DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1996

...NGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

SUBCOMMITTEE ON THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

JOHN EDWARD PORTER, Illinois, *Chairman*

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HENRY BONILLA, Texas
ERNEST J. ISTOOK, JR., Oklahoma
DAN MILLER, Florida
JAY DICKEY, Arkansas
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NANCY PELOSI, California
NITA M. LOWEY, New York

NOTE: Under Committee Rules, Mr. Livingston, as Chairman of the Full Committee, and Mr. Obey, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

S. ANTHONY MCCANN, ROBERT L. KNISELY, SUSAN E. QUANTIUS, MICHAEL K. MYERS, and JOANNE L. ORNDORFF, *Subcommittee Staff*

PART 4

NATIONAL INSTITUTES OF HEALTH

Printed for the use of the Committee on Appropriations

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1996

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Dr. OLDEN. Yes. Well, first of all, I think the National Center for Environmental Health does very little research, especially not laboratory research or toxicological testing. And the Environmental Protection Agency does mission-oriented research, short-term research, that is directed towards some immediate goal. At NIEHS, we do basic research that is long-term. It is not mission-oriented. In other words, there is not a project that we are trying to find an answer to. It is peer-reviewed. It is mainly university-based, whereas the EPA research is mainly in-house and on contracts.

We develop a lot of new methodologies and technologies, whereas the EPA is less interested in that because the standard they have to regulate uses the rodent bioassay. So they are less interested in developing new methodologies of the kind I just described to you. I would say that those are probably the main differences.

Now, with NCI, we are more interested in the role of environmental agents in the etiology of disease. We are concerned about genes only as they relate to gene environment interactions. When we have similar interests as the National Cancer Institute we will collaborate, and occasionally, they will also be interested in some aspect of an environmental agent and we do collaborate on a number of issues.

Mr. PORTER. Thank you, Dr. Olden.

Mrs. Lowey.

COST-BENEFIT REQUIREMENTS

Mrs. LOWEY. Thank you, Mr. Chairman.

Thank you very much for your testimony. In your statement, Dr. Olden, you make reference to NIEHS research that contributed to one of the greatest public health success stories in recent years, the tremendous drop in the levels of lead in our blood. Specifically, since the EPA began to phase down the levels of lead in gasoline and paint 25 years ago, we have seen a 76 percent decline in the mean lead blood levels in children. While no dollar figure can be easily assessed on the value of that decline, we know that countless children have been spared the subtle erosion of mental and psychological functions caused by elevated lead levels in people of all ages, particularly in children.

Had the risk assessment and cost-benefit requirements contained in legislation that recently passed the House been in effect in the mid-1970s, it is my understanding that the EPA's actions back then, which were vehemently opposed by the lead industry, would have been delayed significantly, perhaps by many years.

In reading from this report, I note that the NIEHS and NTP hosted a special workshop on January 11 through 13 and this was important to that dialogue, and it specifically says that recommendations from this workshop will provide a framework for developing risk assessment schemes and prevention programs that will enhance our ability to protect the public health from environmentally caused diseases while maintaining economic vitality.

Given that, would you please comment on the ramifications these new risk assessments and cost-benefit requirements will have on the work of NIEHS?

Dr. OLDEN. Well, the Administration has already articulated its position on that legislation. Let me say my concern is this, the

science, to underscore, to underpin the decisions, is simply not in place to make the kind of decisions that I think need to be made. I am concerned about the quality of the science that goes into the regulatory decisions. And as I said earlier, in my opinion, in most cases, we have to make the decisions at a point where we have very little evidence to make those kinds of decisions.

I am concerned about birth defects, cancers, infant mortality, and not so much about cost benefits. I think those are value judgments that policymakers have to decide. But my concern is that we do not have good scientific bases for making decisions. For example, we do not understand differences in susceptibility. In most cases we do not know what the effects are at low doses. In most cases we are extrapolating from an animal to a human. These are the concerns that I have, not so much about cost benefits.

I think you as a policymaker must be concerned about those, but as the director of a health agency I am concerned about the quality of the decision and the quality of the science that goes into those decisions.

Mrs. LOWEY. I appreciate that, because it would seem to me that with the opposition to this work from the lead industry, I wonder, if this legislation had been in place, whether we would have been able to protect the public. The decisions we make, if this legislation goes through the other body, will not really be adequate because we will not have all the information we need. That is my real concern. I cannot help but believe, due to the pace at which this legislation went through, that many Members were not really thinking of the specifics, such as the lead implications and in a whole range of public health issues.

