MONITORING OF INDUSTRIAL WORKERS EXPOSED TO CARCINOGENS, 1977

HEARING

BEFORE THE

SUBCOMMITTEE ON LABOR

OF THE

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

MONITORING OF INDUSTRIAL WORKERS
EXPOSED TO CARCINOGENS

MAY 9, 1977

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MONDAY, MAY 9, 1977

U.S. SENATE,
SUBCOMMITTEE ON LABOR
OF THE COMMITTEE ON HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 3:40 p.m., in room 4232, Dirksen Senate Office Building, Senator Harrison A. Williams, Jr. (chairman), presiding.

Present: Senators Williams, Javits, and Schweiker.

OPENING STATEMENT OF SENATOR WILLIAMS

The CHAIRMAN. Gentlemen, we will come to order, just a little bit belatedly.

We appreciate your being here at this hour.

Our Subcommittee on Labor and its members have, for many years, had a great concern for the safety and health of our Nation's workers. The landmark Occupational Safety and Health Act of 1970 which was a product of this subcommittee's great efforts, held forth great promise to the working men and women of America.

That promise has not yet been fulfilled. Particularly serious occupational health problems still exist. The purpose of this hearing is to look into one of these problems—how we can keep our workers informed of the risks which they confront in their daily jobs. We are not here today to assign blame. Rather, we are here to understand why this situation exists, and what we can do about it.

Often, little is known about the substances which are used daily in our workplaces. Often the effects of these substances only manifest themselves after years of exposure. The research necessary to develop standards which will prevent harmful exposure to workers is painstaking, time consuming work, and too many substances are still not covered by adequate standards.

Because of this, many workers are still exposed to carcinogens. If we do not now have standards to protect workers from all risks, we must, at the very least, enable workers to protect themselves.

We have recently been reminded that we are not completely successful in this task. However, our Federal agencies are acquiring considerable information about employees who are being exposed to known or suspected carcinogens in the course of their employment. But, these agencies are unable to advise workers that they bear or may bear a risk of getting cancer. The agencies are unable to, in most cases, follow

through with proper medical counseling, which may be necessary if workers are to avail themselves of treatment.

We must understand the reason for these failures, so we can understand what must be done to help our workers. Failure to advise and counsel workers who have been exposed to industrial carcinogens is inconsistent with what we as a nation should be doing to secure the health of our most valuable industrial commodity—our working men and women.

Our goal must be to eliminate occupational health problems not merely to keep track of them. Developing adequate health standards is but a part of this effort. We must insure that workers who are at risk are able to make an informal judgment about whether they want to continue in their jobs. We must insure that workers who have already suffered potentially dangerous exposure are in the position to obtain effective medical treatment. If we do less, our occupational health program is but an empty promise to millions of American workers.

Certainly Senator Javits has expressed his concern, as I have, and we felt it important to have this rather extraordinary late afternoon hearing, which was the earliest time we could arrange it within the Senate schedule.

We appreciate your being here at this time.

Senator Javits.

Senator JAVITS. Thank you very much, Mr. Chairman.

I am grateful to the Chair for the fine public spirit which Senator Williams has shown in granting the request for this hearing which I made when newspaper reports indicated some very serious problems about informing, protecting, and caring for workers who are known to have been exposed to carcinogens at their workplace.

Our purpose in enacting the Occupational Safety and Health Act in 1970 and more recently the Toxic Substances Control Act, in 1976, was to deal with precisely this problem.

It seems to have escaped proper action under worker's compensation laws. One reason's because the latent possibility for grave disease may take years to develop.

This is true for benzidene, and asbestos vinyl chloride and similar toxic agents.

The questions I would like us to address in what must be considered a preliminary hearing, because we will go into this further and more deeply, are the following:

To what extent do Federal agencies compile lists of workers exposed to these agents?

We should bear in mind that so far standards have been promulgated for only 16 substances, and that the General Accounting Office tells us that it may take more than a century, 100 years, to establish the needed standards for the other thousands of hazardous substances.

Second, what efforts are being made by the Federal agencies to notify those workers of their exposure, the risk to their health, and what diagnostic and treatment measures should be undertaken?

Third, how do we locate similarly exposed workers at other worksites throughout the country, and exposed workers who have dropped out of the labor force or shifted to other occupations.

And lastly, what is the Federal responsibility for informing, protecting and caring for those workers at risk, including the adequacy

of existing statutory authority and which agency should most logically be assigned this responsibility.

Today, we are going to focus particularly on NIOSH, that is, the National Institute of Occupational Safety and Health, and on the National Cancer Institute.

Lastly, may I say I thoroughly agree with the Chair.

We are not trying to fix blame.

We are trying to see what can be done to help what may prove to be hundreds of thousands or more of workers who may be in jeopardy, who may be exposed, with full realization that we must be practical, that life and jobs are full of hazards and that nobody in his right mind expects the impossible.

But let's see what is being done, what can be done, and what should be done within reasonable limits to do better than seemingly we are doing from the newspaper reports of this particular situation.

Again, may I express my gratitude to Chairman Williams for the high public spirit which allowed him to grant this hearing, notwithstanding an unbelievably jammed committee schedule.

The CHAIRMAN. Thank you.

Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

First, I want to commend the Chair for calling these hearings.

I think they are very constructive at this time. I have been working on a bill for some months that would have utilized NIOSH in the notification of workers who were exposed to hazardous conditions. This notification would be based on the research that NIOSH does on the hazardous or carcinogenic effects of a particular substance.

So I found it particularly ironic at the time I was working on the bill to involve NIOSH in notification when a substance is determined to be potentially dangerous to workers, that in fact they had already had situations where hazardous and harmful conditions were known and had not notified workers.

I think that this hearing is particularly helpful and certainly will have great bearing on my proposal.

Thank you.

The CHAIRMAN. Now, we will turn right to the National Institute for Occupational Safety and Health, Dr. John F. Finklea, Director, and your associates.

Will you introduce them, please?

STATEMENT OF JOHN F. FINKLEA, M.D., DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH; ACCOMPANIED BY DR. BOBBY F. CRAFT, DIRECTOR, DIVISION OF THE SURVEILLANCE, HAZARD EVALUATIONS AND FIELD STUDIES; DR. JOSEPH K. WAGONER, CHIEF, INDUSTRYWIDE STUDIES BRANCH; AND HOWARD WALDERMAN, ATTORNEY, PUBLIC HEALTH SERVICE OFFICE OF GENERAL COUNSEL, A PANEL

Dr. FINKLEA. Thank you.

On my left is Dr. Joseph K. Wagoner, chief of the industrywide studies branch. Dr. Wagoner has been involved in the field studies conducted by our Institute for some time.

On my right is Mr. Howard Walderman, an attorney with the Public Health Division of the Department's Office of General Counsel. And on my far right is Dr. Bobby F. Craft, director of the Division of Surveillance, Hazard Evaluations and Field Studies.

With your permission, sir, I will try to summarize most of the prepared testimony so that we might have more time for questions and answers, but would really appreciate it if you would allow us to submit the full testimony for the record.

The CHAIRMAN. It will be included totally in the record.

If you can summarize in a way that gives us all the important points of your prepared statement that we need for our questioning, we will proceed that way.

Dr. FINKLEA. Mr. Chairman, NIOSH was established by the Occupational Safety and Health Act of 1970 to conduct programs of research, standards development, technical assistance, and manpower development. One of our Institute's most important responsibilities under this act is to transmit recommended standards to the Occupational Safety and Health Administration (OSHA) in the Department of Labor. The NIOSH recommendations are intended to serve as the basis, along with other available information, for assisting OSHA in developing new standards and in revising the approximately 400 consensus health standards, consisting only of an environmental limit, that were promulgated when the act was passed.

NIOSH has transmitted more than 60 criteria documents recommending new health standards to the Department of Labor. These criteria documents include an environmental limit for workplace exposure, as well as recommendations on the use of labels and other forms of warning, type and frequency of medical examinations to be provided by the employer, sampling and analytical methods, procedures for technological control of hazards, and suitable personal protective equipment. In addition to criteria documents, under a joint standards completion program with OSHA, we have developed draft technical standards for most of the consensus health standards. These standards supplement the existing environmental limits with procedures for informing employees of hazards, monitoring techniques, engineering and control mechanisms, and medical surveillance programs. Once these recommendations have been promulgated into standards, and these standards are enforced, workers should be protected from many of the most serious occupational exposures.

These recommendations are based on laboratory and epidemiologic research conducted by NIOSH and others. This testimony will focus on the kinds of epidemiologic investigations conducted by our industrywide studies program and the procedures we follow in these studies to identify occupationally related hazards and to notify affected workers.

The two most common types of studies we conduct involving workers are retrospective cohort studies and cross sectional medical studies. In cohort studies, we obtain employment records from unions, professional societies, and companies for purposes of classifying workers according to departments where they worked, their job category, and the duration of their employment. Personal identifiers, including name and social security numbers, obtained during this process are used to determine the vital status and current address of the indivi-

duals through records kept by other Federal agencies, such as the Social Security Administration, and, until recently, the Internal Revenue Service. When we learn that an individual is deceased, we attempt to obtain a copy of the death certificate from the State in which the death occurred. Using the death records, we contrast the observed risk of dying from specific diseases among our study population with the risk expected in that population if they had not been subject to the occupational exposures. To make these comparisons, we use as control groups either the general population or another industrial population not exposed to the agent under investigation.

In cross sectional medical studies we elicit a personal history and physically examine workers who have had exposures to agents under investigation as determined by industrial hygiene sampling. The results of these medical examinations are compared with accepted medical norms or similar test results from another population not exposed to the agent in question. In both study approaches the medical, statistical, and industrial hygiene disciplines contribute to the identification of occupationally related health problems.

NIOSH has promulgated regulations governing field investigations—42 CFR part 85A. Under these regulations, it is our practice to meet with company management and with employee representatives before initiating a study to explain its purpose and scope. Before conducting medical examinations, investigators must receive specific approval from the NIOSH human subjects review board and the informed consent of each employee examined. All employees we examine and their designated physicians are notified of the results of these medical examinations. Before releasing final reports on group data—with individual identifiers removed—we provide draft copies to employers and employee representatives for their comments on technical accuracy. The results of our epidemiologic studies are presented in NIOSH criteria documents and technical reports, in scientific journals, at scientific meetings, and at OSHA hearings on workplace standards.

Workplace investigations are also conducted in our health hazard evaluation program. Under this program we respond to requests from employers and employee representatives to investigate a workplace, collect environmental samples, make toxicity determinations, and provide medical examinations for workers. The results of these investigations, including recommendations for work practices, personal protective equipment, and engineering controls, are reported back to plant management, employee representatives, and OSHA.

INFORMATION DISSEMINATION

A vital part of our research program is getting information to those who can put it to good use—workers, employers, occupational safety and health professionals, other government agencies, and other researchers. Toward this end NIOSH has developed a program of information dissemination. This year we will issue over 100 different NIOSH publications and many additional articles appear in scientific journals. We will distribute about 1½ million copies of our publications and additional copies will be available from the Government Printing Office and the National Technical Information Service of the Department of Commerce. One of these documents, used pri-

marily by health professionals, is our annual "Registry of Toxic Effects of Chemical Substances," which in 1976 listed approximately 21,000 different chemicals. A subfile of suspect carcinogens from that list contained 2,400 different substances and another subfile is being developed on pesticides and agricultural chemicals. NIOSH also sponsors conferences and publishes their scientific proceedings. In addition to publishing scientific proceedings of a conference on occupational carcinogenesis, which we cosponsored, we are publishing a version written in nontechnical language to be used by workers and other laymen.

We have developed a series of health and safety guides specifically targeted on small businesses. These guides, covering such diverse establishments as auto repair and body shops, foundries, and sporting goods stores, give general health and safety guidelines and provide a checklist of OSHA regulations applicable to that particular establishment. We also have a series of good work practice manuals for workers in different occupations.

A criteria document, "An Identification System for Occupationally Hazardous Materials," which was transmitted to the Department of Labor in 1974, presented a uniform identification system that would alert employers and employees to hazardous chemicals through placards, labels, and material safety data sheets. This system would provide for the identification of hazardous materials, indicate the degree and type of hazard, describe symptoms of overexposure, and prescribe safe handling procedures, emergency care, and disposal methods. Adherence to such a system would substantially improve the information available on chemical exposures in the workplace.

Criteria documents can serve a useful purpose even before being promulgated into enforceable standards. They are widely distributed and many companies and unions use them as a basis to control hazards even though the documents do not have the force of law. They provide an up-to-date review of the existing literature and state of knowledge on a hazard and serve as an impetus for further research by NIOSH and others.

Late this year NIOSH will publish five documents summarizing in nontechnical language the supplemental information developed on the consensus health standards promulgated by OSHA. One document will be a general guide, one will be a pocket handbook, and the remaining documents will cover respirators, personal protective equipment, and medical monitoring.

We issue current intelligence bulletins when we receive new information on potentially dangerous chemical substances. In 2 to 4 weeks we can provide background information on the chemical, including its known toxicity to man and animals, known producers and users, estimated extent of occupational exposure, and further NIOSH action planned. These bulletins are now distributed to 1,200 representatives from the occupational safety and health community, other government agencies, management, labor, and public interest groups.

NATIONAL OCCUPATIONAL HAZARD SURVEY

Despite these efforts we recognize that employers and employees are still not generally well informed about occupational health hazards. Between 1972 and 1974 NIOSH conducted a national occupational

hazard survey to determine the extent of worker exposure to chemical substances and physical agents. Visits were made to 4,636 workplaces selected to provide 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 chemical and physical agents.

Although we have had access to certain aspects of the survey in making rough estimates of specific workers exposures, we are just now beginning to be able to use the data in establishing priorities and projecting worker exposure to a large number of hazards. A major problem in completing the study is that companies surveyed were often 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. We contacted more than 10,000 manufacturers to identify precisely what chemicals were contained in these trade name products. To date, we have determined the chemical composition of only slightly more than half of those trade name products.

Based on our survey, we estimate that more than 7 million workers in the United States 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 currently 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 percent) of the products containing an OSHA-regulated substance and more than one third (35.4 percent) of the products containing a cancer-causing agent.

In administering our responsibilities under the Occupational Safety and Health Act of 1970, we have identified a number of problem areas in occupational health that are not being adequately dealt with by our institute, by other government agencies, by management, by labor, and by the academic community. We would like to state the problems as we see them and offer suggestions for dealing with them through the combined efforts of various sectors of society.

Informing employees and employers about workplace exposures:

The National Occupational Hazard Survey shows that the widespread use of trade name products and lack of a uniform system for labeling hazardous materials makes it difficult for workers to know what substances they are exposed to. This problem is compounded by the frequent claim that product ingredients are trade secrets, even though they may be known to be toxic or even cause cancer. Interactive effects of certain mixtures can be more toxic than any of its separate components, as for example rust preservatives (nitrites) and emulsifiers (amines) used in some cutting and hydraulic fluids have the potential to combine to form nitrosamines, a potent class of carcinogens.

NIOSH will take the following steps with regard to information collected during the National Occupational Hazard Survey:

One, transmit to OSHA and EPA a listing of trade name products that contain an OSHA-regulated carcinogen.

Two, notify companies that we intend to make information on the presence of an OSHA-regulated carcinogen in a trade name product generally available if it has not been designated as trade secret. If the presence of an OSHA-regulated carcinogen in a product has been designated as a trade secret, we will attempt to remove that designation in accordance with procedures set forth in 42 CFR section 85.7(b). These procedures were administratively adopted by NIOSH to apply to "trade secrets" obtained in the survey. We will notify companies in writing that we question and intend to remove the trade secret designation. Companies have 15 days from notification to provide evidence to support their claim that the information is in fact a trade secret. When trade secret designations are removed, NIOSH will make the information available to the public.

Three, notify companies that have not revealed the composition of their trade name products to NIOSH that we believe they should take immediate steps to inform their customers if one or more of their products contains an OSHA-regulated carcinogen and inform us of what action they are taking.

Four, offer to assist workers, employers, or formulators of trade name products to find out whether or not their products contain an OSHA-regulated carcinogen. We believe responsible trade associations and private laboratories can assist in this effort.

Five, request that the Environmental Protection Agency take regulatory action under the Toxic Substances Control Act that will assure labeling of any trade name product containing an OSHA-regulated carcinogen.

Six, consider similar steps for trade name products containing other OSHA-regulated chemicals or any chemicals newly identified as posing health hazards. We believe, however, that it is important to deal first with currently regulated carcinogens.

Seven, continue our efforts to resolve the components in trade name products collected during our National Occupational Hazard Survey and develop a mechanism to update that survey.

Eight, continue to support adoption of a uniform labeling and warning system such as that recommended in our 1974 criteria document.

Nine, propose that a clearinghouse be established, either by the Government or by private industry, to provide information on trade name products that would protect consumers and workers without revealing legitimate trade secrets. Cosmetic labeling regulations, recently promulgated by the Food and Drug Administration, which list constituents in order of diminishing concentration without revealing the precise amount might serve as a useful beginning.

Medical follow-up of workers exposed to toxic substances:

NIOSH has been criticized for not informing all workers in our past study populations that they may have been exposed to hazardous chemical or physical agents and insuring that they receive the opportunity for diagnosis and treatment where indicated. We recognize the need for such notification and medical followup and have been vocal

in stating that, except in certain limited cases, the need is not now being met. Conducting such a program on our own would be beyond our existing resources and legislative authority, which are primarily directed toward providing the scientific basis for standards to prevent future occupational exposures.

We have already mentioned ways in which we notify workers on the results of our studies. We discuss the results of our research with management and labor at plants where the studies were conducted. Although we do not notify workers individually, unless we have examined them, we expect that those still employed at the plant would generally be informed about our study results by their union or by management. We would not expect that workers in other similar plants would be directly informed about the results of our studies. An even bigger problem involves workers who once worked in such plants but no longer do so. These workers who may have changed jobs or retired are less likely to know of health risks attributable to past workplace exposures.

For certain specific populations shown to be at high risk, we have worked with the National Cancer Institute to insure that medical examinations are provided to affected workers. Two such examples include former asbestos workers in Tyler, Tex., and former benzidene workers in Baltimore. We have also assisted management in providing medical examinations to former workers of a bis-chloromethyl ether plant. We are currently providing medical examinations to all interested current and former employees of the Velsicol chemical plant in Bayport, Tex., who were exposed to the pesticide Phosvel, a neurotoxin.

We are aware that these limited programs do not assure adequate followup of exposed workers. Such a program would require the combined efforts of all government agencies involved in evaluating or regulating substances to which workers are exposed. It would also involve the efforts of private industry and academic institutions that conduct occupational health studies. It would certainly involve those industries which expose their employees to toxic substances and unions representing their workers.

The success of such an effort will also depend on the existence of a supply of occupational safety and health professionals and a health care system adequate to meet the increased demand for services. As a physician, I must also point out that although medical surveillance for early diagnosis and possible treatment of occupational disease can be helpful, it also has its limitations. There are a number of occupational illnesses, including certain forms of cancer, which do not respond well to available medical and surgical treatment. New diagnostic techniques are being developed that might indicate which individuals are at greatest risk, but we do not yet know whether widely applying them would assure diagnosis in time to change the course of the illness. An example of such a technique is exfoliated cytology, that is, examining cells from the respiratory tract, the bladder, and other sites for precancerous changes.

By pointing out the limitations of current medical surveillance techniques, I do not mean to say that medical surveillance of workers at risk is not important—for it is. Potentially high risk workers should in fact be provided with the best medical screening and care that cur-

rent science and technology allow. At the same time we in the Federal Government should encourage research that will provide more effective methods of diagnosis and treatment.

There are additional barriers to assuring adequate followup of exposed workers. The Occupational Safety and Health Act of 1970, unlike section 203 of the Federal Coal Mine Health and Safety Act of 1969, does not provide for the right of transfer to a less hazardous worksite at the same rate of pay once a worker shows clinical evidence of occupational illness. It has been our experience that some workers, once notified that they may have health problems, refuse to seek further medical evaluation because they fear loss of their jobs once their condition becomes known. For example, a lead worker with impaired renal function, who should receive no further lead exposure, may not be able to get such a job assignment, yet is very unlikely to get compensation until clinical disease is further advanced.

Workers' compensation laws do not adequately address occupational diseases, especially those with long latency periods or those that have multiple causes. Workers' compensation laws do not generally provide for payments to a worker who may show evidence of impaired functional ability but not frank clinical disease. Yet evidence of early disease, impaired functional ability, or even a previous work history of exposure to agents that induce disease after a long latency period may be sufficient to limit employment opportunities for workers. This is because the employer of last record is usually responsible for compensation even though exposures at previous worksites may be partially or wholly responsible for late developing illnesses.

The question we must ask is what can each sector of society do now to notify workers about occupational hazards that they encounter and provide adequate medical care and compensation for those affected.

