OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION
UNITED STATES DEPARTMENT OF LABOR

- x

In the Matter of the Proposed Health Standard for Occupational Exposure to Lead, Published on October 3, 1975, 40 Federal Register 45934-48. : Docket No. H-004

- x

POST-HEARING COMMENTS BY THE LEAD INDUSTRIES ASSOCIATION, INC. CONCERNING THE PROPOSED STANDARD FOR EXPOSURE TO LEAD

Debevoise, Plimpton, Lyons & Gates
Attorneys for The Lead
Industries Association, Inc.
299 Park Avenue
New York, New York 10017
212-752-6400

Standish F. Medina, Jr.
John H. Hall
Of Counsel

New York, New York
June 16, 1977

N 27035

Table of Contents

the Secretary of Labor and the Occupational Safety and Health Administration ("OSHA") to follow the procedures required by Executive Orders 11949 and 11821, OMB Circular No. A-107, Department of Labor Order 15-75, and Department of Labor Temporary Directive No. 1. The objection was raised in the Association's prehearing statement, dated February 8, 1977 (Exhibit 29[17]), and reasserted during the hearing itself (Cole 2990).* A detailed statement of the Association's position with respect to this issue is set forth in Appendix B.

Preliminary Statement

The Association recognizes that a revised lead standard should be promulgated and endorses many of the requirements set forth in the Proposed Standard. The Association, for example, agrees that both biological and

---

* Parenthetical references in these Comments are to exhibits submitted as part of the record or to testimony given by particular witnesses. References to exhibits follow the numerical designation assigned in the "Exhibit List" prepared by OSHA's Technical Data Center. Thus, for example, "(Exhibit 127)" would refer to the economic impact study by Charles River Associates, Inc. Bracketed references within exhibit references refer to particular items listed in the attachments to the main exhibit list. References to testimony include the name of the witness (or, in some instances, the group or company on whose behalf the witness is testifying), together with the particular page on which the relevant testimony is found. Thus, "(Cole 2990)" refers to testimony by Dr. Jerome F. Cole on page 2990 of the hearing transcript.

environmental monitoring should be required, that prophylactic chelation therapy should be prohibited, and that hygiene, housekeeping and educational programs should be required. It also agrees that the new standard should establish a biological "action level" which requires the employer to take special, remedial action to protect the worker's health whenever the worker's blood-lead concentration exceeds 60 ug/100g.

Although there is no doubt but that both biological monitoring and environmental monitoring are essential ingredients of any effective, comprehensive health maintenance program (e.g., NIOSH 1313, 1330-31), the fact that both kinds of monitoring are needed does not answer the quite separate question of which OSHA should adopt for purposes of enforcement and compliance under the new standard (Cole 2997-98; Caplan 3866, 3938) (See Wolfe 4189-91) (Exhibit 234[22], at 22). OSHA can resolve that separate issue only by asking and answering the following questions:

(1) What benefits are to be attained by using a biological or an environmental enforcement mechanism, and which mechanism best and most directly protects the health of workers?

(2) If the benefits and protection of the two kinds of enforcement mechanisms are roughly comparable,

which is the less expensive and more practical? Which, in other words, will be accepted and can be implemented more quickly by employers?

(3) Which can be enforced more effectively by OSHA with the least administrative burdens?

LIA respectfully submits that the record establishes that the health of workers will be better protected, with fewer administrative and economic burdens, if OSHA emphasizes a biological rather than an environmental enforcement mechanism.

First, the use of a single air-lead standard for the entire lead industry cannot be justified unless there is a significant relationship between the status of a worker's health and the air-lead level selected as the exposure limit; that is, unless--as OSHA has said--there is substantial "evidence . . . linking that amount [of air-borne lead] to safe levels of lead in the body." There is no such evidence. The record establishes that particular blood-lead levels cannot be correlated with or predicted from particular air-lead concentrations and that the use of a single air-lead standard will not adequately protect workers' health.

Second, only a biological standard accurately reflects <u>total</u> exposure and thereby enables the employer

to protect his workers from the cumulative effects of both occupational and non-occupational lead absorption. Air monitoring, on the other hand, cannot account for absorption caused by poor hygiene, sloppy work habits, or off-the-job exposure. In fact, as the record demonstrates, air monitoring does not even reliably identify the source of lead emissions in the factory and is subject to significant sampling problems and short term variations.

Finally, because of the variety and number of industries which use lead and because of the differences among operations within those industries, establishing a single, numerical air-lead standard applicable to all operations, all processes and all industries serves no meaningful function. Instead, it merely has the effect of maximizing unnecessarily the costs involved. Use of a biological enforcement procedure, by comparison, would minimize OSHA's administrative burdens and would make it much easier for OSHA to enforce the standard. Under LIA's proposal, for example, an employer could be automatically cited for violating the standard merely on the basis of information contained in the biological monitoring records which the employer would be required to maintain.

Although the Association believes that OSHA

should adopt a biological enforcement mechanism, it recognizes the importance of insuring that appropriate engineering controls will be installed by employers covered by the standard. The Association believes, however, that it is important to do so without arbitrarily and inflexibly requiring the installation of expensive equipment if such controls will have few if any demonstrable beneficial effects on workers' health. For these reasons LIA has recommended that the new lead standard require employers to institute engineering controls to reduce air-lead exposures to the extent "feasible" instead of to an arbitrary, largely meaningless air-lead number. The employer, of course, would still be subject to citation if OSHA--upon investigation and after reviewing the employer's written compliance program--determined that it was feasible for the employer to institute additional or different engineering controls and the employer thereafter refused to do so.

If OSHA nevertheless decides to retain an environmental exposure limit for compliance purposes, there are a number of reasons why the existing exposure limit of 200 ug/m3 should not be reduced:

(1) Since few of the major segments of the lead industry appear to be in compliance with the existing standard of 200 ug/m3, no one knows what health

improvements would be achieved were the existing standard to be enforced in conjunction with new requirements for biological monitoring, medical surveillance, proper hygiene, good work practices and worker training. Until we know what benefits, if any, would flow from the existing standard, properly implemented, further modifications of the permissible exposure limit cannot be justified.

(2) Virtually all of the studies submitted to and analyzed at the hearings demonstrate that the reduction of even mean blood-lead levels which might be achieved by moving from 200 ug/m3 to the proposed exposure limit of 100 ug/m3 would be minimal at best--something in the order of two to six ug/100g. In other words, despite the enormous costs and serious competitive impacts involved, reducing the enforcement level would serve little purpose in terms of protecting workers' health. See In re Castle & Cook Foods, 5 O.S.H.C. 1435 (May 19, 1977).

(3) As confirmed by OSHA's own economic consultants, the likely result of promulgating and enforcing the Proposed Standard would be to close down one of the nation's four primary smelters, many of the medium and smaller secondary smelters, and a vast majority--perhaps as many as 113--of the medium

and smaller battery manufacturers. It is undisputed that novel (and, indeed, in some instances untried) engineering controls would be required even to attempt to reach the proposed level. Consequently, the economic and technological problems which would confront the lead industry if the existing permissible level were reduced would be real . . . and inevitable.

We turn now to a more detailed discussion of the issues mentioned above and to an analysis of the evidence presented prior to and during the hearings.

Discussion

I. 60 ug/100g IS A SAFE AND APPROPRIATE ACTION LEVEL SINCE WORKERS WILL NOT SUFFER MATERIAL IMPAIRMENT OF HEALTH IF BLOOD-LEADS ARE BELOW 80 ug/100g.

OSHA has consistently (and correctly) recognized that biological monitoring "more accurately indicate[s] the likelihood of adverse effects" upon employees occupationally exposed to lead than do alternate monitoring techniques. (Exhibit 2, at 45940) Since OSHA's primary responsibility is to protect workers from material impairment of health or functional capacity, the logical starting point for any analysis of what the new standard should require is

a determination of what biological indices should be used as guidelines.

Although no single biological indicator is absolutely foolproof, the record confirms the correctness of OSHA's preliminary observation that,

> "Among all of the biological indicators of lead available today, blood lead concentrations [are the indicators which] correlate best with the appearance of symptoms of lead intoxication . . . ." (Exhibit 2, at 45940)

(See, e.g., Hammond 256, 295; Lancranjan 609; Cole 3011) This was also the conclusion reached last fall in Amsterdam by the Lead Workshop Group which, after considering the latest and best scientific data, decided that "PbB was . . . the reference measurement to which other parameters should be related." The Amsterdam Workshop also concluded that "measurement of EP (or ZPP) was generally felt to be the best secondary parameter to be used but was not yet in a position to replace PbB except for screening purposes." (Exhibit 262) (Cole 3011-12)*

---

* The Amsterdam Conference attendees--whom Dr. El Batawi characterized as "the outstanding 'big wheels' in occupational lead exposure science doing laboratory experiments and sophisticated epidemiological studies" (El Batawi 332) --included Drs. El Batawi, Repko and Seppalainen (who appeared as witnesses for OSHA), Drs. Fischbein and Lilis (who appeared as witnesses at the request of labor), Drs. Malcolm and Williams (who appeared as witnesses at the request of industry), as well as Drs. Forni and Zielhuis, Edward King, and others. (Cole 3136-39) (Exhibit 262)

Although it appears clear that blood-lead determinations should remain the primary biological indicator for purposes of evaluating health risks (at least until further studies have been done to establish appropriate ZPP guidelines), there were considerable differences of opinion as to what is a "proper" or "safe" blood-lead level. LIA submits that the hearing record, considered as a whole and in the context of OSHA's statutory mandate, establishes that 60 ug/100g is an appropriate biological action level and that workers will not suffer material impairment of health or functional capacity if their blood-lead levels are consistently below 80 ug/100g.

A. Statutory Requirements

Dr. Sidney Wolfe of the Public Citizens' Health Research Group correctly observed during the hearings that "OSHA doesn't have the burden of correcting all of the ills of the world." (Wolfe 4214) In promulgating health standards for substances such as lead, the Secretary of Labor is directed to set "the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . . ." 29 U.S.C. § 655(b)(5). (Emphasis added.) The

word "material" was not inadvertently included in the Act. Rather, it was inserted during the course of floor debates in the Senate for the express purpose of indicating that the Act was not designed to require the Secretary to eliminate every conceivable risk to which a worker might be occupationally exposed.

During the debate of the bill in the Senate in October 1970, Senator Dominick proposed an amendment to delete language requiring the Secretary to set standards to insure "that no employee will suffer any impairment of health . . . ." S. 2193, Amendment No. 1054, 91st Cong. 2nd Sess. (October 13, 1970). (Emphasis in original.) Senator Dominick explained that,

> "This requirement is inherently confusing and unrealistic. It could be read to require the Secretary to ban all occupations in which there remains some risk of injury, impaired health, or life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation." Ibid. (Emphasis in original.)

When the amendment reached the floor, Senator Dominick elaborated on his concerns and the need for the amendment.

> "No job can be rendered perfectly safe, and no employee can be made perfectly secure from injury. Hence, it is impossible to fashion criteria which would assure these unattainable goals. . . . It

> is unrealistic to attempt, as this section apparently does, to establish a utopia free from any hazards. Absolute safety is an impossibility and it will only create confusion in the administration of this act for the Congress to set clearly unattainable goals. . . . The difficulty of the language I am dealing with here and that I am trying to delete is the requirement, that the Secretary, in establishing standards, must assure that there will not be any risk at all." Legislative History, at 480-81.

After an interruption to take up other business (and, presumably, after Senator Dominick had conferred with his colleagues), Senator Dominick asked to modify his amendment and Section 6(b)(5) to provide the language--including the word "material"--which now appears in the Act. The modified amendment was accepted and remained in the bill that was approved by both houses and enacted into law.

The net effect of this significant change in the text of the bill was to make it clear that the Act was designed to enable the Secretary of Labor to prevent serious, "material" impairments of health; it was not intended to protect against each and every biological change--however unimportant its health repercussions--which toxic substances might cause.

Although the Secretary may act even when he lacks "absolute certainty as to the deleterious effect of [a particular amount of] a substance on man," Dry Color Manufacturers' Assoc. v. Department of Labor, 486 F.2d 98, 104

(3rd Cir. 1973), he may not promulgate a standard on the basis of arbitrary or speculative assumptions. It must be "supported by substantial evidence in the record considered as a whole", 29 U.S.C. § 655(f), and must be based upon "the best . . . [and] the latest available scientific data in the field", 29 U.S.C. § 655(b)(5).

It is against this legal and statutory background that the Secretary and OSHA must consider the evidence and testimony presented during the hearings.

B. Clinical Effects

Although there was considerable discussion during the hearings as to the significance of the so-called "subclinical" effects of lead exposure, there exists no persuasive evidence to indicate that clinical lead intoxication occurs below blood-lead concentrations of 80 ug/100g. To the contrary, the "best . . . [and] latest available scientific data in the field" indicate that members of the general working population do not suffer any clinical lead poisoning or "material impairment of health or functional capacity" when blood-lead levels are consistently maintained below this concentration.

Dr. Robert Kehoe, perhaps the most highly respected authority on lead intoxication in the world, con-

cluded in an article published only last year,

> "[I]t appears that no case of poisoning occurs until the concentration of lead in the blood reaches at least 80 ug per 100 ml, and most cases of poisoning occur at a level well above this (100-300 ug/100ml)." (Exhibit 294B) (Emphasis added.)

This, of course, is entirely consistent with the view Kehoe expressed fifteen years earlier in his famous Harben Lectures, when he explained that "no case of even the mildest type of poisoning has been induced by the absorption of inorganic compounds of lead" at blood-lead concentrations below 80 ug/100g. (Exhibit 5[33]). It is also consistent with the evidence presented during the hearings.

Among the many physicians and medical academicians who testified during the hearings, only five or six had day-to-day responsibility for protecting workers' health and, like Kehoe, were able to offer opinions based on their own observations and actual industrial experience. All confirmed that Kehoe's conclusion was correct. (Malcolm 2105-06; Williams 1879; Hine 6574-75; Bell 1272; Fishburn 4359; Lorio 2826). The same conclusion has also been expressed by the Chief Medical Adviser of the Health and Safety Executive of the United Kingdom--the British equivalent of OSHA (Williams 1881)--who in November 1976 issued a bulletin to all lead workers stating, among other things,

that

> "People who work with lead usually have a higher level of lead in the blood, but provided that it does not exceed 80 or so, illness in adults is almost unknown. . . . There is nothing particularly alarming about a level of lead in the blood of 80 or more and it certainly does not necessarily mean that you have lead poisoning. All that a level of lead in the blood shows by itself is the conditions to which you have been exposed." (Williams 1882-84) (Exhibit 93)

See also Lane, Diagnosis of Inorganic Lead Poisoning: A Statement, 4 Brit. Med. J. 501 (1968) (at "levels of lead absorption [below 80 ug/100g] the mild symptoms . . . which are common to a number of minor complaints, are not attributable to lead") (Exhibit 3[72], at 21).

Some doctors (particularly those who appeared at the request of organized labor) testified at the hearings that clinical symptoms of lead poisoning had been observed in workers who at the time of the observation had had blood-lead levels below 80 ug/100g. (See, e.g., Epstein 1060; Wolfe 4122) These witnesses, however, were unable to state whether the blood-lead determinations were representative of the levels which existed when the symptoms first occurred. (See, e.g., Wolfe 4180-82) As Kehoe warned last year,

> "Under conditions of prolonged and gradual absorption of lead the time of onset [of symptoms] is

> . . . . uncertain. The symptoms . . . of lead poisoning often persist after the blood concentration has declined well below 80 ug/100ml so that, if the threshold value at the onset is to be known, the concentration must be determined close to the onset of illness." (Exhibit 294B)

Many of these witnesses were also unable to eliminate the possibility that chelating agents had already been used, and use of such agents would also have affected the magnitude of the blood-lead concentrations they observed.*

The problems inherent in trying to set a standard based upon data gathered long after the period of actual exposure are well illustrated by the statement of Dr. Richard Wedeen, who testified as to the possible effects of lead on the renal system. Wedeen observed several lead workers who in his opinion had kidney dysfunction and some of whom at the time of his medical examination had blood-lead levels below 80 ug/100g. He acknowledged, however, that he "had no information of the past record of [their] blood lead levels" (1757); that "the people that [he] examined were not undergoing current exposure and therefore, their blood leads simply didn't reflect their expo-

---

* These and other shortcomings were present in several of the studies--including those by Culver, Blejer, Beritic and Sakurai--which OSHA referred to in the Notice. The Association has already discussed these studies at pages 20-24 of its formal Comments, dated January 16, 1976 (Exhibit 3[72]), and will not repeat that discussion here.

sure history" (1778); and that many of his subjects had "certainly" received prior chelation therapy (1756).* Wedeen quite properly concluded, therefore, that his study could not be used in setting a new health standard. (Wedeen 1758) (See also Cole 3028-29; Williams 1889; Hine 6541-49; Exhibit 218A; Exhibit 294C)

Several union and "public interest" groups urged OSHA to set the biological guideline below the 60 ug/100g action level proposed by OSHA and below the combined 60-and-80 ug/100g standard recommended by the Association; however, it is significant to compare what these witnesses said at the hearing with what they have actually done in practice.

The United Auto Workers, for example, urged OSHA to establish 30-40 ug/100g as the biological guideline (Woodcock 5043), but during labor negotiations in 1976--after the proposed standard had been issued--the union was asking for the establishment of an action level of 80 ug/100g. (Cardinal 5445-46) Presumably the UAW proposed that action level because it was confident that blood-lead concentrations up to 80 ug/100g were "safe". Similarly, the Mt. Sinai medical team and the United

---

* As Dr. Hammond, one of OSHA's witnesses, indicated, many of these same deficiencies were also present in the study by Vitale. (Hammond 264-65)

Steelworkers of America (at whose request Mt. Sinai investigated the health of lead workers in Indianapolis in 1976) argued during the hearings that blood-lead levels in excess of 40 or 50 ug/100g were dangerous. (Lilis 2701; Lloyd 4711-12) But despite their posture at the hearings, when it came to protect the health of the Indianapolis lead workers who had been examined, the only workers to whom Mt. Sinai or the Steelworkers sent letters advising consultation with a physician were those whose blood-lead levels exceeded 80 ug/100g. (Valenta 2983-21 and 2983-22; Becker 5128-29) (See, e.g., Exhibit 185) It is inconceivable that the Mt. Sinai doctors or the Steelworkers would distribute or endorse such a letter if they were convinced that the health of workers with PbB levels in the 40-80 ug/100g range was endangered.

Even NIOSH has been somewhat fluid in the position it has taken at various times. For example, although NIOSH in August 1975 (Exhibit 86A) first urged OSHA to adopt a biological guideline of 60 ug/100g (a position which it later adhered to during the hearing [Baier 1316]), only two months earlier, in June 1975, NIOSH was issuing Health Hazard Evaluation studies stating that blood-lead "levels up to 80 micrograms per 100 grams are considered safe." (Exhibit 3[72], at 20) Other recent NIOSH studies

similarly concluded that "no cases of even mild poisoning should occur" at blood-lead levels below 80 ug/100g, that blood-lead levels "in lead workers . . . [are] not considered escessive [sic] until a level of 80 ug% is reached", and that levels "between 70-80 micrograms per hundred ml of blood are indicative of non-harmful absorption." Ibid.

In summary, the best and most reliable evidence presented at the hearing establishes that the clinical effects of lead poisoning do not occur when blood-lead levels are maintained below 80 ug/100g and that 60 ug/100g is an appropriate action level with an adequate margin of safety. While science will obviously continue to provide additional information about lead intoxication, what is now known fully supports the Association's position. As stated in the Notice, the potential "health hazards associated with . . . the use of [lead], either as a metal or in compound form," have been recognized for centuries. Exhibit 2, at 45934. The literature about such hazards and about the biological effects of lead exposure is voluminous. Because so much is known about the toxicity of lead and about the biological implications of absorbing particular amounts of lead, lead is distinctly different from most other toxic substances. It is this distinct difference which justifies establishing an enforcement mechanism based upon biological monitoring.

cal' directly indicates disease, 'subclinical' can only mean 'does not directly indicate disease', and circumlocution should not have it otherwise." (Exhibit 3[65]; Exhibit 234[8])

Second, it is important to remember that although exposure to lead may cause biological changes, not every biological change which occurs in response to an external stimulus is harmful. Most of those who believe that the biological action level proposed by OSHA is too high proceed on the assumption that virtually any detectable change is automatically deleterious to health and is therefore intolerable. (E.g. Piomelli 466-67; Seppalainen 118; Lilis 2701) That assumption is incorrect. Our bodies respond to innumerable stimuli--temperature, light, physical substances, exertion, and a myriad of others. The fact that a biological change has occurred does not necessarily signal physical injury or even the threat of injury. This is true despite the fact that the biological change is characterized as a "subclinical effect", for as Dr. Bridbord of NIOSH noted, no one "has all of the answers to at what point [subclinical changes] . . . become significant." (Bridbord 1454) The question, therefore, is not whether subclinical effects result from lead exposure, but rather whether those effects have health implications which justify

a particular exposure standard. As indicated by the analyses below, LIA submits that they do not.

