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TESTIMONY ON REPRODUCTIVE EFFECTS

OF LEAD EXPOSURE: SCIENTIFIC

EVIDENCE AND POLICY ISSUES,

Presented

at

the Occupational Safety and Health Administration,

U.S. Department of Labor

Hearing on Occupational Exposure to Lead

FILED

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Background information on witness, as requested by OSHA

My name is Andrea Hricko. Since July, 1975, I have been Health Coordinator of the Labor Occupational Health Program, which is part of the Center for Labor Research and Education, Institute of Industrial Relations, University of California, Berkeley. The Labor Occupational Health Program, primarily funded by the Ford Foundation, works with labor groups and California workers on health and safety problems. We also have a one-year contract with the U.S. Department of Labor, OSHA, to develop health and safety training materials for apprentices.

I have a Masters in Public Health degree from the University of North Carolina School of Public Health. My work experience includes two years with the United States Public Health Service as an epidemiologic investigator and five years with Public Citizen's Health Research Group in Washington, D.C. I was involved in petitioning the Department of Labor to set standards for carcinogens and I have testified at OSHA standards-setting hearings on both carcinogens and vinyl chloride.

While with the Health Research Group, I studied the occupational health hazards on jobs which employ predominantly women and I also examined how on-the-job exposures to certain chemicals could affect the reproductive systems of both men and women. This research culminated in publication of a handbook for workers, Working for your Life: A Woman's Guide to Job Health Hazards, which was released in June, 1976.

Finally, I have recently been awarded a six-week World Health Organization fellowship to study what other countries are doing to protect male and female workers against job hazards that can affect reproduction.

At the request of the U.S. Department of Labor, OSHA Solicitor's Office,
I am appearing at this hearing to testify on the reproductive effects of
lead exposure and the policies which must be adopted to protect workers.

Testimony

The policy issues that we must consider as we search for a response to the reproductive hazards of lead exposure are indeed monumental.

- Does society have a responsibility towards future children or is this solely a "woman's problem"?
- Can employers avoid instituting engineering controls to reduce exposures by the simple expedient of banning all "susceptible" groups of workers?
- Should OSHA permit employers to make women prove they have been sterilized or are otherwise unfertile before they can work in hazardous areas?
- Does denying women the right to certain jobs violate the letter or spirit of sex discrimination laws?
- Mandatory pregnancy tests -- would they be an invasion of privacy?
- What about sperm damage -- does a fertile man deserve equal rights to a safe job?
- When medical reasons dictate that a person not work in hazardous areas, should the worker be offered an equitable transfer?

The answers to these questions, however, transcend the individual dangers posed by exposure to lead. Although this hearing is on the adverse health effects of only lead exposure, it will have a resounding impact on many more than the estimated 1.3 million workers exposed to lead. The issues and answers will determine the future ability of all workers to conceive, father, and raise normal, healthy children -- as well as the future of women's equal employment opportunities.

Scientific evidence on reproductive effects

Lead exposure affects the reproductive systems of both males and females.

These effects include (1) genetic; (2) gametotoxic; (3) intrauterine; and (4) extrauterine. In lay terms, this means that lead can (1) adversely affect the chromosomes; (2) damage the sperm or egg cells prior to conception; (3) affect the developing embryo during pregnancy; and (4) affect the developing baby of an exposed mother who is breast-feeding. (See flowsheet on page 25.

--Historical evidence

Historical information exists on reproductive effects of lead exposure -- but generally at much higher levels than are usual today. Studies have shown, for example, that lead poisoning in women is associated with menstrual disorders, sterility, spontaneous miscarriages, and stillbirths. (In fact, lead has been used at times to induce abortions.) After withdrawal from high lead exposure, some of the women who had suffered these problems recovered and had normal pregnancies. Infants of mothers with lead poisoning have suffered from lowered birthweights, slower growth, nervous system disorders, and have died at younger ages than would have been expected.

As early as 1860, there was also evidence of an unusually large proportion of stillborn children in women whose husbands were exposed to high lead levels. Other studies around the turn of the century revealed an increased number of sterile marriages among men with lead poisoning^(6,13,16,20,25).

The response to these early studies on reproductive effects were policies and, in some countries, special regulations prohibiting employment of women in the lead industry. That these exclusionary policies were directed at women is not surprising because they came at a time in history when women's place was considered to be in the home, and when women were considered to be the weaker

sex and in need of greater protection. This was the period of special protective legislation for women including limitations on the number of hours they could work and the weight they could lift.

But times have changed. Today, many women workers recognize that these special "protections" often serve as a guise for discrimination against them. Thus, many have urged that those laws that do not provide protection be repealed, and that those which are truly protective be extended to male workers. In an age of equal employment opportunities, courts have upheld the repeal of state labor laws designed to protect only women.