NIOSH is taking the following steps:

One, we will seek further assistance from the National Cancer Institute in insuring that specific worker populations are notified and placed in health care systems.

Two, we will ask the National Advisory Committee on Occupational Safety and Health—NACOSH—to advise NIOSH and OSHA on the regulatory, social and health aspects of informing, protecting, and caring for exposed workers.

Three, we have drafted regulations that would enable us to require employers to provide their employees with medical examinations at NIOSH expense under certain circumstances.

Four, we will notify all employees whose medical records were submitted to NIOSH pursuant to provisions in OSHA carcinogen standards of their potential exposure to a cancer-causing agent. We will assist these employees in obtaining access to medical care.

Five, we expect to begin funding educational resource centers to train occupational physicians and nurses, industrial hygienists, safety engineers, and related professionals by the end of the fiscal year.

In addition, we would support the following steps to be taken by others:

One, other government agencies need to examine their provisions for worker notification and followup.

Two, we are supporting OSHA's efforts to promulgate comprehensive health standards at a faster rate. Such standards would prescribe

medical examinations required to be made available by the employer to his employees presently exposed to the hazard.

Three, a mechanism needs to be developed to insure medical examinations for employees who have retired or found other jobs, since it is doubtful that they would be covered by medical surveillance provisions of OSHA standards.

Four, companies and unions must also take responsibility for determining what hazards are present in the workplace and notifying potentially exposed workers.

Five, companies must provide adequate health insurance, job retention, job reassignment, and workers' compensation policies so that the individual worker is adequately protected from the medical and economic consequences of occupational exposures.

The primary purpose of the Occupational Safety and Health Act of 1970 is to establish standards that will reduce workplace exposures to safety and health hazards so that no worker will suffer diminished health, functional capacity, or life expectancy as a result of his work experience.

Until adequate standards are developed, however, we must not forget to provide for the workers suffering as a result of existing workplace conditions.

Mr. Chairman, I will be pleased to answer any questions you or members of your subcommittee may have.

The CHAIRMAN. Thank you very much, Dr. Finklea.

You have at the end of your statement indicated many things that you will do and some that you would do, I gather, given additional authority.

Of course, we were alerted to the problem by your own statement of mid-April relating what was not being done.

That was, in your mind, a failure to adequately notify workers of the risk they were exposed to.

Is that what you stated in April?

Dr. FINKLEA. I think I was responding to questions from the media dealing with the followup of one small group of workers, that is, workers exposed to benzidine. We wanted to point out that the followup issue was a much larger issue than just those workers exposed to benzidine. It would involve any group that had participated in our cohort studies or record studies. People who participate in our studies involving health examinations do receive adequate notification.

The CHAIRMAN. You said in a quotation that the workers had not been informed of the risk they face partly because your agency lacked the necessary funds and authority and partly because of your belief that notification without effective followup system might do more harm than good.

Dr. FINKLEA. Yes, sir.

I think Dr. Newell is going to cover some of the aspects of the demonstration programs that have been done by NCI and NIOSH together.

But I think it is our opinion that if one is to proceed with the notification, there should be a counseling service and there should be a medical care system that is ready, willing, and able to follow through. At least in the demonstration projects this has been the process that has cost several hundred dollars per worker, per year.

In dealing with a large number of workers, this gets to be a pretty large problem. I think that was central to the question of resources.

The CHAIRMAN. In developing the information, necessary to propose regulations, you have learned the risks that are involved in exposure to certain substances. Is that accurate?

Dr. FINKLEA. Through studies that we do or other parts of the Department, yes.

The CHAIRMAN. Now, after you have information sufficient in your mind to suggest standards you submit it to OSHA with suggestions that this material be regulated, is that right?

Dr. FINKLEA. That is correct, sir.

Prior to that, we can also develop current intelligence bulletins, which Senator Schweiker referred to earlier. These bulletins let people know of any new hazard that might have come to our attention before a formal criteria document is prepared.

The CHAIRMAN. After it has gone through the process and there are regulations and standards, then we have a method of bringing protection to workers exposed?

Dr. FINKLEA. That is correct, sir.

The CHAIRMAN. Short of the regulation and the standards there is a risk, and of course that is what we are concerned with in this particular hearing, getting the medical information to workers so that they can be in a position to protect themselves because no standard has been established that will protect them.

Dr. FINKLEA. I understand, sir.

The CHAIRMAN. That is what we are working on and it would be helpful if we can just bring together your proposals. I gather what you are suggesting is that there are certain inadequacies in law following the information that a worker is exposed to a risk, inadequacies in workers' compensation, in transfer to a job without risk, and other elements that are not there in current law.

I gather that you are suggesting you would be limited in notification authority until the law was fully adequate to deal with the worker and see him not harmed in other ways?

Dr. FINKLEA. I think that we do now have the authority to notify workers that a study had been done involving a certain agent and that that worker had been in a group that had been studied.

But I think we would be limited in being able to provide those workers with adequate counseling and adequate access to medical care. When we have been able to inform workers of a possible medical problem discovered in our health hazard evaluation studies, we have sometimes found them reluctant to seek further medical evaluation because of the problems in obtaining adequate workers' compensation or wage rate retention rights which you referred to earlier.

The CHAIRMAN. Well, you know the old adage, "What you don't know won't hurt you."

It is just the opposite here.

What you do not know can be greatly damaging. I am wondering whether the knowledge should not be provided anyway, even though all the elements of job protection and compensation are not yet in place, I will say you mentioned the Coal Mine Health and Safety Act, and we did in that law provide for transfer to a job which contains a lesser risk that the worker had been exposed to previously. We did this in our new mine safety and health bill too, S. 717.

We have not done this generally in industry, and we do not have a national workers compensation law, although Senator Javits, Senator Schweiker, and I and others on this committee, we have been working on that.

We have not provided this transfer right generally, though.

Dr. FINKLEA. I think we have talked about some of the efforts we will be conducting with NCI and we will be looking into demonstration projects involving followup and care of people exposed to bladder carcinogens.

If we are thinking about notifying all workers that may have been involved in studies by our institute or other parts of the Public Health Service, we are talking about notification of many thousands of workers exposed to many different agents. That is something that I think we would like to explore with the National Advisory Committee on Occupational Safety and Health—NACOSH.

I have discussed this issue with NACOSH, which includes representatives from two departments and from management, labor and the health community. They are willing to give us policy advice on how best to make this information available.

I think we are going to run up against a number of issues that are going to be difficult to resolve here and the issues involve balancing of the right to know with the obligation of followup with adequate counseling.

They also involve letting people in particular studies know of the hazard, but not assuring you are giving equal attention to other industries or occupations that may also be equally exposed.

We might be able to identify some of those other workers exposed from our National Occupational Hazards Survey. We are trying to see what is the proper role for management, labor, and government in this area.

We have also talked with Dr. Newell who will be testifying a little later today. The National Cancer Institute and NIOSH will use the problem of bladder carcinogens as examples and ask NACOSH to follow up with policy advice to both HEW and the Department of Labor.

I think we have dealt specifically with other things that may be a problem here.

As you know, under carcinogen standards established under the Occupational Safety and Health Act, we receive records of workers who have been exposed to carcinogens and who have left their place of employment or whose plants are no longer in operation. We have 120 such records now, and we will attempt to follow up with this small group of workers with resources available to the Department.

If we are to be involved with notifying several hundred thousand people or extending that to many hundreds of thousands of people that may have been exposed to these agents, I do think we would have a difficult problem to deal with.

The CHAIRMAN. What was your method of proceeding in the asbestos worker situation in Tyler, Tex., and the vinylchloride in Louisville, Ky.?

Did you receive notification of risk before the standards were promulgated in this area?

Dr. FINKLEA. I would like to pass that question to Dr. Craft, whose division has been in charge of studies in these two areas.

Dr. CRAFT. Thank you.

We were aware of the hazard of asbestos exposure in Tyler, Tex., before the standard was promulgated. This was before the occupational Safety and Health Act was passed.

To my knowledge, the predecessor organization of NIOSH did not issue a formal notification of that hazard. These workers have been included in a medical surveillance program which we are providing cooperatively with the National Cancer Institute.

That, sir, as Dr. Finklea said, is only one small segment of the people that we are aware of who have been exposed to asbestos, how one would then extend that program to all the people who are at that same risk is a complicated issue.

The CHAIRMAN. How about the vinylchloride situation at Louisville?

Are you familiar with that.

Dr. FINKLEA. I think Dr. Newell will be testifying on the demonstration project at the National Cancer Institute, the project that they are conducting with the employer and cooperation of employees there in Louisville.

This is one of the demonstration projects that involves notification, counseling and followup.

He can comment on the resources required for that project.

The CHAIRMAN. Both were in the category of demonstration projects?

Dr. FINKLEA. Yes, sir.

The CHAIRMAN. These demonstrations contemplate that those at risk and those exposed would be notified. Is that not so?

Dr. CRAFT. Right.

The CHAIRMAN. Do you believe from that something can be learned from these demonstration projects to make the problems presented in notification clarified for more general use?

Dr. FINKLEA. I think Dr. Fink and Dr. Newell could better comment on experience their program has had here.

They will also point out some of the limitations to our current medical knowledge that we also discussed.

We need to take a good work history to know the people most exposed to a substance, but even with that information it is difficult at times to predict exactly who is at the highest risk of contracting these diseases with long latency periods.

Our diagnosis techniques for early diagnosis are limited in some of these areas.

I think that we also talked about the followup studies that we have done in Bayport, Tex., to current and former employees of a plant where a potent neurotoxin Phosvel, was used.

Our experience there has been to identify and to examine the employees in the immediate vicinity on a one-time basis. We were concerned about neurotoxicity, which involves a very comprehensive exam, and the cost to us was between $200 and $300 per employee on a one-time basis.

Under the Coal Mine Health and Safety Act, our current expenditures for medical examinations are about $20 per year per coalminer, largely to provide them with the mandated X-ray and pulmonary function examination.

The costs of these programs depend on the scope of the examination, the frequency with which they are done, and the length of time they should be continued.

In terms of a one-time problem, such as neurotoxins to which exposure was not going to occur again, it may be a manageable thing within the resources generally available.

If one were going to consider covering the several hundred thousand people exposed to carcinogens and requiring counseling and comprehensive examinations over a period of years, it would be a very significant effort. It would require resources that are not generally available.

The CHAIRMAN. Thank you.

Senator Javits.

Senator JAVITS. Dr. Finklea, I find your frankness very refreshing and I hope the other witnesses emulate you.

You know, we are in deep trouble on this matter, and I think you are trying to address us and give us the facts as you see them without trying to gild lilies.

I appreciate that.

I think that the workers should, too.

Just to take it step by step, without transgressing too much on time, I would like to get a concept of the order of magnitude of this problem.

Now, as to the number of workers and substances dealt with, bearing in mind that so far you have established standards for 16, I ask you to turn to page 7 of your statement in which you say at the bottom of the page:

> Based on our survey, we estimate that more than seven million workers in the United States are exposed to trade name products containing an OSHA-related toxic substance.

Now, when you relate that to the preceding paragraph, you said:

"Over 70 percent of the exposures identified as trade name products, and so on.

Does, therefore, the figure of 7 million indicate roughly a figure between 9 and 10 million workers exposed to products, trade name or not, containing OSHA-regulated toxic substances?

Dr. FINKLEA. No, sir.

I think we were indicating here that roughly 7 million workers, we believe, are exposed to a trade name product containing an OSHA-regulated substance that we identified during our National Occupational Hazard Survey.

We have only identified about half of the trade name substances, so we would estimate that probably double that number of 14 million might be exposed to OSHA-regulated substance, not just carcinogens.

For carcinogens, we would estimate roughly 300,000 exposed trade name products——

Senator JAVITS. Would you double that figure, too?

Dr. FINKLEA. About 600,000 would be the rule of thumb.

Senator JAVITS. The universe we are talking of would be 14 million workers, out of a total work force employed today of 90 million, exposed to products containing an OSHA-regulated toxic substance, about 600,000 of whom are exposed to products containing 1 of the 16 carcinogens currently regulated?

Dr. FINKLEA. That is correct.

Senator JAVITS. That is based on your determination of the chemical composition of a little more than half those trade name products alone, am I correct?

Dr. FINKLEA. Basically that is based upon composition of trade name products as submitted to us by their manufacturers.

We have in some cases done analytical work with such products but by and large we are depending on information furnished by the manufacturer.

Senator JAVITS. To get an idea of how many of these chemical substances are involved, turn to the top of page 5 and see if that helps us.

You say:

> One of these documents used primarily by health professionals is our annual Registry of Toxic Effects of Chemical Substances, which in 1976 listed approximately 21,000 different chemicals. A subfile of suspect carcinogens on the list contain 2,400 substances and another subfile is being developed on pesticides and agricultural chemicals.

So what is the universe of the chemical substances which corresponds to what you call on page 7 OSHA-regulated toxic substances?

Dr. FINKLEA. OSHA-regulated materials we were talking about on page 7 only related to materials that were covered in the existing OSHA standards, or the consensus health standards required after passage of the OSHA act.

These consensus health standards sometimes deal with more than one substance. So we are probably talking about health standards that affect—it would be substantially more than 400, but probably less than 1,000 agents at this time.

In the agriculture-chemical area, I think we are talking about roughly 1,800 substances.

Senator JAVITS. In round figures, you are talking about 3,000 substances as an order of magniture which present these dangers?

Dr. FINKLEA. Well, right now we have identified about 4,800 substances that we feel we should cover by criteria documents and recommended health standards by 1981. I do not think we would consider that the end of the list. It certainly might be that we would need to look at new chemicals that were introduced as is required by the Toxic Substances Act, and that we would not have all of them in 4,800, but we think we have gone a long way.

Senator JAVITS. As an order of magnitude, you estimate to the universe to be 4,800 substances?

Dr. FINKLEA. More than 4,800.

Senator JAVITS. More than 4,800?

Dr. FINKLEA. Yes; but 21,000 refers to those toxic chemicals that have been tested. Some of those do not come into use, and are of curosity value only.

Senator JAVITS. Now the substances designated as trade secrets are very extensive, I gather. As you say, over 70 percent of exposure identified were recorded as exposures—I'm inserting the word exposures—to trade name products for which chemical composition of the substance was not known by the company.

Dr. FINKLEA. Usually not known to either employer or employee.

Senator JAVITS. Or employee.

Dr. FINKLEA. Yes; because there is no labeling requirements on such mixture.

Senator JAVITS. You found among that figure one-third—reading at the top of page 8—one-third of the products designated as trade secrets, 32.5 percent, contained an OSHA-regulated substance, even more than one-third, to wit 35.4 percent, contained a cancer-causing agent?

Dr. FINKLEA. Of the products that contained an OSHA-regulated substance, about one-third were labeled as trade secrets, and of those trade-name products that contained OSHA-regulated carcinogens, over a third were labeled as trade secrets.

Senator JAVITS. We are dealing, are we not, with an enormous problem imperiling the health of millions of workers.

Dr. FINKLEA. It is a very large problem. We also should point out, Senator, that individual workers may be exposed to more than one of these regulated substances. In fact, that is the usual case.

Senator JAVITS. Now there is a statutory responsibility, is there not, in the original OSHA law to deal with this subject? I'm looking at section 8(c)(3) of the original OSHA law which says, the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measurements, and to have access to records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents.

Here is the very significant provision. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentration or at levels which exceed those prescribed by applicable health and safety standards promulgated under section 6, and shall inform any employee who is being thus exposed of the corrective action being taken.

Now, I ask you: Is that statutory provision actually being performed?

Dr. FINKLEA. Senator, we have recommended in our criteria document on identification of hazardous materials that such a system be adopted. Dr. Craft served on the advisory committee establishing that system, and can comment at some length on it. The system has not yet been adopted by the Secretary of Labor. I think there is an additional complication we referred to earlier, and that is that many industrial chemicals have a composition that is not known to the packager using trade name products. So if I, for example, supplied industrial chemicals to the employer, I might not know the composition of my chemical. I could then ask my supplier what was in the trade name, that the company supplied me, and they in turn might also use a trade name. So it is often a problem of vested trade names for which the actual chemical composition is difficult to obtain.

Senator JAVITS. Does NIOSH have the power to ascertain what is contained in that trade name document?

Mr. FINKLEA. We had requested this information on a voluntary basis, and we have received cooperation from roughly half of the people we had contacted about this. We have had a district court decision on

this case, and Mr. Walderman from the Office of General Counsel might best tell you we have tried to resolve this problem.

Senator JAVITS. Whether or not you have the power, and whether you need power that we can supply by law?

Mr. WALDERMAN. On January 25, 1977, the Eastern District of Pennsylvania held in *U.S.* v. *McGee Industries* that under section 8(b) of the act, NIOSH could require the production of evidence relevant to its authorized activities. One of its authorized activities is to carry out research including the national occupational hazard survey. That case has been appealed by the defendant company. That is where we are now.

Senator JAVITS. Do you need any additional legislative power from Congress which you do not now have?

Mr. WALDERMAN. It is difficult for me to say. I think that the process is rather cumbersome because each instance where there is resistance to furnishing the requested information involves issuance of administrative subpena. Then if the manufacturer does not respond, we must request the Department of Justice to institute a court proceeding to enforce the subpoena.

So on the basis of the case where this proceeding was instituted, it is a long and drawn-out procedure. The authority is there; it is just rather cumbersome.

Senator JAVITS. In other words, if you do need new law, it would be to simplify the procedure?

Mr. WALDERMAN. Yes.

Senator JAVITS. Now, the question I would like to ask you, and then I will pass to Senator Schweiker, is: you say at the bottom of page 10—and this is critical to what we are trying to investigate:

> NIOSH has been criticized for not informing all workers in our past study populations that they may have been exposed to hazardous chemical or physical agents, and insuring that they received the opportunity for diagnosis and treatment where indicated. We recognize the need for such notification and medical followup and have been vocal in stating that, except in certain limited cases, the need is not now being met. Conducting such a program on our own would be beyond our existing resources and legislative authority, which are primarily directed toward providing the scientific basis for standards to prevent future occupational exposures.

Now, I ask you, Dr. Finklea, will you give us an estimate of what it will cost and what facilities and resources will be required to see that the need is being met?

Dr. FINKLEA. Yes, sir. This is one of the matters we will be discussing with the National Advisory Committee on Occupational Safety and Health, and one of the matters that Dr. Newell may answer some questions on, on the basis of their experience in the demonstration projects.

It is a large problem, sir.

Senator JAVITS. You will give us an estimate, as I say, based on all your sources of how large the problem is and what it will take to do it in money and facilities?

Dr. FINKLEA. Yes, sir. We will be happy to do that.

Senator JAVITS. I think that is important. I think at least we ought to know what we are up against in this situation, since it is almost the first time we will have tackled it.

Dr. Finklea, I would also like to put in the record the provisions of section 6(b)(7) of OSHA which deal with the provision of protective equipment, procedures measuring employee exposure, medical exami-

nations, and other tests which employers should make available to employees exposed, et cetera, so that we may affirm that the law covers the full responsibility. The fact is that the law has not been implemented, and this is a shocking thing to us all. Again I emphasize that we are not putting you on the griddle for it; you are just one piece of this whole picture. But it is something that certainly demands our attention.

We are now beginning to give it. Thank you very much.

Dr. FINKLEA. Thank you, Senator. I might add one thing here, I did mention in our testimony we will be working with the Environmental Protection Agency to look into the possibility of getting labeling of trade name products under the provisions of the Toxic Substances Control Act.

I do think that is one legislative provision that will be looked into. It may again involve decisionmaking on an agency-by-agency basis, which would create some of the same difficulties Mr. Walderman described earlier.

Senator JAVITS. Will you also give us at the same time what provisions we ought to add to the law in order to facilitate the action which we are discussing, including descriptions as included in the Pure Food and Drug Act, of what is in the so-called trade secrets. Thank you.

Senator SCHWEIKER. In looking over the issues you raise, and your saying you have no legislative authority to notify, I looked under section 20 of the act, research-related activities. Of course, it goes on to define the role of NIOSH in this regard.

Then it comes to section D. Information obtained by the Secretary, and the Secretary of HEW under this section, shall be disseminated by the Secretary to employers and employees and organizations thereof—now, of course, you have been delegated the job of Secretary to act in his behalf. And my question to you is, why does not that section apply?

Dr. FINKLEA. I think we do try to disseminate the information coming from research and others to worker representatives, to workers and employers. What I think we are talking about here is not just letting people know they have been exposed to something, but adequate medical counseling and adequate medical followup where indicated.

I do not think we are able to do that within existing legislation. I think that we certainly do try to get the results of our studies disseminated to occupation safety and health community, and to worker groups. But we in that case would not be following those workers who had retired or left the industry, because we would be sending information to groups rather than to individuals who may have been at risk in the past. And I think that is where our gap is.