(1) Hematological Effects. The record establishes that the hematopoetic system is very sensitive to the effects of lead exposure and is the first biological "indicator" of such exposure. (See, e.g., Teitelbaum 504) It is also undisputed that enzymes such as delta aminolevulinic acid dehydratase ("ALAD") and ferrochelatase, which are utilized in the biosynthesis of heme and hemoglobin, may be inhibited by even relatively low levels of lead exposure. Such inhibition, accompanied by increased amounts of urinary ALA and free erythrocyte protoporphyrin or zinc protoporphyrin, certainly takes place at blood-lead levels between 30 to 40 ug/100g (Malcolm 2142; Cole 3264), and may occur at blood-lead levels as low as 10 to 15 ug/100g (Piomelli 451-52; Williams 1948). However, as OSHA observed in October 1975, "the point at which [these] changes become sufficiently serious to represent a threat to health is not clearly defined." (Exhibit 2, at 45935) The hearings have done little to provide such a definition.

Neither increased ALA nor inhibited ALAD, nor increased ZPP nor inhibited ferrochelatase is per se harmful. These changes by themselves do not indicate interference with heme production. In fact, just the opposite may be

(Hine 6577) In fact, since the average person in this country has a blood-lead level of approximately 20 ug/100g (Piomelli 449; Cole 3072-73) or higher (Nelson 3989; Estee 2930; Miller 3545; Samuels 4249), and since ALAD may be inhibited even at these low levels, any biological standard designed to eliminate such subclinical effects would be unrealistic as well as unnecessary. It might even preclude lead companies from hiring a substantial percentage of the available workforce and, for all practical purposes, would be the equivalent of requiring a zero exposure level. (See generally Steelworker Panel 5680 [blood-lead standard of "forty . . . is totally unrealistic"])

(2) Neurological Effects. The second category of subclinical effects discussed extensively during the hearings was the slight reduction of nerve conduction velocity which may occur in certain peripheral nerves of workers occupationally exposed to lead. However, as NIOSH representatives pointed out, the data concerning these effects "are not quite as firm" as the data concerning the hematopoetic system (Bridbord 1799), and the effects cannot "really [be] call[ed] . . . a disease" (Baker 1610).

The only detailed study presented at the hearings was that by Dr. Seppalainen, who concluded that

NCV was affected at blood-lead concentrations below 80 ug/100g. (Seppalainen 118) Although acknowledging that "the slowing was slight in degree", she nevertheless concluded that "it should be considered a harmful effect." Ibid. The Association respectfully disagrees, for the reasons set forth below.

Even if Seppalainen's findings were accurate and reliable (which they may not be [see infra at 28-30]), it is clear that the slight reduction in nerve conduction velocities which she found does not constitute "material impairment of health" and does not affect the functional ability of lead workers who have blood-lead levels below 80 ug/100g. As Dr. Baker of NIOSH correctly observed,

> "The problem with nerve conduction velocities is that it is a fairly new test and there have not been any good correlations done between functional abnormalities, that is to say weakness, or other measurements that really get an individual's performance ability that could be related back to a nerve conduction velocity number." (NIOSH 1609)

Dr. Malcolm, for example, computed the difference in a worker's reaction time suggested by Seppalainen's findings, and found that difference to be approximately five ten thousands of a second, a "figure" which he characterized as being "so small as to be meaningless." (Malcolm 2108, 2131) Indeed, even Seppalainen herself has noted that

". . . in terms of health, the importance of slight subclinical neuropathy can be questioned . . . and we did not find any evidence that the well-being of these workers was influenced by the neuropathy, apart from a few complaints of numbness of the arms. Thus, the term poisoning, in its orthodox sense, cannot be applied to these disorders." (Emphasis added.) (Exhibit 5[12])

The observations by NIOSH and by Seppalainen were confirmed by other testimony and evidence at the hearings.

First, a study by Crockford and Mitran (the validity and accuracy of which were never challenged during the hearings) concluded, on the basis of extensive psychomotor tests administered to lead workers, that

". . . a reduced nerve conduction velocity of the magnitude reported in lead workers is not associated with any decrement in performance. . . . No indication of dose response relationships have been found over the blood lead level range of 22 to 79 ug/100ml blood.

"It is suggested that the small shifts in NCV reported in healthy lead workers are probably indicative of shifts in homeostatic mechanisms and that such changes are not suitable as a criterion for setting environmental standards for lead exposure. The use of the term 'damage' in describing such changes in NCV is inappropriate." (Exhibit 234[21])

To the same effect, see Williams 1885, 1903; Malcolm 2108; Cole 3040; Hine 6577.*

---

* OSHA stated in the Notice (Exhibit 2, at 45936) that "the data of Seppalainen agree reasonably well with those" reported by Repko (Exhibit [footnote continued]

Second, while the mean conduction velocities for the lead-exposed subjects studied by Seppalainen were slightly less than the corresponding velocities for the control subjects, the differences were relatively small and the values for the lead-exposed subjects were still well within the normal range. Indeed, the NCV differences observed by Seppalainen were of no greater magnitude (and hence of no greater significance) than the NCV changes which are caused by the consumption of alcohol or by fluctuations in skin temperature. (Williams 1885; Malcolm 2107; see also Seppalainen 123, 133, 159)

Third, although no extensive studies have been conducted as to the reversibility of the slight NCV changes reported by Seppalainen, the limited data so far available indicate that these changes are reversible. (Seppalainen 130; compare Williams 1887) In addition, Seppalainen has stated that there appears to be no greater NCV impact on older workers than on younger workers. (Williams 1887)

None of the foregoing is intended to suggest

[footnote continued] 5[14]). However, the cross-examination of Dr. Repko at the hearings (187-205) established that he had reversed or withdrawn virtually all of his earlier findings and demonstrated that the study, which was underdesigned and poorly analyzed, was faulty both in execution and conclusions. His study did not support either Seppalainen's study or OSHA's proposal. See also LIA's formal Comments, dated January 1976 (Exhibit 3[72]), at 37-40; Exhibit 299, Subsection C, at 5-6.

jects were tested only in 1973. Different rooms were used for the studies. (Seppalainen 124) As a consequence of these differences, it is difficult if not impossible to compare meaningfully the test results from the two groups.

(2) Although the study suggests that the lead-exposed subjects were biologically monitored during the "entire period" of their exposure to lead, six of the 28 subjects--or more than one out of every five workers--had been occupationally exposed to lead prior to the time the monitoring began. It is therefore entirely possible that some or all of these workers had previously had higher blood-lead levels, and that the slight neurological changes observed actually occurred and were caused when blood-leads were higher, not at the lower levels which existed at the time of the monitoring.

(3) There is a serious question as to whether skin temperatures were adequately monitored throughout the testing period and were maintained at the correct level. See Steiner's critique, supra, at 7.

As a consequence of these flaws in the testing procedures, it is entirely possible that the mild neurological effects which were supposedly detected in the lead-exposed group

that . . . deal[s] with this" subject (Hunt 669) is the study (Exhibit 23[38]) by Ioana Lancranjan. The study however, has material flaws and does not support Lancranjan's conclusions that male fertility and sex drive are adversely affected at low blood-lead levels.

Perhaps the most serious shortcoming of Lancranjan's study, as Dr. Zielhuis observed in his review of the literature (Exhibit 24[23]) (Lancranjan 589, 594), is the fact that her biological determinations appear to be erroneous. The urinary ALA and urinary lead measurements generated by Lancranjan's study suggest that the blood-lead levels which she reported are erroneously low (Lancranjan 594-99; Williams 1888). Based on the 1968 Amsterdam criteria, the blood-lead levels which correlate with Lancranjan's urinary findings would be "well over 80 micrograms per 100 ml". (Lancranjan 595) This is confirmed by the fact that Lancranjan thought it necessary to recommend that many of the exposed group with whom she was working, including even the so-called "moderately exposed" workers, be given chelation therapy (Lancranjan

---

[footnote continued] indication of a detrimental health effect on the individual neither do they signify a potential effect to the offspring. There is no evidence so far of any abnormal clone formation important for carcinogenesis or leukaemongenesis in somatic cells of lead exposed subjects." (Exhibit 262; Wolfe 4185) (See also Exhibit 234[20]; Teitelbaum 420)

603-05), a precautionary measure that would have been inappropriate unless blood-lead concentrations were elevated considerably past 80 ug/100g. Lancranjan's study, therefore, cannot be used to support the proposition that male fertility is inhibited at blood-lead concentrations below 80 ug/100g.

The Lancranjan study contains a number of other defects, including the following:

(1) Lancranjan was unable to determine whether her volunteers did in fact abstain from any sexual activity during the three-day period preceding the testing. (Lancranjan 587-88) Had some of the test subjects not abstained, this would have materially affected the data with respect to the number and motility of the sperm studied.

(2) Lancranjan's classification of her test subjects as "poisoned" or "non-poisoned" according to the 1968 Amsterdam Conference criteria was almost totally meaningless in terms of the blood-lead levels involved, since she used a blood-lead guideline to classify some of the workers and a urine-lead guideline to classify others. The result was an overlapping categorization in which "some people with very low blood-lead levels [were put] in the

lead-poisoned group." (Lancranjan 590-93) Consequently, the blood-lead "classifications really aren't very meaningful . . . ." (Lancranjan 592)

(3) Adding to the unreliability of her blood-lead data was the fact that she did blood-lead determinations on only 35 out of her 50 controls. (Lancranjan 593-94)

(4) Lancranjan's control subjects were "mainly" office workers and students--that is, people with sedentary occupations--whereas her lead-exposed group consisted largely of persons engaged in heavy manual labor. (Lancranjan 611) This difference may have influenced the results of her study.

(5) Although the most reliable method of determining the purported effects of lead on the fertility of workers would be to investigate the number and health of the children they had had, Lancranjan was not able to obtain that information. (Lancranjan 606-07)

Lancranjan dismissed these questions as "small details", asserting that her work "was a preliminary study" by which she was "able to show . . .that lead poisoning is able to influence spermatogenesis". (Lancranjan 598-99) (Emphasis added.) The Association submits that the critical question for OSHA's purposes is not whether lead poisoning

has any adverse health implications (which it obviously does) but rather at what exposure level do adverse health effects occur. Lancranjan's study does not answer that question. It was for that reason that Dr. Zielhuis, noting that her study was "based upon data which leave much room for serious questioning," concluded that "standards for occupational lead exposure cannot be based upon" the effects described in Lancranjan's study. (Exhibit 24[23]) (Emphasis in original.) (See also Hine 6593-94; Lancranjan 607) The Association agrees with Dr. Zielhuis' conclusion.

D. Susceptibility of Particular Workers to Lead Intoxication

Prior to the commencement of the hearings OSHA stated that one of the major issues to be discussed was the question of whether the new standard should in part be based upon the purported susceptibility of particular groups which were thought to have "increased susceptibility to lead". (Exhibit 21, at 808-09) The Association submits that this question must be answered in the negative--either because certain of the particular groups that were thought to be susceptible are not, or because the susceptibility involved must be dealt with on an individual and not a group basis.

It is important to keep in mind, as a preliminary

matter, that certain persons--whatever their race, their color or their sex--may have biological characteristics which make it inappropriate for them to be exposed to particular substances or conditions. This, in turn, may mean that they should not engage in particular occupations. The record made in this proceeding establishes conclusively, for example, that persons who are known to be suffering from clinical anemia or from renal insufficiency should not be occupationally exposed to lead at all. (Teitelbaum 518; Williams 2025; NIOSH 1573-74; Cole 3008, 3046-47; Globe Union 4386) This is not because they belong to a particular "group" but because pre-employment or pre-placement medical examination will demonstrate that it could be hazardous for them to absorb any additional lead.

OSHA asserted in the Notice that there is a "likelihood that persons with the sickle cell trait may be subjected to a greater risk" than other persons if they are occupationally exposed to lead. (Exhibit 2, at 45936) The same assertion appeared a year and a half later in OSHA's Environmental Impact Statement, dated February 1977. (Exhibit 31, at 19) The assertion was incorrect when first made and, as OSHA should know by now,

is still incorrect.*

NIOSH confirmed this recently when it investigated a large secondary smelter to determine whether black employees with an "inherited risk of sickle cell disease" might be more susceptible to "deleterious effects from lead exposure". (Exhibit 234[9]) NIOSH concluded that the best available evidence established "that individuals with sickle cell trait are no more susceptible to the effects of lead than are individuals without the trait."

In reaching this conclusion, NIOSH pointed out that,

> "The primary mechanism by which the hemoglobin molecule is affected differs in lead toxicity and in sickle cell trait. The effect of lead exposure does not enhance the fragility of the red blood cells, which is the major mechanism of anemia in sickle cell disease."

Noting that "the medical literature" provided no evidence to support the proposition that persons with the sickle cell trait were more susceptible to lead intoxication than others, the NIOSH report went on to state,

> "Additionally, conversations were held with several medical authorities who are particularly knowledgeable

---

* The fact that a person has sickle cell "trait" does not mean, of course, that he has sickle cell "anemia". Those who do have sickle cell anemia have the same susceptibilities as persons with iron deficiency anemia and should not be exposed to any additional lead.

> in the areas of sickle cell trait and lead toxicity, and all were of the opinion that lead exposure should have no greater effect on individuals with the trait than on those without it. Based upon these findings and professional opinions, it is our judgment that further evaluation into this matter is not warranted at this time. The question of conducting a retrospective morbidity and mortality study was raised in the health hazard evaluation request. This is also felt not to be warranted at this time . . . . A recent study by Cooper and Tabershaw attempts to look at the morbidity and mortality of lead battery workers and smelters, comparing black and white workers with standard morbidity and mortality rates. Although the study has several significant limitations, the findings suggest no difference."

Nothing has happened since the issuance of NIOSH's evaluation study to controvert or disprove any of the conclusions contained in that study. Consequently, it would be arbitrary and capricious for the Secretary to promulgate a new standard on the assumption that a particularly low exposure limit was needed to protect workers with the sickle cell trait.*

OSHA also expressed concern in the Notice as to the possibility that "female employees of childbearing age" might constitute a "group . . . [which has] a greater susceptibility to lead intoxication than the general worker

---

* Equally without foundation is the contention advanced by a few of the union representatives (e.g., Samuels 4251) that a particularly low exposure limit is needed to protect persons with glucose-6-phosphate dehydrogenase deficiency, or "Mediterranean anemia". As Dr. Piomelli observed, the condition "does not warrant . . . any special precaution for these individuals." (Piomelli 464)

population." The evidence submitted at the hearing, however, established that females themselves are not more susceptible than males. (See e.g., Needleman 1116-17; Stellman 1154-55; NOW 2478)(See also NIOSH 1321, 1802) The more serious but quite different question raised by "female employees of childbearing age" is the problem of potential health hazards to the fetus.

The problem of protecting unborn children of female lead workers arises as a consequence of a confluence of several factors:

(1) Lead in the mother's bloodstream crosses the placental membrane and can affect the unborn child.

(2) Although the medical data and studies are not entirely consistent, it is possible--as the Notice suggests--that "the statistical likelihood of clinical symptoms and permanent damage" to the fetus may increase once the blood-lead level of the mother reaches 30 or 40 ug/100g. (Exhibit 2, at 45936) (See also Lundquist 4509)

(3) The fetus may be most vulnerable to the hazards of excess lead absorption during the first trimester (Wrenn 30), at a time when the mother may not even be aware that she is pregnant.

(4) Given the fact, discussed earlier, that the average

person not occupationally exposed to lead has a blood-lead level of 20 ug/100g and some have blood-lead concentrations as high as 40 ug/100g, it would be impossible to insure that the fertile female employed in a lead plant did not absorb amounts of lead which might pose a hazard to her unborn child were she to become pregnant. (Cole 3067-70, 3254; Lundquist 4509, 4513, 4522) (See also Teitelbaum 417) No amount of rhetoric or good intentions will alter the fact that it is technically and economically impossible to reduce the blood-lead levels of lead workers to those of the general population. See infra at 54.

These factors create a dilemma to which there are no easy, pat solutions. As Dr. Cole explained on behalf of the Association at the hearing,

> "Women, quite rightly, want equal employment opportunity . . . [but] there are many jobs in the lead industry where blood-lead levels simply cannot be kept at levels known to be safe for the fetus.
>
> "From a health protection standpoint, there is no feasible solution to this dilemma. However, if it is decided that the commitment to equal employment opportunity overrides the health considerations, then there should be a program which would ensure that the female knows the risks, that the employer is protected from liability, and that information is obtained which would help us better to understand the degree of risk.

> "This program would include fully advising the prospective female employee of the risk to the fetus inherent in the job she wishes, and the carrying out of a full-scale joint Government-industry-labor research program, both retrospective and prospective, of the reproductive consequences of occupational exposure to lead.
>
> "As I mentioned earlier, this was proposed to NIOSH [by ILZRO] with the commitment of industry funds in 1975, with no response. It is clear to us, from our conversations that we have had with labor unions, NIOSH, OSHA, and company officials that no one has a truly satisfactory answer to this problem.
>
> "We can demand, demonstrate, and agitate all we wish but it will not change the basic facts. And if OSHA decides that it must set a standard so low that it is known to be fully protective of the fetus, then we all must bear in mind that there will be very few jobs, indeed, in the lead industry for either men or women." (Cole 3069-70)

The Association, in other words, believes that it is preferable to deal with this very difficult and complicated problem on a case-by-case basis, rather than by setting a standard which, although enormously expensive, would not achieve the desired objective.

This, in essence, was also the answer provided by Constance Dupre, Associate General Counsel of the Equal Employment Opportunity Commission ("EEOC"). (See, e.g., Dupre 4116-17) After explaining that each employer covered by the new standard would have to attempt to make "a reasonable accommodation" in response to the problems involving fertile women, Ms. Dupre agreed with the attorney from

the Office of the Solicitor that "each case has its own particular facts and is decided on those facts." (Dupre 4105) She also made the following points:

(1) Federal law "does not, in and of itself, prohibit any particular employment practice." Rather, it prohibits "an employment practice only . . . [if] it was an overt manifestation of an intent to discriminate against certain persons because of their race, color [or] sex . . . ." (Dupre 4105)

(2) EEOC is not asking OSHA to exclude from its decisional process any factors--such as economic and technical feasibility--which OSHA is required by statute to consider in promulgating health standards. (Dupre 4108)

(3) OSHA is not obligated to set a health standard which would ensure equal employment for all persons. EEOC "would neither object nor commend OSHA" if OSHA set a biological standard of 60, 70 or 80 ug/100g, and EEOC is "neutral to the extent that [EEOC is] not purporting to make OSHA's judgment as to what particular standard should be set up at this time." (Dupre 4117)

The Association agrees with these statements.

E. Mortality Experience of Workers Exposed to Lead

When issuing the Proposed Standard, OSHA expressed concern "that continued low level exposure to lead may increase the risk of developing chronic disease as well as contribute to the shortening of life." (Exhibit 2, at 45936) (Emphasis added.) The Association believes that this concern is without foundation and is refuted by the very Cooper & Gaffey study (Exhibit 5[28]) on which OSHA relied in raising the issue.

The single most important fact about the Cooper & Gaffey study is that a substantial percentage of the more than 7,000 men whose case histories were followed had been hired prior to 1946 (the first year of the 25-year period for which records of lead workers were studied) and had been exposed to air-lead concentrations far in excess of those now permitted. In addition, as Cooper explained when commenting specifically upon the Proposed Standard, "a large proportion of the lead workers we studied had worked in plants with relatively high exposures to lead as well as concurrent exposures to other toxic materials . . . ." (Exhibit 234[5]) (Emphasis added.) OSHA, therefore, would not be justified in concluding that "continued low level exposure" to lead may shorten life or increase

tissue into the bloodstream. (Hammond 316) He also observed that although the question of such "[dumping] has been speculated about for many years", he has "yet to see any data which would convince [him] that" this does occur. (Hammond 315)

To be sure, there were those who apparently disagreed with Hammond's observations, but the opinions they offered were either unsupported by any hard data or were analytically unsound. Sidney Wolfe, for example, presented OSHA with a hypothetical but detailed computation of the amount of lead an imaginary worker might absorb during a lifetime of occupational exposure. (Wolfe 4132-33)(Exhibit 146A) But what Wolfe failed to take into account or even mention, among other things, in his analysis was the fact that the worker who is absorbing lead on a daily basis is also excreting lead. (Wolfe 4211) (See also Hine 6553-54) Wolfe had no empirical basis whatsoever for disagreeing with the conclusions reached by Cooper and Gaffey after their extensive investigation and study. Those conclusions were correct, and the concern initially expressed by OSHA in the Notice was unfounded.

II. THE HEALTH OF WORKERS CAN BE BETTER PROTECTED, WITH LESS EXPENSE AND GREATER FLEXIBILITY, BY ADOPTING A BIOLOGICAL ENFORCEMENT LIMIT INSTEAD OF USING A SPECIFIC AIR-LEAD NUMBER FOR ALL INDUSTRIES AND OPERATIONS.

A. Introduction

There was virtual unanimity at the hearings as to the proposition that the new standard should require employers to conduct both biological and environmental monitoring. As Grover Wrenn, Director of Health Standards Program for OSHA, testified on the first day of the hearings,

> "To protect employees against the myriad of health effects of lead exposure, it appears necessary to establish a comprehensive air and biological monitoring program." (Wrenn 32)

Similar testimony was presented by most other witnesses, including those appearing on behalf of government agencies (NIOSH 1330-31), industry (AMAX 1703; Cominco 2226-28; Cole 3167-68; Caplan 3866; Globe Union 4312; Gen. Batt. 4551) and labor (Teamsters 2203-04; McBride 2961-62, 2973; Woodcock 5040).