Thus, we need to consider the currently available scientific information in light of present social policies and legal mandates in the United States.

--Recent scientific studies

Recent studies, evaluating the effects of much lower lead exposures than those existing at the time of the earlier studies, provide more evidence that lead can damage reproductive processes or the offspring of either males or females. The primary remaining issues are the extent of these effects and the precise blood lead levels at which reproductive damage occurs.

Appallingly little research on this problem has been conducted by either U.S. industry or the government in the last 30-40 years. But an analysis of the recent available data from human and animal studies, both U.S. and foreign, indicates that harmful effects have occurred in both animals and man at blood lead levels around 30ug/100ml, although the correlation between animal blood levels and those in humans is not well established. However, the U.S. Public Health Service has also recommended that blood lead levels in children be kept below

30ug/100ml. Thus, this number appears to be a blood lead level that should not be exceeded without risking reproductive effects.

It is imperative that additional studies be conducted to define more accurately the extent of these reproductive hazards as well as to determine whether or not levels lower than 30ug/100ml can also harm workers or their children. Nevertheless, in light of the already existing data on these and other serious health effects, further delays in reducing exposures cannot be tolerated.

Appendix A details results from selected recent studies which I considered significant in determining the maximum blood lead level which would appear to protect against reproductive harm. Where available, blood lead levels in the workers or subjects studied are given in the Appendix.*

Briefly, the studies described in Appendix A show that lead has caused decreased fertility in male animals⁽¹⁴⁾ as well as sperm abnormalities in animals and man^(14,18). It has also caused impotence in animals⁽¹⁴⁾ and difficulties in erections in workers⁽¹⁸⁾.

Several studies⁽⁹⁾ have demonstrated chromosome changes in workers exposed to lead, although the available evidence shows conflicting results. A few papers suggest that these and other reproductive effects might cease or be reduced sometime after lead exposure stops^(9,24).

In female animals, lead exposure has altered the estrus (menstrual) cycle and has decreased fertility⁽¹⁴⁾. A study of pregnant women and their offspring found that the mothers of premature babies had significantly higher mean lead blood levels than did mothers with normal pregnancies⁽⁷⁾.

* I have reviewed the paper by Zielhuis in which certain studies concerning reproduction are analyzed. Some of his criticisms are noted in the Appendix. Many of the problems he noted do not destroy the overall validity of the studies cited here; they do point toward the need for other studies. As he points out, the human male studies are indicative and not conclusive. I disagree, however, with his contention, that the studies on male reproduction including man and animal do not support lowering male blood leads below 70ug/100ml⁽¹⁵⁾

Lead can cross the placenta; levels of blood lead found in the human fetus or embryo are often comparable with those found in the mother^(2,11), although some studies found less lead in the fetal blood⁽⁷⁾ while others found higher levels in fetal blood⁽⁴⁾.

Yet another study revealed altered enzyme activity (ALAD) in the blood of experimental animals whose mothers were exposed to lead during gestation -- even though the mothers had no such biochemical changes in their blood⁽¹⁵⁾. Thus, subclinical changes can be seen in offspring at lead levels that may not affect the parents. The explanation for this phenomenon may be that because the tissues of the fetus are rapidly developing, they may be more vulnerable to adverse effects of chemicals than are adult tissues.

Pregnant animals administered lead have suffered a variety of malformations^(8,12,19) indicating that lead can have teratogenic effects in several animal species. No specific birth defects, however, have ever been reported in children of lead-exposed parents⁽²¹⁾.

Lead exposure of either parent has been known to adversely affect offspring. E.g. the survival weight of pups past weaning was significantly reduced when either the male or female parent was exposed to lead. The loss was even more dramatic when both parents were exposed.⁽²²⁾

Similarly, animal studies show that offspring suffer learning deficiencies when their mothers are exposed to lead⁽⁵⁾, but that paternal exposure can also be detrimental⁽³⁾. Exposed men and women might easily overlook such subtle, neurologic damage (e.g., slight deficits in IQ, short attention spans, altered behavior, or faulty motor coordination) if it existed in their children.

Finally, lead is known to be secreted in the breast milk⁽¹⁷⁾ and therefore nursing infants may also be at risk.

Certainly not to be overlooked in this discussion are the recent reports showing increased blood lead levels in children of lead workers, resulting from lead dust being inadvertently carried into the home. Many of these children had blood lead levels over 30ug/100ml. Thus, spouses of lead workers -- some of whom may be pregnant -- and their children can be unwittingly exposed to lead by contaminated clothing.