Senator SCHWEIKER. Well, the numbers cited here are only a percentage of the numbers cited in the press stories, which have actually retired—some have retired, but we talk first of the 74,000 workers at risk, and we talk of 123,000 more at risk. You are not saying most of these workers have retired, or are you?

Dr. FINKLEA. No, sir, I think maybe Dr. Wagoner can comment on the employee turnover. I think the original description dealt with roughly a little over 72,000 workers that participated in the studies conducted by our Agency that were addressed primarily toward cancer risk. Actually we had other studies that involved possible risk to cancer and other health risks that involved an additional 162,000

workers. This is over a period of time, since NIOSH was created. In the testimony we were talking about workers who were exposed to substances currently regulated by OSHA. They are, of course, only the 16 OSHA-regulated carcinogens at the present time. What the Institute is doing may involve many or a number of those other 2,400 that were referred to in the testimony. They are two different problems, or really two phases on the same problem. In other words, if we were to restrict notification efforts only to those workers who are exposed to currently regulated carcinogens, it is a very large number nationally but it is a smaller number of workers that the Federal Government may have studied. If we were to be concerned about individual notification for all people who have participated in a Federal study directed toward evaluating workplace hazard, it is a pretty large number that the Federal Government is responsible for, and a much larger number in the general population.

Senator SCHWEIKER. Again, I am not sure I understand what this section refers to if it does not refer to a case in which you know a worker to be at risk, in which there is an indication the worker is at risk, and where you had the worker's name. Why does not section (c) apply? Information obtained by the Secretary, and the Secretary of HEW, under this section, shall be disseminated by the Secretary to employers and employees and organizations thereof?

Dr. FINKLEA. I do not mean to imply that it would not be possible to write letters telling people they had been at risk. But I think if we are to assure that they have adequate medical counselling and adequate medical followup, that is where we run into the problem.

Senator SCHWEIKER. It says nothing about that, doctor, in here. It addresses only information obtained. It does not say whether they have had adequate medical counselling or adequate followup. It does not put any responsibility on you in that regard. I admit that. No question about that. But the question at issue, as I see it, is if we at least inform the people at risk, they can seek their own medical counsel and seek their own medical help. That is the first thing I or you would do, if we were at risk, regardless of whether Government had resources to follow it up. There is absolutely nothing regarding your capacity to follow it up, but it seems it does place primary responsibility on NIOSH to inform employees and organizations thereof.

Where am I missing the boat?

Dr. FINKLEA. I think we are coming at it in a slightly different way. I think we are taking steps to inform employee groups and individual employees, through criteria documents and work practice documents, but not to inform individuals who may have been involved in a record study. I think one of the things we covered in our testimony is that we wanted to work with the National Advisory Committee on Occupational Safety and Health to discuss the best way of taking care of this problem, not only for those people who may have been in a Federal study, but people across the entire range of occupations exposed to that agent.

I think there are two different levels of responsibility here, and I think it is a very large area.

Senator SCHWEIKER. Let us go to the smaller area of responsibility, which as I understand it, is those who were involved in a Federal study. Is that the area?

Dr. FINKLEA. Yes.

Senator SCHWEIKER. Did I miss the point? I understood we had not notified all those people who were involved; is that correct?

Dr. FINKLEA. No, sir, we have not notified all those people. We have notified most of the people that we have worked with under the Coal Mine Health and Safety Act, where we have a notification mechanism. Under the Occupational Safety and Health Act, we have notified people only where we have conducted medical examinations or had personal contact. I would like Dr. Wagoner to perhaps comment on some of the procedures he used——

Senator SCHWEIKER. What I'm trying to find out is who we have not notified. I would like to find out who we have not notified. That is what the issue is.

Dr. FINKLEA. I think the people who would not have found out about this would be people who had retired or left a job or plant where studies were done. I think people who were still working in the plant would probably have found out through management, and/or worker representatives. We have not personally notified the people in those plants.

Senator SCHWEIKER. What does this say? It says, "Notification to employers and employees." This does not say you have to go to the employer and depend on him to tell his employees. It says, the Secretary of HEW will go to the employers and employees and organizations thereof. Where am I missing the point? It hinges on whether you have legislative authority or not. I have trouble understanding why you say there is no legislative authority when that seems pretty broad to me.

Mr. FINKLEA. I think in our statement here we talk about lacking legislative authority to provide adequate medical followup. We would have authority for notification that a worker had been exposed to a harmful substance.

Senator SCHWEIKER. You are saying you do have legislative authority for initial notification. Is that what you are saying?

Dr. FINKLEA. I would think we could write people that they had been exposed. As public health professional and physician, I would like to be assured by my colleagues——

Senator SCHWEIKER. Why do we not do that if that is the case?

Dr. FINKLEA. I think that maybe what would be advised by NACOSH. But I think we should carefully look at the consequences notification would have on the individual's behavior and health. Perhaps Dr. Newell and Dr. Fink can comment on our experience in the two demonstration projects with this problem.

I think it would be very helpful.

Mr. WALDERMAN. Section 20(d), talks in terms of information that has been obtained by the Secretary of Labor and the Secretary of HEW, and it says it shall be disseminated by the Secretary of Labor to employers and employees. I think the gist of section 20(d) was the dissemination of general research, although I must say that I guess information to be——

Senator SCHWEIKER. Section 20 covers basically your whole authority. All your authority is listed under research and related activity, is that not what you are doing in NIOSH, research?

Mr. WALDERMAN. That is true. But when you say the Secretary in this particular statute, it means the Secretary of Labor.

Senator SCHWEIKER. I understand that. But since the information is obtained by you, it says information obtained by the Secretary and the Secretary of HEW, meaning you under delegation of authority, shall be disseminated by the Secretary. So it would seem to me to be a responsibility to you to provide that information to the Secretary of Labor to disseminate. How do you read it?

Mr. WALDERMAN. I think the section has been used——

Senator SCHWEIKER. It says information obtained by you and the Secretary. He has information, and is responsible for disseminating it. But it has to come from you if you have formulated it.

Dr. FINKLEA. That section has been used to refer to health and safety guides, current intelligence bulletins, and to employee safe practice pamphlets developed by us and by the Department of Labor, rather than looking at it as enabling individual notification of workers who may be exposed.

Senator SCHWEIKER. You keep saying that.

What is a worker or organization or employee but the people who are working in that workplace? Again, what am I missing here? What do those words mean if they do not mean what I say they mean?

Mr. WALDERMAN. I think you could probably use that section to give workers the kind of notification you are talking about. There is probably authority there although it has not been used for this purpose. Under section 20(a)(6) the Secretary of HEW has distributed that kind of information to affected employees under the health hazard evaluation portion of NIOSH's program. But I think you are correct. The information has not been disseminated to individual employees.

Under section 20(a)(6), the NIOSH health hazard evaluation program, determinations of potential toxicity are distributed to representatives of employees under the NIOSH regulations. These reports have to be posted for affected workers.

Senator SCHWEIKER. Under what section?

Mr. WALDERMAN. 20(a)(6). It is the same general section you were reading from, out paragraph 20(a)(6).

Senator SCHWEIKER. But that section—that is section 20. Under the whole topic of research and related activities, it has subsections (a), (b), (c), (d), et cetera. Subsection (d) applies to the whole section on research, and the whole research section deals with the very thing you have discovered, who is at risk of cancer and who is not. Subsection (d) applies to the whole section. It goes from (a) to (b) to (c) to (d), and they all modify section 20. That's my point. That information clearly is to be disseminated to employers and employees and organizations thereof in the whole section, related research and other related activities; (c) does not modify (d), or 6 does not modify (e) in any way. That is the general catchall thing to tell somebody they are sick, as I see it. I gather you do not see it that way.

What does that section mean if it does not mean what I think it means? Will somebody explain that to me? If we are not to tell employees and associations of this information obtained, what does it mean if it does not mean what I interpret it to mean to cover in this case?

Dr. FINKLEA. I think we have tried to make such information available. We said we have not used that section of the act to notify individuals.

Senator SCHWEIKER. You have not used it. What does it say to do? To notify employees. Who are employees, but individuals?

Dr. FINKLEA. To notify individuals who may have worked in a place, but be no longer working there—we do try to take a great deal of care to make information available to workers and to employers on both our studies and health recommendations. But I think the situation we described was largely the followup of people who had been exposed in past years. Since many of these record studies start off with employment records that may be 20 years old, a substantial number of workers have changed jobs and retired before you get to do the study. Those are the people who generally would not be aware of the results of the study. I think Dr. Wagoner could give you an idea of the magnitude of that sort of dropout in the usual sort of studies that are done by his group in that effort.

Mr. WALDERMAN. It also may be that retired individuals are not employees under the act.

Senator SCHWEIKER. Say that again.

Mr. WALDERMAN. Retired individuals are not employees since an employee is someone who is employed by the employer.

Senator SCHWEIKER. How about if their association is still in existence? Does that mean that ends your responsibility for notification? In other words, I would not necessarily agree with you on retired employees. But even if you argue that point, how about an association of retired employees or group that represents retired employees.

Mr. WALDERMAN. You would not want to transmit——

Senator SCHWEIKER. It says, organizations thereof.

Mr. WALDERMAN. You would not want to transmit medical information on individual employees or individual persons to an organization, in view of the Privacy Act.

Senator SCHWEIKER. Would you tell the organization that some of their people may be at risk?

Mr. WALDERMAN. They do that now.

Dr. CRAFT. We have examined some workers in a smelter in the Midwest, and we have found some of them have compromised renal function, which means they should not be exposed to lead any more. I would like to tell the employer these employees should not be exposed any more, but the employee must give me his permission to identify him to the employer, and the employee is afraid of getting fired, so he will not permit me to let his employer know. So we are caught in a big circle.

The responsible plant management would wish to know who they are, so they can reassign the employees. Not trusting plant management, the employee is willing to risk his future health for the present job. That is a void in the law.

Senator SCHWEIKER. Let me conclude. I've taken a lot of time. Let me understand one question. Forgetting retired employees, which is obviously a questionable area, though I would disagree with your interpretation, have we notified people who we know to be at risk if they are presently on the job? Have we notified individuals who we know to be at risk in all of our studies who are presently on the job?

Dr. WAGONER. As part of our ongoing studies, anybody who has been examined or is in the facility as an active employee is notified of the hazard and is notified of his individual medical results, as is his designated physician. The real problem is that we live in a very mobile

society, with a major turnover of our labor force, and we can go into a benzidine plant in the United States where they have a current labor force of 60 people, and over 10 years, they may have cycled 600 people in that facility who are dispersed throughout the United States. They are no longer employed by the company in question, but they have been exposed to the agent which has been recently reported to cause bladder tumor in 100 percent of the employees in Italy, 90 percent in Czechoslovakia, and a third of the employees in the United States.

The real question at issue here is the obligation to tell, in a subpopulation, who is most prone toward cancer. And it is not the current employee, as cancer does not occur today as a result of today's exposure, but it occurs 20 years from now after the person is least able to handle, is least aware of the problem.

Senator SCHWEIKER. I understand what you are saying. I further understand that a Philadelphia concern had a problem with cancer just a few years ago. A person on my staff was notified 10 years later that he might be at risk for cancer. Somebody is doing it now. The point is, if somebody is doing it now, why is not NIOSH doing it now? Here we are laying down these great statutes for everybody to follow. When it comes to NIOSH, we do not follow them. In my case, my employee was notified 10 years later that he may be at risk of cancer. Somebody had directed that company to go out and find out where he was, get his social security number, to check his present occupation, which happened to be on my staff. And he was notified 10 years after the fact that he was at risk. Why cannot NIOSH do that with people who have moved or retired? I still have trouble understanding that, but I will not pursue the argument, because I've taken too much time.

Senator JAVITS. I assure you, Senator, we will pursue the argument.

The CHAIRMAN. At a minimum, those who are now employed in a situation or job within an industry that has a risk, do they know their risk?

Dr. WAGONER. We assume that they do, since we inform labor and management.

The CHAIRMAN. That is at a minimum. You're having trouble tracing back to the old employees who have been removed from the scene and are no longer working there. You are having trouble reaching them, is that right? Now, Dr. Finklea, you are quoted as saying you do not have enough funds to do this job. I am just wondering if you, in building up to the budget requests, have asked for a lot more than you have been able to make through OMB, or whether you have been asking for a lot more than have been made available through the budget processes here in Congress?

Dr. FINKLEA. I think that quote may be a bit out of context, Senator. I think we are dealing here with why our agency does not assure adequate identification of people, counseling and medical followup. As I said earlier, we are dealing with several hundred thousand workers exposed to carcinogens, and I think that far exceeds the budget that most health research groups would have. We do our best in the budget process, like everybody else, and we have had growth in our budget since passage of the act. We will try to be good stewards of the funds assigned to us. But if you are asking me would we ourselves with the National Cancer Institute, for example, have the wherewithal to insure adequate counseling and medical followup of all exposed to OSHA regulated carcinogens from now to the end of the expected latency, I

would say that that would be a very difficult question to answer. We would be glad to try to do it. I do not think those resources are available.

The CHAIRMAN. Under the law, do you understand it is your first responsibility, the notification of exposure, to employees?

Dr. FINKLEA. As I understand the law, I do not think we have responsibility for counseling and followup.

The CHAIRMAN. Notification of those having been exposed——

Dr. FINKLEA. I think we have responsibility to make sure information of that exposure is available, yes, sir. And we are trying to do that.

The CHAIRMAN. I heard Dr. Craft suggest it was the employer's responsibility.

Dr. CRAFT. It is the employer's responsibility under the act to inform his employees of their exposure, the signs and symptoms of that exposure, and consequences of that exposure.

The CHAIRMAN. It is, under the law, your obligation to advise the employer of the risk to his employees.

Dr. CRAFT. That is right.

Dr. FINKLEA. I think we have responsibility to inform the whole occupational health and safety community, including employers, employee representatives, and professionals involved.

The CHAIRMAN. We will follow up.

This is a matter that is of fundamental importance to the health of working people, and this is an area where unwise budget cutting does not appeal to the Congress, has not historically, and would not now either.

Senator JAVITS. Especially, Mr. Chairman, as it involves millions of Americans as the witness has testified.

The CHAIRMAN. I think we will want to confer with you to see in our followup what others we should be talking to about what might be lacking in legal authority. It looks as though the law was more comprehensive than might have been popularly thought after reading some of the newspaper accounts.

We will probably submit other written questions for a written response.

Thank you very much.

Senator JAVITS. Can we set a time, Mr. Chairman, within which we would like an answer—would 2 weeks be adequate?

Dr. FINKLEA. I think to get full evaluation by the National Advisory Committee on Occupational Safety and Health, it would take us probably anywhere from 3 to 6 months to look at the problem. We can give you some estimates of the size of the problem, and medical care followup of problems that could be encountered for OSHA-regulated carcinogens, and perhaps for other OSHA-regulated substances in the work force in a shorter period of time.

Senator JAVITS. Give us that in, say, 2 or 3 weeks.

Dr. FINKLEA. Yes, sir, I think we can do it for you in 3 weeks.

Senator JAVITS. Is that agreeable?

The CHAIRMAN. That is fine.

Senator JAVITS. I ask unanimous consent that that information will be a part of the record. It will be forwarded to us within 3 weeks.

The CHAIRMAN. Without objection, that is the way it will be.

[The prepared statement of Dr. Finklea and the above-mentioned material subsequently supplied, follows:]

Statement of

Dr. John F. Finklea, Director
National Institute for Occupational Safety and Health
Center for Disease Control
Department of Helath, Education, and Welfare

Before the
Subcommittee on Labor
Senate Committee on Human Resources

May 9, 1977

Testimony of Dr. John F. Finklea, Director
National Institute for Occupational Safety and Health
Center for Disease Control
Department of Health, Education, and Welfare

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear before you today to discuss how we have implemented certain aspects of our research program mandated by the Occupational Safety and Health Act of 1970. I am accompanied by Dr. Bobby F. Craft, Director of the Division of the Surveillance, Hazard Evaluations and Field Studies; Dr. Joseph K. Wagoner, Chief of the Industrywide Studies Branch; and Mr. Howard Walderman, an attorney with the Public Health Division of the Department's Office of General Counsel. The primary subject of our testimony today will be a discussion of our efforts to notify workers of health hazards they may have encountered on their jobs and to assist them in entering the medical care system for early diagnosis and treatment if indicated. We will also point out a number of areas where further efforts are required by NIOSH, by other government agencies, by industry, by organized labor and by the academic community.

NIOSH was established by the Occupational Safety and Health Act of 1970 to conduct programs of research, standards development, technical assistance and manpower development. One of our Institute's most important responsibilities under this act is to transmit recommended standards to the Occupational Safety and Health Administration (OSHA) in the Department of Labor. The NIOSH recommendations are intended to serve as the basis, along with other available information, for

assisting OSHA in developing new standards and in revising the approximately 400 consensus health standards that were promulgated when the act was passed.

NIOSH has transmitted more than 60 criteria documents recommending new health standards to the Department of Labor. These recommended health standards are transmitted to OSHA in the form of criteria documents which include an environmental limit for workplace exposure, as well as recommendations on the use of labels and other forms of warning, type and frequency of medical examinations, sampling and analytical methods, procedures for technological control of hazards, and suitable personal protective equipment. In addition to criteria documents, we have developed supplemental information on measurement of employee exposure, medical surveillance, complaince, training, recordkeeping and work practices for most of the approximately 400 existing consensus health standards. Once these recommendations have been promulgated into standards, and these standards are enforced, workers should be protected from many of the most serious occupational exposures.

These recommendations are based on laboratory and epidemiological research conducted by NIOSH and others. This testimony will focus on the kinds of epidemiological investigations conducted by our industrywide studies program and the procedures we follow in these studies to identify occupationally related hazards and to notify affected workers.

The two most common types of studies we conduct involving workers are retrospective cohort studies and cross sectional medical studies. In cohort studies we obtain employment records from unions, professional

societies, and companies for purposes of classifying workers according to departments where they worked, their job category, and the duration of their employment. Personal identifiers, including name and social security numbers, obtained during this process are used to determine the vital status and current address of the individuals through records kept by other Federal agencies, such as the Social Security Administration, and, until recently, the Internal Revenue Service. When we learn that an individual is deceased we attempt to obtain a copy of the death certificate from the State in which the death occurred. Using the death records, we contrast the observed risk of dying from specific diseases among our study population with the risk expected in that population if they had not been subject to the occupational exposures. To make these comparisons we use either the general population or another industrial population not exposed to the agent under investigation as control groups.

In cross sectional medical studies we elicit a personal history and physically examine workers who have had exposures to agents under investigation as determined by industrial hygiene sampling. The results of these medical examinations are compared with accepted medical norms or similar test results from another population not exposed to the agent in question. In both study approaches the medical, statistical, and industrial hygiene disciplines contribute to the identification of occupationally related health problems.

NIOSH has promulgated regulations governing field investigations (42 CFR Part 85A). Under these regulations, it is our practice to meet with company management and with employee representatives before initiating a study to explain its purpose and scope. Before conducting

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medical examinations, investigators must receive specific approval from the NIOSH Human Subjects Review Board and the informed consent of each employee examined. All employees we examine and their designated physicians are notified of the results of these medical examinations. Before releasing final reports on group data (with individual identifiers removed) we provide draft copies to employers and employee representatives for their comments on technical accuracy. The results of our epidemiologic studes are presented in NIOSH criteria documents and technical reports, in scientific journals, at scientific meetings, and at OSHA hearings on workplace standards.

Workplace investigations are also conducted in our health hazard evaluation program. Under this program we respond to requests from employers and employee representatives to investigate a workplace, collect environmental samples, make toxicity determinations, and provide medical examinations of workers. The results of these investigations, including recommendations for work practices, personal protective equipment, and engineering controls, are reported back to plant management and employee representatives.

INFORMATION DISSEMINATION

A vital part of our research program is getting information to those who can put it to good use--workers, employers, occupational safety and health professionals, other government agencies, and other researchers. Toward this end NIOSH has developed a program of information dissemination. This year we will issue over 100 different NIOSH publications and many additional articles appear in scientific journals. We will distribute about one and one half million copies of our publications and additional copies will be available from the

Government Printing Office and the National Technical Information Service of the Department of Commerce. One of these documents, used primarily by health professionals, is our annual Registry of Toxic Effects of Chemical Substances, which in 1976 listed approximately 21,000 different chemicals. A subfile of suspect carcinogens from that list contained 2,400 substances and another subfile is being developed on pesticides and agricultural chemicals. NIOSH also sponsers conferences and publishes their scientific proceedings. In addition to publishing scientific proceedings of a conference on occupational carcinogenesis which we co-sponsored, we are publishing a version written in non-technical language to be used by workers and other laymen.