There was a fundamental difference of opinion, however, with respect to which monitoring technique should be used as the primary compliance mechanism. Essentially,

two points of view emerged: many witnesses endorsed the approach taken in the Proposed Standard, arguing that OSHA should establish a single air-lead number for enforcement purposes but should also establish a biological action level; others endorsed the approach contained in the Association's alternate proposal, which recommended that the standard contain both a biological action level and a biological enforcement limit, as well as a flexible, non-numerical environmental provision requiring all employers to institute and use engineering controls to reduce air-lead exposures to the extent "feasible". The Association believes that the record establishes that its proposal is preferable to the approach recommended by OSHA since it will better protect the health of lead workers, with less expense and with more efficient and effective enforcement.

There are at least three reasons why a biological rather than an environmental standard should be used for enforcement purposes:

(1) OSHA's proposal rests on the assumption that particular blood-lead levels can be correlated with and predicted from particular air-lead concentrations. The evidence presented at the hearing establishes conclusively that this assumption is

and healthy work conditions without wasting enormous sums for controls that would not have any demonstrable beneficial effect.

Each of these reasons is analyzed in greater detail below.

B. Correlation of Air-Lead With Blood-Lead Levels

(1) OSHA's Methodology. OSHA has candidly acknowledged on numerous occasions that the proposed environmental exposure limit--which it characterizes as "the heart of the proposal" (Exhibit 234[37])--was selected because of "evidence" supposedly "linking that amount to safe levels of lead in the body." Ibid. As it explained in the Notice,

> "[E]stablishing the permissible exposure limit requires first a determination of the blood lead levels associated with adverse effects and symptoms of lead exposure and then correlating these blood lead levels with airborne concentrations of lead." (Exhibit 2, at 45938) (Emphasis added.)

OSHA's assumption, which is the critical premise of the Proposed Standard, was again repeated in the Environmental Impact Statement, where OSHA explained that "the correlation between blood lead levels and air lead levels has been used in arriving at the proposed air lead exposure limit . . . ." (Exhibit 31, at 27)

It is thus undisputed that OSHA has proposed

the use of an environmental exposure limit for compliance purposes because, relying on a mathematical formula, it believes that a particular "target" blood-lead level for individual workers in any sector of the lead industry can be achieved merely by reaching a particular occupational air-lead level. It is completely understandable that OSHA would like to have such a formula, but, in fact, such a formula simply does not exist.

As explained earlier, OSHA must promulgate health standards "on the basis of the best . . . [and] the latest available scientific data in the field." The best and the latest available scientific data were reviewed by 38 experts who participated last September in the Amsterdam Conference. The conclusion reached by those experts, many of whom testified at the hearings, was as follows:

> "According to data presented by King et al (1976) at the Workshop it appears that any relationship between lead in air and lead in blood is not sufficiently precise for a lead in air standard to be derived. The [Workshop] Group did therefore not propose a permissible level for lead in air." (Exhibit 262) (Cole 3013-14)*

---

* It appears that El Batawi was the only participant in the Amsterdam Conference who disagreed with this conclusion (Medina 5370; cf. El Batawi 349), but as he himself admitted at the hearing, even after he had presented his views at the Amsterdam Conference and had argued against the position ultimately adopted, the other experts agreed "that the relationship between blood and air was not sufficiently [footnote continued]

Virtually every study involving occupational lead exposure which was presented to and discussed during the hearings confirms that the Amsterdam Workshop's conclusion was correct. OSHA, therefore, would be unjustified in retaining, let alone reducing, the existing environmental exposure limit. Indeed, even OSHA's own economic contractor concluded that,

> ". . . it is not possible to assess the effect [of the Proposed Standard] on the blood-lead distribution because, on the basis of studies that have been obtained, there is apparently no simple relationship between air-lead exposure and blood-lead concentration." (Exhibit 26, at 3-1)

(2) Variability Factors. Before turning to an analysis of the relevant studies, it is perhaps appropriate to interject a brief discussion of the factors which confound any attempt to correlate blood-lead levels and air-lead levels in the occupational setting.

The problem inherent in OSHA's approach was succinctly and accurately summarized by the impartial witnesses who appeared on behalf of Bell Laboratories to describe their experiments with ZPP.

[footnote continued] precise to come up with a lead in air standard." (El Batawi 348-49) Perhaps his views were not accepted because, as pointed out by Dr. Lloyd of the Steelworkers, Dr. El Batawi "is not qualified in biostatistics or in epidemiology." (Lloyd 4975)

> "It . . . [is] intrinsically difficult to correlate air levels to a biological parameter . . . since air is certainly only one of the sources [by] which lead enters the human body." (Eisinger 2462)

Similar remarks were made by a host of other witnesses. William Lloyd of the Steelworkers, for example, commented on the "many other variables that are involved in addition to just the level of exposure", and observed that "because there is variation from a number of sources . . . it is very difficult to tie things down to a very exact kind of . . . [air-lead] number." (Lloyd 4899) Dr. Mirer of the United Auto Workers similarly observed that as air-lead exposures are reduced, "ingestion and unmeasured . . . airborne exposures become a factor in confounding the correlation" between air-leads and blood-leads. (Mirer 5299) (See also Hammond 256; Samuels 4268)

The record developed at the hearing fully corroborates Dr. Lloyd's and Dr. Mirer's observations. There are, indeed, "a number of sources"--apart from the air-lead concentrations of the work environment--which contribute materially to the amount of lead absorbed by a lead worker. These sources include the following:

(1) The individual worker's hygiene habits can significantly affect his blood-lead levels (Wrenn 53; Hammond 267; Teamsters 2062-64, 2094; NIOSH 1466-

67; Cole 3034-35; Voltmaster 3601-02; UAW 5287-88; Steelworkers 2983-1), particularly if he smokes or eats in exposed areas (Globe Union 4315; Stewart 2591-92; Samuels 4264; Hydrate 1231) (Exhibit 294D) or bites his fingernails (Dynolite 1241; Bell 1665; Mosher 2817-18; Cole 3159).*

(2) The extent to which a worker absorbs lead also depends upon his personal work practices and the care he takes in handling lead materials. (See, e.g., Wrenn 53; Teamsters 2061-62, 2069-70, 2094; OCAW 1046)

(3) Another obvious factor which influences the total amount of lead absorbed by an employee is his off-the-job activities and non-occupational exposure. (See, e.g., Cole 2994; Caplan 5738; Wrenn 54) The worker's physiological characteristics also have an impact. (Cole 2995; Hammond 284)

(4) A worker's blood-lead level will also be affected by the extent and manner of the housekeeping performed by the company. (First 2325-26, 2380; Teamsters

---

* Virtually all witnesses agreed that the new standard should prohibit workers from smoking or eating in exposed areas. (See, e.g., OCAW 1047; NIOSH 1407-08, 1846-47; Williams 2018; Teamsters 2205-06; NOW 2517; Stewart 2607; Steelworkers 2983-12; Cole 3107; BCI 3838; UAW 5049) The Association concurs in that recommendation.

2069; Stewart 2591-92; Globe Union 4301; UAW 5287) No matter how low the air-lead levels, if dust is allowed to accumulate or if cleaning is done by improper methods (such as dry sweeping), lead intake will be much higher than it otherwise would be. (Cole 2995)

(5) Still another factor which influences the amount of lead absorbed by a particular employee is the particle size and solubility of the lead to which he is exposed. (Hydrate 1218; AMAX 1265-66; Hammond 283; Cominco 2224-26; First 2389; Gen. Batt. 4540, 4550) A man working with lead sulfide (galena), for example, will absorb considerably less lead than a man whose job exposes him to fumes of lead oxide which are smaller in size and more soluble. (Exhibit 234[16]) (Cole 2995)

Because of these factors--all of which influence lead absorption but none of which is dependent upon the ambient air-lead levels to which the employee is exposed--it is impossible to establish a meaningful relationship between occupational air-lead concentrations and individual blood-lead levels.

The general impact of these factors is manifested in at least three different ways. First, workers who are

exposed to the same air-lead concentrations may have significantly different blood-lead levels. (See, e.g., Cal. OSHA 6807; Teitelbaum 410; Bell Labs 2468-70; Lynam 3065-66; Voltmaster 3600; BCI 3687; Globe Union 4350; Gen. Batt. 4549) Second, even when working in an environment with supposedly "safe" air-lead levels, workers may have dangerously elevated blood-lead levels. (Wrenn 55; NIOSH 1408-09, 1494-98; Cominco 2226; Cole 3110; Wolfe 4199; Globe Union 4345-48; Cal. OSHA 6828; Woodcock 5060)* And, third, because of the importance of these non-measurable factors, particularly at the lower air-lead level ranges, reducing occupational air-lead concentrations has very little impact in reducing blood-lead levels. See infra at pages 106-15.

(3) Studies. We turn now to a general discussion of the several studies which were submitted to OSHA prior to and during the course of the hearings.

The "most recent" (UAW 5372) and perhaps best study done with respect to the relationship between air-

---

* It was presumably for this reason that Dr. Mirer of the United Auto Workers stated that "air lead level alone won't protect the workers." (5365) Dr. Mirer might have had in mind the testimony of the president of Estee Battery Co., who stated that he has a blood-lead level of 50 ug/100g even though he spends less than 20 minutes a day in his factory. (Scheinbaum 2929) Air sampling certainly would not protect someone with his propensity for absorbing lead.

lead concentrations and blood-lead levels is the "Manchester Study" by Edward King and his colleagues at the National Occupational Hygiene Service, Ltd. in England. (Exhibit 234[22]) Because the Study was specifically designed to investigate this issue, and because it was performed over an extended period of time, with a relatively large number of subjects, in different work environments but under actual occupational conditions, the data obtained are more reliable and more representative than those produced by any other experiment or investigation so far conducted.

The Manchester Study was sponsored by the International Lead Zinc Research Organization, Inc. and involved more than 100 volunteer workers from a lead-acid battery factory, a pigment factory and a primary smelter. Personal air sampling was conducted in the two factories during a ten-week period and in the smelter during an eight-week period. Each volunteer wore his sampler for one full working shift one day each week, on different days of the week during the testing period. Blood samples were obtained from the subjects at the beginning, middle and end of the survey. Respirators were not in use at the two factories, and were used in the smelter by only a few of the subjects tested (and even then only for very brief periods of time, when the air sampling instruments were switched to "off").

No chelating agents were used by the subjects.

The Manchester Study establishes that under actual working conditions it is impossible to correlate or predict particular blood-lead levels with or from particular air-lead levels. (Williams 1878; Malcolm 2110; Cominco 2223; Cole 3013-14) Plotted on the graph below, for example, are the data points representing the mean air-lead and blood-lead levels for each of the workers tested by the Manchester Study. Even without statistical analysis, it

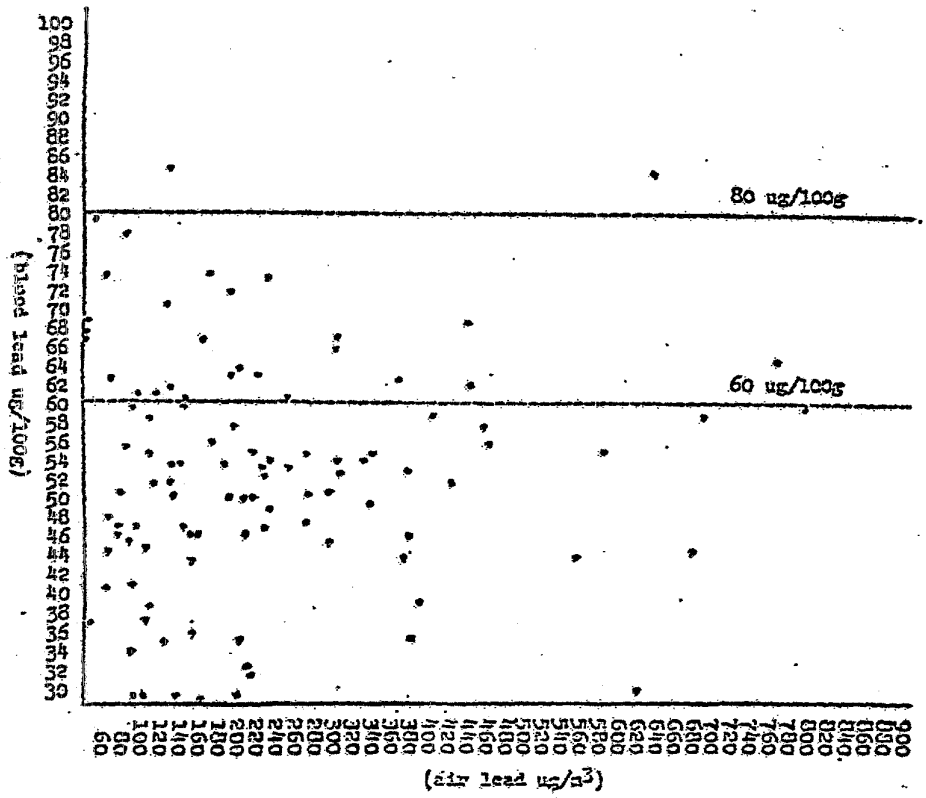


Figure 1

at best usually in the range of only a few micrograms per 100 grams of whole blood. See infra at 106-14.

The conclusions set forth in the Manchester Study were confirmed by the data made available to NIOSH and OSHA by the Delco-Remy Division of General Motors Corporation (the "GM data"). A detailed statistical analysis and discussion of the GM data were prepared by Drs. Buncher, Gartside and Lerner of the College of Medicine at the University of Cincinnati. (Exhibit 285) NIOSH, which obtained the data in early January, also submitted a report analyzing the data. (Exhibit 86D) Both analyses further corroborate the proposition that "air lead . . . is simply not closely enough related to blood-lead so that one can declare an air lead determination which is meaningfully predictive for a particular worker." (Exhibit 285, at 13)

Set forth below as Figures 2 and 3 are the blood-air scattergrams from the Cincinnati anaylsis and the NIOSH analysis, respectively. They indicate, as did the graph from the Manchester Study, that the relationship between air-leads and blood-leads is too tenuous to permit air-lead concentrations to be used as the primary mechanism for protecting workers' health. As NIOSH pointed out in its discussion of the GM data, "the correlation coefficient of the individual blood lead levels with the average of

Figure 2

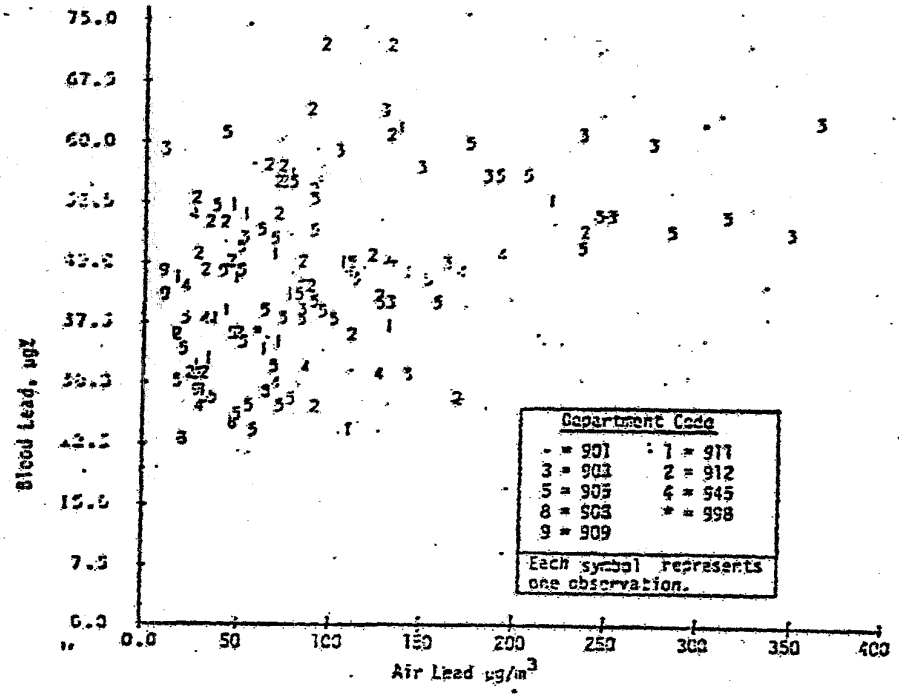
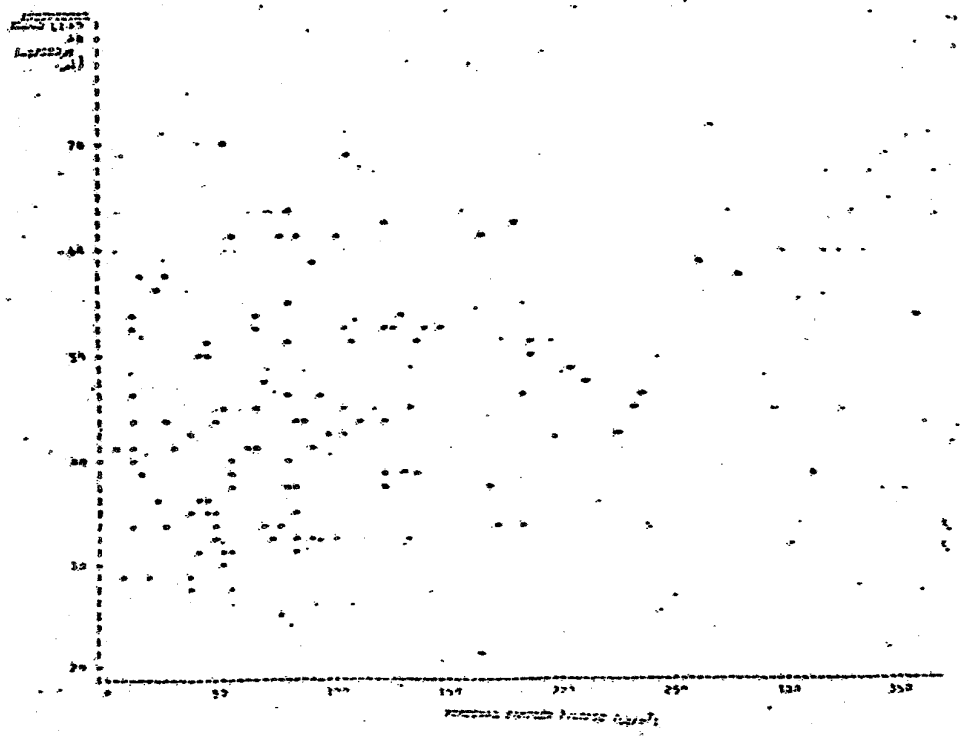


Figure 3



DUP040006920

the individual's air lead levels over this period of time was 0.22." (Exhibit 86D, at 7) This means, of course, that only four percent of the variation in blood-leads observed in these workers can be explained by the air lead levels to which they were exposed.* (See NIOSH 1437) It is small wonder, therefore, that NIOSH, even after having had more than three months to study the GM data, was forced to admit that it did not have "hard data" to "show without any doubt, a relationship between air and blood, at air levels and blood levels across the whole spectrum of exposures." (Baier 1393)

When OSHA first issued the Proposed Standard in October 1975, it relied almost entirely on the 1969 study (Exhibit 5[32]) by Dr. Michael Williams. (See, e.g., Wrenn 27; Ryer 5500) The Williams study was also "one of the key studies" on which NIOSH relied when recommending that the current air-lead standard of 200 ug/m3 be reduced to 150 ug/m3. (Bridbord 1327) And a year and a half later, in February 1977, OSHA--although presumably at least

---

* The Cincinnati analysis by Drs. Buncher, Gartside and Lerner pointed out, in this connection, that "the lesson from these data is obvious. . . . [T]wo-thirds of the variability . . . must be attributed to other sources of variation, as for example, ingestion, personal hygiene, individual biologic variability, outside sources of lead such as hobbies, activities, and so forth." (Exhibit 285, at 13)

aware of the Manchester Study and Amsterdam Workshop report (Ryer 5491-92)--was still asserting, this time in the Environmental Impact Statement, that "the study of Williams, et al. . . . is the most comprehensive reported study of its kind." (Exhibit 31, at 27) Williams' study, however, does not support OSHA's assumption as to an air-blood relationship; indeed, properly analyzed, it refutes that assumption.

We note first that Dr. Williams himself has sharply criticized OSHA's interpretation of his study on the ground that it "has been used mistakenly . . . for the derivation of lead-in-air standards." (Exhibit 234[8]) As Williams explained,

> "It is illogical to set an air standard in terms of blood lead and then rely on air leads rather than blood leads, unless there is a good reason for doing so. I know of no such reason and the variability of air sampling is a very great reason against it." Ibid.

Second, and perhaps more important, the Williams study was simply too limited in scope to support the conclusions OSHA drew from it. The two-week study involved only 39 workers in a single kind of lead plant (a lead-acid battery factory); only 29 of the workers were occupationally exposed to lead (the remaining ten were employees in the plastics department and were used as controls);

and of the 29 exposed workers, only 19 were directly involved in the study, since blood-lead samples from ten of the 29 were thought to be contaminated.* What OSHA has done, in other words, is to take the results of tests performed on only 19 men, working in a single kind of plant over a two-week period, and to extrapolate from that data to an entire industry involving thousands of workers and hundreds of different operations and processes.

