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AIRBORNE LEAD REDUCTION ACT OF 1984

HEARING
BEFORE THE
COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE
NINETY-EIGHTH CONGRESS
SECOND SESSION

ON

S. 2609

A BILL TO AMEND THE CLEAN AIR ACT WITH REGARD TO MOBILE
SOURCE EMISSION CONTROL

JUNE 22, 1984

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to the median, the risk for minor malformations almost doubles. And as you go to the 98.8 percentile, it almost triples.

So lead may be involved, as it has been demonstrated in animals, in affecting the developmental program.

We have also followed forward from that group of individuals 250 children and seen them at every 6-month intervals, and we're measuring their development. And in an article which has been accepted for publication, we demonstrate, controlling for 120 nonlead covariates, that umbilical-cord-blood lead predicts infant IQ as measured by Bailey scales at 6 and 12 months of age.

So it may be that a determinant of infant outcome at 6 and 12 months of age is established by lead exposures while the fetus is in utero. That corresponds very nicely with animal studies conducted over the last 15 years.

In summary, I think a prudent and neutral evaluator of the body of data, not just my own group's, could not escape the conclusion that low-dose effects of lead affect children's brains and forward studies of lead show an effect on the development and the incidence of minor malformation.

I think the larger mystery here is why our society has been so slow to recognize this threat—it's been 40 years since Dr. Byers' paper in the American Journal of Disease in Children—and why it's so slow to deal with it effectively and promptly.

I congratulate you and the committee, sir, for seizing the leadership on this vital public health problem and would be prepared to answer your questions.

Senator STAFFORD. Thank you, Doctor.

Now Dr. Cole.

STATEMENT OF DR. JEROME F. COLE, PRESIDENT, INTERNATIONAL LEAD ZINC RESEARCH ORGANIZATION, INC., ACCOMPANIED BY DR. ROBERT BORNSCHEIN, ASSOCIATE PROFESSOR, UNIVERSITY OF CINCINNATI

Dr. COLE. Thank you, Senator. My name is Jerome F. Cole. I am president of the International Lead Zinc Research Organization, and I am appearing here today at the request of the Lead Industries Association, which is the trade association for the lead industry in the United States. With me is a consultant to ILZRO, Dr. Robert Bornschein. Dr. Bornschein is a researcher, an expert on studies pertaining to neurobehavioral effects of lead. He is an associate professor at the University of Cincinnati and is very familiar with the scientific studies pertaining to the neurobehavioral effects that Dr. Needleman was referring to. He is here to answer any questions that you may have. He is also prepared to answer any questions regarding the current ongoing prospective studies which were the subject of the EPA-sponsored meeting in Cincinnati that was referred to earlier by Dr. Goldstein, and also of course his own work, which is a very large study being sponsored by the U.S. National Institutes of Environmental Health Sciences.

The research that ILZRO, our organization, and others have conducted indicate that lead that has been used in paint in the past and is still present in old deteriorating housing is far and away the primary cause of elevated blood lead levels in children.

Frankly, we think that over the past decade the Government has been shooting at the wrong target when they have been so active in attempting to get the lead out of gasoline. Lead has been used in gasoline for over 60 years. Over that time, despite extensive research efforts on the part of industry, and academia, and the Government, there is simply no evidence that anyone in the general public has ever been harmed by this usage.

We are aware, of course, of the claims and the arguments of those who would further restrict or ban the use of lead in gasoline. These generally include an inflated estimate of the contribution of leaded gasoline to lead absorption as measured by the lead content in blood, and further, a onesided, and I think an alarmist, view of the medical and health evidence pertaining to the impact of low-level-lead exposure.

Over the years there have been a number of studies that have attempted to estimate the contribution of leaded gasoline to lead in blood. Virtually none of these studies have been definitive. However, a picture has emerged which is fairly consistent; and that is that the contribution of leaded gasoline to lead in blood is relatively small.