We have developed a series of health and safety guides specifically targeted on small businesses. These guides, covering such diverse establishments as auto repair and body shops, foundries, and sporting goods stores, give general health and safety guidelines and provide a checklist of OSHA regulations applicable to that particular establishment. We also have a series of good work practices manuals for workers in different occupations.

A criteria document, "An Identification System for Occupationally Hazardous Materials," which was transmitted to the Department of Labor in 1974, presented a uniform identification system that would alert employers and employees to hazardous chemicals through placards, labels, and material safety data sheets. This system would provide for the identification of hazardous materials, indicate the degree and type of hazard, describe symptoms of overexposure, and prescribe safe handling procedures, emergency care, and disposal methods. Adherence to such a

system would substantially improve the information available on chemical exposures in the workplace.

Criteria documents can serve a useful purpose even before being promulgated into enforceable standards. They are widely distributed and many companies and unions use them as a basis to control hazards even though the documents do not have the force of law. The provide an up-to-datereview of the existing literature and state of knowledge on a hazard and serve as an impetus for further research by NIOSH and others.

Late this year NIOSH will publish five documents summarizing in non-technical language the supplemental information developed on the consensus health standards promulgated by OSHA. One document will be a general guide, one will be a pocket handbook, and the remaining documents will cover respirators, personal protective equipment and medical monitoring.

We issue current intelligence bulletins when we receive new information on potentially dangerous chemical substances. In 2 to 4 weeks we can provide background information on the chemical, including its known toxicity to man and animals, known producers and users, estimated extent of occupational exposure, and further NIOSH action planned. These bulletins are now distributed to 1,200 representatives from the occupational safety and health community, other government agencies, management, labor, and public interest groups.

NATIONAL OCCUPATIONAL HAZARD SURVEY

Despite these efforts we recognize that employers and employees are still not generally well informed about occupational health hazards. Between 1972 and 1974 NIOSH conducted a National Occupational Hazard Survey to determine the extent of worker exposure to chemical substances

and physical agents. Visits were made to 4,636 workplaces selected to provide 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 chemical and physical agents.

Although we have had access to certain aspects of the survey in making rough estimates of specific workers exposures, we are just now beginning to be able to use the data in establishing priorities and projecting worker exposure to a large number of hazards. A major problem in completing the study is that companies surveyed were often 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. We contacted more than 10,000 manufacturers to identify precisely what chemicals were contained in these trade name products. To date, we have determined the chemical composition of only slightly more than half of those trade name products.

Based on our survey, we estimate that more than 7 million workers in the United States 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 currently 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.

INFORMING EMPLOYEES AND EMPLOYERS ABOUT WORKPLACE EXPOSURES

In administering our responsibilities under the Occupational Safety and Health Act of 1970, we have identified a number of problem areas in occupational health that are not being adequately dealt with by our Institute, by other government agencies, by management, by labor, and by the academic community. We would like to state the problems as we see them and offer suggestions for dealing with them through the combined efforts of various sectors of society.

The widespread use of trade name products and lack of a uniform system for labeling hazardous materials makes it difficult for workers to know what substances they are exposed to. This problem is compounded by the frequent claim that product ingredients are trade secrets, even though they may be known to be toxic or even cause cancer. Interactive effects of certain mixtures can be more toxic than any of its separate components, as for example when rust preservatives (nitrites) and emulsifiers (amines) used in some cutting and hydralic fluids have the potential to combine to form nitrosamines, a potent class of carcinogens.

NIOSH will take the following steps with regard to information collected during the National Occupational Hazard Survey:

.Transmit to OSHA and EPA a listing of trade name products that contain an OSHA-regulated carcinogen.

.Notify companies that we intend to make information on the presence

of an OSHA-regulated carcinogen in a trade name product generally available if it has not been designated as trade secret. If the presence of an OSHA-regulated carcinogen in a product has been designated as a trade secret, we will attempt to remove that designation in accordance with procedures set forth in 42 CFR section 85.7(b). These procedures were administratively adopted by NIOSH to apply to "trade secrets" obtained in the survey. We will notify companies in writing that we question and intend to remove the trade secret designation. Companies have 15 days from notification to provide evidence to support their claim that the information is in fact a trade secret. When trade secret designations are removed NIOSH will make the information available to the public.

.Notify companies that have not revealed the composition of their trade name products to NIOSH that we believe they should take immediate steps to inform their customers if one or more of their products contains an OSHA-regulated carcinogen and inform us of what action they are taking.

.Offer to assist workers, employers, or formulators of trade name products to find out whether or not their products contain an OSHA-regulated carcinogen. We believe responsible trade associations and private laboratories can assist in this effort.

.Request that the Environmental Protection Agency take regulatory action under the Toxic Substance Control Act that will assure labelling of any trade name product containing an OSHA-regulated carcinogen.

.Consider similar steps for trade name products containing other OSHA-regulated chemicals or substances or any chemicals newly

identified as posing health hazards. We believe, however, that it is important to deal first with currently regulated carcinogens.

.Continue our efforts to resolve the components in trade name products collected during our National Occupational Hazard Survey and develop a mechanism to update that survey.

.Continue to support adoption of a uniform labelling and warning system such as that recommended in our 1974 criteria document.

.Propose that a clearinghouse be established, either by the government or by private industry, to provide information on trade name products that would protect consumers and workers without revealing legitimate trade secrets.

Cosmetic Labeling regulations, recently promulgated by the Food and Drug Administration, which list constituents in order of diminishing concentration without revealing the precise amount might serve as a useful beginning.

Medical Follow-up of Workers Exposed to Toxic Substances

NIOSH has been criticized for not informing all workers in our past study populations that they may have been exposed to hazardous chemical or physical agents and ensuring that they receive the opportunity for diagnosis and treatment where indicated. We recognize the need for such notification and medical follow-up and have been vocal in stating that, except in certain limited cases, the need is not now being met. Conducting such a program on our own would be beyond our existing resources and legislative authority, which are primarily directed toward providing the scientific basis for standards to prevent future occupational exposures.

We have already mentioned ways in which we notify workers on the results of our studies. We discuss the results of our research with management and labor at plants where the studies were conducted. Although we do not notify workers individually, unless we have examined them, we expect that those still employed at the plant would generally be informed about our study results by their union or by management. We would not expect that workers in other similar plants would be directly informed about the results of our studies. An even bigger problem involves workers who once worked in such plants but no longer do so. These workers who may have changed jobs or retired are less likely to know of health risks attributable to past workplace exposures. Forcertain specific populations shown to be at high risk we have worked with the National Cancer Institute to ensure that medical examinations are provided to affected workers. Two such examples include former asbestos workers in Tyler, Texas, and former benzidene workers in Baltimore. We have also assisted management in providing medical examinations to former worker of a bis-chloromethyl ether plant. We are currently providing medical examinations to all interested current and former employees of the Velsicol Chemical Plant in Bayport, Texas, who were exposed to the pesticide Phosvel, a neurotoxin.

We are aware that these limited programs do not assure adequate follow-up of exposed workers. Such a program would require the combined efforts of all government agencies involved in evaluating or regulating substances to which workers are exposed. It would also involve the efforts of private industry and academic institutions who conduct occupational health studies. It would certainly involve those

industries which expose their employees to toxic substances and unions representing their workers.

The success of such an effort will also depend on the existence of a supply of occupational safety and health professionals and a health care system adequate to meet the increased demand for services. As a physician, I must also point out that although medical surveillance for early diagnosis and possible treatment of occupational disease can be helpful, it also has its limitations. There are a number of occupational illnesses, including certain forms of cancer, which do not respond well to available medical and surgical treatment. New diagnostic techniques are being developed that might indicate which individuals are at greatest risk, but we are not yet sure that widely applying them would assure diagnosis in time to change the course of the illness. An example of such a technique is exfoliated cytology, that is, examining cells from the respiratory tract, the bladder, and other sites for pre-cancerous changes.

By pointing out the limitations of current medical surveillance techniques, I do not mean to say that medical surveillance of workers at risk is not important. Potentially high risk workers should in fact be provided with the best medical screening and care that current science and technology allow. At the same time we in the Federal government should encourage research that will provide more effective methods of diagnosis and treatment.

There are additional barriers to assuring adequate follow-up of exposed workers. The Occupational Safety and Health Act of 1970, unlike section 203 of the Federal Coal Mine Health and Safety Act of 1969, does not provide for the right of transfer to a less hazardous worksite at

the same rate of pay once a worker shows clinical evidence of occupational illness. It has been our experience that some workers, once notified that they may have health problems, refuse to seek further medical evaluation because they fear loss of their jobs once their condition becomes known. For example, a lead worker with impaired renal function may not be able to get a job assignment that does not involve lead exposure and is very unlikely to get compensation until clinical disease is further advanced.

Workers' compensation laws do not adequately address occupational diseases, especially those with long latency periods or those that have multiple causes. Workers' compensation laws do not generally provide for payments to a worker that may show evidence of impaired functional ability but not frank clinical disease. Yet evidence of early disease, impaired functional ability, or even a previous work history of exposure to agents inducing disease with a long latency period may be sufficient to limit employment opporutnities for workers. This is because the employer of last record is usually responsible for compensation even though exposures at previous worksites may be partially or wholly responsible for late developing illnesses.

The question we must ask is what can each sector of society do now to notify workers about occupational hazards they encounter and provide adequate medical care and compensation for those affected. NIOSH is taking the following steps with regard to worker notification and follow-up:

.We will seek further assistance from the National Cancer Institute ensuring that specific worker populations are notified and placed

in health care systems.

.We will ask the National Advisory Committee on Occupational Safety and Health (NACOSH) to advise NIOSH and OSHA on the regulatory social and health aspects of informing, protecting, and caring for exposed workers.

.We have drafted regulations that would enable us to require employers to provide their employees with medical examinations at NIOSH expense under certain circumstances.

.We will notify all employees whose medical records were submitted to NIOSH pursuant to provisions in OSHA carcinogen standards of their potential exposure to a cancer-causing agent. We will assist these employees in obtaining access to medical care.

.We are accepting applications to fund educational resource centers to train occupational physicians and nurses, industrial hygienists, safety engineers, and related professioanls and expect to begin funding these centers by the end of the fiscal year.

In addition, we would support the following steps to be taken by others:

.Other government agencies need to examine their provisions for worker notification and follow-up.

.We are supporting OSHA's efforts to promulgate comprehensive health standards at a faster rate. Such standards would prescribe medical examinations required to be made available by the employer to his employees presently exposed to the hazard. It is doubtful, however, that former employees could be covered by these provisions.

.Companies and unions must also take responsibility for

determining what hazards are present in the workplace and notifying potentially exposed workers.

.Companies must provide adequate health insurance, job retention, job reassignment, and workers' compensation policies so that the individual worker is adequately protected from the medical and economic consequences of occupational exposures.

The primary purpose of the Occupational Safety and Health Act of 1970 is to establish standards that will reduce workplace exposures to safety and health hazards so that no worker will suffer diminished health, functional capacity, or life expectancy as a result of his work experience. Until adequate standards are developed, however, we must not forget to provide for the workers suffering as a result of existing workplace conditions.

Mr. Chairman, I will be pleased to answer any questions you or Members of your Subcommittee may have.

THE RIGHT TO KNOW

PRACTICAL PROBLEMS AND POLICY ISSUES ARISING FROM EXPOSURES TO HAZARDOUS CHEMICAL AND PHYSICAL AGENTS IN THE WORKPLACE

Prepared by the National Institute for
Occupational Safety and Health,
Center for Disease Control,
U.S. Department of Health, Education, and Welfare

July 1977

C O N T E N T S

I. EXECUTIVE SUMMARY AND CAVEATS

SUMMARY:

Implementing Congressional mandates intended to minimize health and safety risks arising from exposures to hazardous chemical and physical agents is one of the most difficult long range problems faced by the Executive Branch.

Large numbers of workers (as well as substantial numbers of the general population) have already been exposed and are continuing to be exposed to a wide variety of potentially harmful chemical and physical agents. Most of these citizens are unaware of such exposures. This problem exists primarily because the potential health risks of new technologies and the commercial utilization of new chemicals has not been carefully considered or has not been well understood prior to their introduction into commerce. Even where health risks were well understood, industry has at times been reluctant to take steps that adequately protect workers and consumers.

Congressional concern has been expressed about the failure of the Federal Government to provide timely, adequate information to individual workers facing an increased risk of developing cancer and other diseases as a result of workplace exposures. The Senate Human Resources Committee has brought this issue to the forefront by requesting an investigation into "the social responsibility of biomedical research for occupational health and the need for employers with knowledge to take affirmative action to notify and provide fair health protection from exposure to health related environmental risks and to assure protection for workers and their families from work-related environmental health risks."

The National Institute of Occupational Safety and Health conducts a number of activities which provide information to employers and workers on workplace hazards and their control. In spite of the efforts of NIOSH, the need for informing workers is not always fully met. Clearly workers have the right to know whether or not they are exposed to hazardous chemical and physical agents regulated by the Federal Government. However, this right is linked to a complex series of problems which must be faced and resolved if any worker notification effort is to be succesful. A number of these are summarized below.

Notification. Serious questions can be raised about whether notification in and of itself would be helpful to the individual. In some cases, it could be detrimental without assuring that provision has been made for counseling and medical follow-up and treatment.

Measurements. The lack of consistent monitoring of workplace exposures to hazardous substances makes it difficult to assess worker exposure to specific agents. This could result in notification of some workers who are not at risk.

Follow-up. There is a major gap in health and safety legislation dealing with past exposures to occupational health hazards. When workers exposed to carcinogens or other agents causing delayed toxicity leave one job for another or leave the workforce voluntarily or through retirement, there is currently no effective mechanism for notification, and for arranging and paying for medical examination.

Cancer Screening Procedures. The application of cancer screening procedures to apparently healthy individuals at risk is very complex. There are few, if any, simple procedures which can be applied to asymptomatic individuals repeatedly for many years at some interval which have been scientifically studied in proper clinical trials.

Transfer Rights. Up to the present time employees covered by the Occupational Safety and Health Act have not been provided with transfer and wage-retention rights when their functional capacity has been impaired or when they are at increased risk because of heavy exposure to OSHA regulated substances. This is in direct contrast to the Coal Mine Health and Safety Act which provides such protections. Consequently, unprotected workers may hesitate to seek desirable medical follow-up because their current employment may be jeopardized or future job opportunities limited.

Worker's Compensation. State workers' compensation systems do not adequately identify or equitably deal with occupational health problems. In general little or no provision is made to provide for medical examinations of former workers who were exposed to toxic agents, including carcinogens, but who are not clinically ill. Diagnosed occupational diseases generally are not adequately compensated.

Health Insurance. Most existing health insurance policies do not provide for diagnostic procedures or follow-up examinations made necessary by exposure to toxic substances in the workplace or in the general environment.

Inflationary Impact. Inflationary impact statements required for occupational safety and health standards consider only direct outlays by industry. They do not consider the costs of workplace exposures including counselling and medical follow-up which are now hidden or being borne by others. The cost of research will also be increased if agencies are to notify and counsel all individuals involved in studies utilizing records

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and not involving personal contact. No provision now exists to pay for any follow-up examinations that may be requested by persons included in such record studies.

Disclosure. A major stumbling block to identifying exposed workers is the failure of chemical re-packagers and primary producers to show the chemical composition of their product.

POTENTIAL CANDIDATES FOR NOTIFICATION

The following are estimates, based on information derived from current NIOSH studies and surveys of health hazard exposures in the American workplace:

--As many as 880,000 American workers, or one percent of the current labor force of 84 million persons currently face full or part-time exposure to carcinogens regulated by the Occupational Safety and Health Act (OSHA).

--One in every four American workers (approximately 21 million) currently may be exposed on either a full or part-time basis to OSHA-regulated hazardous substances. Upwards of 40 to 50 million persons or 23 percent of the general population in the United States may have had exposure to one or more of OSHA-regulated carcinogens or hazardous substances during their working lifetimes.

COSTS

--The aggregate annual costs of physical examinations for workers currently exposed to carcinogens on either a full or part-time basis are estimated to be about $230 million. The actual amount would depend on particular examination costs and the degree or worker participation.

--The annual costs to society of monitoring workers with either full or part-time exposures to all OSHA-regulated hazardous substances including carcinogens could range between $675 million and $2 billion.

POLICY IMPLICATIONS

Based on the results of this preliminary assessment of the magnitude and impact of the workers' right to know under OSHA, the following are principle policy implications for investigation and consideration by DHEW, DOL, Interior, ERDA, EPA, DOD, and other involved Federal agencies and the Congress.

--requirement of employers to notify all workers both past and present about exposures to Federally regulated toxic substances;

--transfer and wage retention rights for exposed and disabled workers beyond those currently in force under existing law or major industrial union collective bargaining agreements. This in turn has very strong implications in possible future disability claims.

--mandatory disclosure of trade product chemical contents through amendment of the Toxic Substances Control Act and enforcement by the EPA and OSHA;
--financial incentives to facilitate the development and introduction of industrial products with fewer possible carcinogenic properties or hazardous exposures. This would avoid the extensive social costs of monitoring and compensating current exposures with their untoward results on both workers and the general community.

CAVEATS:

The rough estimates provided in this report should be viewed as a first, but hopefully useful, approximation of the problems and issues which flow from the right to know. A great deal of further discussion and refinement will be necessary. Throughout the report the authors have emphasized the uncertainties inherent in preparing this first approximation. A number of these caveats should be re-emphasized.

--There may well be conscientious responsible persons who disagree with the basic assumption that workers and the general public have a right to be informed about current and past exposures to toxic substances that pose actual or potential health risks.
--Serious questions can be raised about whether or not it is necessary to notify individuals directly even though very few would deny the need to better inform employers and employees about workplace exposures through more general educational measures.
--Estimates of the numbers of workers exposed to various chemicals are not nearly as precise or as current as one would like. These estimates will be improved as the National Occupational Hazards data base becomes more easily accessible and is updated.
--The duration and intensity of exposure to hazardous substances currently regulated by the Occupational Safety and Health Administration are not well quantified. Better definition of the extent of exposure is important if one is to deal effectively with the "right to know" problem because the best known determinant of health risk is the extent of exposure. Exposures below the "action level," usually set at one-half of the recommended environmental limit, would not generally require medical follow-up.
--With better definition of the scope and frequency of the medical examinations required and more experience in demonstration projects, cost estimates might change appreciably.
--It is likely that research will uncover new workplace hazards and reveal that exposures to some agents previously considered to be relatively innocuous do in fact pose significant health risks.

II. INTRODUCTION

Implementing Congressional mandates intended to minimize health and safety risks arising from exposures to hazardous chemical and physical agents is one of the most difficult long range problems faced by the Executive Branch. Current public policy recognizes the right of citizens to be informed about known hazards and to participate in the regulatory process. Congress has also enacted the Toxic Substances Control Act which among other things can require the labelling of existing chemical mixtures and is intended to prevent the introduction or restrict the commercial use of new chemicals and substances which may pose an unreasonable risk to health or to the environment.

As part of the overall effort, the Public Health Service as well as other Federal Departments and Agencies have accelerated their research to identify new environmental contaminants and workplace hazards and to define more adequately the scope of hazards that were already suspected or clearly recognized.

Large numbers of workers and substantial numbers of the general population have already been exposed and are continuing to be exposed to a wide variety of potentially harmful chemical and physical agents. Most of these citizens are unaware of such exposures. This problem arose because the potential health risks of new technologies and the commercial utilization of new chemicals were not carefully considered or were not well understood. Even where health risks were well understood, industry has at times been reluctant to take steps that adequately protect workers and consumers. Control of workplace exposures and prevention of chemical contamination of communities continue to be vexing problems for the Federal Government.

At a minimum, workers and members of communities exposed to substances or physical agents that are clearly hazardous have a right to know that such exposures have occurred. Notification of workers and communities does not, however, complete the process. Once notified, workers and exposed members of the general community require counselling and may need or demand medical examination. Mechanisms exist to handle accidents and the immediate acute effects of accidental chemical contamination, but mechanisms are generally not in place to provide for counselling and medical examination when the health effects of workplace exposures or environmental contaminations are delayed. In the case of carcinogens, a latency period up to several decades may elapse between workplace exposures and the appearance of a clinically recognizable cancer. Delayed effects other than carcinogenesis are also being recognized with increasing frequency. The signs and symptoms of delayed toxicities may be rather non-specific and involve a number of organ systems or may be

recognized as distinct clinical diseases such as the pneumoconioses.

As additional recommended health standards for the workplace are promulgated under the Occupational Safety and Health Act, employers will continue to be required to notify, counsel and provide preventive medical services for employees exposed to many of the more hazardous agents. The Federal Coal Mine Health and Safety Act also provides a mechanism to deal with these issues. Relatively few employers provide these services when Federal laws or regulations do not require them. There is, however, a major gap in health and safety legislation dealing with occupational health hazards. When workers exposed to carcinogens or other agents causing delayed toxicity leave one job for another or leave the workforce voluntarily or through retirement, there is no mechanism to provide or pay for notification, counselling and medical examination.