The plain and simple truth of the matter is that OSHA's extrapolation from the Williams study was not justified. (Williams 1877) It was for this very reason that El Batawi deleted the references to the Williams study from his prepared remarks (El Batawi 319), explaining that,

> ". . . the reason for this was that the study was over-interpreted beyond the amount of information that was contained in it and that . . . there was [sic] some calculations and speculations based on that study . . . which the unit in WHO caring for environmental pollution is now questioning . . . ." (El Batawi 353-54)

Dr. Lloyd of the United Steelworkers made a similar observation, noting that "one of the difficulties in estimating

---

* Even with respect to the remaining 19 workers, Williams was unable to be entirely confident of the accuracy of the blood-lead determinations, since, at the time he did his study, the laboratory performing the tests did not participate in any interlaboratory control checks. (Williams 1907)

blood lead levels from . . . [Williams' study] is, of course, the small number of observations . . . ." (Lloyd 4704) If there was any doubt remaining as to the limitations of the study, Dr. Williams himself resolved that doubt:

> "OSHA have . . . relied almost entirely on only one minor study to obtain an air standard for a whole industry. As the authors of this study, my colleagues and I were aware of some of its limitations. Only twenty-nine battery workers in only one kind of lead factory were investigated and the blood tests of over one-third of these men were rejected as unreliable.
>
> "After our results were first published we discovered a 23% error in the method of personal sampler calibration. Each man was studied for only two weeks and we have no good evidence that his air leads over that period were typical of his normal exposure. The particle size and solubility of the air lead particles and the respiratory minute volumes of the men were not measured, so there is no reason to suppose that our findings are relevant to other lead trades. But OSHA have applied our results lock, stock and barrel to other industries. This is not only surprising, but could be considered negligent. A more responsible approach would be to arrange further investigations on a reasonable scale by several different investigators, and in the meantime enforce present standards which are so widely accepted in so many countries." (Exhibit 234[8])

There exists yet another reason why OSHA's reliance on the Williams study was misplaced. It is possible to develop a statistically significant regression line from the Williams study only if the data from the unexposed control group is included to "tie . . . down the bottom end of the regression [line]." (Williams 1911)

This is apparent from the scattergram of the data from the Williams study, set forth below as Figure 4.

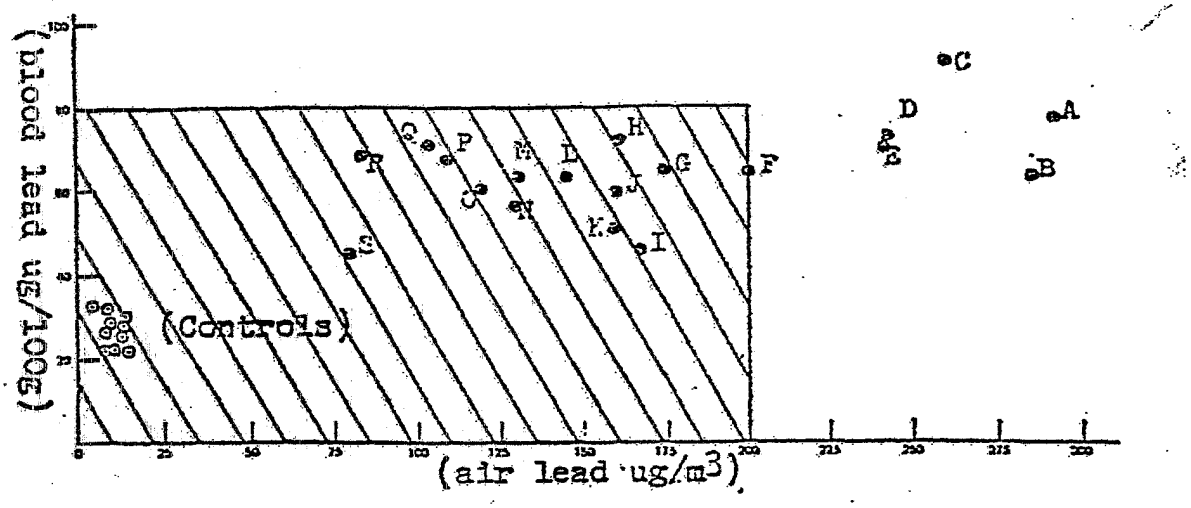


Figure 4

It is a mistake, however, to include the control data from these computations, for at least two reasons:

(1) As Dr. Lynam pointed out when testifying for LIA, "there is no reason to have a control group" in this kind of study. "We are not doing behavioral testing . . . [and] we are not doing types of tests which you want to compare with a control population. [The study] is just looking at air lead exposures versus biological indicators of absorption" in the same population. "There is no reason for a control group. Each man is essentially his own control.

You are measuring his air lead exposure . . . [with] lead absorbed, by looking at . . . all indicators of [his] lead absorption." (Lynam 3062-63) In other words, "what we are interested in is looking at workers who are occupationally exposed and not comparing workers occupationally exposed to a control population." (Lynam 3162) OSHA itself appears to have recognized this shortcoming when it observed in the Environmental Impact Statement that Williams' "regression equation is unduly weighted by data at either extreme . . . ." (Exhibit 31, at 28)

(2) Because "critical data are missing" from the Williams study in the lower occupational exposure ranges (see Environmental Impact Statement [Exhibit 31], at 28), Williams' regression line and projections are valid only if there is a linear relationship between air-lead levels and blood-lead levels through the full range of exposure, from 0 ug/m3 to the upper air-lead concentrations. It is undisputed, however, even by those who believe that air-leads and blood-leads can be meaningfully correlated, that no such linear relationship exists. (See, e.g., Hammond 266; Epstein 1053; Steelworkers 4054; Lloyd 4904) The extrapolation OSHA makes from the Williams data,

therefore, is totally without merit. (Malcolm 2137; Globe Union 4313)

If the controls are properly excluded from the statistical analysis of the limited Williams data, then it becomes evident that Williams' own study confirms the fact that there is no meaningful relationship between blood-lead levels and occupational air-lead concentrations, and that the regression line for the occupationally exposed workers is relatively flat. (Williams 1923, 1926-27; Malcolm 2137; Cole 3064-65)

In addition to the Manchester Study, GM data and Williams study, other information, empirical observations and statistical data were submitted during the hearings, all of which--like the conclusions reached by OSHA's own economic contractor (Exhibit 26, at 3-1)--indicate that blood-lead levels cannot be predicted from or correlated with air-lead levels. Among the evidence were the following items:

(1) General Battery presented an analysis of reliable air-lead and blood-lead data gathered from regular monitoring of 30 workers. "When the data [were] subjected to statistical analysis, the coefficient of correlation confirm[ed] that there is no linear"

fits in with [his] own experience" and that of companies with which he has been associated (Malcolm 2110).

(5) The Manager of Environmental Control for Cominco, Ltd. testified on the basis of Cominco's "long experience" that "there is not [a] clear relationship between air-lead level and lead absorption by humans in the range between 100 and 200 micrograms per cubic meter." (Doyle 2221)

(6) Similar testimony was presented by Roger Winslow, president of Voltmaster Company. Explaining that Voltmaster "has been sampling and plotting employee blood leads every six weeks since 1972" and had taken "additional air lead samples" when the Proposed Standard was issued, Winslow stated that the Company found no meaningful relationship between air-lead levels and blood-lead levels. "Our records," he said, "show low blood leads in the presence of high air leads, high blood leads in the presence of low air leads, low blood leads in the presence of low air leads, and high blood leads in the presence of high air leads." (Voltmaster 3600)

Other witnesses testified to the same effect (e.g., Lorio 2828; BCI 3851), including Dr. Sidney Wolfe of the Health

Research Group, who pointed out that "workers in similar areas can have widely divergent blood lead levels" and "can have elevated biologic levels where the air levels are at or near normal" (Wolfe 4143).

(4) Conclusion. A few weeks before the hearing began, NIOSH asked for bids on a proposed project, observing in the accompanying "Statement of Work" that there was a "fundamental question" as to "whether an air lead or blood lead standard . . . should be used for compliance purposes." (1392)(Exhibit 78) In view of the overwhelming weight of the evidence presented at the hearing it may be fair to conclude that the "fundamental question" posed by NIOSH has been answered. Since--contrary to OSHA's basic assumption--an environmental exposure limit cannot be "linked to safe levels of lead in the body", then manifestly the health of workers can be more completely and more reliably protected by emphasizing biological monitoring as the primary compliance mechanism. This is particularly true, as explained below, in view of the serious disadvantages of air sampling, the advantages of biological monitoring, and the availability of a more flexible, alternative method of ensuring the installation of appropriate engineering controls.

C. Advantages and Disadvantages Of the Monitoring Techniques

(1) Environmental Monitoring. Although air sampling should be conducted routinely by employers to evaluate the effectiveness of new and existing engineering controls (Cole 2998), environmental monitoring--and hence use of a numerical air-lead standard--is "a grossly ineffective method of investigating a plant which is running in the normal manner" (Williams 1994). It is undisputed, for example, that air sampling and environmental monitoring have at least three major disadvantages:

(1) Air sampling does not reflect an employee's total exposure and therefore cannot indicate reliably who is and who is not at risk. It does not detect variations in personal hygiene habits or work practices which cause some workers to absorb larger amounts of lead than other employees in the same work environment. (Cole 3010; Stewart 2605) Nor does air sampling measure lead absorption resulting from off-the-job activities. (NIOSH 1407; Caplan 5738)

(2) Air sampling typically measures only short-term exposures which have little biological significance and which vary widely from day to day. (Cole 3010;

Hammond 268) As Dr. Williams explained, "I think that even when air leads are measured, they are so variable from day to day, minute to minute, month to month, person to person, that it is very difficult to get information about health effects" from the measurements. (Williams 2046) Air sampling also does not take into account the variability that occurs as a result of differences in particle size and solubility. (Hydrate Batt. 1218)

(3) Short-term monitoring by personal samplers is subject to enormous errors, many of which are caused by contamination of the sampling head, poor calibration or improper supervision. (See Varner 6465-66) The Deputy Director of NIOSH, for example, agreed that "to be sure of the integrity of" samples obtained from "a man wearing a personal monitoring device," it would be necessary to have "that individual watched during the whole course of [his] shift." (Baier 1534) Other witnesses testified to the same effect. (See, e.g., Caplan 3950; Cominco 2251)*

---

* Even the position of the sampling head may have a significant effect on air-lead measurements. In one test, for example, Williams demonstrated that when two personal sampler filter heads were simultaneously worn only 5 inches apart, the mean concentrations measured by those samplers differed by 22 percent. (Exhibit 234[6])

e.g., NIOSH 1532-34; Stewart 2606-07; Caplan 3867, 3950; Wolfe 4193-94; Williams 1994, 2045; Cominco 2251; Teamsters 2088) For example, the following colloquy took place with Dr. Wolfe:

> Q: "[L]et's assume that you come in and you put a personal sampler on a worker, and he wanders around and does different jobs, and the end of the day comes, and you have taken the sample for the full eight hours shift, and you take it off and you find it reads 1,000 micrograms. Can you say to yourself, we know where the source of the air emission is?"
>
> A: "No. What you can say to yourself is that that worker has breathed in air with an average lead concconcentration of 1,000 micrograms." (4194-95)

The same testimony was given by Albert Stewart, an industrial hygienist testifying on behalf of the AFL-CIO:

> Q: "Can you always tell from air sampling results what the sources of emissions are?"
>
> A: "Not the source. No."
>
> Q: "Can you tell me why?"
>
> A: "Well, it depends where your pump is [and where the worker has been] . . . . You cannot tell where the material comes from simply because you have a sample that tells you you've got lead on it." (Stewart 2606-07)

And from NIOSH:

> Q: "You said we would use air sampling to identify sources. Now consider this situation. This room is part of a lead smelter. We have a man who is

working in all parts of the room at various times and he's wearing a personal monitoring device over the eight hour shift. The final analysis shows the concentration is let's say 400 micrograms per cubic meter of lead in air. Does that tell you anything about the specific sources?"

A: "No. The whole . . . line of questioning . . . points up how futile the air sample is . . . ." (Baier 1532-33)

(See also Caplan 3950 ["this time weighted eight hour average . . . would not identify any particular sources of his exposure"])

The record also establishes that the problems of delay are no less inherent in environmental monitoring than in biological monitoring. Under the Proposed Standard each employer would have to conduct air sampling once every month if air-lead levels were above the proposed exposure limit of 100 ug/m3. (To conduct monitoring more frequently than this would be neither feasible nor realistic.) And yet even this "delay" might permit hazardous conditions to develop. (See, e.g., First 2361; McBride 2961) Since there will be delays of one kind or another regardless of whether an air-lead or blood-lead standard is adopted, the answer is to require both kinds of monitoring to be done regularly but to make the determination of which should be used for enforcement purposes on the basis of the other considerations discussed in these

Comments.

The contention that biological monitoring measures exposure only after the "harm" has been done also misses the point and is really only another way of stating that biological monitoring must be done with sufficient frequency to permit remedial steps to be taken before a worker's health is impaired. With this second proposition LIA is in complete agreement. It is for that reason that LIA has proposed a monitoring schedule which is both more rigorous and more meaningful than that proposed by OSHA.

Under the Association's proposal, every potentially exposed employee would receive a blood-lead determination and medical examination before beginning employment. Thereafter, he would have a monthly blood-lead determination for a period of at least four months. The initial pre-employment examination would make it possible to keep the highly susceptible individual, including those who already have anemia or renal dysfunction, away from lead exposure altogether. The subsequent monthly lead determinations would also allow the employer to protect the worker who, for whatever reason, absorbed lead at unsafe levels. For example, the employee who had poor hygiene or personal work habits would be detected, and corrective measures could be taken and training provided

well before his health was endangered. Air sampling, even sampling done every month, would not provide the same safeguards.

After the initial four-month period of employment, the frequency with which blood-lead determinations would be provided, under the Association's proposal, for any particular individual would depend upon the results of that worker's most recent previous blood-lead determination.

(1) If the prior blood-lead determination was below 40 ug/100g, the employee would receive further biological monitoring within a year.

(2) If the prior blood-lead determination was between 41 and 60 ug/100g, the next biological monitoring for that individual would have to be conducted within the next three months. (Compare Hammond 306 ["if the blood lead is fluctuating between 30 and 60, a semi-annual examination would be adequate"])

(3) If the prior blood-lead determination was above 60 ug/100g, the worker would have to have his next blood-lead determination within the next month.

This schedule would be in addition to any other biological

monitoring which might be done by alternate "screening" techniques--such as ZPP, ALA or urine-lead tests. It would also be in addition to special monitoring which might be required if there were a significant process change or if the worker changed jobs within the same factory.

The important point to note in considering the schedule proposed by LIA is that the frequency of the monitoring for the particular worker is determined by the results of that same worker's prior blood-lead determination--not by the results of air sampling, as would be the case under OSHA's proposal. Given the admitted shortcomings and variability of air sampling, including the fact that workers in supposedly "safe" environments can have elevated blood-lead levels, it would be a serious mistake to make protection of the individual worker's health depend upon a measurement not directly related to his well-being. (Cole 3009-10; Wolfe 4143)

The third reason given in support of the proposition that OSHA should retain an environmental exposure limit for enforcement purposes is that such an exposure limit somehow better encourages employers to install proper engineering controls. The record, however, demonstrates that just the opposite is true.

The plain fact of life is that a single, in-

flexible air-lead number does not work and will not work. That is why few if any companies in the major sectors of the lead industry, despite the good faith efforts of most, are consistently in compliance even with the existing standard. (Cole 3017; Steelworkers 4642-43; UAW 5276) See infra at 102. The problem lies not so much with the particular exposure limit selected as with the fact that a single (and, in our opinion, arbitrary) number has been picked to serve a function for which it is ill suited. Moreover, inasmuch as the existing standard of 200 ug/m3 has not worked, it is difficult to understand why OSHA believes that its enforcement problems will disappear as soon as it adopts an even less workable, more stringent standard. What is needed, we submit, is not a different number but a new and more flexible approach. LIA has proposed just such an approach, the environmental control aspects of which are discussed in more detail in Section "D" below.

(2) Biological Monitoring. The disadvantages inherent in environmental monitoring are avoided by the use of biological monitoring.* Such monitoring reflects

---

* Again, it must be emphasized that LIA is not recommending that requirements for environmental monitoring be eliminated from the new standard. As we have already explained, both environmental and biological monitoring should be performed by all employers [footnote continued]

an employee's total exposure, detects variations in personal hygiene habits and work practices, measures absorption from non-occupational sources, and takes into account the many variables--such as air-lead fluctuations, particle size and solubility--which air sampling cannot measure. It is precisely because the Association agrees with OSHA that biological monitoring "more accurately indicate[s] the likelihood of adverse effects" to employees who are occupationally exposed to lead that it has proposed both a biological action level and a biological enforcement level. It is also for that reason that many of OSHA's own witnesses agreed with the approach recommended by the Association. (See, e.g., Hammond 267, 287 ["biological monitoring is far more important . . . than reliance on air lead data" in terms of protecting workers' health]; Piomelli 489 ["biological [monitoring] would be more important" because it "will take into consideration the primary issue, which is the health of the worker"]) (See also Bell Labs 2469-70 ["would have more faith in the biological monitoring"]; Caplan 3939)

[footnote continued] covered by the standard. Those who opposed LIA's alternate proposal at the hearing typically acted as if LIA was urging OSHA to rely upon biological monitoring alone. LIA has not done so, and to pretend otherwise is merely to disregard if not distort LIA's real position.

(3) The employer should provide the employee with more intensive biological monitoring and medical surveillance.

Second, LIA urges OSHA to put some teeth into the biological action level by also establishing a biological enforcement level. We further propose that the biological enforcement level be based on blood-lead levels and that it be set at 80 ug/100g. If an employee is found to have a blood-lead concentration (as determined and confirmed by a certified laboratory) which exceeds the exposure limit and if the employer knew or should have known that the employee previously had a blood-lead level in excess of the action level, the employer could automatically be cited for violating the standard. Under LIA's proposal, a presumption that a violation had occurred could be established merely on the basis of information contained in the biological monitoring records which the employer would be required to maintain. In addition, of course, the employer could be cited if he had failed to conduct the required biological monitoring or had failed to take the remedial steps required when he learned that the employee's blood-lead concentration had exceeded the action level. (Cole 3002)

A number of questions were raised during the

hearings concerning the wisdom of adopting a blood-lead enforcement level as the primary compliance mechanism. The Association submits that the record fully and satisfactorily answers each and every one of these questions.

Perhaps the most frequently heard but least valid objection is the contention that it is "morally repugnant" and inherently unfair to use workers as "guinea pigs" in determining whether the workplace is safe. (See, e.g., McBride 2961; Wolfe 4200; Woodcock 5072)*

A worker in a lead factory, unlike a "guinea pig", is not being subjected to new or novel conditions; he is already in the factory, and all that is happening is that proper use is being made of data which in any event would be available. LIA's proposal no more uses the worker as a guinea pig than does OSHA's proposal, which also contains extensive requirements for biological monitoring: LIA would penalize the employer for failing to take the steps necessary to prevent a worker's blood-lead level

---

* The absurdity of the contention is well illustrated by the testimony of Lloyd McBride, the new president of the United Steelworkers, who argued that "biological monitoring [for compliance purposes] makes the employee the guinea pig" (2961) but then turned around and asserted that biological monitoring should be used "as a means of checking the effectiveness of the environmental monitoring" (2982). If anyone's position makes the worker a "guinea pig", it is that of the Steelworkers, not LIA.

from exceeding a particular concentration, OSHA's proposal would penalize the employer for failing to take appropriate action after the worker's blood-lead level had exceeded a particular concentration. (Compare Woodcock 5073-74) There is no substantive difference. As witness after witness testified, having a biological enforcement level is therefore neither "morally repugnant" nor inconsistent with good hygiene principles. (See, e.g., Smith 4589-90; Lloyd 4961; Woodcock 5073-74; Caplan 3940-41; Nelson 4048-49; Varner 6464)

A second objection which has been raised in response to LIA's proposal is that it would somehow be unfair to penalize the employer when the worker's elevated blood-lead level may have been caused in part by factors (such as off-the-job exposure) over which the employer has little control. OSHA itself made this argument in October 1975 in explaining why it had declined to include a biological enforcement level for compliance purposes in the Proposed Standard. (See Exhibit 2, at 45938) The Association strongly disagrees with OSHA's position and with the reasoning behind it. Indeed, we submit that the position shows a shortsighted and misplaced solicitude for the employer which can only inure to the detriment of the worker.

We start from the proposition that no employer

If, for example, an employee's blood-lead level reaches the action level because of the employee's poor work practices or because of his off-the-job activities, these causative factors should be discovered by the employer when he takes the remedial steps required at the action level. Having discovered the reasons for the employee's elevated blood-lead levels, the employer is then in a position to advise the employee concerning the measures the employee can and should follow to insure his own well-being and safety. The employer is also then in a position to determine whether the employee's occupational exposure should be reduced and, if so, by what means.

A third question raised at the hearings concerning the adoption of a biological enforcement level was whether such an enforcement mechanism would be too cumbersome and difficult to enforce. We believe that it would not and that, if anything, it would significantly reduce OSHA's administrative burdens. As explained earlier, under LIA's proposal an employer could be cited automatically on the basis of biological monitoring results, and a presumption that a violation had occurred could be established merely by using the employer's monitoring records. In most instances, it would not even be necessary for the OSHA inspector to conduct further biological monitoring once he had

inspected those records. Enforcement, therefore, would usually be simple, inexpensive and expeditious.

The OSHA inspector, naturally, would not be precluded from arranging and making additional blood-lead determinations if, for whatever reasons, he thought that such determinations were appropriate. But again, the administrative burdens would not be significant. A trained medical technician or a nurse accompanying the inspector, for example, could take the requisite samples in less time than is now required for properly conducted air sampling. (See, e.g., Exhibit 248, at 2-3) Alternatively, the new regulation could simply authorize the inspector to require the company to conduct the necessary monitoring, in the inspector's presence and in a manner specified by him. (See e.g., Varner 6466-67) In addition, newly developed biological monitoring techniques, such as the zinc protoporphyrin tests, could be used for screening. Indeed, when these new techniques are refined and become more reliable, they may be able to replace completely the present testing methods. (Cole 3003)

Blood-lead analyses are, of course, subject to error, as is any laboratory determination, and obviously care, expertise and experience are required in the collection and analysis of a sample of blood. (Cole 3005-07)

monitoring and--although by different mechanisms--would require the installation of appropriate engineering controls.