The most recent thorough review of this issue was carried out by Dr. Peter Elwood of the U.K. Medical Research Council epidemiology unit in Cardiff, Wales. And I have attached a copy of Dr. Elwood's review to my statement, and I would hope that it would be included as well.¹

Dr. Elwood's conclusion is that while it is impossible to make a reasonable estimate of the total contribution of gasoline lead to blood lead, all the studies put together indicate that both from air and other routes of exposure, the contribution of gasoline lead is small.

I should also point out at this stage that Dr. Elwood is not alone in that view. Others have also indicated that the contribution of lead in gasoline is relatively small. In fact, a study that was carried out in Dallas—there has been a large lead controversy going on in Dallas—back in 1982, and I believe Dr. Houk was a part of that, indicated that in areas of heavy traffic, the contribution of lead in gasoline, as indicated by traffic density, was 1 microgram per deciliter. That's considerably lower than the levels that he was talking about here earlier today based on the NHANES II data.

We have heard a lot about the NHANES II data and the correlation between the reduction of lead in gasoline and lead in blood over the same period, 1976 to 1980. It's true, of course, that lead in gasoline was reduced over that period of time and so did blood leads come down over that same period of time.

However, to suggest that all, or even most, of the decline in blood lead was caused simply by a reduction of lead in gasoline is, in our view, simplistic and dangerous. I think it's simplistic because the analysis ignores the impact of other, concurrent private and governmental initiatives. In fact, there are some 14 governmental regulations on the books right now that require control of lead in the environment.

¹ Retained in committee files.

It's also dangerous because by erroneously attributing so much of the contribution of lead in blood to one source, it tends to endanger other programs which are far more meaningful in terms of reducing the likelihood of lead poisoning in children.

Just recently, the Department of Housing and Urban Development came out with a proposal that would weaken their abatement effort in cleaning up old-lead-based paint in housing, and the basis for that was the analysis of the NHANES data which Dr. Houk mentioned earlier.

We would refer you once again to the report by Dr. Elwood for specific criticisms of the NHANES II data. But we would also ask you to review the report which I have also included with my statement, which was from an independent peer review group which was gathered at the request of the U.S. Environmental Protection Agency.

This NHANES II time trend analysis review group reviewed the analysis from a statistical standpoint. While in a narrow sense the review group confirmed the correlation that Dr. Houk mentioned earlier, it did point out several weaknesses in the analysis.

Also—and I think this is very important because of what we heard earlier—the group strongly warned against using the NHANES II data for estimates of the impact of gasoline lead on blood lead beyond the limits of the data, beyond 1980, which was the last year of the data. And yet, that's precisely what the EPA Office of Policy Analysis has done when it used the NHANES II data to predict the blood-lead levels of children in 1988 in its draft final report on the costs and benefits. They have used those, they have monetized those supposed benefits, and it's a clear violation of the recommendations of the EPA-appointed peer review group.

Therefore, we believe that reliable data show that lead in gasoline is a minor source of lead in blood. We recognize, however, that there are those who claim that even at low levels of lead in blood, there are adverse health effects. The most provocative and alarming of these claims is that low-level-lead exposure is associated with behavioral effects and learning disabilities.

The work of Dr. Needleman here is most often cited as the support for this premise. His study, which has been controversial from the beginning, was published in 1979 and has received an enormous amount of publicity and accounts for the general perception that low-level-lead exposure is harmful.

However, in 1983, late 1983, EPA also appointed another independent peer review committee to review Dr. Needleman's work and also the work of Dr. Ernhart. They were critical of both studies. In addition, the committee examined several studies, one of which was referred to—by Dr. Needleman.

But regarding his study, the committee concluded that because of errors in analysis, the Needleman paper neither supports nor refutes the hypothesis that low or moderate levels of lead exposure lead to cognitive or other behavioral impairments in children.

The committee also reviewed all the other studies and concluded, finally, that the committee knew of no studies that to date have validly established, after proper control for confounding variables, a relationship between low-level-lead exposure and neuropsychologic deficits in children.

The lesson that we should learn from this is that just getting a paper in print does not mean that it's gospel. Most recently, Dr. Needleman has commented on his paper in the Journal of the American Medical Association, and that has been referenced here today. And I would only note that at the recent Clean Air Science Advisory Committee, Dr. Julian Chisolm, who is an expert on pediatric lead poisoning, recommended that this paper be submitted to competent geneticists and teratologists for very cautious review because, and I quote: "I don't think that it was particularly * * * when it was originally presented that it was very well received."