The practical problems and policy issues flowing from the principle that workers and the public have a right to know can be better understood by considering the answers to the following ten questions:

--Why aren't employers and employees already informed about current and past exposures?

--What steps have Federal Agencies taken to inform workers and control exposures?

--How many workers are exposed to hazardous or toxic substances currently regulated by the Occupational Safety and Health Administration (OSHA)?

--How can individual workers be notified?

--What counselling might be necessary?

--What kinds of medical examination might be required?

--What are the estimated costs of notification, counselling and medical examination?

--What steps can NIOSH take to provide notification and medical follow-up for exposed workers?

--What policy issues should be considered?

--What important caveats must be kept in mind?

III. WHY AREN'T EMPLOYERS AND WORKERS ALREADY INFORMED ABOUT CURRENT AND PAST EXPOSURES?

Employers and employees are still not generally well informed about occupational health hazards. Between 1972 and 1974 the National Institute for Occupational Safety and Health (NIOSH) conducted the National Occupational Hazard Survey (NOHS) to determine the extent of worker exposure to chemical substances and physical agents. Visits were made to 4,636 workplaces selected to provide a cross-section of industry by type and size. The NIOSH teams collected general information about each plant such as its major product or service, the number of employees, available illness and injury statistics, the availability and kind of medical care. They also recorded the number of workers in each job category potentially exposed to chemical and physical agents.

Although we have had access to certain aspects of the survey in making rough estimates of specific worker exposures, we are just now beginning to be able to use the data in establishing priorities and projecting worker exposure to a large number of hazards. We have found that an individual employee is often exposed to more than one substance regulated by the Occupational Safety and Health Administration (OSHA). A major problem in completing the study is that employers were often not aware of the chemical composition of the substances used in their plants. Over 70 percent of the exposures identified were recorded as trade name products for which the chemical composition was not known to the company. We have contacted more than 10,000 manufacturers to identify precisely what chemicals were contained in these trade name products. To date, we have determined the chemical composition of only slightly more than half of those trade name products. Some of the manufacturers who responded stated that their trade product contained trade secrets. Of those trade products which contained OSHA regulated substances, 32.5 percent were designated as trade secrets by the manufacturer and a portion of these were OSHA regulated carcinogens.

The National Occupational Hazard Survey shows that the widespread use of trade name products and lack of a uniform system for labelling hazardous materials makes it difficult for workers to know the nature of substances they are exposed to. This problem is compounded by the frequent claim that product ingredients are trade secrets, even though ingredients may be known to be toxic or even cause cancer. Furthermore, interactive effects of certain mixtures can be more toxic than any of the separate components. For example, rust perservatives (nitrites) and emulsifiers (amines) used in some cutting and hydraulic fluids

have the potential to combine to form nitrosamines, a potent class of carcinogens.

There are a number of other factors that also contribute to the problem. Educational programs for workers and employers are not as well developed in the United States as in a number of other countries. Plant health and safety committees are an exceptional rather than a common finding in the United States. Industrial hygiene and occupational health services are not available or not utilized by most businesses. Trained occupational health professionals are in short supply and most of the nurses and physicians working in the field are treatment oriented and have received little formal training in toxicology, ergonomics or industrial hygiene. Occupational health personnel are not generally responsible for and usually have only limited involvement in care and rehabilitation of workers who become ill or who are injured. This discontinuity in the health care system contributes to several problems. Physicians caring for ill or injured workers often do not elicit detailed work histories and occupational health personnel often don't have available to them knowledgeable medical specialists with a variety of clinical skills. There are also other social and educational factors that tend to limit the interest of health professionals in workplace problems.

IV. WHAT STEPS HAS NIOSH TAKEN TO INFORM WORKERS AND CONTROL WORKPLACE HAZARDS?

A vital part of any research program is getting information to those who can put it to good use, in this case unions, employers, occupational safety and health professionals, other government agencies, and other researchers. Toward this end NIOSH has developed a program of information dissemination. This year we will issue over 100 different NIOSH publications and many additional articles will appear in scientific journals. We will distribute about one and one half million copies of our publications. Additional copies will be available from the Government Printing Office and the National Technical Information Service of the Department of Commerce.

One of these documents, used primarily by health professionals, is the annual Registry of Toxic Effects of Chemical Substances, which in 1976 listed over 25,000 different chemicals. A sub-file of suspected carcinogens from that list contained nearly 2,000 substances and another sub-file is being developed on pesticides and agricultural chemicals. NIOSH also sponsors conferences and publishes their scientific proceedings. In addition to publishing scientific proceedings of a conference on occupational carcinogenesis, which we co-sponsored, we are publishing another version written in non-technical language to be used by workers and other laymen.

We have developed a series of health and safety guides specifically targeted on small businesses. These guides, covering such diverse establishments as auto repair and body shops, foundries, and sporting goods stores, give general health and safety guidelines and provide a checklist of OSHA regulations applicable to that particular establishment. We also have a series of good work practices manuals for workers in different occupations.

A criteria document, "An Identification System for Occupationally Hazardous Materials," which was transmitted to the Department of Labor in 1974, presents a uniform identification system that would alert employers and employees to hazardous chemicals through placards, labels, and material safety data sheets. This system would provide for the identification of hazardous materials, indicate the degree and type of hazard, describe symptoms of overexposure, and prescribe safe handling procedures, emergency care, and disposal methods. Adherence to such a system would substantially improve the information available on chemical exposures in the workplace.

One of NIOSH's most important responsibilities under the Act is to transmit recommended standards to the Occupational Safety and Health Administration (OSHA) in the Department of Labor. The NIOSH recommendations are intended to assist OSHA in developing new standards and in revising and completing the approximately 400 consensus health standards which consist only of environmental limits that were promulgated when the Act was passed.

NIOSH has transmitted more than 60 criteria documents recommending new health standards to the Department of Labor. These criteria documents include an environmental limit for workplace exposure, recommendations on the use of labels and other forms of warning, type and frequency of medical examinations to be provided by the employer, sampling and analytical methods, procedures for technological control of hazards, and suitable personal protective equipment. Criteria documents serve a useful purpose even before being promulgated as enforceable standards. They are widely distributed and many companies and unions use them as a basis to control hazards even though the documents do not have the force of law. They also provide an up-to-date review of the existing literature and state of knowledge on a hazard and serve as an impetus for further research by NIOSH and others.

In addition to criteria documents, under a joint Standards Completion Program with OSHA we have developed draft technical standards for most of the consensus health standards. These standards supplement the existing environmental limits with procedures for informing employees of hazards, monitoring techniques, engineering and control mechanisms, and medical surveillance programs. Once these recommendations have been promulgated as standards and these standards are enforced, workers should be protected from many of the most serious occupational exposures. Late this year NIOSH will publish five documents summarzing in non-technical language the supplemental information developed on the consensus health standards promulgated by OSHA. One document will be a general guide, one will be a pocket handbook, and the remaining documents will cover respirators, personal protective equipment and medical monitoring.

We also issue current intelligence bulletins when we receive new information on potentially dangerous chemical substances. In two to four weeks we can provide background information on the chemical substance, including its known toxicity to man and animals, known producers and users, estimated extent of occupational exposure, and further NIOSH action planned. These bulletins are now distributed to 1,200 representatives from the occupational safety and health community, other government agencies, management, labor and public interest groups.

NIOSH has promulgated regulations governing field investigations (42 CFR Part 85a). Under these regulations, it is our practice to meet with company management and with employee representatives before initiating a study to explain its purpose and scope. Before conducting medical examinations, investigators must receive specific approval from the NIOSH Human Subjects Review Board and the informed consent of each employee examined. All employees we examine and their designated physicians are notified of the results of these medical examinations. Before releasing final reports on group data (with individual identifiers removed) we provide draft copies to employers and employee representatives for their comments on technical accuracy. The results of our epidemiologic studies are presented in NIOSH criteria documents and technical reports, in scientific journals, at scientific meetings, and at OSHA hearings on workplace standards.

The two most common types of epidemiologic studies we conduct involving workers are retrospective cohort studies and cross-sectional medical studies. In cross-sectional medical studies we elicit a personal history and physically examine workers who have had exposures to agents under investigation as determined by industrial hygiene sampling. The results of these medical examinations are compared with accepted medical norms or similar test results from another population not exposed to the agent in question. Examined workers are notified of the results.

In cohort studies we obtain employment records from unions, professional societies, and companies for purposes of classifying workers according to departments where they worked, their job categories, and the duration of their employment. Personal identifiers, including name and Social Security Numbers, obtained during this process are used to determine the vital status and current address of the individuals through records kept by other Federal agencies, such as the Social Security Administration, and, until recently, the Internal Revenue Service. When we learn that an individual is deceased, we attempt to obtain a copy of the death certificate from the State in which the death occurred. Using the death records, we contrast the observed risk of dying from specific diseases among our study population with the risk expected in the general population or other groups not exposed to the substance of hazard.

At plants where the studies are conducted, we discuss the results of our research with management and labor. Although we do not notify workers individually unless we have examined them, we expect that those employed at the plant will be informed about our study results by their union or by management. We would not expect that workers in other similar plants would be directly informed

about the results of our studies. An even bigger problem involves workers who once worked in such plants but no longer do so. These workers, who may have changed jobs or retired, are less likely to know of health risks attributable to past workplace exposures.

Workplace investigations are also conducted in our health hazard evaluation, safety, and technical assistance programs. Under these programs we respond to requests from employers and employee representatives to investigate a workplace, collect environmental samples, make toxicity determinations, and provide medical examinations for workers. The results of these investigations, including recommendations for work practices, personal protective equipment, and engineering controls, are reported back to plant management, employee representatives, and OSHA. Also, the results of the health hazard evaluations are required to be posted for thirty days in the area of the investigated plant.

V. HOW MANY WORKERS ARE EXPOSED TO OSHA REGULATED SUBSTANCES?

Although it is known that hundreds and perhaps thousands of chemical substances have the potential to induce cancer or to increase the risk of cancer, it is obvious that exposure to these chemicals does not always result in disease. This is one of the factors which could unduly arouse anxiety in the notification of workers.

For purposes of this paper estimates were based only on exposure to OSHA regulated substances because at this point in time they appear to represent the greatest risk to the overt development of disease.

NIOSH has conducted thirty-five cohort or record studies directed toward over twenty-five different regulated substances including five of the sixteen carcinogens already regulated by OSHA and four other carcinogens where stringent regulations have been recommended (see Appendix A). This list was compiled with the help of epidemiologists in the Cincinnati and Morgantown laboratories. Some were conducted as far back as 1967, and some of the project officers are no longer with NIOSH. The number of workers involved in each study represents the best available information at this time. It is possible that these numbers may change when the individual study records are reviewed. These thirty-five studies dating back to 1967 involve over 100,000 workers. Other Federal research programs, have lists of tens of thousands of persons who may also require examinations.

The first step in determining the costs associated with notifying workers of the potential toxic exposures at their worksite consists of roughly estimating the number of workers involved. Recognizing that at best it will be necessary to establish a priority for the order in which workers are notified and at worst the costs and other problems of notifying all workers would be prohibitive, a variety of estimates are provided. These estimates are differentiated by the nature of substances included and by whether the potential exposure is full time.

The major source of information on broad ranges of potential exposures to OSHA regulated substances is that contained in the National Occupational Hazard Survey (NOHS). Between 1972 and 1974 the National Institute for Occupational Safety and Health (NIOSH) conducted this survey to determine the prevalence of worker exposure to chemical substances and physical agents.

In the National Occupational Hazard Survey, no attempt could be made to determine the actual exposure of individual workers. Rather, potential exposure was determined by the presence of substance at the worksite. If, however, the substance was present only in a closed system from which no exposure could occur, no potential exposure was recorded. Potential exposures were divided into two categories: (1) Part time, defined as a potential exposure of at least 30 minutes per week and not more than 4 hours per day; (2) Full time, defined as a potential exposure of 4 hours or more per day. Since the occurrence of toxic effects depends on the intensity, duration and frequency of exposure, and since simultaneous or sequential exposures to a number of different substances may also alter toxicity, we cannot easily assess what health risks are faced by individual workers.

At this time only preliminary results are available from the NOHS survey. Facts relevant to this paper can be summarized as follows:

--Approximately 7.5 million persons in the work force were exposed to one or more trade name substances discovered to date to contain an OSHA regulated substance.
--Approximately 310,000 persons in the work force were exposed to one or more trade name substances discovered to date to contain a carcinogen.
--Approximately 5 percent of persons exposed to one or more trade name substances discovered to date to contain an OSHA regulated substance or a carcinogen have been exposed for more than four hours per working day (full time).
--Ninety-five percent of persons exposed were exposed at least 30 minutes per week and not more than four hours per day (part time).

Approximately 70 percent of exposures, hazardous or otherwise, arise from trade name substances. Approximately 50 percent of the trade name substances have been identified as to content.

Since the NOHS survey results do not presently provide estimates of the total number of persons exposed to all products containing OSHA regulated substances or specified carcinogens, approximations have been developed based on NOHS estimates of total workers exposed to trade name products which have been analyzed for content to date.

To estimate the numbers of exposed workers, three assumptions are necessary. These assumptions may be disproven at some future time when more complete processing of NOHS data is possible. How-

ever, they are necessitated now by the limitations of the existing data. The assumptions are:

1. Toxic substances occur in the remaining 50 percent of trade name exposures in approximately the same percentages as in those which have been translated into their chemical composition.
2. The proportion of toxic potential exposures among non-trade name substances is approximately identical to that among the trade name substances.
3. Trade name substances not analyzed for content to date and non-trade name exposures affect a completely different group of workers than trade name substances already analyzed for content.

Based on these assumptions and the above facts from the NOH Survey, the total number of workers currently exposed to all OSHA regulated carcinogens and to all OSHA regulated substances either used in trade name products or in generic form are projected as shown in Table 1.

Violations of these assumptions may lead to biases in the estimates. The dependence of the estimates on trade name data (necessitated by the existing time constraints of the study) probably underestimates exposures to basic materials such as asbestos and lead which would seldom be hidden by trade names. Although the third assumption may lead to overestimation of the number of workers, this effect would not be sufficient to offset the underestimation caused by the reliance on trade name data. For example others have suggested that as many as one million workers may be exposed to asbestos, an OSHA regulated carcinogen. This estimate clearly exceeds our estimate of 880,000 workers exposed part-time or full time to OSHA regulated carcinogens.

The potential magnitude of the problem of workers exposed to OSHA regulated carcinogens and OSHA regulated substances can be seen in Table 2. Although the full-time exposure to carcinogens of up to 44,000 workers may be considered more significant, it is important to recognize that the part-time exposure to carcinogens may involve repeated peak exposures and thus be equally dangerous.

When the broader range of OSHA regulated substances is considered, the number of exposed workers increases dramatically. The full-time exposure to these substances is estimated to be as high as 1,050,000 workers and the full and part-time exposures are estimated as high as 21,000,000.

TABLE 1

BASES OF ESTIMATES OF MAXIMUM NUMBERS OF WORKERS CURRENTLY EXPOSED TO CARCINOGENS & TO OSHA REGULATED SUBSTANCES

Numbers of persons exposed full time or part time to OSHA regulated Substances[a]		Number of persons estimated from NOHS to be exposed to a trade name substance discovered to date to contain an OSHA Regulated Substance		Total number of Trade Name Substances in NOHS / Number of Trade Name Substances in NOHS analyzed for content to date[b]		Total Exposures in NOHS / Trade Name Exposures on NOHS[c]
21,407,011	=	7,484,969	x	2	x	1.43
Number of persons exposed full time or part time to OSHA regulated carcinogens		Number of persons estimated from NOHS to be exposed to a trade name substance discovered to date to contain an OSHA regulated carcinogen		Same as Above		Same as Above
879,839	=	307,636	x	2	x	1.43
Number of persons exposed full time to an OSHA regulated substance		Number of person exposed full time or part time		Full time Exposures / Full time and part time exposures		
1,050,000	=	21,000,000	x	.05		
Number of persons exposed full time to an OSHA regulated carcinogen[a]		Number of persons exposed full time or part time to OSHA regulated carcinogen		Full time Exposures / Full time and part time exposures		
44,000	=	880,000	x	.05		

[a]Estimated

[b]Since only half of the generic chemicals in trade name products have been identified we assume other half will be comparable and thus must multiply by 2

[c]Since only 70% of exposures arise from trade name products, it is necessary to use the reciprocal of 70% to arrive at estimates of total exposures

TABLE 2

ESTIMATED NUMBERS OF WORKERS EXPOSED TO CARCINOGENS AND OSHA REGULATED SUBSTANCES

TYPE OR WORKERS	ESTIMATED NUMBER
Workers in NIOSH studies potentially requiring notification	101,000
Workers currently exposed full time to OSHA regulated carcinogens	44,000
Workers currently exposed full time to all OSHA regulated substances	1,050,000
Workers currently exposed full time or part time to OSHA regulated carcinogens	880,000
Workers currently exposed full time or part time to all OSHA regulated substances	21,000,000

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Estimates of workers currently exposed represent only part of the problem. The NOHS data were based on a cross-sectional survey of exposure to hazardous substances. Thus, estimates of total persons at risk due to exposure must consider workers who have been exposed at some prior time over their total working life.

The current labor force is approximately 84 million. There are approximately 22 million persons over the age of 65. Using a typical participation rate of 60 percent of the general population, over 13 million of these would be retired from long-term working status. Thus, approximately 100 million persons in the current general population have been in the labor force for significant periods of time during their life time.

Approximately eight to nine percent of workers change occupations in a given year. Numerous studies of occupational mobility indicate that (1) movement is most likely to occur between ocupations that are closely related in work requirements, (2) occupational mobility patterns have been stable over time, (3) mobility rates are highest for occupations with limited training requirements, and (4) mobility shows a strong negative correlation with age.

However, none of the mobility studies nor the NOH Survey provides adequate data to determine movement into and out of industries in which exposure to hazardous substances may be prevalent. Given the high mobility rates one could reasonably assume that the number of persons in the general population who have been exposed for some substantial period of time to OSHA regulated substances and carcinogens is at a minimum two to three times greater than for a given point in time represented by data in the NOH Survey. Thus, the backlog of workers exposed to OSHA regulated substances could be as many as 40 to 50 million persons in the general population.

VI. HOW CAN INDIVIDUAL WORKERS BE NOTIFIED?

Federal agencies conducting cohort studies would need to trace each individual whose records were included in a previous study and to write, telephone or otherwise contact such individuals. Because records of such studies are covered by the Privacy Act and because the fact of prior exposure might compromise the employment opportunities of an individual worker, it would not seem appropriate to involve employers unless the worker were still employed at the plant where exposures took place. Unions, however, might be able to play an active role in the process.

On the other hand, it would seem equitable that employers undertake the responsibility of informing all current and former workers about exposures to OSHA-regulated substances. In practice, this may not be possible since employment records may have been discarded and since exposures will often not be known. During the years since past exposures occurred, mergers and changes in products and processes could further complicate the task.

A reasonable question to ask is which workers could most benefit from notification. Workers exposed to substances which cause delayed toxicity or which cause permanent impairment of functional capacity would seemingly benefit most. For these workers to benefit, adequate provision for compensation and health care are necessary.

A related question is when to notify a worker who has been exposed to a non-regulated, but potentially hazardous, material or substance. Notification before the findings of research are generally accepted by the scientific community could add to confusion on the part of the worker and rejection of corrective action on the part of management. On the other hand, delay until an agent falls under regulation may lead to undue exposure and risk.

A variety of record systems might be used to trace individuals. The most cost effective systems are those of the Internal Revenue Service and the Social Security Administration. There are legal and administrative barriers to the utilization of these systems by Federal research groups. Unless these barriers are removed, more expensive tracing mechanisms such as credit bureaus would be needed. Employers would have no difficulty in notifying currently employed workers or workers covered by their retirement plans. Employers would be forced to utilize commercial tracing sources, such as credit bureaus, to find many former employees, however.

In either case, health professionals involved in notifying workers would need to compose a number of different letters addressing different types of exposures and different health risks. These communications must be carefully worded and should indicate where the worker can obtain any necessary additional information.

VII. WHAT COUNSELING MIGHT BE NECESSARY?

Workers notified about exposures will probably need further counseling as will health professionals, worker representatives and legal advisers who become involved. Federal health agencies have conducted demonstration projects that identified, notified and provided medical examinations for workers exposed to asbestos and vinyl chloride monomer, which are carcinogens, as well as to workers exposed to leptophos, a pesticide that causes neurotoxicity. In each of these studies, questions arose about the relationship of workplace exposures to personal habits and about legal liability and compensation. Attempts to deal with the delayed effects attributable to therapeutic use of diethylstilbesterol (DES) have also demonstrated the need to have counseling services available. Notification without counseling services can have a number of undesirable results. Some may react by denying any personal risk, others may be so over-concerned that their mental well being is impaired. Notification without counseling and adequate medical examination may prove socially disruptive and lead to an undermining of confidence in government and perhaps also in private industry or even labor unions.

