at a standards hearing or with a compliance problem, and long-term research that will assist us in developing criteria for standards in the years to come.

In planning its fiscal year 1977 program, NIOSH decided how much of its research program should be directed at filling gaps in previously issued standards recommendations, at filling gaps in future specific standards recommendations, at providing information generally useful to future standards recommendations, and at providing useful needed occupational safety and health information not directly related to standards development. Each fiscal year 1977 research project was put into one of those four categories, and the research budget was allocated with the NIOSH targets for those areas in mind.

In Chapter 9 of the draft GAO report, it was stated that 37 NIOSH research projects were reviewed and only 10 had produced at least some information that was used in criteria documents. NIOSH disagreed with

GAO's analysis of these projects and they deleted the statement from the final report. However, since other conclusions in the report are based on the initial GAO analysis of those projects, I would like to discuss their analysis in some detail.

There is no indication that the projects were chosen in a statistically valid manner nor that they are representative of the NIOSH health research program. The projects also span the fiscal years 1972 to 1975 and there was no attempt in the analysis to indicate any improvement in relating research projects to scheduled criteria documents during those years. There are other errors in the GAO analysis. They only evaluated 36 projects, not 37. Included in the 36 are 2 safety research projects, which are outside the scope of the GAO study. Also included are two projects dealing with uranium ~~mining~~ or milling, which is performed by NIOSH under authority of the Public Health Service Act.

Of the remaining 32 projects, an additional 5 should be deleted from the analysis. Two projects were cancelled soon after they were initiated. Two other projects included in the GAO analysis were not research projects: one provided technical assistance to State and Federal agencies and others in asbestos sampling procedures; the other provided essential analytical chemistry laboratory services to the NIOSH research program. Two other projects tested by GAO should only be counted as one because they were actually two different aspects of the same research investigation on talc. This would be consistent with the way GAO has handled other similar occurrences in the analysis. The two projects were separated within NIOSH for accounting reasons as they were conducted in different branches within the same division. This leaves 27 projects that we believe should be considered further.

Of those 27 projects, 15 have in fact produced information that was used in criteria documents developed by September 30, 1976. The GAO analysis did not take into consideration those projects which were directed at providing information for criteria documents to be developed in fiscal year 1977 and beyond. This gives a distorted view of the NIOSH research program and also fails to recognize the long lead time required to complete the kinds of research most useful in developing criteria documents. Review of the remaining 12 projects indicated that 6 of them were directed toward providing information either for criteria documents issued since September 30, 1976, or documents to be issued in fiscal years 1977 through 1981. Of the remaining 6 projects, 3 are behavioral research, specifically mandated by Section 20(a)(1) of the Occupational Safety and Health Act. Research of this type frequently is not intended to relate directly to criteria documents.

Analysis of GSA Material Safety Data Sheets

We would also like to report on our progress in analyzing the adequacy of the material safety data sheets collected by the General Services Administration (GSA), as required by Federal Standard 313A. We reviewed a statistical sample of 224 of the over 3100 data sheets collected by GSA and rated the information supplied on each of the sections contained on the sheets by the following scale: 0 (for no data), 1 (serious deficiencies, either errors or omissions), 2 (adequate information to give some indication of the hazards), and 3 (completely filled in with extensive data). Fewer than 30 percent of the sheets we analyzed contained adequate information in all sections.

We were particularly interested in determining how much information

was supplied in two sections of particular importance for employee protection. One of these was the section requesting information on the names and composition of hazardous ingredients. The sheets achieved an average score of 1.3 on this section, with 67 of the sheets containing no information and only 29 containing extensive information. The major weakness we observed was that the sheets contained very general descriptions of hazardous materials, referring to them only as "solvents" or "thinner." The other section we were particularly interested in was the section on health hazard data, including emergency first aid procedures and effects of overexposure. Fifty sheets contained no information in this category and 64 contained inadequate information. Only 38 sheets contained extensive information.

In general, our analysis showed that the material safety data sheets submitted to GSA lacked a good deal of the information required by Federal Standard 313A. Data on product composition and health effects were particularly weak. However, for every category, a number of the sheets contained excellent information. This indicates to us that if GSA suppliers take the data sheet requirement seriously, they are able to submit good information. We are submitting a report on our analysis to GSA and plan to work with them in improving the quality of material safety data sheets submitted to the Federal Government.

Madam Chairman, we will be pleased to answer any questions you or members of your Subcommittee may have on our implementation of the Occupational Safety and Health Act.