The EPA peer review process that has been carried out on several controversial issues in the preparation of the new ambient air quality criteria document I think has been very valuable for clarifying the real meaning, or lack of meaning, of particularly controversial studies. We would urge that this process be extended to other studies before they're accepted at face value.

To assume a priori that minor biochemical changes are harmful would, if adopted as a general policy, open a floodgate of unnecessary regulations on virtually every substance in our environment. Quite simply, we don't think that the scientific and medical data at hand warrant the further reduction of the lead content in gasoline. And those who claim that they do, I believe, are engaging in improper scientific extrapolation.

At the outset, Senator Durenberger quoted Benjamin Franklin. I, at the end of my prepared statement, quoted from Mark Twain. And I would ask you to read it.

But in conclusion, I think the point that I would like to make is, in quoting from Mark Twain: "One gets such wholesale returns of conjecture out of such trifling investment of fact." And I think that unfortunately has been the case with much of what has been said in the past and here today about lead in gasoline.

Thank you.

Senator STAFFORD. Thank you, Dr. Cole.

We will, without objection, incorporate the various documents attached to your statement in the record by reference.

Now, we don't want to invite a general and lengthy debate in view of the number of witnesses yet to be heard. But might I ask members of the panel if any of you wish to briefly respond to the comments of any other member of the panel?

Dr. Houk.

Dr. HOUK. The documents that are being submitted as part of Dr. Cole's statement are clearly from a draft document prepared by EPA that says on its cover: "Not for distribution. Do not cite," and has not necessarily been accepted by the CASAC yet.

Dr. Cole in his statement has a half quote about the cause and causality of the NHANES II data. I think if you read the entire thing, that you will see that is taken out of context.

Epidemiologic studies, Senator, never prove conclusively cause and effect. They determine associations where they exist, remove as many confounders as is possible, so that reasonable people can make reasonable decisions.

The only way to prove cause and effect of blood lead in children's lead level and air-lead-blood level is to take children and put them in a breathing chamber and have them breathe air with different

lead levels. And fortunately, we live in a society where that sort of experimentation is not possible.

Senator STAFFORD. Is there any further comment from anybody.

Dr. Cole.

Dr. COLE. I just might respond briefly, sir. The documents that I included have been circulated very widely by the U.S. Environmental Protection Agency all over this country and all over the world. I don't think that there is anything at all secret about them.

Finally, the peer review group on NHANES II data did in fact stress the lack of proof of causality. They also said that they could not necessarily accept the assumptions that there were not other factors involved in the reduction of lead in blood over the same period of lead in gasoline; they simply didn't have the data that would enable them to make such a judgment.

Senator STAFFORD. Thank you.

Dr. Needleman.

Dr. NEEDLEMAN. Just to respond to Dr. Cole's statement about the ECAO appendix that he quoted commenting on my work and Dr. Ernhardt's. He's not really up to date. At the CASAC meeting referred to by Dr. Goldstein, I responded to every one of the questions raised by this review panel, and the Clean Air Science Advisory Committee they advised ECAO that there was no need for this appendix anymore, that my responses had been adequate.

So Dr. Cole is relying on an unpublished report that has not been accepted by EPA.

Senator STAFFORD. Now, Dr. Goldstein, please.

Dr. GOLDSTEIN. Thank you, Senator.

Let me see if I can put into perspective the CASAC, Clean Air Scientific Advisory Committee, process. Dr. Cole has mentioned two of the documents that have been developed as part of our criteria document processes, which are review of the entire literature. But the peer review process that EPA depends upon in its decisionmaking is really that by the Clean Air Scientific Advisory Committee. These are, in a sense, documents which are being reviewed by the Clean Air Scientific Advisory Committee. They do not represent the peer review that we are concerned with, and that will be formally done through with the Clean Air Scientific Advisory Committee.