A necessary part of worker notification and counseling is the provision for a telephone hotline where the workers, their physicians and others may call for additional information on exposure and follow-up. Hotline services offered by NCI and CDC although not geared specifically to environmental/occupational cancer problems, provide experience revelant to the estimation of costs.

It is estimated that 35 to 50% of the private physicians may avail themselves of such a service based on the premise that non-occupational health physicians may not be aware of the adverse effects associated with exposure to certain chemicals, and also the fact that there are few protocols detailing appropriate surveillance procedures for former workers who were previously exposed to agents which may increase the risk for cancer or cause other delayed toxicities.

VIII. WHAT KINDS OF MEDICAL EXAMINATIONS MIGHT BE REQUIRED?

Chemical agents may cause damage to a single target organ or to a multiplicity of organs, and the associated physiological changes may be subtle or profound. In addition, certain agents such as carginogens may not demonstrate an effect until 20 or 30 years after exposure. For this reason, the advisable follow up medical examinations would vary in complexity and in frequency of performance, depending on the agent or agents to which the worker is exposed. The type and frequency of examination would also depend on whether or not the worker is still exposed to the agent or agents. For example, a worker continuing to have exposure to organic dusts from agricultural products should have yearly pulmonary function tests to see if there is any evidence of pulmonary changes. A worker needs only a pulmonary function test at termination of employment to determine if his past exposure has resulted in pulmonary disease.

Workplace exposures frequently involve more than one regulated substance at a single job station. Over a working lifetime, a single worker may also be sequentially exposed to a number of toxic substances. For example, a number of workers involved in saccharin manufacturing were previously exposed on the job to OSHA-regulated carcinogens that cause bladder cancer. Such considerations require that medical examinations be somewhat tailored by the attending physician to fit the needs of the individual worker-patient.

Despite these complexities, four general categories of medical examination and follow-up can be identified.

- A single, simple examination required only once for workers previously exposed to agents not known to cause cancer or other delayed effects after exposure has been terminated. For example, an exam for a worker previously exposed to organic agricultural dust but no longer exposed to an OSHA regulated substance might involve an interim history, and simple tests of pulmonary function.

- A single complex examination required only once for workers previously exposed to agents not known to cause cancer or long delayed toxicities after exposure has terminated. For example, for a worker exposed to leptophos but no longer exposed to an OSHA regulated substance, an examination might require an interim history, physical examination and non-routine diagnostic tests.

- Recurring, but simple examinations required for workers who continue to be exposed to toxic agents not known to cause cancer. Workers exposed to organic dust or lead would, for example, fall into this category.

- Recurring, complex examinations for workers exposed to carcinogens or other agents known to cause delayed effects in the past or on a continuing basis. Some examples are workers exposed to asbestos or vinyl chloride monomer or bischloromethyl ether.

The type of follow-up examination required for each type of chemical exposure was ascertained by consulting the Standard Completion Program recommendations for medical follow-up.

IX. WHAT ARE THE ESTIMATED COSTS OF NOTIFICATION COUNSELING AND MEDICAL EXAMINATIONS?

A number of steps are involved in estimating the cost of meeting the obligation imposed by the right of workers to know about toxic exposures. The complexity of the problem is increased greatly when we recognize that many workers who have been notified of their toxic work exposures will seek further information regarding the implications of the exposure and recommended medical care. In many cases, workers will subsequently seek the recommended medical examinations. The costs of this entire system, including the process of notification, counseling, and follow-up medical examinations, are costs which are incremental to society with respect to fulfillment of the worker's right to know. That is to say, the realization of these costs occurs either directly or indirectly because of the worker becoming aware of his exposure. Because the worker has a right to know, however, it would be improper to avoid these costs by failure to inform the worker. In order to properly avoid these costs, the worker must be made aware of the toxic nature of substances at his work site and must be protected from possible adverse effects through control and monitoring of potential hazards. Unfortunately, this latter and correct method of avoiding these costs to society has not been adequately carried out in the past. It therefore becomes necessary to determine the magnitude of this too frequently hidden liability.

Each of the costs involved in notification, counseling and medical follow-up are considered in turn. It should be noted that the direct bearer of the costs will depend on who performs the particular task. Insofar as industry can be required to meet their obligations with regard to the workers's right to know, the costs should not be borne directly by the government. However, there is no requirement for industry to do so at the present time. To avoid having the taxpayer shoulder the entire burden of notification, this omission in the law should be addressed.

The costs and even the feasibility of obtaining names of workers identified only through a statistical study such as the NOHS are virtually impossible to obtain. The process first involves determining firms in Standard Industrial Classification (SIC) categories where exposures are expected. The Bureau of Labor Statistics (BLS) in the Department of Labor is able to locate firms associated with SIC codes through the use of unemployment insurance files. While BLS has reportedly performed this service for NIOSH in the past at no charge, the magnitude of the problem at hand suggests that such an informal arrangement could not be used. Once a plant has been located, it is necessary to obtain the list of workers from the firm.

For workers currently or recently employed, this may be a fairly simple task. For many firms, however, it may be virtually impossible to provide lists of names of workers who are previously employed and worked in tasks where potential exposures to particular substances are likely to have occurred. With insufficient information on the likely exposures of workers, the numbers of names to be searched and notified may increase

dramatically from the estimates included here. There is no way to estimate the extent to which this would occur or the costs involved in obtaining the names of the individuals from the plants. In the past it has been necessary for NIOSH to find cooperative employers or unions in order to obtain the names of the individuals exposed. The right of NIOSH to require firms to divulge this information is currently being questioned by a large corporation.

The costs of locating workers varies with the way in which the search is conducted and with the level of difficulty encountered.* The most efficient searches are performed through the Internal Revenue Service (IRS). Costs of obtaining an address through IRS are 30 to 50 cents per name. Under current law, however, this source is not available to NIOSH. Furthermore, it must be recognized that the ability of IRS to conduct the necessary searches may well depend on the numbers of names for which addresses must be obtained. The resources required to obtain a few thousand names for the purposes of conducting a study may be available in slack times while those required for obtaining current addresses for millions of individuals could be another matter.

Information can be obtained from the Social Security Administration (SSA) for about the same costs as from the IRS. Because there is a delay when SSA obtains the information from IRS, the information available is not as current as that available from IRS. The ability of SSA to provide the resources required for a massive search must be questioned as was that of the IRS.

If searches cannot be conducted through IRS or SSA, it is necessary to use the services of credit reporting firms. This increases the costs by orders of magnitude. A simple search by these firms costs about $20. In past NIOSH experience, more complex searches have cost as much as $50. The average cost is $25 - $50 per name. For purposes of estimating this cost we will assume that IRS/SSA would be responsible for necessary searches at a cost of 40 cents per name.

Composition of an appropriately worded letter of notification is not a trival task. It is necessary to attempt to motivate the worker to seek appropriate follow-up while not unduly alarming the worker or the worker's family. Based on NIOSH experience in composing letters to notify industry of potential hazards, each different type of letter may cost approximately $400. While a special letter will not be required for each substance, a range of 10 to 20 essentially different letters is reasonable. For purposes of estimating this cost we assume 15 different letters at $400 each.

Printing, mailing, addressing and related mechanical costs run approximately $1 to $2 per notification. Considering the complexity of ensuring the workers receive appropriate letters with correct indications of the substances to which they were potentially exposed, the cost could run as high as $3 per letter since a significant amount of customizing may be necessary. It is also virtually certain that a larger number of letters than shown in the estimates will be used because of an inability to avoid sending multiple letters to individuals who have been employed in a number of affected worksites. The price of $1.50/worker is used to estimate this cost.

*These costs do not include the costs of personnel responsible for managing the search.

Cost estimates for a hotline counseling service are based on the experience of the Center for Disease Control (CDC) in operating an interstate VD hotline service to answer questions from concerned individuals in any of the states except Hawaii and Alaska. CDC pays for training volunteer operators, rental of the telephone lines, and certain other public information expenses. CDC does not pay for housing or most personnel costs. The costs to CDC for this operation is $1 per call. We have adjusted the cost of the hotline for workers to $3 - $6 to reflect additional costs of housing, personnel to man the phones, and the more complex nature of the worker-related phone calls. The figure of $4.50 per call is used to estimate this cost.

The need for appropriate information to be developed to respond to the needs of the medical profession is great. In the case of carcinogens, for example, NCI has stated that they do not have a professional concensus for most of the protocols needed for the follow-up of non-symptomatic patients. In order to assemble the best available information regarding appropriate follow-up procedures, it will be necessary to hold a number of conferences of experts. The cost per conference will be approximately $25,000. Considering the various potential cancer sites and the variety of organs that can be affected by other toxic substances, 15 to 20 conferences would be required for a total cost of $400,000 to $500,000. For estimates we assume 15 conferences at $25,000 each.

Dissemination of information to physicians can be accomplished by having the hotline refer such inquiries to appropriate consultants.

The costs of medical surveillance can cover a very wide range. Certain procedures such as the taking and reading of X-rays are less expensive when carried out as part of a special program such as the Coal Mine Health and Safety Act than when they are carried out as part of the ordinary medical system. Urinalysis, blood counts, routine blood chemistries and the usual tests of pulmonary function taken individually are basically simple. When more complex surveillance is required, the costs rise dramatically. In a recent NIOSH sponsored conference, the consensus was that the physical exam and laboratory tests frequently suggested in NIOSH recommendations costs about $200.

That estimate may be low for many complex exams. In NCI demonstration programs, follow up for patients and the offspring of patients who had been administered DES cost $300 - $400 per person. Examination of asbestos workers in another demonstration project cost $400 to $500 per examination. Monitoring of workers exposed to vinyl chloride monomer in Louisville, Ky., cost $800 - $1,000 per worker. Given this wide range of possible costs and the fact that for purposes of estimation it is not possible to be precise regarding the exact procedures required for each substance, we chose as typical lows and highs $50 and $100 for simple procedures and $200 and $500 for complex procedures.

It is estimated that between 60 and 80% of the workers will participate in follow up examinations. This estimate is based on the experience of NCI in demonstration products involving follow up of workers exposed to asbestos and vinyl chloride (82 to 97% participation), and the

experience of NIOSH in the Coal Miners Survey where a high percentage of the workers participate in examination programs. The high worker participation in these studies may be attributed to two factors (1) the miners received job transfer rights or compensatory payments if a work-associated disability was found and (2) participation in follow-up is higher if clinical facilities are directly tied into the surveillance programs. Since this may or may not be the case here, a more conservative estimate of worker participation was used.

The costs potentially associated with notification of workers depends upon the nature and cost of medical surveillance required. It is therefore necessary that the estimates of potential exposures be allocated to categories of medical follow-up for costing. Furthermore, the required medical follow-up depends upon whether the worker is currently being exposed or was exposed some time in the past. The estimates provided result from the following process.

For each OSHA regulated substance found in the NOHS, a category of medical surveillance was determined. Using data from the NOHS regarding the number of workers potentially exposed to each substance, the proportion of potential exposures in each examination category was determined and applied to estimates of persons exposed to determine the potential number of each type of medical follow-up required. This procedure inflates the number of inexpensive surveillance procedures required. This bias would arise when, for example, a worker is exposed to two substances one of which requires a simple exam, the other a complex exam. In many cases, his participation in the complex surveillance procedure would obviate the necessity for the simple one. The extent of this potential bias cannot be determined. The results of these estimates are shown in Table 3. The greatest burden is associated with those workers requiring complex surveillance for life. Although only 200,000 workers, representing 25% of the total workers currently exposed full time to OSHA regulated substances require complex lifetime surveillance, they represent the major portion of costs because of the costly and recurring nature of the exams.

The estimated surveillance costs for potentially exposed workers who seek medical follow-up is shown in Table 4. This table assumes a life extectancy of 37 additional years for the average worker currently employed. The costs associated with recurring examinations required only during the time the worker is exposed assume two examinations per worker. This is based on the "quit rate" for manufacturing as published for BLS. Of course as new employees are exposed, these costs too would take on a recurring nature. Costs associated with these "future" exposures are not included, however.

The sensitivity of surveillance costs to varying levels of participation and varying levels of medical costs can be seen in Table 4. For each worker group the highest estimate of surveillance costs is more than three times the lowest cost. For final cost estimates the mid-point between the lowest and highest estimates was used.

Table 5 shows total costs for the alternative groups of workers. Given the high costs involved, these alternatives provide policy makers with a range of costs which might be undertaken. Approximate average

annual costs are also shown there. Because of average ages and life expectancy being used throughout, a more meaningful distribution of costs over time is not available.

Even when consideration is limited to carcinogens substantial costs are involved. The total cost associated with workers currently exposed to OSHA-regulated carcinogens full-time is around $424 million. The cost for both full and part-time workers is nearly $8.5 billion. We believe that any worker exposed to a carcinogen for four or more hours a day should receive follow-up care.

If consideration is extended to workers currently exposed full-time or part-time to any OSHA regulated substance, total program costs are estimated to be $54 billion. Most of these would be incurred for workers requiring lifetime surveillance. Based on an average life expectancy of 37 years, this represents an annual cost of nearly $1.5 billion.

It should be noted that all of the cost estimates ignore possible additional employer liability or compensation costs resulting from discovery of compensable physical impairment during examination, entitlements under various federal and state programs, and recovery for damages under possible third-party legal actions, brought by workers, their employers or insurance companies.

TABLE 3

PERSONS POTENTIALLY EXPOSED BY SOURCE OF NIOSH INFORMATION AND CATEGORY OF REQUIRED SURVEILLANCE

Recommended Follow-up	Workers in NIOSH Cohort Studies*	Est'd. currently regulated	Number of persons exposed to OSHA carcinogens	Maximum number of persons currently exposed to OSHA regulated substances	
		Full time	Part time	Full time	Part time
None	0	0	0	200,000	3,115,000
One time simple	7,000	0	0	230,000	4,830,000
One time complex	500	0	0	140,000	2,940,000
Simple during exposure	NA	0	0	20,000	420,000
Simple for life	0	0	0	10,000	210,000
Complex during exposure	NA	0	0	200,000	4,200,000
Complex for life	93,000	44,000	880,000	250,000	5,250,000
TOTAL	100,500	44,000	880,000	1,050,000	21,000,000

*Excludes studies in which workers were notified

TABLE 4

ESTIMATED SURVEILLANCE COSTS FOR PERSONS POTENTIALLY EXPOSED WHO SEEK MEDICAL FOLLOW-UP
(Millions of Dollars)

Worker Group	60% Participation		80% Participation	
	Low[2]	High[3]	Low[2]	High[3]
NIOSH Cohort Studies[1]	$ 192	$ 480	$ 256	$ 640
Workers currently exposed to OSHA regulated carcinogens full time	195	490	260	650
Workers currently exposed to OSHA regulated carcinogens full and part time	3,900	9,760	5,210	13,000
Workers currently exposed to OSHA substances full time	1,200	2,975	1,600	4,000
Workers currently exposed to OSHA substances full time and part time	25,080	62,500	37,000	83,000

1 Because these studies were conducted over a period of years and in many instances involved cohorts selected by age, costs cannot be properly adjusted for life expectancy of workers involved. Costs shown are for current exposures and assume a life expectancy of 17 years as compared with 37 years for other groups.

2 Low estimates are based on $50 for simple and $200 for complex exams.

3 High estimates are based on $100 for simple and $500 for complex exams.

TABLE 5

TOTAL COST ESTIMATES FOR DIFFERENT GROUPS OF WORKERS*

	Workers in NIOSH Epidemiological Studies	Workers Currently Exposed to OSHA Regulated Carcinogens Full Time	Workers Currently Exposed to OSHA Regulated Carcinogens Full Time or Part Time	Workers Currently Exposed Full Time to OSHA Regulated Substances	Workers Currently Exposed Full Time or Part Time to OSHA Regulated Substances
Number of Workers**	101,000	44,000	880,000	1,050,000	21,000,000
Obtain Addresses	$ 40,000	$ 18,000	$ 352,000	$ 420,000	$ 8,400,000
Compose Letters	3,000	3,000	3,000	6,000	6,000
Print and Mail	152,000	66,000	1,320,000	1,575,000	31,500,000
Hotline	114,000	50,000	990,000	1,181,000	23,625,000
Conferences	200,000	200,000	200,000	375,000	375,000
Surveillance	415,769,000	423,280,000	8,465,600,000	2,580,500,000	54,193,000,000
TOTAL	$416,278,000	$423,617,000	$8,468,465,000	$2,584,057,000	$54,256,906,000
Approximate years	17	37	37	37	37
Approximate Annual Cost	$ 24,000,000	$ 11,000,000	$ 229,000,000	$ 70,000,000	$ 1,466,000,000

*Groupings used here are not usually exclusive and should not be summed.
**Cost of locating names of all workers included in NIOSH studies not included.

X. WHAT STEPS CAN NIOSH TAKE TO PROVIDE NOTIFICATION AND MEDICAL FOLLOW-UP FOR EXPOSED WORKERS?

The present NIOSH budget does not provide for counseling and medical follow-up. It is possible for NIOSH to assume responsibility for the notification of workers in its cohort studies. However, the participation of the Social Security Administration and/or the IRS is essential to keep the costs within reason. Notification will require reprograming monies from the NIOSH carcinogen program to cover the estimated $309,000 cost of obtaining addresses, composing letters, printing and mailing and operating a hotline. It will also mean NIOSH personnel will have to be diverted from essential ongoing research projects. For example a retrospective study of 2,000 - 10,000 workers requires 1 - 3 man-years of effort. Therefore, attempting to notify at least 100,000 workers would conservatively take 10 - 30 man-years of effort. In addition, it should be noted that the above effort would not include notification of other workers in the same plant who were not included in NIOSH studies.

NIOSH would make available the recommendations from the Standards Completion Program to those in the medical community who may need additional information for the follow-up of exposed workers.

NIOSH is willing to work with the Division of Cancer Control and Rehabilitation of the National Cancer Institute in their present efforts to develop medical surveillance protocols for follow-up in people exposed to chemical carcinogens.

The estimated cost associated with the surveillance of workers is over three orders of magnitude greater than that of notification. This could prompt the decision to notify workers without providing for surveillance. Such a decision would reduce the benefits of notifying workers and would impose the cost of follow-up on other segments of society.

An important aspect of notification is to permit the worker to seek appropriate medical care for purposes of prevention and early detection of disease. If we fail to provide for a system for medical follow-up, the worker will know he has a problem but may not be able to do anything about it.

If workers seek a private source of care through an insurance group such as Blue Cross and Blue Shield, then that group will have to absorb the cost which will ultimately be passed on to other members of the group through higher payments. Furthermore, these plans seldom provide for testing of asymptomatic subscribers.

In view of the extremely high costs associated with reducing the consequences of high exposures to workers in the work place, it would seem more prudent for industry to institute intensive monitoring procedures and appropriate engineering controls to ensure low levels of exposure to physicial and chemical agents and thus avoid a recurrence or further growth of this problem.

XI. WHAT POLICY ISSUES SHOULD BE CONSIDERED?

The right of workers to know of past or current exposures to OSHA regulated substances intertwines with a number of policy issues involving the conduct of research by Federal agencies, trade secrecy protection, legislation dealing with health and safety regulation, health care financing, contamination of the community environment and workmen's compensation. A number of Federal Departments and Agencies conduct studies on workers where positive findings have resulted and the workers can be identified. Research groups in NIH (principally NIEHS and NCI), CDC, FDA, EPA and ERDA are all likely to face problems in dealing with the right to know. The Social Security Administration, the General Services Administration, the Internal Revenue Service and the Bureau of Labor Statistics of DOL would need to be involved in discussions concerning notification. All of the parties involved in implementing the Toxic Substances Control Act and the Occupational Safety and Health Act could contribute to the solution. The Occupational Safety and Health Administration through a required uniform labeling and warning system for workplace hazards and through a vigorous program to establish health standards and assure compliance with those standards can ensure notification, counseling and medical examination for workers currently exposed to toxic substances.

-If research agencies are to notify and counsel all individuals involved in studies utilizing records and not involving personal contact, the costs of these studies will be substantially increased. No provision now exists to pay for any follow-up examinations that may be requested by persons included in such record studies.

-A major stumbling block is the failure of chemical repackagers and primary producers to show the chemical composition of their products. Steps are being taken to promote voluntary disclosure. It may be possible for EPA to require that labeling of industrial chemicals include product composition. New legislation may be required if EPA is forced to go through the hearing process for each chemical constituent contained in trade name products.

-Since adoption of an effective uniform labeling and warning system for chemicals found in the workplace might be hindered by revealing trade name composition, an interim step might be a requirement that the Materials Safety Data Sheets submitted to the General Services Administration be improved, collated and made generally available to employers and employees.