Dr. OLDEN. The costs for regulatory compliance as well as for health care costs are enormous, and it seems to me that it would be a wise policy to make the investment to do the science. And as soon as that could be done, with a fraction of the resources that it would take to enforce regulations that may or may not be required, we could rehabilitate or treat humans who have disabilities or diseases as a consequence of these exposures.

RISK ASSESSMENT

Mrs. LOWEY. So you share my concern that it may be very difficult to protect the public because hard data will not be available at the time decisions will have to be made?

Dr. OLDEN. Well, risk assessment is not an exact science, so in most cases we will never have all the data to eliminate all the uncertainties. However, I think with a different kind of orientation, the way we do the science, that we can have much of the data in hand when the decision must be made.

For example, it takes four to five years to complete a rodent carcinogenicity bioassay. It takes another year and a half or so to have that data peer reviewed and reported out. So we are talking anywhere from five to six years from beginning to end. During that time, one could conduct some limited epidemiological studies in human populations, so you would have that additional data. You could also do some mechanistic studies.

In other words, ask the question could this particular chemical alter a function in humans and you could do dose response studies

in that period of time. And having mechanistic information would be very important in the risk assessment decision. So I think we can improve the database.

Mrs. LOWEY. Well, I thank you, and I do not know whether there have been any results published as a result of that dialogue as yet from the January 11 through 13 conference.

Dr. OLDEN. I don't think the report is out yet. The purpose of that conference was, as we develop the new technologies and methodologies, to convince regulatory agencies to use those new technologies and methodologies. And, secondly, regulatory agencies are, in many cases, constrained by legislation. The benchmark now for carcinogenicity and toxicity is carcinogenesis with the rodent bioassay, so they have the use of the rodent bioassay. So if we developed a different model that would be just as effective, they still have to get permission, authority, approval to use that, even if they wished to do that.

So we have to educate not only policymakers but we also have to educate and get buy in on the part of regulatory agencies. So that is why we had the three groups together at the conference in Research Triangle Park. And the report will be ready in May. So about two months from now.

Mrs. LOWEY. I appreciate that, because, as we know, the Senate operates on a different schedule. And when this bill is considered in greater detail, hopefully, through adequate hearings, there will be some thought given to the impact on public health. So I thank you.

BREAST CANCER GENE

Another question about the relationship between the discovery of the BRCA–1 gene for breast cancer and environmental factors. Could you discuss in greater detail how you believe the discovery of the gene for breast cancer and information on environmental causes of breast cancer are related? Does the discovery of the gene provide us any new information about environmental causes of breast cancer?

Dr. OLDEN. Not yet. Environmental agents fundamentally act two ways. They mutate or alter genes or they modulate gene function or they impair cellular signaling mechanisms. So we were interested in genes because we are interested in understanding how environmental agents interact with those genes, and BRCA–1 is just one example of genes that we are interested in. We are interested in other genes involved in other processes as well.

What we wanted to do was to isolate the gene and then create a transgenic animal. In other words, put that gene into a mouse and create an animal model of human breast cancer. Then we can expose those animals to various environmental agents including estrogens, which are at the top of our list, and ask do they in any way interact with that particular gene, or others, to increase the susceptibility of breast cancer, to increase the occurrence of breast cancer in an animal model system.

So by having the gene, it allows us to probe which environmental agents interact with genes and how they interact with genes; are they going to cause additional mutations or will they modulate at some other level.

Mrs. LOWEY. Well, thank you, Dr. Olden, and thank you, Mr. Chairman.

Mr. PORTER. Thank you, Mrs. Lowey.

Mr. Bonilla.

SUPERFUND WORKER TRAINING PROGRAMS

Mr. BONILLA. Thank you, Chairman.

Hello, Dr. Olden, it is good to see you again.

Dr. OLDEN. How are you?

Mr. BONILLA. Fine, thank you. I would like to begin with a program that we have received some questions on that distributes grants through your Institute. You state in your testimony that the programs supported by NIEHS are consistent with the goal of prevention of human disease and disability, and aid in the formation of economic growth and the promotion of public-private partnerships.

I have a series of questions about a program that I think is not a promotion of public-private partnerships.

My first question is how much does NIEHS spend for grants for the training and education of workers who are or may be engaged in activities related to hazardous waste removal or containment or emergency response?

Dr. OLDEN. We spend, I believe, in the neighborhood of $20 million a year for support of our EPA Superfund Worker Training Program.

Mr. BONILLA. I had a figure that I thought was correct but perhaps it is not, of $37 million.

Dr. OLDEN. You are probably including training initiatives with DOE and other agencies. The EPA Worker Training Program is in the neighborhood of $20 million.