Perhaps I could just briefly sum up some of my other disagreements with Dr. Cole by agreeing with him on his depiction of Dr. Julian Chisolm as being one of the leading experts in the treatment of lead poisoning in children and knowledge about lead poisoning in children, and point out to you that Dr. Chisolm has just reviewed the evidence and has recommended, along with other people in the field, that the level, the action level for blood leads be dropped from 30 to 25 micrograms per deciliter.

So obviously, he finds compelling some degree of the evidence for effects below 30 micrograms per deciliter.

Senator STAFFORD. Dr. Houk, did you want to speak further?

Dr. HOUK. Senator Stafford, I have been before this committee many times in the past discussing the issue of dioxins, trichlorethylene, ethylene dibromide, and other chemicals. We make public health assessments concerning these chemicals generally on the basis of animal toxicologic studies. We feed animals large doses of a

chemical. Then we extrapolate the effects on that animal of low doses of that chemical. We then extrapolate that information to the human population, and then we add a safety factor of 10, or 100, or 1,000 in making our recommendations.

What we are talking about here on lead is observed adverse health effects in people. We don't have to have high-dose feedings, and all this extrapolation. This is observed.

Lead is also an equal opportunity toxin, if you wish; virtually everybody in the United States is exposed to it through its sources. It is a very highly pervasive toxic material that is now in our environment. It has probably contaminated more people at more hazardous levels than even cigarette smoke.

There is no room for uninformed debate on the issue. The reasonable debate now occurring is: at what levels below 30 do these effects occur? If one says an abnormality on a laboratory test or a physiologic abnormality is not a real health concern, as a physician I would suggest that if I had some abnormal electrical activity of my heart measured on electrocardiogram, in which I felt no chest pain, I still would consider that I have heart disease and potential for having a myocardial infarction.

Thank you.

Senator STAFFORD. Is there further discussion?

Dr. Cole.

Dr. COLE. Mr. Chairman, I think that the issue here is probably not going to be resolved in—by just simple statements of belief, which I believe is what Dr. Houk has brought forward. I think a thorough examination of the data, such as I have suggested, is the only way that one can actually reach conclusions regarding the validity of studies which impact upon this issue.

However, just so you know that I am not particularly by myself, even though perhaps on this panel I find myself in that way and on some other panels from time to time, recently, Dr. Halpin, director of parental and child health services of the State of New Jersey, made a statement to the Centers for Disease Control, and I quote: "Lowering the definition of lead poisoning from 30 to 25 should only be done with the general agreement of the pediatric community. Currently, such support does not seem to exist."

Therefore, I am not alone, sir.

Senator STAFFORD. Thank you all very much.

Senator Durenberger.

Senator DURENBERGER. Yes, Mr. Chairman. I will try to be brief.

I want to start by thanking Dr. Needleman for his comments and to indicate that as a trustee of another children's hospital in this country I have always admired both Pittsburgh and Boston for their particular contributions, but then to say something on behalf of children's health centers across this country as they have grown in their specialties from the days when children's hospitals were crippled children's hospitals, largely, to the point in time where as an institution it seems to me that children's health centers and hospitals in this country are making some enormous contributions to our understanding of the variety of health effects that society and America has on our children.

It isn't only the publicity-generating, frontier-breaking activities of your liver transplant units, but I would say probably, as you

look at a lot of children's health centers in this country, it's what they are doing in the area of prevention and the area of mental health which is your expertise. And obviously, this is an area in which, as everyone has said, it's very difficult for us to dot the i's and cross the t's.

But I just want to say to you that I am, while I have seen Dr. Houk here many, many times, as he indicated earlier, and Dr. Goldstein has been in front of our subcommittee a number of times, I think that some pediatricians may disagree with the thesis that is offered here today, there is little doubt in my mind that Dr. Needleman and the experience that he has indicated to us that he has and that I think comes from a variety of people that I know associated with pediatric health care, at least in the mind of one member of this committee carries a great deal of weight. And I am not about to put them on a scale and find out how many pediatricians are on this side and how many pediatricians are on the other side.

Wednesday of this week I chaired a hearing on maternal and child health and the future of that effort that the Government has been helping society make, and I know the variety of concerns that are expressed in this country.