-Inflationary impact statements, required for Occupational Safety and Health Standards consider only outlays by industry. They do not consider potential cost savings or increased productivity for industry nor do they consider that workers have a right to know about exposures to workplace hazards and that the costs of counseling and medical follow up are now hidden or being borne by

others. Changes in the structure of or the requirement for such statements should be considered.

-Employees covered by the Occupational Safety and Health Act have not been provided with transfer and wage-retention when their functional capacity has been impaired or when they are at increased risk because of heavy exposure to OSHA regulated substances. This is in direct contrast to the Coal Mine Health and Safety Act which provides such protections. Consequently, unprotected workers may hesitate to seek desirable medical follow-up because their current employment may be jeopardized or future job opportunities limited.

-Providing transfer and wage rate retention rights for workers exposed to OSHA-regulated carcinogens having significant functional impairment as a result of exposures to agents like asbestos, cotton dust, silica, lead and certain other metals might be dealt with in regulations or may require new legislation.

-A number of episodes involving contamination of the general environment with toxic substances pose problems much like those discussed in the workplace. Current problems involving environmental contamination with polybrominated byphenyls and quarry dust pose problems involving notification, counseling, medical follow-up and compensation. In Japan, environmental contamination episodes involving cadmium and mercury contamination were followed by enactment of an environmental compensation law. Current Federal legislation in this country can provide for research, notification and counseling but there is no easy way to pay for diagnostic determination of adverse effects or any necessary medical follow-up.

-Most existing health insurance policies do not provide for diagnostic procedures or follow-up examinations made necessary by exposure to toxic substances in the workplace or in the general environment. Workers no longer in the labor force may not be covered by the Occupational Safety and Health Act. A number of other groups of workers, such as State and local governmental employees currently in the workforce may be exposed to toxic substances including carcinogens but may not be protected by OSHA standards. These gaps could be closed by legislation dealing with occupational safety and health, by changes in State compensation systems or by provisions for such care in proposals for national health insurance.

-Workmens' compensation systems in the States do not adequately identify or equitably deal with occupational health problems. In general little or no provision is made to provide for medical examinations or former workers who were exposed to toxic agents including carcinogens but who are not clinically ill. State or Federal legislation reforming workmens' compensation could deal systematically with and establish a mechanism for notification, counseling and any necessary medical follow-up. Clearly the right of workers and citizens to know whether or not they are exposed to hazardous chemical and physical agents regulated by the Federal Government is linked to a complex series of policy issues that need to be considered together.

APPENDIX A

NIOSH EPIDEMIOLOGIC STUDIES OF WORKERS EXPOSED TO CARCINOGENS AND OTHER HAZARDOUS SUBSTANCES

APPENDIX

NIOSH EPIDEMIOLOGIC STUDIES OF WORKERS EXPOSED TO CARCINOGENS AND OTHER HAZARDOUS SUBSTANCES*

TYPE OF EXPOSURE	NAME OF STUDY	NUMBER OF WORKERS STUDIED	TYPE OF FOLLOWUP EXAM REQUIRED
Arsenic	Study of Arsenic Workers	200	Recurring complex for current and ex-employees
Asbestos	Study of hard rock gold miners	2,000	Complex recurring exams for both exposed and ex-employees
Asbestos	Cincinnati Resp. Disease Study	200	Complex recurring exams for both exposed and ex-employees
Asbestos	Study of workers in Tyler, Texas Asbestos Plant	3,500	Recurring complex exam for current and ex-workers
Asbestos	Studies of workers in asbestos related industries	4,125	Recurring complex exam for current and ex-workers
Auto exhaust (Carbon Monoxide-Hydrocarbon)	New Jersey Motor Vehicle Examiners	1,453	Recurring complex exams for both present and ex-employees
Benzene	Study of workers exposed to Benzene	4,000	Recurring complex exam for both current and ex-employees
Benzidine	Study of workers exposed to Benzidine	1,500	Recurring complex exam for both current and ex-employees
Beryllium	Beryllium/sarcoidosis study	10,000	Recurring complex exam for current and ex-workers

*This table subject to change when individual records are studied.

NIOSH EPIDEMIOLOGIC STUDIES OF WORKERS EXPOSED TO CARCINOGENS AND OTHER HAZARDOUS SUBSTANCES*

TYPE OF EXPOSURE	NAME OF STUDY	NUMBER OF WORKERS STUDIED	TYPE OF FOLLOWUP EXAM REQUIRED
Betanaphthylamine	Betanaphthylamine Worker's Study	1,500	Recurring complex exam for both current and ex-employees
*Bischloromethyl ether	Study of workers exposed to Bischloromethyl ether	702	Recurring complex exam for both current and past employees
Cadmium	Study of Cadmium workers	800	Recurring complex exam for current and ex-workers
Carbon Monoxide	Union Pacific Carbon Monoxide Study	200	Recurring complex exams for present employees. Single complex exam for ex-employees
Chloroprene	Chloroprene Study	800	Recurring complex exam for both current and ex-employees
Cotton Dust	Byssinosis Study of North Carolina	250	Recurring simple exam for presently exposed - simple single exam for ex-employees
Cotton Dust	Byssinosis Research	1,500	Simple recurring exam for presently exposed - simple single exam for ex-workers
Cotton Dust	Byssinosis Study	200	Simple recurring exam for presently exposed - simple single exam for ex-employees
Dichlorobenzidine	Study of workers exposed to Dichlorobenzidine	226	Recurring complex exam for both current and ex-employees

*Bichloromethyl ether is no longer manufactured in the U.S. Workers in NIOSH study have been informed of exposure

NIOSH EPIDEMIOLOGIC STUDIES OF WORKERS EXPOSED TO CARCINOGENS AND OTHER HAZARDOUS SUBSTANCES

TYPE OF EXPOSURE	NAME OF STUDY	NUMBER OF WORKERS STUDIED	TYPE OF FOLLOWUP EXAM REQUIRED
Fibrous glass	Studies of workers exposed to fibrous glass	10,000	Complex recurring exams for both exposed and ex-employees
**Leptophos	Study of workers at Bayport, Texas	350	Single complex exam
Methyl Butyl Ketone	Study at Columbus Coated Fabrics	300	Complex recurring for present employee - Complex single exam for ex-employees
Naphthyloketone asbestos, Benzene	Study of Paint Trade Workers	4,000	Recurring complex exam for both current and ex-employees
Perchloroethylene	Perchloroethylene Study	2,000	Recurring complex exam for both current and ex-employees
Polychlorinated Biphenyls	Polychlorinated Biphenyls Study	3,000	Recurring complex exam for both current and ex-employees
Polynucleated aromatics	Machinists exposed to cutting oils	5,000	Recurring complex exam for both current and ex-employees
Polyvinyl chloride	Workers exposed to Polyvinyl Chloride in Plastic's Industry	7,600	Recurring complex exams for both present and ex-employees
Radon daughters	Uranium Miner Study	15,000	Complex recurring exams for both exposed and ex-employees
Silica	Vermont Granite Workers' Study	2,500	Recurring simple exam for present and ex-employees
Silica	Silicosis Study	1,332	Recurring simple exam for present and ex-employees

**Leptophos is no longer manufactured in the U.S. Exposed workers located by NIOSH had neurological examinations.

NIOSH EPIDEMIOLOGIC STUDIES OF WORKERS EXPOSED TO CARCINOGENS AND OTHER HAZARDOUS SUBSTANCES

TYPE OF EXPOSURE	NAME OF STUDY	NUMBER OF WORKERS STUDIED	TYPE OF FOLLOWUP EXAM REQUIRED
Styrene Butadiene	Styrene Butadiene Study	6,000	Recurring complex exam for both current and ex-employees
Sulfur Dioxide	Utah Sulfur Dioxide Study	200	Recurring complex exams for present employees. Single complex exam for ex-employees
Talc Asbestos	Workers exposed to Talc	1,500	Complex recurring exams for both exposed and ex-employees
Uranium	Uranium Mill Working Study	3,000	Complex recurring exams for both exposed and ex-employees
Vinyl Chloride	Study of Pottstown Chemical Workers	2,550	Recurring complex exam for both current and ex-employees
Wood particles plus other unidentified chemicals	Paper pulp and Plywood study	5,000	Recurring complex exam for both current and ex-employees

An additional group of 50,000 Anesthesiologists were studied by NIOSH. Results of this study have been shared with theappropriate professional societies who, in turn, should notify the individual anesthesiologist members in their society.

The CHAIRMAN. Our next witness is Dr. Guy R. Newell from the National Cancer Institute, and two of his associates.

Dr. Newell, we appreciate your appearance this afternoon.

STATEMENT OF GUY R. NEWELL, JR., M.D., ACTING DIRECTOR, NATIONAL CANCER INSTITUTE, ACCOMPANIED BY DIANE J. FINK, M.D., DIRECTOR, DIVISION OF CANCER CONTROL AND REHABILITATION; AND JAMES A. PETERS, D.V.M., M.P.H., DIRECTOR, DIVISION OF CANCER CAUSE AND PREVENTION

Dr. NEWELL. Mr. Chairman and members of the committee:

It is a pleasure for me to appear before you today to discuss the activities of the National Cancer Institute in the area of occupational carcinogenesis. Accompanying me are Dr. Diane Fink, Director, Division of Cancer Control and Rehabilitation, and Dr. James Peters, Director, Division of Cancer Cause and Prevention.

The primary mission of the NCI is to conduct research aimed at cancer prevention, detection and diagnosis, and treatment and rehabilitation. With the passage of the National Cancer Act of 1871, Congress established the cancer control program to strengthen our ability to translate the results of research through the conduct of demonstration projects and through dissemination of information, both to the lay public and professionals. The general purpose of cancer control demonstration activities is to bridge the gap between research and application in the practice of medicine and public health. The intent of the program is to take cancer research and development outputs in prevention, diagnosis and treatment aspects, and evaluate their effectiveness in controlled community groups by obtaining statistically sound data. The findings of successful demonstration programs are communicated to the practitioners of medicine and the public where these findings can be applied.

Your staff, Mr. Chairman, asked that we describe our involvement in environmental carcinogenesis. NCI's involvement in environmental carcinogenesis is a broad one consisting of four major areas of activity:

One, the study of known environmental carcinogens including radiation, tobacco, chemicals—including drugs—and hormones. Control demonstration programs are appropriate in this area since our major need is to demonstrate the effectiveness of new discoveries and communicate these discoveries to practitioners.

Two, screening for new cancer causing agents. This includes use of long-term animal testing as well as short-term methods. For example, the action taken by the Consumer Product Safety Commission on the flame retardant TRIS was based largely on results from our screening system.

Three, efforts to identify patterns of environmental carcinogenesis. This includes epidemiologic research of persons or groups at high risk because of geographic location, ethnic background, family history, occupational exposure, or other factors.

Four, the support and conduct of research into the fundamental mechanisms of cellular processes of carcinogenesis. This research will hopefully provide us with the methods for prevention of cancer in man.

NCI has a long history of concern about occupational exposure to carcinogens. Much of what is known about occupational carcinogens was supported either directly or indirectly by NCI funds. However, the NCI does not have any authority to inform individual workers of exposure to known carcinogens. We do, however, widely disseminate through scientific publications, the press, and professional groups the fact that specific agents may be carcinogenic.

In most of our epidemiologic studies, the source of worker information is existing records, such as, medical records, employment records, and union rosters. Compiling such information about the workers is usually followed by tabulation of death certificates, so during the study we do not have any direct contact with individual workers and would not know if individuals would be at excess risk until the completion of the study. In control demonstration programs, our sources of information on exposed individuals are similar. If an individual is part of a cancer control prevention and surveillance demonstration program, he or she would be so notified through the process of obtaining informed consent to participate. We are following a cohort of former asbestos workers in Tyler, Tex., and a cohort of individuals exposed to vinyl chloride in Louisville, Ky.

The purpose of these demonstration programs is to develop prototype programs for a limited segment of the population and to test the feasibility of following individuals in such a group. These programs are limited in time and scope and are aimed only at testing technologies, in order to avoid the danger of premature recommendations and the promotion of inadequately tested new technologies.

Our information dissemination efforts do not normally focus on specific worker populations but provide information to practitioners, institutions, health departments, and the community at large. For example, we are in the process of surveying carcinogenic agents to identify those which warrant particular control activity and then to provide recommendations for practical control and prevention methods. Knowledgeable experts have selected 96 candidate chemicals and developed basic information on them. Extensive information is now being developed on 20 chemicals from this list. Monographs are being prepared on asbestos, vinyl chloride, and DES. These monographs will be made available to the public, health practitioners, employers, and those who regulate occupational safety.

To carry out its function, the NCI works closely with many Federal agencies—in particular, NIOSH. Through an interagency agreement, NCI has transferred over $4 million to NIOSH in support of 25 separate research projects. Regular meetings between NCI and NIOSH senior staff are held to develop programs of mutual interest. The Assistant Secretary for Health's Committee to Coordinate Toxicology and Related Programs serves as a focus for environmental carcinogenesis among several Federal agencies within the PHS and includes representation from NCI, NIEHS, NIOSH, OSHA, EPA, and CPSC. In cooperation with the Occupational Safety and Health Administration of the Department of Labor, we are jointly developing educational material on occupationally related cancers for distribution to more than 100,000 workers.

As carcinogens are identified and the possibility for further demonstration programs becomes evident, we plan to assess the state of the

art, to develop proper models or prototypes for the specific carcinogen, and to present these to our National Cancer Advisory Board for their recommendation and approval on a case-by-case basis.

In the broader area of cancer care, the NCI has meticulously avoided setting up a separate, parallel, or duplicative health care system for cancer patients. Our efforts are directed toward dissemination of information to effect the best possible care within the health care system. In all honesty, it is not clear who should have the responsibility for identifying workers with exposure to carcinogens, following them and providing for early intervention where possible, such as periodic screening for early diagnosis or early treatment of disease after it is detected. It does seem clear that such identification and follow up entail providing health care for these individuals, and, as I said earlier, neither the NIH nor the NCI believes that its funds were appropriated for these activities.

In two instances we are engaging in following populations at high risk—former workers in Tyler, Tex., exposed to very high levels of asbestos, and workers in Louisville, Ky., exposed to vinyl chloride. Both these cases were undertaken as demonstrations to see if they were feasible, practical, and beneficial. The purpose of following high risk populations is to change the outcome in those who develop disease—specifically to reduce the effects of the disease. If available intervention strategies do not do this, then the cost and effort of such screening will have been useless. Past efforts at screening for early detection for a variety of diseases have been almost totally unsuccessful.

In summary, NCI is and should continue to be the agency for major research and demonstration efforts of the Federal Government for identifying cancer-causing agents and developing ways of reducing the effects of known agents through research methodology. To the extent that worker identification and followup are necessary to perform these functions then it is entirely appropriate that we identify workers and follow them up and also that we work closely with NIOSH, OSHA and other appropriate Federal agencies. Once new knowledge has been gained, our responsibility is to disseminate it to those agencies who have regulatory authority, to the appropriate professional and lay groups and to those in the health care system responsible for delivery of health services.

In conclusion, let me assure you, sir, we are very sensitive and sympathetic about this problem. We believe we can best serve it by continuing to identify cancer-causing agents and demonstrating what is feasible to do about them, and by making this information available to the health care delivery system.

We appreciate the opportunity to be with you this afternoon, and we will attempt to answer any questions that you or the subcommittee may have.

The CHAIRMAN. Thank you very much, Dr. Newell. I'm encouraged to hear that you are actively in cooperation. You mentioned both the Occupational Safety and Health Administration, and NIOSH. You mentioned the money which was transferred from the Institute, the National Cancer Institute, to NIOSH.

Dr. NEWELL. That is correct.

The CHAIRMAN. We so frequently hear of interagency cooperation, but upon examination, it seems more a happy conclusion than a fact of life.

Let me see. I would like to understand this degree of cooperation a little better and know a little bit more about that transfer of funds, and the purpose.

Dr. NEWELL. Several years ago, NCI was engaged in more occupational research than we had been previously. What happened is, Dr. Walderman, who was sitting here earlier was with the National Cancer Institute, and was responsible for most of our occupational studies. When he left us and moved to NIOSH, he took those studies with him, and we felt that it was best to do that, because he had initiated the studies. With his departure, there was sort of a hiatus in our funding of occupational research, because we felt that we did not want to duplicate what NIOSH was doing.

Now, during the past year and a half a couple of things have happened. One, we set up an environmental epidemiology branch, and, second, we published the Atlas of Cancer Mortality, with which you may be familiar, the maps which show the pictures of death rates throughout the country.

When the maps were published, new clues became evident as to additional industries which might represent a cancer hazard. We wanted to follow up on those clues.

That situation then provided stimulus for us to get back in the picture, if you will, and increase our efforts to conduct work in this area. So we increased our own efforts and at the same time NIOSH had some projects they wanted to do but could not fund. We decided the most direct way was just to go ahead and fund their projects.

I would be happy to submit a list of those projects for the record if you do not have them.

The CHAIRMAN. I understand we do have that. That is encouraging.

It was a gratuitous situation with Dr. Walderman being at the Institute, and then lateralled into NIOSH. At any rate, do you find this eases communication of information between you and NIOSH? If you have some information which they should have, there's no doubt about it getting there, is that correct?

Dr. NEWELL. That is correct. Since the transfer of funds, we have been meeting, Dr. Peters and his staff, with Dr. Finklea and some of his people at least once every 6 weeks. When we transfer funds from one agency to another, there is always the problem of who then is responsible for the conduct of the research. Is it NCI, since the funds were given to us, or is it the other agency since they are doing the work? We try to get around this problem by frequent meetings, so that we can agree with what they are doing, and they agree with what we intended to fund. This frequent communication is a convenient way of getting around some of the problems.

The CHAIRMAN. When it comes to notification of risk, environmental risk, the National Cancer Institute will broadly state for public consumption information about the risk. But the specific incidental exposure in the workplace comes within the responsibility of NIOSH, right?

Dr. NEWELL. In my opinion, correct.

The CHAIRMAN. You are not charged under any laws with providing specific notification?

Dr. NEWELL. That is correct.

The CHAIRMAN. But you do have broad public notification responsibilities?

Dr. NEWELL. No doubt about that, yes.

The CHAIRMAN. And then other agencies of Government are charged with the care of exposed individuals; they do the specific action, FDA has its specific charge and so on.

Well, I have nothing further. Thank you very much. It is excellent testimony.

Senator Javits.

Senator JAVITS. I wanted to get a sense of the order of magnitude. I notice that you gave NIOSH $4 million for a whole list of studies.

Dr. NEWELL. My list is a little different. It is essentially the same.

Senator JAVITS. In view of the very long list of agents, vast numbers of people involved, and the fact that your agency is so enormously financed—we fought for you, you are the most financed agency in the National Institute of Health—do you not think you ought to do more with NIOSH—as long as they are taking on this job of dealing with so many hundreds of thousands of people—to compare those at risk with cancer who are involved in these industrial hazards, and the aggregate number of people in the country who are at risk of cancer? Doesn't this require a greater utilization of the resources of your particular institute?

Dr. NEWELL. If the opportunities were there, we could do more with them. I think that we are for the most part fulfilling our obligations in working with them. I do not know of any other opportunity available that we are not trying to work with them on. Of course, $4 million is not at all the total amount we spend on environmental carcinogenesis. That is a much broader area as you know.

Senator JAVITS. This was essentially for asbestos study and vinyl chloride study; is that right? Now there are a whole list of studies.

Dr. NEWELL. There are about 25, but the $4 million provided to NIOSH was not used for the asbestos and vinyl chloride studies.

Senator JAVITS. A whole list of miscellaneous studies. I think what we will have to develop is, as you say, whether or not the opportunity is there, and what it will take to exploit that opportunity and then we can determine whether or not the National Cancer Institute is doing all it can and should.

One other thing about your testimony disturbs me. I do not say that invidiously, just a worrisome finding. Look at page 8. You will see relating to the Tyler and Louisville study respecting asbestos and vinyl chloride, you go on to say, "if available intervention strategies do not do this," to wit, change the outcome of those who develop diseases to reduce the effects of the diseases, then I go on to quote you, "then the cost and effort of such screening will have been useless. Past efforts at screening for early detection for a variety of diseases have been almost totally unsuccessful."

Now explain that last paragraph to me, because that is very alarming.

Dr. NEWELL. What I am referring to—you remember several years ago there was sort of a vogue or fashion to set up so-called multiphasic screening clinics. In those, a variety of blood tests, let us say, were going to be studied. For example, blood tests to screen for abnormal liver functions as a predictor of early liver disease. Those kinds of

multiphasic screening programs, in my opinion, really were not very successful in picking up early disease where intervening in some way could change the outcomes. The problem was that the blood tests themselves were not specific enough, and considering the number of different areas in which a blood test might pick up a disease, the number of pick-ups was so small compared to the number of individuals screened that the final outcome was really not changed in any remarkable kind of way. It is really that kind of mass screening for relatively rare events that I was referring to.