Equally without merit is the argument that a biological enforcement level would not work because of worker reluctance. As indicated by OSHA's own Economic Impact Statement, most battery companies and secondary smelters and all of the primary smelters already conduct routine biological monitoring. (Exhibit 26) Employee resistance is almost non-existent, apparently for the obvious reason that the workers know that the best way to stay healthy is to have regular check-ups. (Cole 3081-82; Varner 6464-65) (Exhibit 248, at 4) Moreover, virtually every union leader who was questioned about this issue during the hearings testified that his or her union would support biological monitoring and would encourage worker participation in monitoring programs. (See, e.g., Teamsters 2204-05; McBride 2983-7 and 2983-8) The same indication of union support has been exhibited outside the hearing room. The Coalition for Workers' Rights, for example, when organizing union participation in the May 3 regional hearing in San Francisco, distributed a flier (Exhibit 255A) which not only supported the concept of biological monitoring but in fact demanded, among other things, that

of equally effective choices." (Wrenn 61) Secretary of Labor F. Ray Marshall made precisely the same point a few days later during a press conference on March 22, when he said that when there are different means of compliance and "one way costs a whole lot less than some other way, then [OSHA has] to consider that" in writing the regulations. BNA Occupational Safety & Health Reporter, Current Report at 1323 (March 24, 1977). Organized labor echoed the same sentiment:

> "If two alternative means of meeting an . . . equally effective occupational lead exposure standard [exist], you would want the one that minimized cost to the employer or consumer." (Steelworkers 4677) (See also UAW 5373)

The Association submits that its proposal, which emphasizes the importance of biological monitoring but which also includes provisions requiring environmental monitoring and the installation of all "feasible" engineering controls, constitutes the very type of preferable alternative to which OSHA, Secretary Marshall and the unions made reference.

The Association recommends that the new lead standard should require every employer covered by the standard to institute engineering controls to reduce air-lead exposures to the lowest level "feasible", as "feasible" is defined below. The standard should also require the

employer to establish and implement a written compliance program which includes provisions for such engineering controls, and should make it mandatory for each such program to be filed with OSHA.

Under LIA's proposal, an employer could be cited for violating the standard in any of the following circumstances, among others:

(1) He could be cited if he failed to establish a program in the first instance;

(2) He could be cited if he failed to file the program with OSHA; and

(3) He could be cited if he failed to implement and follow the program, whether filed or not.

In addition, if OSHA--upon investigation and after reviewing any employer's written compliance program--determined that it was feasible for the employer to institute additional or different engineering controls and the employer thereafter refused to do so, OSHA could commence enforcement proceedings. (Cole 3019-20)

Those who oppose LIA's recommendation suggest that OSHA does not have the funding or manpower to review closely each and every one of the written programs which would be submitted. They also contend that the alternate

environmental mechanism proposed by LIA would involve too much delay and would leave the employer with too much discretion in determining what should or should not be done. These objections, however, ignore the realities of the difficult enforcement problems confronting OSHA.

OSHA, for all practical purposes, is already conducting the very kind of review and participating in the same kind of discussions being proposed by LIA. The only novel aspect of LIA's suggestion is that this review and these discussions should take place before a citation is issued rather than during post-citation abatement negotiations. "Feasibility", however defined, is already an integral element of any abatement negotiation, and is and has to be considered and resolved on a company-by-company, plant-by-plant basis. As a consequence, the procedural differences between the two approaches are minimal: the same kind of review will be conducted; the same staffing will be required; and the same environmental programs will be adopted or enforced.

The practical differences, on the other hand, between OSHA's approach and LIA's proposal are substantial.

(1) By requiring the immediate, mandatory submission and implementation of written compliance programs, LIA's proposal will encourage the sort of prompt,

voluntary compliance which must exist if workers' health is to be protected. (See Wrenn 62; Caplan 5752-53)

(2) By encouraging an atmosphere of cooperation and assistance, LIA's proposal will reduce if not eliminate much of the adversarial relationship between regulator and regulated which often leads to a wait-and-see attitude on the part of many employers.

(3) It is undisputed that hundreds of the smaller and medium-sized lead companies--although efficiently and profitably run--lack the engineering expertise necessary to accomplish the needed changes. (Woodcock 5055) In fact, they may be unable even to find qualified consultants to advise them. (See, e.g., Caplan 3933; Miller 4973) By offering advice to such companies instead of automatically issuing citations based on a single air-lead number, OSHA under LIA's proposal will both assist the companies and better protect the health of the workers employed by them.

There is yet another and perhaps even more important difference between the approaches. By suggesting that every lead company should attempt to reach a single air-lead number by engineering controls regardless of the

extent to which such controls actually reduce air-lead concentrations, OSHA virtually assures that enormous sums of money will be spent for controls which serve no beneficial purpose whatsoever in protecting workers' health. (Caplan 5798, 5815; Godsey 6493-94) As Charles River Associates explained,

> "Because the lead industry utilizes a wide variety of processes which create varying air-lead emissions and are not equally susceptible to effective engineering control devices . . . the inflexible OSHA regulations which eliminate alternative compliance strategies by mandating an identical compliance sequence for the entire industry will result in inefficient and wasteful expenditures and unnecessary impacts on industry structure. If the regulations were to allow firms greater flexibility in the methods they could use to attain a certain benefit level, they would be more efficient and reduce unnecessary costs." (Exhibit 127, at 6-7)

The Association agrees with this analysis.

The Proposed Standard, for example, would require a primary smelter to spend $1 million for engineering controls to reduce air-lead levels around a blast furnace from, say, 500 ug/m3 to 450 ug/m3 even though no health benefit results from the expenditure. (See Caplan 5807; Stewart 2611 [has seen "well over a million bucks go right down the tube [although] . . . employer in all honesty tried to abate"]) The Association's proposal, by comparison, would not require the expenditure of what would be

wasted funds. Instead, it would introduce an element of reasonable flexibility into the enforcement procedures, a flexibility which would take into account the fact that the lead industry encompasses a multitude of different sectors using hundreds of disparate operations and processes. (See generally Caplan 5800-05)

LIA's recommendation certainly does not give the employer uncontrolled discretion in determining what engineering controls are required. The employer is not given carte blanche to decide what money he will spend; his written compliance program would always be subject to OSHA's scrutiny and, if necessary, administrative challenge.

In this connection, the Association also believes that it is essential for OSHA to provide guidelines as to what will or will not be deemed "feasible". LIA agrees as a general proposition that the new lead standard should not attempt to provide a single, inflexible definition of "feasible". But we also believe that the standard should contain a statement of general factors or guidelines to be considered in determining what engineering controls would be feasible in particular circumstances.

Among the general factors which LIA urges OSHA to incorporate as guidelines are (a) the nature of the technology available, (b) the cost and availability of

new or modified controls and the financial impact of such controls on the plant in question, (c) the predicted and relative effectiveness of such controls in protecting workers against material impairment of health and functional capacity, and (d) the availability and relative effectiveness of other means of protecting the workers. We would endorse, for example, the particular language proposed by Knowlton Caplan at the regional hearing in St. Louis:

> "'Feasible' means that the method or equipment is available on the market, has been used before with success in the same or closely similar applications, or the technology exists to create the equipment and implement the method with reasonable assurance of success; that the method or equipment will result in reducing the exposure to or below the TWA standard or is necessary to reduce the exposure to a level where the reasonable use of administrative controls or personal protective equipment which is not unduly onerous to the employee will adequately protect the health of the employee; that the number of employees exposed and the severity of the exposure are included in a cost-effectiveness consideration of the implementation of such controls; and that seriousness of the potential risk to the employee health is given due weight in all the considerations." (Exhibit 244) (Caplan 5791-93)

Without such a definition, the lead companies, and particularly the smaller and medium-sized firms which lack engineering know-how, will literally have to guess about what the term means and what they are expected to do to

III. IF OSHA DECIDES TO RETAIN A SINGLE AIR-LEAD EXPOSURE LIMIT, THE LIMIT SHOULD NOT BE LOWER THAN 200 ug/m3.

The Association believes, for the reasons already discussed at length, that OSHA can best protect the health of workers occupationally exposed to lead by adopting a biological standard as the primary compliance mechanism. If OSHA nevertheless decides that the new standard should contain an environmental exposure limit (a decision which itself would be contrary to the weight of the evidence submitted in this proceeding), it should retain the existing exposure limit of 200 ug/m3 and combine it with appropriate requirements for biological monitoring, medical surveillance, hygiene and work practice procedures, and employee training.

OSHA would not be justified in reducing the air-lead standard below 200 ug/m3 for the following reasons:

[footnote continued] enforceable through civil or criminal sanctions is unconstitutionally vague unless it provides a "reasonable warning of the proscribed conduct in light of common understanding and practices". Ryder Truck Lines, Inc. v. Brennan, 497 F.2d 230, 233 (5th Cir. 1974). OSHA standards are subject to this constitutional safeguard. See, e.g., Hoffman Construction Co. v. OSHRC, 546 F.2d 281 (9th Cir. 1976); Allis-Chalmers Corp. v. OSHRC, 542 F.2d 27, 30 (7th Cir. 1976) ("test . . . is whether the standard is so indefinite that men of common intelligence must necessarily guess as to its meaning"); Brennan v. OSHRC, 513 F.2d 713, 716 (8th Cir. 1975).

(1) Until OSHA knows whether the health of lead workers can be protected through compliance with the existing air-lead standard, there is no reason to modify that standard.

(2) Reducing air-lead levels from 200 ug/m3 to 100 ug/m3 would accomplish very little (if any) reduction even in <u>average</u> blood-lead levels, despite the enormous expense and despite the fact that the individual worker would still not be adequately protected.

(3) The proposed environmental exposure limit is economically and, in many instances, technically infeasible and, notwithstanding the minimal health gains, would materially alter and disrupt the competitive market structure which now exists in the major sectors of the lead industry.

Each of these three reasons is discussed in further detail in the sections below.

A. Enforcement of the Existing Environmental Exposure Limit

In the first major draft of their impact statement, OSHA's economic contractors correctly pointed out that,

passage from the draft impact statement before it was put in final form, as far as the Association was able to determine no data or study was furnished to OSHA to disprove the accuracy of the statement.*

The statement by OSHA's principal economic contractor, that enforcement of 200 ug/m3 might "eliminate the bulk of the problem" and generate the same benefits as the Proposed Standard, is particularly significant when one considers the fact that the new standard will undoubtedly require hygiene and work practice procedures, medical surveillance, biological monitoring and worker training, none of which is required under the present standard. In other words, if compliance with the existing standard might "eliminate the bulk of the problem", the likelihood of the same benefits occurring will be even greater if the existing standard is combined with the additional requirements for monitoring and work procedures.

---

* At the hearings David J. Burton, who was in charge of the supplemental study which lead to the "final" impact study, testified that he "tend[ed] to disagree with the statement." (Burton 891) He candidly pointed out, however, that he "[was] not going to say what the statement should say", and added that he "[didn't] know that much about the health effects and so forth" since he "[hadn't] been involved in that particular area" in working on the earlier drafts. (Burton 892) Arvil Adams, the economist who replaced John Short, the apparent author of the statement, testified simply, "I could not comment on the statement since it wasn't mine and I have no comment." (Adams 891)

The validity of the statement was confirmed by the testimony of several of the witnesses at the hearing. Dr. Teitelbaum, for example, described a plant in which there were elevated air-lead concentrations and "workers with blood leads ranging up to 86". After management had consulted with Teitelbaum, the plant was closed down and cleaned up. When operations resumed, "with the air leads 200 or below, and the housekeeping improved . . . the blood-lead [levels] of the workers ranged in the 40's and 50's" even after six months of renewed production. (Teitelbaum 496-97) See also OSHA's Economic Impact Statement (Exhibit 26) at 5-76 ("In one [foundry], employee exposures of approximately 200 ug/m3 were associated with blood lead levels ranging from 25 to 65 ug/100g blood.").

What all of this means is that "until such time as it can be proven that even when enforced rigidly and uniformly, the existing standard still does not protect adequately, any changes in the permissible exposure limit should not be promulgated." (Mosher 2788) As Dr. Cole emphasized when testifying on behalf of the Association, given the admitted economic disruption which the Proposed Standard would cause, "until one [is able to] judge . . . whether or not you have achieved a benefit, a satisfactory

benefit, from enforcing the present standard, it doesn't seem to us to be logical to take it a step further." (Cole 3093)

Certainly it is not "logical" to take the existing exposure limit "a step further" merely because, as witnesses like George Becker of the United Steelworkers testified, health problems have occurred in work environments with exposure levels far in excess of the present standard. (See, e.g., Becker 4998-99) Indeed, Mr. Becker himself acknowledged that his "description of the conditions which [he has] seen" and the "problems which [he] described" were not relevant to the question of whether the existing exposure limit should be reduced. (Becker 5125) Also irrelevant to this particular issue was the testimony from the Steelworker panels, which were assembled in response to Mr. Becker's written request (Exhibit 210) to find workers who could relate "horror stories of economic hardship because of high blood lead."

If OSHA chooses to disregard the evidence concerning the appropriateness of a biological enforcement level and instead adopts a single air-lead standard for the many sectors of the lead industry, the "logical" place to begin is by enforcing the existing exposure limit, not by experimenting with new but unnecessarily low limits.

In this connection, the Council on Wage and Price Stability stated, in its comments on the Proposed Standard, that

> "[I]n view of the very large costs associated with proposed standards and the absence of any quantification of the incremental benefits attributable to the proposal, we would urge OSHA to seriously consider alternative, less costly means of protecting workers from the hazards of lead poisoning. Such alternatives might include strict enforcement of the existing standard coupled with biological monitoring." (Exhibit 77, at 5)

As indicated below, the Council was quite correct in expressing concern about "the very large costs" of the Proposed Standard and about the absence of "incremental benefits attributable to the proposal".

B. Health Benefits of Reducing the Air-Lead Exposure Limit

Even if OSHA mistakenly retains an air-lead exposure limit in the new standard, OSHA should not contemplate reducing the existing limit unless it is first satisfied, on the basis of substantial evidence, that the reduction can reasonably be expected to have a significant impact in better protecting workers' health. No such evidence exists, although as Leonard Woodcock noted, "the question of [achieving] incremental [health] advances becomes a critical matter, no question about it." (Wood-

cock 5085)* Indeed, notwithstanding the obvious importance of this question, a large number of the witnesses who supported the Proposed Standard were not able to say what health benefits, if any, would be achieved by reducing the air-lead standard from 200 ug/m3 to 100 ug/m3. (See, e.g., El Batawi 359; Lancranjan 593; Burton 886-87; NIOSH 1433-34; cf. Wrenn 64; UAW 5372)

The only evidence submitted during the hearings with respect to the purported health benefits of reducing the existing environmental exposure limit was based upon attempts to predict air-blood correlations for groups rather than individuals. Several witnesses, for example, argued that statistically significant regression lines could be developed from the different studies by focussing on average or mean blood-lead levels rather than the blood-lead level of the individual worker. In other words, they argued that it is possible, particularly under controlled circumstances, to fit the data into models which purport to define the relationship between airborne lead levels and blood-lead concentrations. There are at least three reasons, however,

---

* To the same effect, see the testimony of David Nelson of the United Steelworkers at pages 4673-74 of the hearing transcript: "OSHA has to evaluate whether there is a benefit. That evaluation is basically an evaluation that should be made on the basis of whether or not there exists evidence to suggest that harm is done to workers at 200 that is not done to them at 100 in the instant case."

why this argument does not justify reducing the exposure limit from 200 ug/m3 to 100 ug/m3:*

(1) As discussed in detail earlier, see supra at 50-54, no model takes into consideration the tremendous variability in sources of exposure which the individual worker encounters in his workplace. Consequently, even though it is possible to develop some sort of regression lines for statistical purposes, the confidence limits around those lines are so wide as to render the "prediction factor" virtually worthless for purposes of protecting the individual worker's health.

(2) The regression lines which were developed from several of the studies presented at the hearing differed significantly from each other. Even though it was possible in some instances to derive regression lines which purported to show a statistically significant relationship between mean blood-lead

---

* The same reasons, of course, are applicable to the issue of reducing the exposure limit below 100 ug/m3. Such a further reduction would, in addition, be procedurally and legally impermissible, since OSHA would not have given interested parties the requisite public notice or made possible the necessary hearing with respect to such agency action, and would not have undertaken, let alone completed, the required economic impact study with respect to the feasibility and competitive impacts of the change.

levels and mean air-lead levels, the differences among those regression lines confirmed that no one regression line can reliably predict even average blood-lead levels. (See, e.g., Cole 3036-37, 3110-12; Lynam 3112-15)

(3) The reduction in average blood-lead levels which might be achieved by reducing air-lead levels from 200 ug/m3 to 100 ug/m3 is minimal at best, something in the range of 1.5 ug/100g to 6 ug/100g or so. These slight benefits simply do not justify the economic burdens, technological disruption and adverse competitive impacts which would flow from adoption of the proposed exposure limit.

Each of the major studies which was made a part of the record in these proceedings confirms that the health benefits to be expected from reducing the exposure limit would, in Dr. Hammonds' words, be very "modest" indeed. (Hammond 266-67) The reason why the change in average blood-lead concentrations is so limited lies in the undisputed fact that the relationship (if any) between air-leads and blood-leads is not linear and that at "exposure levels particularly above 50 micrograms per cubic meter . . . the air/blood relationship curve begins to flatten out." (Epstein 1053) Virtually every witness who spoke to the point

agreed that this "flattening" phenomenon does occur. See, e.g., Hammond 260 ("over that range of 100 to 300 [ug/m3] there does not appear to be a very large incremental rise in blood lead"); NIOSH 1320 ("incremental changes in air lead exposure" between 0 ug/m3 and 100 ug/m3 "produce greater increases in blood lead than do" similar changes between 100 ug/m3 and 200 ug/m3); Steelworkers 4903-04 ("over 100 air lead . . . you have a falling-off of the rate of increase" of blood-lead levels); Williams 1889 ("reduction in air lead from 200 to 100 micrograms would have very little effect on blood lead").

The first of the studies discussed at the hearings was the analysis presented on behalf of OSHA by Dr. Hammond. Hammond constructed a model based primarily on data reported in the earlier Azar study. The model indicated that,

> ". . . as air lead increases, its impact on PbB . . . becomes progressively smaller. Thus, excursion of air lead exposure over the suggested maximum of 100 ug/m3 would likely have only modest impact on the internal dose as reflected in PbB's. . . . [S]eeming discrepancies . . . only serve to highlight the fact that the impact of air lead on blood lead is very much dependent upon the background of non-air sources of lead." (Exhibit 54)

Under Hammond's model, moving from air-lead exposures of 200 ug/m3 to exposures of 100 ug/m3 would result in a predicted blood-lead reduction of only 1.8 ug/100g, from

42.5 ug/100g to 40.7 ug/100g. Given this "rather small" change, Hammond--although preferring a biological standard (267)--agreed that "an air lead level of 200 [would be] satisfactory . . . as a guideline." (Hammond 269)

Hammond himself recognized the "limitations" of his analysis, since it was based largely upon studies involving "general ambient air, not industrial air". (Exhibit 54) When questioned about this, however, he pointed out that "the model which was developed on the basis of general ambient air lead exposure seems to be fairly consistent [with] or to predict fairly well for industrial situations." (Hammond 273) He concluded that the regression equation he developed "is quite consistent with the limited experimental data available concerning industrial exposure." (Exhibit 54)

By the time the hearing began, of course, the "experimental data" was not all that "limited", since by then the results of the Manchester Study and the GM data were available. Both confirm the accuracy of Hammond's prediction that moving from air-lead concentrations of 200 ug/m3 to 100 ug/m3 has only a "modest impact" on blood-lead levels.

The cumulative data from all three factories investigated in connection with the Manchester Study (Exhibit

234[22]) suggest that reducing air-lead exposures from 200 ug/m3 to 100 ug/m3 will produce a corresponding reduction in mean blood-lead levels of only 3.4 ug/100g. (Medina 1422) Analyzed on a factory-by-factory basis, the data produced the following statistics (Lynam 3112-14):

Factory	PbB at 200	PbB at 100	Difference
1	52.4 ug/100g	49.2 ug/100g	3.2 ug/100g
2	46.8 ug/100g	45.4 ug/100g	1.4 ug/100g
3	62.6 ug/100g	57.3 ug/100g	5.3 ug/100g

Dr. Cole quite correctly concluded that these changes were not "meaningful". (Cole 3114-15) Even Dr. Fischbein of Mt. Sinai agreed that a blood-lead level difference of three micrograms had "no biological significance whatsoever". (Fischbein 2762)

The GM data corroborate the conclusions reached in the Manchester Study. The statistical model developed on the basis of that data by Drs. Buncher, Gartside and Lerner at the University of Cincinnati indicates that,

> ". . . a worker having an air lead exposure of 200 micrograms Pb/m3 would have a predicted blood lead in the range of 30 to 68 ug/100g, with a 95 percent degree of confidence. Halving the exposure to 100 ug Pb/m3 would result in a predicted blood lead between 24 and 61 ug Pb/100g. . . . [I]f one considers a group of workers, the predicted mean blood lead for an air lead exposure of 200 ug Pb/m3 is 49, while halving the exposure to 100 ug/m3 results in a predicted mean blood lead of 44. Reducing air lead by 100 ug/m3 from 200 down to 100 results in a

mean decrease of 5 ug/100g blood lead." (Exhibit 285, at 13-14) (Emphasis added.)