Mr. BONILLA. How many workers trained under the grants program under SARA are actually working or have worked in the hazardous waste field subsequent to attending the NIEHS grantee training program?

Dr. OLDEN. I think I am right in saying that all of them currently—they were employed in the hazardous waste industry before they took our training and they went back to their jobs. That was a requirement early on. Now we are creating a new program where that is not a requirement.

This year we were given $3 million to develop a similar program for low-income, young, unemployed inner-city workers, and that program is just getting started and I think we have not actually awarded a single grant yet, but that will happen soon.

But in the program you are referring to, all of the individuals are already employed in some industry and they come, they take our training and they go back to their previous job.

Mr. BONILLA. These workers you just referred to that are to be part of the program, you said inner-city workers?

Dr. OLDEN. Yes.

Mr. BONILLA. What qualifications would they have for participating in this program?

Dr. OLDEN. You have two things. First of all, they have to be supported—the individuals who apply for the grant have to demonstrate to us that they have or will have employment once the

training is completed. Also, the individuals will have to be willing to take certain courses in mathematics, in arithmetic, for example, because one of the complaints that we hear is that many inner-city workers, low-income, unemployed, lack the skills for the highly skilled labor force. And when we train them, we want to be certain and the trainers want to be certain that these individuals are employable.

So not only do they have to take the training, it is a longer course than the other one, but they also have to attend a community college for a period of time. So it is a longer course. It could be one or two years. The other one is a matter of days or weeks. It could be a six weeks, eight weeks course. But these are individuals who are already employed so it is a different program.

We are trying to reach the unemployed and difficult to employ. It provides special skills.

RELATIONSHIP BETWEEN TRAINING AND WORK

Mr. BONILLA. What relationship, Doctor, if any, is there between the training being given under these grants and the work being done in the field?

Dr. OLDEN. Well, I am now insisting on a study to get that information. But the individuals I can say who have been trained are all employed. Now, whether they are being trained for jobs that exist today or whether they are being trained for jobs that exist in the future is, I think, the concern. But, clearly, none of the individuals that are trained are unemployed.

The environment is a growing industry, so there are a lot of jobs in the hazardous waste industry. Matter of fact, there are more jobs at the present time than there are people. So I do not think that is an issue, although I think we need to demonstrate that we are, indeed, training people for jobs that are going to be there for the next decade and beyond. But I think at the moment there is no doubt that we are doing that.

Mr. BONILLA. Do you have any mechanisms now in place that monitor the effectiveness of these programs?

Dr. OLDEN. Yes, we do. It was put in place at the beginning of the program in 1987, because as I indicated, we wanted to be certain that we are training people for jobs that do or will exist in the future. And so we have made it a requirement that all the grantees have to do an evaluation.

Mr. BONILLA. What involvement, if any, do the employers of hazardous waste workers have in this grant program or in the training and have they been involved at all in the course design or the actual training? The employers themselves.

Dr. OLDEN. The employers—well, the grants go to joint labor-management funds, universities, community colleges, and unions. The unions have been involved in the creation of the curriculum, but the employers, which would become a State or a county, no, they are not at all involved, to my knowledge, in the development of the curriculum.

Mr. BONILLA. We are getting near to the crux of what I am trying to get at and that is, does this involve the private sector or not or does it just involve your Institute and labor unions, and in my

view it should. There is a circle here that is not completed if employers are not also participating in this program.

Dr. OLDEN. Well, some employers are sponsoring training courses at their plant sites—they are not involved in the design of the curriculum, but they are participating in the sense that they have said to us that this training is desirable and necessary. Because they pay. We do not pay for people to come. They come for weeks or days at the expense of their employer. We pay for the development of the curriculum. We pay for the trainer, the individuals who actually do the teaching. But these people are employed and on the payroll of their employers. So it is a partnership between the employer, our grantees, and the Institute.

Mr. BONILLA. I have a series of questions related to this, Doctor, but to accommodate this committee's time today, I will submit these for the record, if I could, and I would appreciate it if you would get back to me on that.

Dr. OLDEN. All right. I would be very pleased to do that.

Mr. BONILLA. Thank you.

Mr. PORTER. Thank you, Mr. Bonilla.

Mr. Stokes.

Mr. STOKES. Thank you, Mr. Chairman.

Dr. Olden, nice to see you again.

Dr. OLDEN. Thank you.

ASTHMA

Mr. STOKES. Dr. Olden, studies reveal that African Americans and Hispanics living in inner-city areas may have unusually high rates of asthma morbidity and mortality. To what extent is research in this area covered in your Institute?