Senator JAVITS. Yet, doctor, in the case of pap smears there is a very high degree of success.

Dr. NEWELL. You are right. Pap smears are a very specific test going after a very specific disease, and you know what the disease is that you are going after, and you can apply the screening in a rather specific population. Because we know the risk factors that make women at high risk, the benefit of using the pap test to screen for the disease is much greater than a broad, more random kind of approach. There are some very specific things that can be done.

Senator JAVITS. You say there are some very specific things that can be done. What can be done?

Dr. NEWELL. I will let my colleague have a crack at it.

Senator JAVITS. Identify yourself.

Dr. FINK. I am Dr. Diane Fink, Division of Cancer Control and Rehabilitation, NCI.

Right now, we are in the process of examining those screening strategies which could be applied either to large populations or populations at high risk. Dr. Newell is quite correct that in most circumstances the standard medical history and physical examination still proves to be of our major backbones in cancer screening. Pap tests provide a valuable screening tool for cervical cancer. In areas of breast cancer screening, particularly in older women, we have some techniques which have been proven by scientific, clinical trials. However, when you get much beyond that, at least in the National Cancer Institute's view, in dealing with cancer of the lung, or cancer of the large bowel, and possibly cancer of the bladder, we are still in the process of conducting research trials to get evidence as to whether these techniques truly alter the course of the disease, and add to the benefit of those individuals who might be at risk.

Let me cite a "for instance." The National Cancer Institute is sponsoring at three institutions, including Mayo Clinic, studies to look into the use of sputum cytology and bronchoscopy in heavy smokers. The study is still underway, and should be completed within a couple of years, to determine whether with lung cancer this combination of screening techniques will alter the survival or effects of the disease.

At the current time we do not have evidence to be able to say that these are truly beneficial procedures that can be applied to a large-scale population. When you get beyond screening, the question in lung cancer is: Are cancer treatment techniques for lung cancer available to improve the overall effects of the disease? Other than surgery alone and possibly radiation most treatment of lung cancer is still in the experimental stage or research stage.

Senator JAVITS. You feel, Dr. Newell, the state of the art just does not allow us to make any broad scale exams in this field of industrial hazard?

Dr. NEWELL. Let me put it this way, Senator. I think the state of the art does not allow us to launch any demonstration programs other than those we have going on now.

On the other hand, I think as a physician, if I were in practice, and I had a patient, and I were taking a history, and I were taking an occupational history, which all physicians do, it would be very important for me to know that an individual has worked in an industry or in a plant where he has been exposed to some occupational hazard. I would follow him more closely, first of all, probably more frequently. I would certainly pay more attention to the history of cancer and other diseases in his family.

I would follow his family more closely. I would do all of these things. That would be very positive and could be very beneficial. That could be done, as you were alluding to earlier, by letting the individual worker know that he has been in some kind of unhealthy environment. That information can be translated, given to his physician. That is important.

Senator JAVITS. Who do you think ought to carry that burden of notice? You do not think it is NIH? It is obviously not for you. Now NIOSH has been trying. Who do you think ought to have this responsibility?

Dr. NEWELL. In all honesty, I do not know. I think it probably ought to be NIOSH or OSHA.

Senator JAVITS. OSHA is a much larger agency. NIOSH was intended originally to be an experimental agency.

Dr. NEWELL. It sounds more like an OSHA problem to me.

Senator JAVITS. Does not what you conclude about screening also emphasize not only notice but the need for protective and preventive techniques?

Dr. NEWELL. Absolutely.

Senator JAVITS. Who should be engaged in those, NIOSH or you?

Dr. NEWELL. I think we should be engaged in trying to determine what should be done in terms of prevention or intervention. For example, in the Tyler, Tex., study, with former asbestos workers, part of our program there is to, for example, educate the smokers to stop smoking, because if we could get them to stop smoking, then we know their risk would go down. We are trying to use the latest available techniques, sputum cytology, for example. We are trying a multibarrelled approach in a very defined setting.

Now, once we know what works, we give that to OSHA and they can then implement it on a much larger scale is the way I see it and the way I see the problem. And we are perfectly happy to accept that responsibility.

Senator JAVITS. Thank you very much.

The CHAIRMAN. Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Doctor, a New York Times story in April said that Dr. Finklea added that this kind of program, that is, a cancer notification, counseling and medical attention program, had been recommended in a 1973 cancer control planning conference, and that the National Cancer Institute recently had been asked to provide the required funds.

What is the status of that?

Dr. FINK. The Cancer Control Planning Conference in 1973 that was referred to suggested that NCI and cancer control program de-

velop several limited activities in the area to test the feasibility, benefits, et cetera, that Dr. Newell was speaking of. At present, our discussions with NIOSH in the area of bladder cancer will involve development of the state of the art and strategies to deal with the bladder cancer problem and exposed individuals. This assessment will be a three-way activity between NCI's cancer control program and national bladder cancer project working cadre, which is a research activity, and NIOSH. Once we develop the strategy and understand what types of techniques should be used in workers that have been exposed to potential bladder carcinogens, we will be able to determine whether demonstration programs such as Tyler and Louisville should be carried on.

Senator SCHWEIKER. You are proceeding, then, with bladder control projects?

Dr. NEWELL. Yes; what we plan to do is to hold a state-of-the-art workshop. That is where we get experts in and decide what can be done practically.

Senator SCHWEIKER. Will that differ from your asbestos and vinyl chloride projects, or is it basically the same pattern?

Dr. NEWELL. Yes.

Senator SCHWEIKER. Yes; it will differ? Or, yes; it is the same?

Dr. NEWELL. Yes; it is basically the same pattern. The asbestos population had already been defined; the Tyler, Tex., group is well known. At the time the cancer control program came along, there had been no concerted effort to follow these people or to try to do what could be done for them.

We took that on as one of our early projects to demonstrate what demonstration is, in a sense. Then the vinyl chloride problem came later, and now we will take on the bladder problem. What we will do is, we will provide scientific input, and we will provide that to NIOSH and OSHA, and we will continue to work with them to follow this through.

Senator SCHWEIKER. That is all I have, Mr. Chairman.

The CHAIRMAN. To follow up, let me understand, those demonstrations, you were part of the notification process, were you not?

Dr. NEWELL. In the demonstration projects, all the individuals know they are in the study. They know the purpose and they know they are part of the high-risk group. That process is achieved through our informed consent procedure.

The CHAIRMAN. Doctor, in describing the inadequacy of multiphasic screening in reaching cancer diagnosis, it sounded to me as though you were discounting multiphasic for all phases of diagnosis. You did not mean that?

Dr. NEWELL. No.

The CHAIRMAN. There are multiples of matters that can be——

Dr. NEWELL. Yes.

The CHAIRMAN. You were just limiting this.

Dr. NEWELL. I might add, to give you a figure for some of the costs of this, in the Louisville and Tyler projects the cost is about $800 to $1,000 per individual per year.

Senator SCHWEIKER. $800,000?

Dr. NEWELL. $800 to a $1,000 per individual per year.

The CHAIRMAN. That is followup?

Dr. NEWELL. That is for following them, but it is not for their medical treatment.

The CHAIRMAN. What is included in that?

Dr. FINK. Let me go over that. Basically, Louisville and Tyler represent a very similar problem. The workers have been identified in some way. They are notified of their potential risks. Then they are set up under a medical surveillance program that involves history, physical and certain laboratory tests, and screens, either on a once-a-year basis, or a one-every-six-months basis, depending on the level of exposure. In addition, they get counseling, health education, and we collect data and statistics.

What that amounts to, as Dr. Newell pointed out, is something in the range of $800 to $1,000 per worker per year. as you realize, out of the Tyler program and out of the 800-odd workers exposed in the Tyler plant, we estimate that about one-third of the workers or a little over 200 will develop lung cancer.

What we are talking about are programs that in the case of both Tyler and Louisville will follow up about 1,000 workers, spending about $1 million per year for each project, and this is the very most that can be done. Those are the levels of dollars we are talking about. The cancer pickup rate will be something less than 200 cases in Tyler, which represents high incidence group, on down to Louisville, where there will be many fewer cancers.

The CHAIRMAN. Many fewer?

Dr. NEWELL. Like 7 to 8 in Louisville. We are now following individuals at $1,000 per year, and the expected pickup rate is 7 to 8 cancers. So as I said earlier, if we cannot do anything substantive about a cancer when it is picked up, then the cost effectiveness of the whole operation has to be severely looked at.

The CHAIRMAN. When you say, cannot do anything about it——

Dr. NEWELL. If we cannot treat it or detect it earlier, so that the treatment is more effective, then the cost-benefit ratio has to be looked at very carefully.

The CHAIRMAN. Does this not all get combined with an understanding of exposure and then preventive standards can be applied so that has to be figured into the cost-benefit, as they say.

Dr. FINK. One of the things that Dr. Newell is pointing out is that taking on these worker groups for surveillance programs from a demonstration point of view, and trying to work out the kind of programs that might be taken on by other segments of society, for all asbestos workers is very expensive. But through these kinds of studies, we may find less expensive and equally effective ways of dealing with these exposures.

[The prepared statement of Dr. Newell, and the biographical sketches of Dr. Newell, Dr. Fink, and Dr. Peters, follow:]

FOR RELEASE UPON DELIVERY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NATIONAL CANCER INSTITUTE

STATEMENT OF

GUY R. NEWELL, M.D.

ACTING DIRECTOR

NATIONAL CANCER INSTITUTE

BEFORE THE

LABOR SUBCOMMITTEE

OF THE

SENATE COMMITTEE ON HUMAN RESOURCES

MAY 9, 1977

Mr. Chairman and Members of the Committee, it is a pleasure to appear before you today to discuss the activities of the National Cancer Institute in occupational carcinogenesis. Accompanying me are Dr. Diane Fink, Director, Division of Cancer Control and Rehabilitation and Dr. James Peters, Director, Division of Cancer Cause and Prevention.

The primary mission of the NCI is to conduct research aimed at cancer prevention, detection and diagnosis, and treatment and rehabilitation. With the passage of the National Cancer Act of 1971, Congress established the Cancer Control Program to strengthen our ability to translate the results of research through the conduct of demonstration projects and through dissemination of information, both to the lay public and professionals. The general purpose of cancer control demonstration activities is to bridge the gap between research and application in the practice of medicine and public health. The intent of the program is to take cancer research and development outputs in prevention, diagnostic and treatment aspects, and evaluate their effectiveness in controlled

community groups by obtaining statistically sound data. The findings of successful demonstration programs are communicated to the practitioners of medicine and the public where these findings can be applied.

Your staff asked that we describe our involvement in environmental carcinogenesis. NCI's involvement in environmental carcinogenesis is a broad one consisting of four major areas of activity:

1. The study of known environmental carcinogens including radiation, tobacco, chemicals (including drugs) and hormones. Control demonstration programs are appropriate in this area since our major need is to demonstrate the effectiveness of new discoveries and communicate these discoveries to practitioners.
2. Screening for new cancer causing agents. This includes use of long-term animal testing as well as short-term methods. For example, the action taken by the Consumer Product Safety Commission on the flame retardant TRIS was based on results from our screening system.

3. Efforts to identify patterns of environmental carcinogenesis. This includes epidemiologic research of persons or groups at high risk either because of geographic location, ethnic background, family history, occupational exposure, or other factors.

4. Support and conduct research into the fundamental mechanisms of cellular processes of carcinogenesis. This research will hopefully provide us with the methods for prevention of cancer in man.

NCI has a long history of concern about occupational exposure to carcinogens. Much of what is known about occupational carcinogens was supported either directly or indirectly by NCI funds. However, the NCI does not have any authority for informing individual workers of exposure to known carcinogens. We do, however, widely disseminate through scientific publications, the press, and professional groups the fact that agents may be carcinogenic. In most of our epidemiologic studies, the source of the worker information comes from existing records, such as, medical records, employment records, and union rosters. This information about the workers is usually followed by tabulation of death certificates so that during the study we do not have any direct contact with individual workers and would not know if individuals themselves would be at excess risk until the completion of the study. In control demonstration programs, we obtain our sources of information on exposed individuals from similar sources. If an individual is part of a Cancer Control Prevention and Surveillance Demonstration Program, he or she would be so notified through

informed consent of their risk. We are following a cohort of asbestos workers in Tyler, Texas, and a cohort of individuals exposed to vinyl chloride in Louisville, Kentucky. The purpose of these demonstration programs is to develop prototype programs on a limited segment of the population and to test the feasibility of following such individuals. These programs are limited in time and scope and aimed only at testing technologies, in order to avoid the danger of premature recommendations and promoting inadequately tested new technologies.

Our dissemination efforts do not normally focus on specific worker populations but do provide this information to practitioners, institutions, health departments, and the community at large. For example, we are in the process of surveying carcinogenic agents to identify those which warrant particular control activity and to provide recommendations for practical control and prevention methods. Knowledgeable experts have selected 96 candidate chemicals and begun to develop extensive information on them. Monographs are under development for asbestos, vinyl chloride, and DES.

These monographs will be made available to the public, health practitioners, employers, and those who regulate occupational safety.

To carry out its functions, the NCI works closely with many Federal agencies--in particular, NIOSH. Through an interagency agreement NCI has transferred over $4 million to NIOSH in support of 21 separate research projects. Regular meetings between NCI and NIOSH senior staff are held to develop programs of mutual interest. The Assistant Secretary for Health's Committee to Coordinate Toxicology and Related Programs serves as a focus for environmental carcinogenesis among several Federal agencies within the PHS and includes representation from NIOSH, OSHA, EPA, and CPSC. In cooperation with the Occupational Safety and Health Administration of the Department of Labor, we are jointly developing educational material on occupationally related cancers for distribution to more than 100,000 workers.

As carcinogens are identified and the possibility for further demonstration programs becomes evident, we plan to assess the state of the art, to develop proper models or prototypes for the specific carcinogen, and to present these to our National Cancer Advisory Board for their recommendation and approval on a case-by-case basis.

In the broader area of cancer care, the NCI has been meticulous in avoiding setting up a separate, parallel, or duplicative health care system for cancer patients. Our efforts are directed toward dissemination of information to effect the best possible care within the health care system. It is not clear who should have the responsibility for identifying workers with exposure to carcinogens, following them and providing for early intervention where possible, whether it be periodic screening for early diagnosis or for treatment of disease after it is detected. It does seem clear that this is basically providing health care for these individuals, and, as I said earlier, neither the NIH nor the NCI believes that its funds were appropriated for these activities.

In two instances we are engaging in following populations at high risk--workers in Tyler, Texas, exposed to very high levels of asbestos, and workers in Louisville, Kentucky, exposed to vinyl chloride. In both these cases this was undertaken as a demonstration project to see if such were feasible, practicable and beneficial. The purpose of following

high risk populations is to change the outcome in those who develop disease--specifically to reduce the effects of the disease. If available intervention strategies do not do this, then the cost and effort of such screening will have been useless. Past efforts at screening for early detection of a variety of diseases have been almost totally unsuccessful.

In summary, NCI is and should continue to be the major research and demonstration effort of the Federal government for identifying cancer causing agents and developing ways of reducing known agents and in identifying carcinogenic hazards through research methodology. To the extent that worker identification and follow-up is necessary to do these, then it is entirely appropriate that we engage in it, and that we work closely with NIOSH, OSHA and other appropriate Federal agencies. Once new knowledge has been gained, our responsibility is to disseminate it to those agencies who have regulatory authority, to the appropriate professional and lay groups and to those in the health care system responsible for delivery of health services.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Public Health Service, National Institutes of Health, National Cancer Institute

Biographical Sketch

NAME:	Guy Rene Newell, Jr., M.D.
POSITION:	Acting Director, National Cancer Institute
BIRTHPLACE AND DATE:	Bogalusa, Louisiana; September 21, 1937
EDUCATION:	Tulane University, 1959, B.S. Tulane University, 1962, M.D. Harvard School of Public Health, 1968, M.S. in Hygiene (Epidemiology)

EXPERIENCE:

Present	Acting Director, National Cancer Institute
1973-76	Deputy Director, National Cancer Institute
1972-73	Associate Professor and Head, Section of Chronic Diseases, Dept. of Epidemiology and Biostatistics, Tulane University
1970-72	Assistant Professor, Department of Epidemiology and Biostatistics, Tulane University
1968-70	Executive Secretary, Biometry and Epidemiology Contract Review Committee, National Cancer Institute
1968-70	Assistant for Program, Viral Oncology Area, National Cancer Institute
1967-68	Assistant in Medicine (Oncology) Peter Bent Brigham Hospital
1965-67	Assistant Resident in Medicine, The Johns Hopkins Hospital Baltimore, Maryland
1963-65	Research Planning Associate, Office of the Director, National Cancer Institute, NIH
1962-63	Intern in Medicine, The Johns Hopkins Hospital, Baltimore, Maryland

ASSOCIATION MEMBERSHIPS:	American Academy of Political and Social Science American Association for the Advancement of Science American Association for Cancer Research American Society of Clinical Oncologists American Federation for Clinical Research American Medical Association American Public Health Association Society for Epidemiological Research
PUBLICATIONS:	Author or co-author on over 40 scientific publications

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service, National Institutes of Health, National Cancer Institute

Biographical Sketch

NAME:	Diane Joanne Fink, M.D.
POSITION:	Director, Division of Cancer Control and Rehabilitation, National Cancer Institute (NCI)
BIRTHPLACE AND DATE:	Chicago, Illinois; July 27, 1936
EDUCATION:	University of Wisconsin, Pre-Medical Stanford University, B.S., Medical Science, 1957 Stanford University, M.D., 1960
EXPERIENCE:	
Present	Director, Division of Cancer Control and Rehabilitation, NCI Chairman, U.S. Delegation on US-USSR Exchange on Cancer Control/Cancer Centers
1974	Associate Director for Cancer Control, NCI
1973	Chief, Treatment Branch, Cancer Control Program, NCI
1971-73	Program Director for Chemotherapy, Division of Cancer Research Resources and Centers, NCI
1969-71	Chief, Oncology Section, Veterans Administration (VA) Hospital, San Francisco
1966-69	Staff Physician in Charge of Cancer Chemotherapy Section, VA Hospital, San Francisco
1965-66	Post-Residency: Research Associate--Immunohematology, VA Hospital, San Francisco
1963-65	Residency in Internal Medicine: Cancer Chemotherapy, Hematology, VA Hospital, San Francisco
1961-63	Residency in Internal Medicine: Kaiser Foundation Hospital, San Francisco
1960-61	Internship: Kaiser Foundation Hospital, San Francisco
1967-71	Chairman, Tumor Board, VA Hospital, San Francisco
1966-71	Pacific VA Cancer Chemotherapy Group, Principal Investigator and Executive Secretary
ASSOCIATION MEMBERSHIPS:	American Association for Cancer Research American Association of Cancer Education American Cancer Society--Director-at-Large Committees for Tobacco & Cancer, Medical and Scientific, Professional Education, Public Education, and Service and Rehabilitation American Medical Association American Medical Women's Association American Public Health Association American Society of Clinical Oncology Committee on Clinical Practice American Society of Hematology Society for Occupational and Environmental Health
PUBLICATIONS:	Author or co-author of over 20 scientific publications

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Public Health Service, National Institutes of Health, National Cancer Institute

Biographical Sketch

NAME:	James Alexander Peters, D.V.M., M.P.H.
POSITION:	Director, Division of Cancer Cause & Prevention, NCI
BIRTHPLACE & DATE:	Pensacola, Florida; October 7, 1928
EDUCATION:	Auburn University, Auburn, Ala., 1943, D.V.M.
	University of Michigan, Ann Arbor, Michigan; 1968, M.P.H. (Epidemiology)

EXPERIENCE:

1972 - Present	Director, Division of Cancer Cause & Prevention, NCI
1971 - 1972	Deputy Scientific Director, Etiology, NCI
1970 - 1971	Assistant to Scientific Director, Etiology, NCI
1969 - 1970	Head, Program and Data Analysis Unit, Carcinogenesis, Etiology, NCI
1968 - 1969	Office of Associate Scientific Director for Carcinogenesis, Etiology, NCI
1964 - 1968	Epidemiology Branch, Demography, Etiology Area, NCI (Temporary Duty Station - East Lansing, Michigan)

ASSOCIATION MEMBERSHIPS:

American Association for the Advancement of Sciences

American Public Health Association

Commissioned Officers Association, USPHS

Drug Information Association

Omega Tau Sigma

Public Health Cancer Association

Publications: Author or Co-Author on 15 scientific publications

The CHAIRMAN. Excellent. We thank you.

[Whereupon, at 5:50 p.m., the committee was adjourned, subject to the call of the Chair.]

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