The analysis of the GM data presented by NIOSH at the hearing used a slightly different approach but made the same point. When individual blood-lead values were compared with average personal sampler air-lead measurements, the GM data showed that at 200 ug/m3, 91.43 percent of the workers had blood-lead concentrations below 60 ug/100ml, whereas at 100 ug/m3, 92.31 percent were below 60 ug/100ml--a change of only .9 percent, despite the reduction in air-lead exposures. Similarly, at the other end of the biological spectrum, at air-lead levels of 200 ug/m3, 7.62 percent of the workers had blood-lead concentrations below 30 ug/100ml, and at 100 ug/m3 8.97 percent were below 30 ug/ml, a difference of only 1.25 percent. (Exhibit 86D, Table 20) (NIOSH 1442-43)

That only minimal benefits can be expected to result from halving the existing exposure limit is further confirmed by other studies and data submitted at the hearing, including evidence from General Battery (Smith 4569, 4588), ASARCO (Nelson 4055), and Globe Union (Lundquist 4350). Even Dr. Williams' limited data, when properly analyzed without the controls, indicate that little if any reduction in blood-lead levels is accomplished by re-

ducing air-lead exposure from 200 ug/m3 to 100 ug/m3. (Cole 3064-65; Williams 1923)

To realize just how meaningless are the purported benefits which are supposed to flow from the Proposed Standard, one need look no further than the discussion entitled "Computation of Benefits" in the impact study prepared for OSHA by its economic contractors. (Exhibit 26, at 3-2 and 3-3)

DB Associates "computed" the benefits by assuming (a) that the Proposed Standard would result in reducing air-lead exposures to no more than 100 ug/m3, (b) that this air-lead reduction would "result in a reduction of blood-lead concentration levels" to no more than 60 ug/100g, and (c) that workers with blood-lead levels below 60 ug/100g have "virtually no risk of clinical disease or death due to occupational exposure to lead." Having made these assumptions, DB Associates then performed a simple mathematical computation, based on the number of workers in the lead industry, to determine how many workers "should experience some benefit". The flaws in this analysis are self-evident.

(1) As DB Associates itself admits, even "the effect of 'best effort' compliance on reducing existing air-lead distributions cannot be accurately predicted . . . ."

4665, 4969-70)* As a consequence, the unions simply did not "have any hard data to disprove Mr. Caplan's statement" (Steelworkers 4686), or for that matter, the statements by DB Associates or CRA. Their unsupported criticisms are, in fact, unsupportable.

The first and perhaps most often stated criticism by the unions was that the economic problems described by OSHA's witnesses and by industry experts involved imaginary costs which, like those in the vinyl chloride industry, would never be incurred. (See, e.g., Samuels 4250; Woodcock 5052-53) The record conclusively demonstrated, however, that the lead industry--unlike the vinyl chloride industry--is not "crying wolf".

The cost estimates presented by the vinyl chloride industry turned out to be exaggerated largely because extensive engineering controls were not really needed to reduce hazardous air exposures to safe levels. That is not true with respect to the lead industry. Witness after witness--

---

* When asked why they had not consulted any engineers in an effort to obtain reliable cost data, one of the union representatives replied that no such efforts had been made "because of the immense cost involved". (Steelworkers 4663-64) And yet this very same union, during its hearing presentation, argued that no company should be able to obtain even a variance unless the company first conducted just such an engineering study--that is, the same kind of study and cost evaluation which the Steelworkers, with all of its economic muscle and clout, claimed were too expensive. (Steelworkers 4697)

from industry, from government and, indeed, from labor--testified that the vinyl chloride and lead industries involved totally different technologies and that extensive, additional engineering controls would in fact be required if the Proposed Standard were adopted. (See Cole 3032-33; Cal. OSHA 6531-33; NIOSH 1433; UAW 5277, 5359-60; Caplan 3859, 3862, 3934, 5789-90, 5804-07; Estee 2947-48; Miller 3590; Voltmaster 3631, 3637-38; Burton 882; General Batt. 4590) Indeed, as explained earlier, the expenditures which would be required by the lead standard would in all probability not even bring most companies into compliance with the proposed exposure limit. Whatever the shortcomings of the cost analyses presented by the vinyl chloride industry, the lead industry manifestly does not deserve to be tarred with the same brush.

The second major objection by the unions (asserted, ironically, despite their failure to obtain any supportive cost information) was that the data base used by DB Associates, CRA and Caplan was woefully inadequate. (See, e.g., Steelworkers 4622) This contention is patently frivolous.

By the time DB Associates, CRA and Caplan had completed their investigations and studies, they had obtained extensive information from all of the primary

smelters, all of the major and many of the smaller battery companies (including the 12 representative plants surveyed by Knowlton Caplan [3694-95]), and many of the secondary smelters. (See generally Exhibits 26, 127, 288, 138C and 138D) Personal visits were made to numerous plants in all three industry sectors. Much of the data and estimates were gathered or developed independently (Adams 722, 763-64; Caplan 3923) and in many instances were double checked (e.g., CRA 3350-52). The studies are nevertheless consistent; each thus confirms the accuracy of the findings in the others. Given the diverse nature of the lead industry and the time limitations within which the investigators were working, the data base was more than adequate and entirely reliable.

Apart from the adequacy of the data base, the unions raised an issue as to "incremental costs", asserting that the only relevant economic information was that which related solely to the costs of reducing air-lead levels from the present standard of 200 ug/m3 to the proposed standard of 100 ug/m3, not from the status quo to 100 ug/m3. (See, e.g., Steelworkers 4628-29) There are at least two reasons why this assertion is incorrect.

(1) In considering the actual economic impact of a proposed regulation, OSHA necessarily must take into

account all of the costs which will be required to attempt to comply with that regulation. Inasmuch as few companies in the lead industry are consistently in compliance with the existing standard, it would be impossible for OSHA to determine the real impact of the Proposed Standard merely by looking at the incremental instead of the total costs. As CRA explained, it was necessary to focus on "the cost of going from the status quo to the 100 microgram level because those are the relevant costs for considering what the ultimate impact on industry structure would be after attempting to comply with the proposed standard. Only knowing the marginal cost from 200 to 100 would not be sufficient . . . to do those calculations." (CRA 3343-44) (See Burton 803; Adams 884; CRA 3323)

(2) The record does contain extensive evidence with respect to incremental costs. It shows that it will cost approximately three times as much to attempt to achieve 100 ug/m3 as it would to achieve 200 ug/m3. (See CRA 3323, 3340-43; Noe 1279-80, 1284; Cominco 2230, 2250; AMAX 1264, 1652-53; Caplan 3942-44) In other words, most of the competitive impact of the Proposed Standard would be caused

by attempting to reduce air-lead levels from the existing standard to the proposed enforcement limit, not by going from the status quo to 200 ug/m3. Studies and analyses by Knowlton Caplan demonstrated that this is true for both primary smelters (Caplan 5709) and secondary smelters (Exhibit 138D; Caplan 3943-44), as well as for battery manufacturers (Exhibit 138C; Caplan 3942; CRA 3320). In the battery industry many of the operations are already at or near the present exposure limit (Miller 3587), and consequently most of the cost will be incurred in reducing air-lead levels from 200 ug/m3 to 100 ug/m3. (Burton 803) For smaller battery companies, economies of scale in compliance come into play, and the disparities in costs per unit are even larger. (Caplan 3941-42)

In short, whether the economic feasibility of the Proposed Standard is considered in terms of total costs or in terms of incremental costs, the competitive impact will be enormous.

An objection was also raised on the ground that the estimates by DB Associates, CRA and Caplan were exaggerated because of "double counting". The unions argued, for example, that many of the engineering controls for which costs were estimated are already required by EPA reg-

ulations or were in place (see, e.g., Steelworkers 4627); they also argued that the projected dollar-impact was inflated because it included estimated expenditures by companies which would be going out of business before the amounts were actually spent (e.g., UAW 3325). The record, however, does not support these contentions.

All three of the experts who prepared economic or cost analyses testified that duplicative costs were eliminated to the extent possible. CRA, for example, specifically asked the firms from which it obtained information to exclude "any double counting". (CRA 3364) Caplan also deleted from his computations expenditures for equipment which was already in place. (Caplan 3629, 5756; Mirer 5355-56). Similarly, DB Associates eliminated double or overlapping costs whenever they or the companies were able to identify them. (Burton 820, 880) Most of the union arguments on this issue involved but one plant owned by one company---ASARCO's El Paso smelter--but even there the money expended for EPA controls increased productivity whereas the money which would be required for OSHA controls would not. (Nelson 4655-56) As DB Associates explained in a related context,

> "While there is some overlap between EPA and OSHA controls, the requirements that are being placed upon the industry by EPA relate more to the control

of direct combustion emissions from such items as furnaces and so forth. They have not been concerned with the fugitive type emissions within the plant and in the work environment." (Burton 811) (See also Burton 881 [EPA requirements increase El Paso costs of complying with OSHA regulations])

With respect to the question of "double counting" expenditures by companies which may be going out of business, it is self-evident that the competitive impacts of the Proposed Standard cannot be accurately assessed without first determining what the potential costs would be for all of the companies covered by the new standard. This is precisely what DB Associates, CRA and Caplan did. Moreover, even with respect to those companies which would be forced out of business before incurring expenses, the monies not actually spent by them

> ". . . would be balanced by the cost to society from lost production that may well occur through exiting of a firm . . . . [T]he disruption associated with lost capacity and unemployed resources would be an appropriate kind of balance . . . . To the extent that those firms exit the industry, and no one picks up that capacity, the lost production from those firms, the unemployed resources that exist are a cost to be charged against that standard." (Adams 1017-19)

(See also Adams 1012-13; CRA 3325)

The unions also complained about the fact that neither DB Associates nor CRA included in their computations any assessment of the benefits to be gained by tax

credits or allowances (e.g., Steelworkers 4629), and that neither discussed in its report the availability of loans from the Small Business Administration. CRA's report, however, did discuss the availability and impact of SBA loans. (See, e.g., Exhibit 127, at 3-19) The union arguments, furthermore, are totally irrelevant to the major competitive repercussions which would flow from enforcement of the Proposed Standard. A company which will go out of business because its expenses exceed its revenues will have no use of tax gimmicks and will not be able to repay (and perhaps not even obtain) loans from the SBA. (See Steelworkers 4691) As Dr. Burrows explained when describing CRA's study,

> "To determine the impact on market structure, it was sufficient to know what the full costs were and to compare these to the existing profit margins of the firms to see whether the firms would be able to stay in business or not. It was not of direct interest to us to determine how much of the costs would be borne by the shareholders and how much of the costs would be borne by the U.S. Treasury . . . because if the costs are greater than the profit, they are going to go out of business. It does not matter if the costs are also a tax deduction." (CRA 3367-68)

In sum, the objections raised by the unions are a series of "quibbles" (Mirer 1015) and nit-picks which do not effectively challenge let alone disprove the conclusions reached both by DB Associates and by CRA. If anything, the cost estimates by both firms may have been

conservative. Neither consultant, for example, included in its analysis many of the sectors of the lead industry which will be affected by the Proposed Standard. (See, e.g., Adams 722; Burrows 3276) DB Associates understated costs by not including projections for developmental controls which may be required but turn out to be unsuccessful. (Burton 872-75) Nor were the costs of heated make-up air added to their computations. (Burton 807) By the same token, CRA reduced many of the cost estimates received from Caplan and applied a conservatively low cost of capital in its analysis. (Caplan 3923, 3938; see Exhibit 127, at 3-19)

OSHA is required to consider the economic and competitive impact of proposed regulations and possible alternatives. The evidence presented establishes that the proposed reduction of the air-lead limit will materially disrupt competition. Since the Association's proposal will protect workers as fully as the Proposed Standard but without adverse competitive impacts, and since reducing the air-lead limit will, by itself, have only "modest" benefits at best, the Association's alternative should be adopted.

(c) Rate Retention. Closely related to the issue of economic feasibility, because of the potential cost impacts involved, is the question of whether a "rate re-

tention" provision should be included in the new standard to protect employees from loss of earnings and seniority status when they are transferred to other positions because of elevated blood-lead levels. The Association believes that the nature and terms of any rate-retention program adopted by a particular employer for his employees, as well as the discipline of employees who disregard hygiene and work practice regulations, are not yet appropriate matters for regulation by OSHA. (See Wrenn 94 [OSHA has "consciously avoided . . . intrusions into traditional labor-management relations"]) We submit that the record fully supports this conclusion.

The unions argued on numerous occasions (see, e.g., McBride 2965-66) that the absence of a rate retention provision would constitute a disincentive to employees to submit to physical examinations because they would fear that an adverse medical opinion could result in loss of employment. They made the same arguments during the coke oven hearings. See 41 Fed. Reg. 46742, 46780 (October 22, 1976). OSHA declined to include such a provision in the coke oven standard, however, because the record was "deficient . . . in a number of relevant areas" and did "not contain sufficient evidence on the propriety, scope and implications of a rate retention requirement . . . ."

Ibid. The very same points made by OSHA in the Preamble to the coke oven standard are equally applicable here:

(1) There is "a range of different types of rate retention provisions and the record contains no evidence on the relative merits of various types of provisions."

(2) The record "is silent on the interplay between these various types of rate retention provisions and collective bargaining agreements in the . . . industry. . . . [I]t is not clear, for example, what rights a transferred employee would have under a rate retention provision in relation to other employees with seniority under applicable collective bargaining agreements and what principles would govern the termination of the retained rate."

(3) The record "does not focus on the issue of whether an employer should be responsible for the employee's retention of his rate of pay where the medical condition which is the basis for the transfer is caused by conditions other than . . . exposure or the applicability of the rate retention requirement in circumstances where it is difficult or impossible to determine the specific etiology of the employee's medical condition."

(4) The record "contains no evidence on the impact of such a provision within a larger industrial framework and [does not] assess . . . the extent to which varying circumstances in other industries would warrant different treatment of this issue."

Although the unions were aware almost half a year before the hearings began that OSHA needed this kind of information to consider adopting a rate retention provision, the unions did nothing to furnish such data. OSHA therefore faces precisely the same problems it faced when issuing the coke oven standard. As was true there, OSHA has no

alternative but to conclude

> ". . . that further exploration of this issue is necessary in order to deal in considerably more depth with the numerous issues raised by such a provision."

The need for such "further exploration" is even more obvious if one considers the different economic impact which would result from removing workers from exposure at, say, 30 ug/100g (as some witnesses urged) as opposed to 80 ug/100g (as recommended by LIA). Since it would be virtually impossible to keep an occupationally exposed worker's blood-lead concentration below 30 ug/100g, adopting a rate retention provision in conjunction with an unnecessarily low biological standard would in all probability bankrupt every single lead company in the nation.

It is important to emphasize that the responsible union representatives who testified at the hearing recognized the complexities involved in providing for rate retention (see, e.g., Woodcock 5079-80), and appeared to agree with the proposition that appropriate qualifications and limitations have to be imposed even for a privately bargained rate retention program (see Woodcock 5079; McBride 2983-8 and 2983-9).* Among the limitations which are appropriate

---

* Both Mr. Woodcock, then president of the United Auto Workers, and Mr. McBride, the president-elect of the United Steelworkers, also appeared [footnote continued]

in such a program are the availability of alternate positions, reasonable time limitations, and exclusions for hazards not caused by the work environment.

Conclusion

For the reasons stated above, the Lead Industries Association, Inc., respectfully requests that the Secretary of Labor and OSHA adopt the Association's recommended proposal in lieu of the Proposed Standard.

Dated: New York, New York
June 16, 1977

Respectfuly submitted,

DEBEVOISE, PLIMPTON, LYONS & GATES
Attorneys for The Lead
Industries Association, Inc.
299 Park Avenue
New York, New York 10017
(212) 752-6400

Standish F. Medina, Jr.
John H. Hall
Of Counsel

[footnote continued] to agree that even if OSHA did not adopt a rate retention provision, a worker with elevated blood-lead levels should be removed from high exposure areas. (See Woodcock 2983-8; McBride 5080) (See also Wolfe 4219-21)

Comparison of Proposals by OSHA and LIA with Respect to Health Standards For Occupational Exposure to Lead

OSHA Proposal

1. General Approach

Although recognizing that biological monitoring "more accurately indicate[s] the likelihood of adverse effects" to employees who are occupationally exposed to lead, OSHA nevertheless proposed that for compliance purposes the standard should contain a "permissible exposure limit" based solely on air sampling and environmental monitoring. That approach is based upon the assumption that a meaningful correlation exists between blood-lead levels and air-lead levels and that a reduction of air-lead levels from 200 ug/m3 (the present standard) to 100 ug/m3 (the proposed permissible exposure limit) will cause a corresponding reduction in blood-lead levels.

2. Monitoring

Every employer covered by the new lead standard should conduct both biological monitoring and environmental monitoring.

LIA Proposal

1. General Approach

The health of workers can be best and most promptly protected by promulgating a standard which emphasizes the proper importance of biological indices and medical surveillance and which establishes a simple, effective and inexpensive enforcement procedure directly utilizing those indices. Employers covered by the standard should be required to conduct regular environmental monitoring and should adopt and submit to OSHA written compliance programs designed to reduce air-lead levels, to the extent feasible, by engineering controls; however, a specific air-lead level number should not be adopted for enforcement purposes, since such a compliance mechanism (even if based on the proposed permissible limit of 100 ug/m3) will not accomplish the objectives of protecting workers' health.

2. Monitoring

LIA agrees that every employer covered by the new lead standard should conduct both biological monitoring and environmental monitoring. The frequency with which such monitoring is conducted should depend upon the function to be served by the type of monitoring in question.

OSHA Proposal

3. Blood-Lead Levels

If an employee is found to have a blood-lead level at or above 60 ug/100g, the employer must "take immediate steps to reduce the employee's blood lead level to below" that concentration. However, no "permissible exposure limit" based on blood-lead levels has been proposed by OSHA "because of the many individual variables involved over which the employer has little direct control, such as poor personal hygiene of employees and off-the-job exposures."

LIA Proposal

3. Blood-Lead Levels

LIA agrees that it is appropriate to establish a meaningful "action level" of 60 ug/100g which, if exceeded by any employee, would require the employer to take immediate steps to insure that the employee in question has not and will not suffer any material impairment of health or functional capacity, including (a) providing the employee with more intensive biological monitoring and medical surveillance, (b) determining and, to the extent feasible, eliminating the causes--including insufficient engineering controls, poor hygiene and poor work habits--of the employee's elevated blood-lead level, and (c) providing the employee with more intensive advice and instruction concerning the hazards and sources (including off-the-job activities and improper diet) of overexposure and the measures which can be taken to avoid such overexposure.

LIA submits that inasmuch as blood-lead determinations and medical surveillance are the most accurate and reliable methods of detecting and preventing overexposure to lead, the standard should also establish a biological "exposure limit" for compliance purposes. A confirmed blood-lead level of 80 ug/100g is an appropriate "exposure limit" for compliance purposes because (i) the best available evidence establishes that no employee will suffer material impairment of health or functional capacity if his blood-lead levels are consistently below 80 ug/100g, and (ii) so long as OSHA establishes a margin or "cushion" between the biological "action level" and "exposure limit", imposition of sanctions on the employer is not inappropriate even if the employee's elevated blood-lead level may have been caused in part by factors (such as poor hygiene) unrelated to the work environment.

OSHA Proposal

LIA Proposal

(a) If an employee is found to have a blood-lead concentration (as determined and confirmed by a certified laboratory) exceeding the exposure limit and the employer knew or should have known that the employee previously had a blood-lead level in excess of the action level, the employer could automatically be cited for violating the the standard.

(b) A presumption that a violation has occured could be established on the basis of information contained in the biological monitoring records maintained by the employer. Enforcement, therefore, would in most instances be simple, inexpensive and expeditious.

(c) When any employee is found to have a confirmed blood-lead concentration exceeding the biological exposure limit, he should immediately be removed from occupational overexposure to lead.

OSHA Proposal

4. Rate Retention

The lead standard proposed by OSHA contains no provision with respect to rate retention. See generally OSHA's Preamble to the final standard for exposure to coke oven emissions, 41 Fed. Reg. 46742, at 46780 (October 22, 1976).

5. Frequency of Biological Monitoring

Biological monitoring must be provided by the employer at least every six months to each employee exposed to air-lead concentrations at or above an environmental action level of 50 ug/m3, and at least every two months to each employee exposed to air-lead concentrations in excess of a permissible exposure limit of 100 ug/m3. Monitoring for employees in the latter category must continue for at least four months after the last exposure above the permissible air-lead limit. Urine lead-level determinations can be used as a "screening" mechanism to determine when blood-lead tests are required.

LIA Proposal

4. Rate Retention

LIA believes that, as a general principle, an employee should not be discharged merely because he has a blood-lead level in excess of the biological exposure limit. However, LIA also believes that the nature and terms of any rate-retention program adopted by a particular employer for his employees, as well as the discipline of employees who disregard hygiene and work practice regulations, are not appropriate matters for regulation by OSHA.