One of the issues that came up since we have blocked maternal and child health moneys was the fact that moneys formerly categorically granted for lead-paint poisoning seemed to be declining in their utilization, while others, particularly the pregnancy-prevention programs, prenatal- and postpartum-health-care activities are increasing.

But just on this whole issue that Dr. Cole raised of how much of the problem comes out of tailpipes and how much of it comes out of Tom Sawyer's paintbrush, would anybody want to contradict what Dr. Cole said relative to lead paint poisoning versus tailpipe poisoning?

Dr. NEEDLEMAN. Thank you for your comments, sir.

I don't want to contradict Dr. Cole. I just want to say that one of the reasons that there has been this paralysis in dealing with this is that the problem of lead has been passed around like a dirty relative. The lead additive industry would say it's old paint. HUD, because they don't want to bite the bullet on billions of dollars to delead houses, says it's lead in the atmosphere. The paint industry says, "Yes, it may be paint, but it's paint that's already sold 50 years ago," and nobody will say, "Well, it may be all of these things, and let's have a directed sequential approach as we do with medical problems."

If somebody comes in with four problems, you take them each individually and then attempt to remedy it.

Lead in the atmosphere, lead emissions deserves attention. Lead in housing deserves attention. And it's time to stop saying it's either this or that.

Senator DURENBERGER. Dr. Houk.

Dr. HOUK. The high-dose sources of lead in this country, Senator, are lead in paint, lead in dust and soil. The lead in the dust in soil gets there from lead in paint, lead from the deposition of automobile emissions and other emissions and previous land use.

It is quite correct to say that lead paint is probably the major cause of overt lead poisoning in this country. Children who have blood leads in the eighties and the sixties, who are overtly poisoned, and have encephalopathy and die, usually one can x ray their abdomen and find paint chips.

We are not dealing with that issue—although that is a very important issue, and the height of that issue has been, I believe, rather successfully dealt with in the lead-paint-poisoning program. There is still a lot of lead in houses, and that needs to be addressed, and I choose to address those with equal vigor as I address the gasoline issue, be that landlord a governmental agency or a private entity.

But we have a source of lead in this country of around 8 micrograms that is from the air. It is a controllable source. We can now adequately control the amount of lead used in gasoline. We cannot as a country afford at this point to right now remove all of the lead paint from the interior and the exterior of 50 million homes. We can prevent the lead in gasoline at this particular point.

There are no safety factors in this issue. Let's say, for example, that we all agree that lead causes nothing below 30 and only above 30. Well, establishing a level of concern of 30 has absolutely no safety factor.

Children who have blood leads of 80 are at very high risk of dying. I think we would all agree that death is an adverse health effect. If we used our usual procedure of putting in even a tenfold safety factor, then we would regulate the blood lead down to 8 micrograms. The mean blood-lead levels of the children in this country are substantially higher than that. So even if we had a tenfold safety factor from death, we are in excess of that safety factor for the majority of our population.

Senator DURENBERGER. Dr. Goldstein, the lead criteria study discusses the ability of lead particulate to stay airborne and travel great distances. Can you give us some information on how far it can travel before it comes to Earth as dust?

Dr. GOLDSTEIN. Dr. Grant is here with me and has reviewed that data more extensively than I have.

Dr. GRANT. Emissions from automobiles in heavily trafficked areas do carry out to within several hundred yards or whatever of the roadside and so on and are deposited there, primarily within about that area.

It can, or some may travel further. In cities, certainly with heavy-density traffic and on major highways or whatever, intersections of Interstates and so forth of this sort of thing, there can be quite considerable deposition in the surrounding areas.

Senator DURENBERGER. Dr. Goldstein, we're going to have a witness later this morning who will say something like the following: "The EPA expert committee of pediatric neural behavioral evaluations has recently concluded that the committee knows of no studies that to date have validly established a relationship between low-level lead exposure and neuropsychological effects in children."

He is going to be quoting from an EPA-sponsored statement. I wonder if you could shed some light on that for us?

Dr. GOLDSTEIN. Well, again, there, as part of EPA's criteria document approach we have developed—Dr. Grant has been very much