Dr. OLDEN. We are concerned about the environmental component of asthma, and we are cofunding, in fact, some of those inner-city projects that Dr. Fauci referred to. We are cofunding some projects with the Institute of Allergy and Infectious Diseases.

We are interested in three aspects. Asthma is a very high priority of our Institute. We have supported for a long time a number of studies called the Six City Study, the Twenty-four City Study, and the Five City Study to look at the health effects of air pollution. We focused on fiber toxicology; we focused on particles in the atmosphere, both large and small, and how they impair pulmonary function. We have looked at ozone, acid aerosols, and also nitrogen and sulfur dioxides.

Mr. STOKES. Are there any significant findings?

Dr. OLDEN. Well, it has been in the press. Matter of fact, I think in yesterday's paper, but certainly in the press in the last week or so a number of articles have appeared describing the work of one of our grantees, Doug Dockery, at Harvard Medical School, in which he found that people in the nation's most polluted cities are 15 to 17 percent more likely to die prematurely than those in cities with the cleanest air. Now, these are cities that meet clean air standards, but in those most polluted cities, there is an increased mortality, cardiovascular as well as pulmonary. That is due to small particles in air, not the ones that are regulated, which are the larger ones.

So, yes, there have been breakthroughs. The air is certainly getting cleaner, but we are spending more time indoors and it is probably indoor allergens, as Dr. Fauci pointed out, that are the problem. Our houses are tighter. We are using more synthetics in construction and that is probably part of the problem. So probably it is not only outdoor air.

LEAD POISONING

Mr. STOKES. Dr. Olden, what is the status of the treatment of lead poisoning in children clinical trial?

Dr. OLDEN. The treatment for kids who have clinical symptoms, that is who have blood lead levels in excess of 45 micrograms per deciliter of blood, is very good. There is no treatment at the present time for children who have blood lead levels below 40 micrograms per deciliter of blood.

When the treatment was developed many years ago for clinical lead poisoning, it was not known that low lead levels caused any effect. But now we know that lead levels all the way down to 10 micrograms per deciliter of blood cause neurological impairment, IQ neuromotor problems, and behavioral problems.

Now we are supporting, sponsoring, a multicenter clinical trial to develop a treatment for these low blood lead levels, and we are focusing on the range between 25 and 40 micrograms per deciliter of blood. And we are in the second year of a multicenter trial.

ENVIRONMENTALLY-RELATED DISEASES IN CHILDREN

Mr. STOKES. What other significant research is underway at your Institute to address environmental-related diseases in children?

Dr. OLDEN. Well, we are very interested in susceptibility. We are interested in susceptibility to pesticides. We are interested in which environmental agents influence developmental genes. And we have a study that is ongoing to look at both.

We have, in fact, just recently awarded six grants to look at environmental agents that influence the genes that are known to be involved in development. We initiated a NTP study to look at both pre- and post-natal development following exposure to different pesticides.

Mr. STOKES. Thank you, Dr. Olden. Thank you, Mr. Chairman.

FACILITY CONSTRUCTION

Mr. PORTER. Thank you, Mr. Stokes.

Dr. Olden, last year you testified that $10 million would be needed in 1995 and $23 million in 1996 to complete construction of your lab and office space complex at the Research Triangle Park in North Carolina. Although you received the $10 million in 1995, the Administration requests only $6 million in 1996 instead of $23 million. Does that represent a slowdown in construction or are you rethinking the scope of the project? If the Administration's funding requests are approved, how long would it take to finish?

Dr. OLDEN. We made a decision not to build. There were two parts to the construction. There was a laboratory unit and an office. And we made the decision not to construct the office portion. So we have enough money in hand, with the exception of the $6

million requested and that is for the utilities. So the money for the construction of the facility is in hand. We simply need the $6 million to put the utilities into this building.

PARKINSON'S DISEASE

Mr. PORTER. Your Institute is scheduling a workshop on the link between environmental toxins and Parkinson's Disease. What implications does the exploration of this Parkinson's toxic link have for other neurological disorders?

Dr. OLDEN. Well, there is some evidence to suggest that Parkinson's is caused by exposure to heavy metals, zinc, manganese, and mercury. We have, for a number of years, had substantial research programs not only in lead but also looking at mercury toxicity and zinc. And so what we want to do is bring together a group of experts and explore what is known, more about the role of zinc and mercury. This is what we are going to focus on. We want to know what is the state of the science and is there sufficient evidence to suggest their involvement so that we can get the scientific community involved or to define a research agenda for those two metals.