5. Frequency of Biological Monitoring

In order to establish each individual's exposure, every exposed employee should receive a blood-lead determination before beginning employment. Thereafter, he should have a monthly blood-lead determination for a period of four months. Following the initial four-month period, and based upon the results of his most recent blood-lead determination, an employee should have (in addition to any other biological monitoring which may be done by alternate "screening" techniques) a blood-lead determination according to the following schedule:

OSHA Proposal

LIA Proposal

Previous Blood-Lead Level	Frequency of Blood-Level Determination
Below 40 ug/100g	At least yearly
41-60 ug/100g	Every 3 months
Above 60 ug/100g	Monthly

LIA believes that it is inappropriate and unwise to make the frequency of biological monitoring depend upon the results of air sampling, since (a) air sampling does not detect variations in personal hygiene habits or work practices which cause some workers to absorb larger amounts of lead than other employees in the same work environment (including those with low air-lead levels), (b) air sampling does not measure lead absorption resulting from off-the-job activities, (c) air sampling typically measures short-term exposures which have little biological significance, and (d) air sampling measurements with currently available devices are subject to enormous errors and are not reliable indicators of lead exposure.

OSHA Proposal

6. Use of Chelating Agents

Chelating agents shall not be routinely administered to employees and shall not be administered at all except by, and at the discretion of, a licensed physician.

LIA Proposal

6. Use of Chelating Agents

LIA agrees with the position taken by OSHA but would add two further requirements:

(a) Non-Exposure. When a licensed physician has determined that an employee is intoxicated by lead and that chelating agents should be administered to him, the employee should be removed from further occupational lead exposure until such time as the chelation therapy has been completed and the physician deems it safe for the employee to return to his former position.

(b) Medical Records. In the event that chelating agents are administered to any employee and that information is available to the employer, the medical records maintained by the employer for that employee should contain information regarding (i) the circumstances which necessitated chelation therapy, and (ii) the nature and extent of the therapy.

OSHA Proposal

7. Air-Lead Levels

No employee may be exposed to airborne concentrations of lead greater than a "permissible exposure limit" of 100 ug/m3, as determined on an 8-hour time-weighted average, based on a 40-hour workweek. Every employer covered by the standard must establish and follow (but need not file with OSHA unless "requested" to do so) a written program to reduce air-lead levels to or below the permissible exposure limit. The employer must also immediately institute engineering controls to reduce exposure to or below the permissible exposure limit, except to the extent that such controls are not feasible. Where engineering controls which can be instituted are not sufficient to reduce air-lead exposures to the permissible exposure limit, such controls must nonetheless be used to reduce exposures to the lowest practicable level.

LIA Proposal

7. Air-Lead Levels

The new lead standard should require every employer covered by the standard to institute and use engineering controls to reduce air-lead exposures to the extent "feasible" (see paragraph "8" below) to promote a safe and healthy work environment. The standard should also require the employer to establish and implement a written compliance program and should make it mandatory for each such program to be filed with OSHA.

Although employers should be subject to compliance proceedings if they fail to use engineering controls to reduce air-lead levels to the extent feasible, the new standard should not establish a specific, numerical air-lead exposure limit for enforcement purposes. A specific numerical standard is inappropriate because (a) particular blood-lead levels connot be correlated with or predicted from particular air-lead levels (including those in the 100-to-200 ug/m3 range), (b) at these levels, a reduction of air-lead concentrations from 200 ug/m3 to 100 ug/m3 does not cause a corresponding or significant reduction of blood-lead levels, and (c) it is not technologically feasible to reduce air-lead levels to the environmental exposure limit proposed by OSHA in a number of specific lead operations and processes. Adoption or continued use of a specific air-lead number for enforcement purposes, therefore, will probably discourage employers from promptly complying voluntarily with the new standard.

Voluntary compliance can more effectively be encouraged and OSHA's enforcement activities better facilitated by providing for the mandatory submission of written compliance programs and by issuing citations in any of the following circumstances: (a) failure of the employer to establish a program, (b) failure of the employer to file the program, or (c) failure of the

OSHA Proposal

LIA Proposal

employer to implement and follow the program, whether filed or not. In addition, if OSHA--upon investigation and after reviewing any employer's written compliance program--determines that it is feasible for the employer to institute additional or different engineering controls and the employer thereafter refuses to do so, OSHA may commence enforcement proceedings.

Although OSHA will not initially be able to review all of the plans submitted, it does, even now, have the necessary staffing to review and comment upon the plans submitted by those companies which, based on OSHA's past enforcement experience or on comments from labor unions, it has reason to believe may have unnecessarily high air-lead levels or inadequate engineering controls. Mandatory submission of compliance programs by all employers covered by the standard will enable OSHA to develop engineering guidelines more quickly, since OSHA will know what others are doing and can do in a wide range of situations and circumstances.

Moreover, since the feasibility of engineering controls has to be considered and resolved on a company-by-company basis, it makes little difference--in terms of OSHA's staffing needs or in terms of the program ultimately agreed upon--whether the review by OSHA takes place before a citation issues or during post-citation abatement negotiations. What will make a difference is the employer's greater willingness to propose and implement a compliance program which is related to and based upon biological indices and feasible engineering controls rather than an arbitrary air-lead number. Finally, establishing an air-lead standard based upon feasibility rather than an arbitrary air-lead number would better protect the health of employees engaged in short-term or outdoor work, including construction work, where air monitoring is virtually meaningless and engineering controls play little role.

OSHA Proposal

8. Feasibility

Although OSHA has not proposed any definition or guidelines as to what is or is not "feasible", it has consistently taken the position in other contexts that a balancing of both economic and technological factors is appropriate in determining what is or is not feasible.

9. Training, Hygiene and Housekeeping

The standard proposed by OSHA contains extensive and detailed provisions with respect to training, hygiene and housekeeping requirements.

LIA Proposal

8. Feasibility

Although the new lead standard should not attempt to provide a single, inflexible definition of "feasible", the standard should contain a statement of general factors to be considered in determining what engineering controls would be feasible in a particular plant for a particular employer. Among the factors which LIA believes should be considered, with respect to the particular plant or factory in question, are (a) the nature of the technology available, (b) the cost of new or modified controls and the financial impact of such controls, and (c) the predicted and relative effectiveness of such controls and of other protective devices in protecting workers against material impairment of health and functional capacity.

9. Training, Hygiene and Housekeeping

LIA agrees that the new lead standard should contain appropriate provisions with respect to (a) conducting employee training and education, (b) installing and maintaining proper hygiene facilities, including showers and clean lunchrooms, and (c) implementing effective housekeeping practices. LIA notes, however, that a number of the specific proposals put forward by OSHA in this area--such as the requirements that all employers must "launder, maintain, and dispose of all protective clothing" and must "ensure that employees . . . wash . . . before . . . smoking or applying cosmetics"--may be unrealistic or too inflexible. These proposals, and others which raise similar problems, will presumably be commented upon by interested parties during the forthcoming hearings.

APPENDIX B

This Appendix B sets forth and explains the Associations's objection to the procedures followed by the Secretary of Labor and OSHA in scheduling and conducting hearings on the Proposed Standard without first having completed and obtained certification of an Economic Impact Statement, as required by Executive Orders 11821 and 11949, OMB Circular No. A-107, DOL Order 15-75, and DOL Temporary Directive No. 1.

A. Procedural Requirements

On November 27, 1974 President Ford issued Executive Order 11821 (Exhibit 14A), directing that

> "major proposals . . . for the promulgation of regulations or rules by any executive branch agency must be accompanied by a statement which certifies that the inflationary impact of the proposal has been evaluated."

The Order further specified that the required evaluations had to be done in accordance with criteria and procedures established by the Director of the Office of Management and Budget, and that the Director of OMB, in developing such criteria, had to consider among other things the "cost impact" of proposed standards on consumers, businesses and markets, as well as the effect of proposals

on competition. The Order provided that it would expire on December 31, 1976, unless extended.

It is undisputed that the Proposed Standard issued by OSHA on October 3, 1975 constitutes a "major [regulatory] proposal" within the meaning of Executive Order 11821.

In accordance with the Executive Order, the Director of OMB issued Circular No. A-107 (Exhibit 15) on January 28, 1975, prescribing guidelines for the identification and evaluation of major proposals such as the Proposed Standard. The Circular contained the following provisions, among others:

(1) The Circular directed "each agency . . . [to] develop procedures for the evaluation" of major proposals, and specified that such evaluations should include, inter alia, "a comparison of the benefits to be derived from the proposed action with the estimated costs and inflationary impacts" and "a review of alternatives to the proposed action that were considered, their probable costs, benefits, risks, and inflationary impacts compared with those of the proposed action";

(2) The Circular required each agency to "designate an official to be responsible for compliance with this

Circular . . ."; and

(3) The Circular provided in substance that no major regulatory proposals were to be issued unless "accompanied by a statement which certifies that the inflationary impact of the proposal has been evaluated."

OMB's Circular No. A-107 contained no expiration date and remains in force to this day.

Although the OMB Circular specified that impact statements had to accompany major proposals at the time the proposals were first issued, OMB and OSHA agreed that this requirement might create regulatory problems with respect to a number of standards, including the Proposed Standard, which OSHA was already working on and which it expected to publish by September 30, 1975. Accordingly, in a letter dated September 2, 1975 (Exhibit 234[27]), Acting OMB Director George C. Eads approved "a procedural variant", but only on the condition that "the full intent and purposes of the Executive Order were preserved." Under the procedural variant OSHA was permitted to issue the Proposed Standard without first completing the impact statement, but it was required to publish the required impact statement "at least 30 days prior to any scheduled hearing . . . ."

As required by the OMB Circular, the Department of Labor developed procedures for the evaluation of major regulatory proposals. These were entitled "Policy and Criteria for Evaluation" and were issued as Order No. 15-75 in November 1975. Order No. 15-75 established a certification procedure, defining the term "certification" to mean

> "a statement by the initiating Agency, concurred with by ASPER [Office of the Assistant Secretary for Policy, Evaluation, and Research], that the proposed actions . . . have been reviewed in accordance with the criteria specified in Section 5." (Emphasis added.)

Section 5, in turn, set forth a number of "identification criteria", including "effects on market structure." The Order provided that it would expire on December 31, 1976, presumably because that was the date on which the Executive Order was scheduled to expire.

The mechanics of the certification procedure required by DOL Order No. 15-75 were described in greater detail in DOL Temporary Directive No. 1 (Exhibit 234[32]), which was also issued in November 1975. The Temporary Directive specified that each impact statement had to be submitted to ASPER within a particular time frame so that ASPER could review the document "for its appropriateness and analytical content." The Directive, like Executive Order 11821 and DOL Order 15-75, contained an expiration

date of December 31, 1976.

On December 31, 1976 President Ford issued Executive Order 11949 (Exhibit 14B), extending the requirements of Executive Order 11821 through 1977 and amending the title of the old order from "Inflationary Impact Statements" to "Economic Impact Statements". Although the Executive Order and OMB Circular No. A-107 (both of which required evaluation of impact statements by appropriate guidelines, criteria and procedures) remained in full force and effect throughout 1977, neither the Department of Labor nor OSHA issued, published or proposed any guidelines, criteria or procedures to replace DOL Order No. 15-75 or Temporary Directive No. 1. Nor, in view of the extension of Executive Order 11821, did either indicate that the DOL Order and Directive had in fact expired.

B. OSHA's Impact Statement

OSHA submitted its draft Economic Impact Statement to ASPER for its review in mid-1976. (Burton 865-66) (Exhibit 234[29]) ASPER, however, refused to approve the impact statement, and in a memorandum, dated November 5, 1976, from Abraham Weiss to Dr. Morton Corn, explained why "the IIS is not acceptable" and why "a major effort will be required before ASPER's approval can be given."

(Exhibit 234[30]) ASPER found that the "analytical content" was not appropriate and that "the data on which estimates of costs and benefits are based are totally inadequate". In discussing the purported benefits to be attained under the Proposed Standard, ASPER observed that "given the lack of any well established dose-response relationship [between air-lead concentrations and health], the benefits of setting up the proposed lead standard are difficult to determine." ASPER also emphasized that it was important "to have some feeling for how costs and benefits change for some alternative standards." (Emphasis added.) (See also Exhibit 77, at 5)

As a consequence of ASPER's refusal to approve the draft impact statement, OSHA requested DB Associates "to develop a new report which would satisfy the ASPER criteria . . . ." (Burton 866-67) DB Associates completed its work in February 1977, but for reasons of "administrative expediency", OSHA chose not to seek ASPER's "formal concurrence in issuing" the study and setting the hearing dates. (Wrenn 74-75) In other words, notwithstanding the fact that DB Associates' entire efforts had been geared to satisfying criteria established by ASPER following ASPER's rejection of the draft study, OSHA did not even submit the final report to ASPER for its comments, let alone approval,

before issuing the study and scheduling the hearings.

C. Analysis and Conclusions

OSHA manifestly ignored both the letter and the spirit of the applicable procedural requirements in issuing the impact statement and conducting the hearings without ASPER's concurrence in the adequacy of the impact statement.

The Executive Order and OMB Circular have required, since early 1975, that impact statements be prepared and evaluated according to guidelines and criteria established by the agency in question. The Department of Labor's own guidelines, in turn, specified that ASPER's concurrence was a condition of the required certification process. OSHA itself recognized that it was required to follow these guidelines and to obtain ASPER's approval, and it was for that reason that OSHA submitted the preliminary draft to ASPER for its review and then retained DB Associates to do further work when ASPER found the draft totally unacceptable.

OSHA's failure to obtain ASPER's concurrence in the certification process cannot be explained away on the grounds of "administrative expediency". Nor can it be justified on the ground that DOL Order No. 15-75 and Temporary Directive No. 1 purported to expire on December 31, 1976. OSHA was required by the Executive Orders and OMB

Circular to establish and publish evaluation guidelines and criteria and to review its impact statements according to those guidelines and criteria. Either OSHA was required to continue following Order No. 15-75 and the Temporary Directive, or it was required to issue and follow new guidelines. It did neither.

The Association's objection to OSHA's failure to follow its own procedures does not involve mere technicalities and is not frivolously raised for purposes of delay. Quite the contrary. One of the primary functions of the guideline and certification procedures required by the Executive Order, OMB Circular and DOL's own rules was to ensure first, that the enormous costs of proposals such as OSHA's lead standard would in fact be justified by the benefits which would accrue from those proposals and, second, that the relative merit and costs of alternative solutions would be adequately considered.

The Association has objected precisely because it believes that the environmental exposure limit proposed by OSHA will not achieve the intended benefits. Instead--despite its severe economic impact--the air-lead exposure limit in the Proposed Standard will have little if any beneficial effect in terms of better protecting workers' health. It was this very concern which was partially re-

sponsible for ASPER's rejection of OSHA's draft impact statement last November. (See generally Exhibits 234[30, 33-36]) Apparently aware that its final Economic Impact Statement would also be rejected by ASPER for the same reasons, OSHA arbitrarily elected to sidestep the procedures which it previously followed and which it was obligated to follow. By doing so, it prevented ASPER from confirming that the Proposed Standard will not accomplish the desired benefits. As the Council on Wage and Price Stability correctly pointed out when commenting on the Proposed Standard,

> "This new study [the final Economic Impact Statement by DB Associates] . . . lacks an analysis of the costs and benefits of alternative occupational lead standards or of alternative methods of achieving compliance with the proposed standard." (Exhibit 77, at 5)

A properly completed and certified Economic Impact Statement, on the other hand, would have supported the Association's contention that its alternate proposal is preferable to the proposal issued by OSHA.

(2) DB Associates also recognizes that it is impossible to assess the effect of reducing air-lead exposures because "there is apparently no simple relationship between air-lead exposure and blood-lead concentration" and because "occupational air-lead exposure is only one of several courses contributing to blood-lead concentrations."

(3) Finally, DB Associates concedes that "even if the effect of altering the air-lead exposure distribution upon the blood-lead concentration distribution could be predicted with certainty, the effect on worker health could not."

In other words, each and every one of DB Associates' assumptions is, by its own admission, questionable, incorrect or irrelevant. The purported "benefits", therefore, are nothing more than the mathematical results of an arbitrary computation (Adams 789-90, 895); they certainly do not justify the imposition of a reduced air-lead exposure limit which, in contrast to the Association's proposal, will have devastating economic repercussions and be technically infeasible in many operations. See generally In re Petersen Mfg. Co., 5 O.S.H.C. 1223 (April 6, 1977); In re Republic Granite Co., 4 O.S.H.C. 1711 (September 30, 1976).

C. Feasibility

No single topic has generated more controversy and misunderstanding in OSHA's rule-making proceedings than the question of "feasibility". The lead hearings were no exception. Notwithstanding the sound and fury produced, an objective analysis of the evidence submitted, viewed in the context of OSHA's statutory mandate, indicates that the proposed environmental exposure limit is not feasible and that, in view of the viable alternative recommended by the Association, the minimal benefits which might flow from the proposed reduction cannot justify the costs involved.

(1) Statutory Requirements. Section 6(b)(5) of the Act states that the Secretary of Labor, when promulgating health standards dealing with toxic substances,

> ". . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . . ." 29 U.S.C. § 655(b)(5). (Emphasis added.)

The language about feasibility is not precatory, it is not a suggestion, it is not a recommendation. It is a statutory mandate which has the effect of prohibiting the Secretary from promulgating a standard which is infeasible.

As the legislative history and decisional au-

thorities make clear, the concept of feasibility has two separate elements.

The first element is the concept of technological feasibility. As the Court of Appeals for the District of Columbia explained, "practical considerations can temper protective requirements. Congress does not appear to have intended to protect employees by putting their employers out of business . . . by requiring protective devices unavailable under existing technology . . . ." Industrial Union Department v. Hodgson, 499 F.2d 467, 476-77 (D.C. Cir. 1974). In other words, Section 6(b)(5) "explicitly confines the Secretary's rulemaking authority within technologically feasible boundaries." American Federation of Labor v. Brennan, 530 F.2d 109, 121 (3d Cir. 1975).

The Secretary, of course, does not necessarily have to rely upon presently available technology, since, as the courts have also held, the Act is to be viewed as a "technology-forcing" piece of legislation. Society of Plastics Industry, Inc. v. OSHA, 509 F.2d 1301, 1308 (2d Cir.), cert. denied, 421 U.S. 992 (1975). This does not mean, however, that the Secretary can arbitrarily set a standard without some reasonable expectation that the technology can be developed in the immediate future. He need not dismiss a proposed standard as infeasible as long as "the necessary technology looms on today's horizon",

and this "necessarily implies consideration both of existing technological capabilities and imminent advances in the art." American Federation of Labor v. Brennan, supra, 530 F.2d at 121-22. (Emphasis added.)

The second element is the concept of economic feasibility. It is now well established that feasibility "include[s] problems of economic feasibility" as well as technological feasibility, Industrial Union Department v. Hodgson, supra, 499 F.2d at 477, and that "a standard that is prohibitively expensive is not 'feasible'", American Federation of Labor v. Brennan, supra, 530 F.2d at 122. See also In re Continental Can, 4 O.S.H.C. 1541, 1546 (August 24, 1976) ("As used in the Act, 'feasibility' contemplates economic as well as technological feasibility.") The courts have therefore emphasized that they

> ". . . will not impute to congressional silence a direction to the Secretary to disregard the possibility of massive economic dislocation caused by an unreasonable standard. An economically impossible standard would in all likelihood prove unenforceable, inducing employers faced with going out of business to evade rather than comply with the regulation." American Federation of Labor v. Brennan, supra, 530 F.2d at 123.

The feasibility requirement does not preclude the Secretary from promulgating standards which may be "financially burdensome" or which threaten "the economic demise of an

employer who has lagged behind the rest of the industry in protecting the health and safety of employees". Industrial Union Department v. Hodgson, supra, 499 F.2d at 478. The Secretary is not, however, allowed to adopt a standard which causes "massive economic dislocation" or which "adversely" affects "the competitive structure . . . of the industry". Ibid.

A number of the union representatives who testified at the hearing argued that (a) "standards should be set . . . without taking into consideration economic feasibility" (e.g., McBride 2960; D. Nelson 4639, 4661), and (b) "economic concerns only become relevant after a standard [has been] promulgated and enforced" (UAW 5323).* Indeed, this may have been the position of OSHA itself. Grover Wrenn, for example, testified (Wrenn 67) that OSHA's most recent "statement of policy" was set forth in the court papers submitted on behalf of the agency in Oil, Chemical & Atomic Workers Int'l Union v. Usery, Civil Action No. 76-365 (D.D.C.), where the government's Memorandum in opposition to plaintiff's motion for summary judgment em-

* However, when asked whether OSHA was "required by statute and decisional law to consider economic feasibility, notwithstanding [his union's] policy position", Lloyd McBride, the new president of the Steelworkers, replied, "I will not quarrel with OSHA's obligation to take that into consideration." (McBride 2979)

phasized that

> ". . . the Assistant Secretary [Morton Corn] has repeatedly stated his policy that while economic-feasibility information is essential to informed and responsible rulemaking, even the direct economic costs of proposals to regulated employers--let alone their independent impact on the general economy, if any--will not in foreseeable circumstances alter the substantive terms of final OSHA standards set for sound health reasons. Instead they will be used solely to determine whether and what delayed effective dates may be needed to facilitate the Act's central goal of insuring widespread voluntary compliance with mandatory requirements." Memorandum, dated June 1976, at 6-7. (Emphasis added.)

The Association respectfully submits that this position is legally untenable and is flatly inconsistent with the express policy mandate set forth in the Occupational Safety and Health Act.* If, however, this is in fact OSHA's present policy, OSHA should so state at the time the new

---

* Even apart from the fact that the Act expressly states that the Secretary "shall" set standards to protect health "to the extent feasible", the position described in the government's Memorandum would have the practical effect of relieving OSHA of its obligation to establish the feasibility of a standard. OSHA takes the position that in an "enforcement action" it is the burden of the employer, not the burden of OSHA, to prove feasibility." (Wrenn 80) Consequently, if the "economic costs of proposals" will not "alter the substantive terms of final OSHA standards" but will be considered only for scheduling and then for abatement purposes in enforcement actions--where OSHA says the employer has the burden of proof--OSHA will have effectively side-stepped its responsibility to determine for itself that the standard is "feasible", as required by the Act.

standard is promulgated in order to permit the issue to be resolved properly by the courts.