ELECTROMAGNETIC FIELDS

Mr. PORTER. Last year we discussed the possibility of health effects of electromagnetic fields.

Dr. OLDEN. Yes.

Mr. PORTER. It sounded then as if the jury was still out. Have any more findings been released in the past year that can more definitively answer this question?

Dr. OLDEN. Mr. Chairman, it is a five-year study and last year we were in year one. This is, obviously, year two. We do not know the answer yet, but I was told this morning, as I rode up on the plane with my colleague who is in charge of this, that I will have the data in 1997, which is when I am supposed to have it.

Let me say we do know some things. This is an area that has been explored primarily by physical scientists prior to our involvement. There are some epidemiological studies to demonstrate there are weak associations between exposure to EMF and certain cancers, leukemias, for example.

However, there is simply no biological explanation for why EMF should cause cancer or any disease or dysfunction. So what we wanted to do, first of all, was controlled laboratory studies in animals to develop the biological basis for plausibility. One of the hypotheses was that a hormone called melatonin was depressed by exposure to EMF and that this allowed for proliferation of the cancer cells that had already been initiated.

In the animal studies—they may be behaving differently from humans—to date we see no evidence that EMF is altering in any way melatonin production, as assayed by the amount of melatonin in the blood. The biological plausibility has been not been established yet, but it is a new program.

Mr. PORTER. Melatonin is produced by the pituitary gland; is that right?

Dr. OLDEN. Pineal.

Mr. PORTER. Pineal. I will get these things after a while.

Let me ask the Members of my subcommittee whether they have additional questions. Mr. Stokes? Mrs. Lowey?

ENVIRONMENTAL INJUSTICE

Mr. STOKES. I have one additional question I would like to pose, Mr. Chairman, if you don't mind, and then I will submit the others for the record.

Mr. PORTER. All right.

Mr. STOKES. Dr. Olden, as environmental mandates are being relaxed, what are the implications for increased environmental-related disease and increased environmental injustice? That is, what are the environmental-related diseases that would be most threatening to the health of the American people and specifically to our children that could result?

Dr. OLDEN. Well, Mr. Stokes, that is difficult to answer. I tried to point out earlier that we do not understand how children differ from adults in terms of susceptibility. We regulate now as if all of us are 170 pound males and that is simply not true. I heard the other day that someone said we regulate us as if everyone is an Arnold Schwarzenegger, so that is not correct.

Children are different from adults biologically, and we have lots of evidence that they are more susceptible. For example, in the lead studies, adults are exposed to lead also, but the critical time period is from conception to age six years old. That is also the issue with pesticides. Children's eating habits are different. They consume more water. So if there are pollutants, toxins in water, pesticides in foods, children may be affected more.

So it is clear that children, senior citizens, and socioeconomically disadvantaged people are probably the victims of what is typically known as environmental injustice. Children, because we simply ignore them—we look over their heads in regulation. Poor people, because they live and work in the most hazardous environments. In the case of senior citizens, their immune systems are suppressed, and we measure for healthy adults. So if regulatory standards are relaxed, clearly the individuals that will be affected first are the same groups that are at higher risk presently: children, the poor, and senior citizens.

Mr. STOKES. Would you subscribe to the fact that there is such a thing as environmental injustice?

Dr. OLDEN. Well, it is clear that poor people have more morbidity and mortality. And they suffer from diseases that are preventable. It is true, well-established, that they live in the most hazardous environments, they work in the most hazardous occupations, and if you believe, as I do, that these environmental agents that we demonstrate are carcinogens or cause birth defects or cause pulmonary dysfunctions, then if you believe that they cause diseases in humans, then I think that some of the morbidity, excessive morbidity and mortality of these groups must be related to where they live, where they work, or the fact that they are children or the fact that they are senior citizens.

Yes, I do. I think there is great evidence of that.

Mr. STOKES. Thank you, Dr. Olden. Mr. Chairman, I will submit the balance of my questions for the record.

Mr. PORTER. Thank you, Mr. Stokes.

Mrs. Lowey.

LONG ISLAND BREAST CANCER STUDY

Mrs. LOWEY. Thank you very much, and I appreciate again the testimony. And I wonder if there is an update that you can share with us on the Long Island breast cancer study. I know this is a joint study between your Institute and NCI and if there is any information you can share, Dr. Olden, I would be appreciative.

Dr. OLDEN. I will have to submit that. I know we are conducting a case controlled study that is cofunded with the National Cancer Institute as part of the Long Island breast project, but I am sorry I cannot give you an update on that.

[The information follows:]