(2) Technological Feasibility. The record establishes beyond a shadow of a doubt that OSHA's economic contractors were correct in their conclusion that,

> "The installation of engineering controls does no[t] ensure compliance with the proposed permissible limits. Indeed, it is our opinion that a number of operations will not be able to achieve the permissible limit with technically feasibile [sic] engineering controls alone." (Exhibit 26, at 4-5) (Emphasis added.) See also pages 5-7 (primary smelters), 5-31 (secondary smelters), 5-50 (battery manufacturers), 5-80 (foundries), and 5-98 (pigment manufacturers).

Indeed, the evidence presented during the hearings demonstrates that in many specific operations, particularly in the primary and secondary smelter sectors, feasible engineering controls do not exist to reduce air-lead exposures to the existing let alone proposed air-lead standard.

Lead is "used in scores of industries and occupations" (Exhibit 26, at 2-3) involving at least 57 different SIC codes, more than 70,000 establishments and 5.3 million employees (Exhibit 234[24], at 1). The technologies used in these sectors vary greatly. What is technologically feasible in one operation in one sector of the lead industry will in all probability have little if any relevance to the other sectors. (See, e.g., NIOSH

1424; Stewart 2604; Caplan 5750-52) Thus, it is virtually meaningless to talk, as many witnesses did, about what is technologically feasible for the industry as a whole. Each sector is for all practical purposes a separate industry, and the problems of sector "X" cannot be answered simply by looking at what is possible in sector "Y".

With respect to primary and secondary smelters, the evidence showed that there were operations which would "not be able to achieve 100" ug/m3 <u>regardless of cost</u>. (See, <u>e.g.</u>, Caplan 3930-31) (See also Exhibit 26, at 4-5) There are also operations for which even achieving 200 ug/m3 is "doubtful". (Caplan 3931, 5688, 5691-97) An industrial hygienist from AMAX, for example, testified,

> "Our primary smelter is now engaged in a major engineering program intended to reduce airborne levels to 200 micrograms per cubic meter. . . . Our engineers have investigated the programs and technology currently in use at other smelters throughout the world, and firmly believe that the technology is not available to meet this proposal [of 100 ug/m3]." (Roy 1264)

Kenneth Nelson of ASARCO similarly testified that,

> "My own opinion, based on personal observation and study of lead smelting and refining operations in the United States, Australia, Belgium, Canada, England, Germany, Japan, Mexico, Sweden, [and] Yugoslavia is that it is not feasible technologically, using present methods of smelting and refining, to achieve and maintain, by engineering controls, the proposed limit of concentrations of

> 100 micrograms per cubic meter at all work stations, at all times in lead smelters and refineries." (Nelson 3971-72) (See also Varner 6405-07)

The accuracy of the observations by DB Associates, Caplan, Roy and Nelson were confirmed by every competent engineering study submitted prior to and during the hearings. (See, e.g., AMAX Study, Exhibit 3[108]; ASARCO Study, Exhibits 3[106] and 142C; St. Joe Study, Exhibit 3[103]) (See also Burton 796-97, 815-16)

Similar if perhaps slightly less severe technical problems exist in the other major sectors of the lead industry, although it appears that they too will be unable to meet the proposed standard in many operations. In the battery industry, for example, Knowlton Caplan of Industrial Health Engineering Associates, Inc., on the basis of an intensive study of twelve representative companies, concluded that it would not be possible "to control lead-in-air to 100 ug/m3 by application of known, standard dust control techniques to existing plants" without using developmental equipment which had never been tried, let alone been succesfully used. (Exhibits 29[29A] and 288) As Caplan explained,

> ". . . these considerations make it clear . . . that compliance for most battery manufacturers is at the margin of technological feasibility and could only be achieved with great difficulty, even assuming that

it were economically feasible." (Caplan 3696)*

Notwithstanding the theoretical possibility that developmental controls might--apart from the costs involved--enable battery manufacturers to reduce air-lead exposures to 100 ug/m3, most small manufacturers said that they would not be able to use such controls successfully. (See, e.g., Lancaster 3420; Continental 3754; Dynolite 1247) Even DB Associates acknowledged that "in some [battery] operations where there is a high degree of manual labor involved," engineering controls could not reduce air-lead exposures to 100 ug/m3. (Burton 802)

Several witnesses testified on behalf of the unions that the lead "industry" would have no difficulty meeting the proposed exposure limit, and some even suggested that it was technologically feasible to reduce air-lead levels to 50 ug/m3. None, however, presented any reliable data to support these conclusory assertions, and, in fact, most were not competent to testify concerning the engineering problems posed by the Proposed Standard.

---

* It was generally acknowledged during the hearings that Knowlton Caplan's study of the battery industry was the most detailed and reliable analysis available. Dr. Mirer of the United Auto Workers, for example, observed that "Caplan's study is the best thing available in terms of . . . the details of costs of particular equipment . . . ." (Mirer 5308)

The Teamsters, for example, argued that "we can today achieve levels . . . of less than 50 micrograms per cubic meter of air" (2066), but their witness was not a ventilation design engineer, had had "no direct experience" of any kind with primary smelters, and was relying heavily upon "a recent study done by a student at the California State University at Northridge" which merely indicated that some of the employees in 17 battery plants were "working at the less than 100 microgram level". (2083, 2065) Dr. Mirer, an industrial hygienist with the United Auto Workers, gave similar testimony. But Dr. Mirer is not an engineer (5352), and he himself acknowledged that he had no particular expertise with respect to "air exposure control technology" for primary smelters, secondary smelters, pigment plants or shipbuilding (5352-53).

Similarly, Albert Stewart, an industrial hygienist testifying on behalf of the AFL-CIO, had had no experience of any kind "in terms of monitoring or . . . proposing engineering controls" for primary smelters, and only one experience with secondary smelters. Even Dr. First, who appeared as an OSHA witness, had "not had the opportunity of [designing] engineering controls for a primary lead smelter" and said that he was not "prepared to do that [kind of a] design at this moment." (First 2412)

Whatever the expertise and competence of these witnesses to offer opinions with respect to the battery industry (an area in which Knowlton Caplan has far more extensive and practical experience), they certainly were not in a position to say whether the Proposed Standard was technologically feasible in the many other industry sectors which would be affected by a reduced exposure level.

Nor were the technological feasibility problems of the primary and secondary smelters answered by testimony concerning possible new processes.

With respect to the primary smelters, for example, Frank Block of the Bureau of Mines testified about research being done to determine whether lead could be commercially refined through a chemical extraction process rather than by pyrometallurgical procedures. (Block 3386 et seq.) Mr. Block acknowledged that (a) the project is in its preliminary stages, (b) the Bureau has yet to determine full-scale, commercial feasibility, (c) the Bureau "does not have a firm idea as to the lead emission[s] that would occur in the commercial context," (d) it will take another five years even to design let alone build a pilot plant, and (e) the cost of each full-scale commercial operation would be in the range of $50-100 million. (Block 3405, 3412-13)*

* Although Mr. Block himself was unfamiliar with the technology of working smelters, [footnote continued]

It is evident, therefore, that this particular research cannot be relied upon to solve any of the technical problems which the Proposed Standard would create. (See First 2394 [not aware "of any promising new or even proved technology that could replace the present technology of lead smelting and refining"])

Similar testimony as to alternative processes--this time with respect to secondary smelters--was presented by Svend Bergsoe, president of Paul Bergsoe & Son. Mr. Bergsoe testified in substance that his company had developed and was using a smelting process which reduced air-lead levels to below 100 ug/m3 around the furnace area. Whatever the merits of the process for a secondary smelter that was preparing to build a new plant, Mr. Bergsoe's testimony indicated that it was not a viable alternative for plants already in existence:

(1) The process related only to the smelting operations of secondary smelters and did not include the refining operations. It could not be used at all

---

[footnote continued] he stated that others within the Bureau of Mines had developed "a considerable amount of expertise" with respect to the technical problems of primary and secondary smelters. (Block 3410, 3416) The Association has been informed that OSHA staff members working on the lead proposal interviewed these experts prior to the commencement of the hearing, but none of them was called to support the technological feasibility of the Proposed Standard.

by primary smelters, battery manufacturers or other lead companies. (Bergsoe 5143-44, 5192-93)

(2) The process is not a retrofit process but requires the construction of an entirely new plant. (Bergsoe 5192) For an existing secondary smelter, this would mean not only building a new plant for the smelting operations but re-building the old plant in which the refining operation is housed.

(3) The cost of each furnace two years ago was $2.5 million, and since most secondary smelters in this country would need two furnaces, the cost for the smelting operations alone would be over $5 million per plant. (Bergsoe 5181, 5189-90)

(4) Although air-lead levels are purportedly under 100 ug/m3 around the furnace area, they are considerably higher in the storage areas. Workers in such exposed areas would have to be fully enclosed to be protected. (Bergsoe 5155, 5193-94) Even around the furnace, air-lead exposures are much higher whenever the furnace freezes up or is cleaned. (Bergsoe 5198)

The Bergsoe process, therefore, would not solve the feasibility problems which would exist if the Proposed Standard were promulgated. (See generally Exhibit 234[24], at para. 3.3.2.4.4)

The feasibility problems inherent in the Proposed Standard are unnecessarily aggravated by the suggested prohibition against recirculating ventilated air.

Section 1910.1025(f)(3) of the Proposed Standard states that "air from any exhaust ventilation system for lead shall not be recirculated into the workroom." The Association submits that by using available technology, employers are able effectively and reliably to clean exhaust air and to do so more efficiently and less expensively than by using "fresh air". (Caplan 3694, 3716-20, 3880-81, 3918-19; BCI 3684-85)

Since the outdoor ambient air in the vicinity of a lead plant often contains a relatively high air-lead concentration, properly designed recirculation systems may furnish the workplace with air that is in fact lower in lead concentration than the air which would otherwise be drawn in through conventional air systems. Such recirculation also permits the employer to recapture and reuse virtually all of the heat generated through the compression system and filtration equipment, and thus makes it possible to conserve substantial amounts of fuel. Where the energy used to drive such systems is recovered, greater volumes of air can be drawn through the exhaust systems, thus affording even better ventilation for the

workroom and greater protection for the worker. There is ample precedent for cleaning and recirculating exhaust air from substances (such as vinyl chloride) which are admittedly more hazardous than lead. See 29 C.F.R. § 1910.1017(f). Such recirculation should also be permitted here.

The technological problems which would be created by the Proposed Standard also include the very serious difficulties of even obtaining the necessary new engineering controls in a timely manner. It is undisputed, for example, that a company covered by the new standard could not simply rush out and acquire new equipment; it would first have to consult with a competent engineer. (See, e.g., Caplan 3932-33; First 2328; Teamsters 2060) But it is also undisputed that because there is a very "thin pool of experienced and competent engineers" (First 2310), it will take several years for the entire industry merely to obtain the necessary advice (Caplan 3933). Once the requisite advice had been obtained, the industry would still need a number of years to obtain the engineering controls required. (Caplan 3932; First 2382, 2409) As Dr. First observed, even without the extraordinary demand that would be generated by a new standard, it already takes 22 to 26 weeks to obtain delivery of "common items

such as large blowers". (First 2382)

As a consequence, even if the proposed air-lead limit were technologically and economically feasible and could be expected to accomplish significant benefits (none of which is true), it would still require five to ten years to implement. This is all the more reason for OSHA to adopt the more effective and less expensive alternative proposed by the Association.

(3) Economic Feasibility. Two extensive studies were undertaken with respect to an analysis of the economic impact of the Proposed Standard: one by DB Associates, Inc. (with assistance first from John Short & Associates, Inc. and later from A.V. Adams Associates, Inc.) on behalf of OSHA (Exhibit 26), the other by Charles River Associates Incorporated ("CRA") on behalf of the Association (Exhibit 127). Both agree that even with respect to just the primary, secondary and battery sectors of the lead industry, total capital costs will be in excess of $400 million and annual costs will be approximately $100 million. (Exhibit 26, at 2-9 and 2-10; Exhibit 127, at 2) If DB Associates is correct in assuming that there are 8,100 workers in the smelting and battery industries with blood-lead levels in excess of 60 ug/100g (Exhibit 26, at 3-2), this would mean an annual cost of more than $12,000 for each such employee.

More importantly, both economic consultants agree that the impacts on the competitive structure of these industries will be even more severe than the simple dollar figures indicate. As CRA explained, by way of general summary,

> "The adverse impacts on the economy of the standard . . . are far worse than is indicated by the cost numbers above. The impacts of the regulations will be unevenly distributed, resulting in the shutdown of numerous plants and consequent loss of jobs. The economic dislocations will tend to be concentrated in specific regions rather than dispersed evenly throughout the economy.
>
> "The proposed OSHA regulations will create severe financial difficulties for the four non-Missouri primary lead facilities. The remaining plants will suffer a serious loss in earnings. . . . We conclude that 113 of approximately 143 firms in the battery industry will be forced to close down. This will result in five large producers supplying nearly 90 percent of the market. Similar impacts will occur in the secondary industry: many small plants will be forced to shut down, leaving a smaller number of large firms with most of the market. There is no reason to believe that the smaller plants which are most likely to be forced out of business are poorly run or are unsafe; they simply do not have the financial capacity to absorb the costs of compliance and continue to compete with the larger producers. In short, it is clear that the proposed lead regulations will substantially and permanently alter the market structure of each of these important lead sectors." (Exhibit 127, at 2) (Emphasis added.)

The costs and competitive impacts of the Proposed Standard are discussed below in two subsections: the first briefly summarizes the nature of the impacts which both DB Associ-

ates and CRA agreed will occur if the standard proposed by OSHA is adopted and enforced; the second analyzes several of the questions which were raised--particularly by organized labor--concerning the assumptions and methodology used by DB Associates and CRA. A third subsection considers the related but separate economic issue of "rate retention" and "earnings protection".

Throughout the discussion below it is important to keep three things in mind:

(1) The analyses presented at the hearings dealt almost entirely with only three sectors of the lead industry--primary smelters, secondary smelters and battery manufacturers. While these are admittedly among the largest and most hazardous sectors, they represent but 24,400 out of more than 1.2 million lead workers and 238 out of more than 43,000 lead establishments in the "major exposure" industries. (Exhibit 26, at 2-13)

(2) It is clear that it is "the expenditures associated with the engineering controls required by the [proposed] standard" which will cause "the major dollar costs of compliance" under that standard. (Exhibit 127, at 5-6) But as explained earlier, the benefits, if any, which can reasonably be expected to flow

from the engineering controls made necessary by a reduced air-lead standard are totally uncertain and are "modest" at best.

(3) The capital expenditures and annual costs estimated by DB Associates and CRA "are not those which will guarantee compliance," only of attempted compliance. They are no more than the "estimated costs of all [purportedly] necessary, technically feasible and available controls" which the Proposed Standard will require. (Exhibit 26, at 5-12)

In short, the economic and competitive impacts discussed below represent but a fraction of the total "costs" to be incurred and may well constitute expenditures which produce no benefits whatsoever.

(a) Economic Impact. There are seven major primary lead production facilities, operated by four firms, in the United States. The data presented at the hearings indicate that the capital cost of attempted compliance with the Proposed Standard for these firms will be approximately $50 million (Exhibit 26, at 2-9; Exhibit 127, at 2) with annual costs of between $10 and $14 million (Exhibit 26, at 2-10; Exhibit 127, at 2). As a consequence,

> "The OSHA lead standard will have a substantial impact on two of the four major firms in the primary

> lead smelting and refining industry. When put in context with recent E.P.A. requirements, the financial viability of the primary smelting operations of Gulf Resources [Bunker Hill] and Asarco is placed in doubt." (Exhibit 26, at 1-2, 6-16) (See also Exhibit 127, at 7-10, 19-24; Adams 726; CRA 3277-78)

Obviously, "if one or more producers of primary refined lead should be forced to shut down lead refining operations", as expected, because of an inability to pass through the additional costs of attempted compliance, "concentration in primary refined lead production could increase substantially." (Exhibit 26, at 6-26)

The potential impacts are even more severe with respect to the secondary lead industry. Of the approximately 50 plants which make up this sector (Exhibit 127, at 10), there "are a large number of small firms which might be forced out of the industry because of an inability to pass on the costs of compliance. . . ." (Exhibit 26, at 1-2) (See also Adams 726, 916; CRA 3278) In fact, in their earlier draft reports, OSHA's economic contractors estimated that "enforcement of the proposed standard . . . could eliminate 17-19 independent [secondary] smelters comprising approximately . . . 15% of the secondary market . . . ." (Exhibit 234[24], at 2; Exhibit 234[25], at 4) The inevitable effect of this will be "increasing concentration within the lead industry, primarily in secondary

lead," an industry already dominated by relatively few firms. (Exhibit 26, at 6-7)

Similar problems face the starting, lighting and ignition battery industry. There are approximately 200 plants and 143 firms in this sector (Exhibit 127, at 12), of which five firms already account for some 80 percent of total production capacity (Exhibit 26, at 1-2). The economic impact of the Proposed Standard will be significant.

> "[T]here are a large number of very small independent battery producers who are not likely to be able to survive the OSHA standard. Their cost disadvantage vis-a-vis the large producers is such that it would be difficult to comply with the OSHA standard and remain profitable. . . . [In addition,] employment productivity will decline between 9.1 and 11.5 percent." (Exhibit 26, at 1-2)

Because of higher compliance costs per battery in plants producing less than 1,000 batteries per day, "approximately 113 independent producers will be forced to cease operations" if the Proposed Standard is adopted. (Exhibit 127, at 12) (See also Exhibit 234[24], at para. 4.3.3.2.3 ["small independent manufacturer . . . would find it virtually impossible to raise the required capital"]) In this connection, three additional factors should be noted:

(1) There is absolutely "no reason to believe" that the

113 independent battery manufacturers referred to above are unprofitable, poorly run or unsafe. (Exhibit 127, at 38) (See Adams 906; First 2318; Cole 3072, 3089; CRA 3278-79; BCI 3847-48) But because of economies of scale in compliance, and because of their already extended financial capability, the smaller companies will be unable to absorb their higher unit-costs of compliance and still compete with the larger producers. (See, e.g., Exhibit 127, at 38; Exhibit 26, at 6-39 and 6-42; Caplan 3693-94, 3715-16; Steelworkers 4685; Burton 725-26, 906, 986; CRA 3278, 3347-49; Woodcock 5055)

(2) Despite having greater per unit manufacturing costs than larger producers, small battery firms are able to compete effectively for smaller accounts (Exhibit 127, at 30), and, indeed, they play "a competitive role . . . in terms of battery prices" (Woodcock 5083). They do so by offering "a number of services to their customers which larger firms cannot always offer, including quicker and more flexible delivery schedules, more credit flexibility and better warranty cooperation, greater aid to jobbers in selling to an area, and pick-up of used batteries from small customers for credit." (Exhibit 127, at 30) (See

also Burton 907; Estee 2923-25, 2949; Laher 3493; Crown Batt. 3758-59; BCI 3670; Manix 3424-26; CRA 3296-97) These services would be lost were the Proposed Standard adopted and enforced.

(3) The closing of 113 small battery plants will lead to a loss of capacity of 8.1 million battery units, representing about half of the productive capacity not presently accounted for by the five largest battery companies. This, in turn, will increase the five-firm market share from 80 to 90 percent. (Exhibit 127, at 12)*

Leonard Woodcock, therefore, was absolutely correct when he emphatically agreed with the proposition that 100 to 115 small and medium-sized battery companies were not

---

* After concluding that "the OSHA lead standard is likely to bankrupt many small storage battery producers, possibly as many as 100 small companies," DB Associates went on to state in the final Economic Impact Statement that "this probably would not have a significant impact on the competitive structure of [the] battery industry . . . ." (Exhibit 26, at 6-42) This latter statement was clearly erroneous, as DB Associates itself appears to have recognized at the hearings. See, e.g., Adams 726 ("this will probably substantially weaken competitive pressures in the industry"), Adams 730 ("lessening of competition is considered serious . . . in the case of the battery industry"), and Adams 909 ("has the potential of limiting competition even further in an already highly concentrated industry").

expendable. (Woodcock 5083)

(b) Methodology and Assumptions. The most outspoken critics of the economic analyses by DB Associates and CRA, and of the supporting data provided by Knowlton Caplan of Industrial Health Engineering Associates, Inc., were the several major unions which participated in the hearings. Before discussing their objections (none of which has any merit), it is worth commenting briefly on the evidence which the unions themselves presented--or, to be more accurate, did not present.

In the several months preceding the hearings, the United Steelworkers, the United Auto Workers and the United Rubber Workers had extensive dealings with many of the largest lead companies and were permitted to tour and inspect numerous plants and factories. (See, e.g., Steelworkers 4713, 4968-69, 5101-02; UAW 5058, 5272-73; URW 2562) Notwithstanding this considerable access, not one of the unions bothered to "cost anything" (Mirer 5308), and not one retained engineers to prepare estimates based on the inspections and tours which the union hygienists took (e.g., UAW 5352, 5358-59; URW 2563-64; Steelworkers 4973). Nor did any of the unions ask to bring an engineer into the plants they visited. (See, e.g., Steelworkers