To reiterate, further studies need to be done to determine the precise exposure to lead that can adversely affect reproduction or the later development of children of lead-exposed parents. But the combination of already existing studies of damage in both males and females is enough evidence that serious detrimental effects on reproduction can occur in either sex. Enough is now known to constitute a clear call to preventive action.

Response of Industry

It is important to briefly examine the response of industry to this scientific evidence of the harm to both male and female reproduction. In what may be a first at an OSHA standards hearing, industry does not appear to dispute the fact that lead exposure can adversely affect reproduction. In fact, industry has reacted to some of the scientific evidence about these hazards of lead exposure. The following case examples are representative of industrial policies that, in some instances, have been implemented on a nationwide scale:

Bunker Hill Smelter, Kellogg, Idaho:

37 women at the Bunker Hill smelter in Kellogg, Idaho, were informed last year that they could no longer work in lead operations at the smelter because of the potential effects of lead on their future children. Women who were fertile were transferred to jobs that the company said were safer, but not all of the transfers were at the same rate of pay. (28)

St. Joe's Mineral Corporation, Monaca, Pennsylvania, smelter:

Only 27 of the 1500 workers in the zinc smelting division were women. In August, 1974, 17 women were transferred out of "high lead" areas unless they could prove that they could no longer bear children. One woman was sterilized and only then was she allowed to return to her job. The transferred women earned an average of \$.20 per hour less than on their previous jobs (27).

General Motors of Canada, Ltd., lead storage battery plant, Oshawa, Ontario:

A mother of four who was employed at the lead storage battery plant was one of six women told they would have to prove they were no longer fertile in order to continue working with lead. She had herself sterilized instead of being transferred to a lower-paying position (29).

Increasingly, as these examples reveal, the response of industry has been to "protect" women workers from lead's reproductive hazards by refusing to hire them or by forcing them to prove that they can no longer bear children. For obvious reasons, this facile approach to a serious problem is patently unfair.

Moreover, industry has not come up with any similar "protections" for their fertile male workforce.

Why has industry focused only on women, when there is also evidence of harm to men? Why do they so readily embrace the studies demonstrating harm to females and their offspring and so insistently dispute the validity or ignore the studies involving males? Presumably, industry witnesses at this hearing will address this question. But several reasons have already become clear. First of all, it must be realized that the traditional exclusion of women from the lead industry has resulted in a proportionately small number of women working there today. Thus, they are excluding only women because it is easier (and cheaper) to move these women out than it is to institute the necessary controls to protect all workers -- men and women.

They are also singling out women because -- as some corporate medical people have pointed out -- they fear liability if a worker gives birth to a deformed baby. (This fear has resulted in certain companies' "selecting out" all women or all fertile women because of difficulties in quickly determining when a woman becomes pregnant. In essence, they consider all women pregnant at all times.) It is not as easy to make the causal link between a male worker's lead exposure and the miscarriage of his wife or their inability to conceive a child. Thus, the chance that a male worker would sue, or that he would successfully sue, his employer in the lead industry because of reproductive damage is more remote than a woman worker's.

Effects of exclusionary policies

The selection of only women workers for protection from reproductive hazards by modern industry is similar to the protective labor legislation of the early part of this century. But in the 1970's we need a contemporary approach to protecting workers; we should not rely on what was done 50 years ago as an easy solution to our current problems.

One of the most dramatic changes in the workforce in the last 50 years has been the increasing number of women workers. This phenomenon cannot be ignored when setting OSHA standards. The changing pattern in employment of women reflects a basic transformation in American life. Changes in the economy, wars, a move to the cities, advances in technology, educational achievements, changing social attitudes and marriage patterns, legalized contraception and abortion, the rising divorce rate, new equal employment laws, the feminist movement, the growth of day care, -- all have contributed to the changing status of women in the job market.

There are now 36 million women workers in the United States; about 65% of them are of child-bearing age. Thus, if women in the childbearing years could not work where there was lead exposure, then almost 2 out of every 3 female applicants for the estimated 1.3 million lead jobs would be turned away. Because employment opportunities for women are already severely limited by other external factors, closing the door to 1.3 million jobs is unacceptable.

But, some people still argue that women don't need jobs as much as men do. Facts simply don't support this myth. Gone are the days (if they ever really existed) when most women worked for "pin-money". Gone also is the picture

of the typical American family with working husband, homemaker-wife, and two children. According to a March 1977 Labor Department study, this "typical" family now makes up only 7% of the nation's families. More significantly, however, over half of all women workers are single, widowed, divorced, or separated, or have husbands who earn less than \$7,000 per year. Moreover, 1 out of 10 working women are heads of household; for minority women, the number is 1 out of 5. Thus, women work because they must.

Finally, despite equal employment and equal pay laws, women still earn substantially less than their male-counterparts. In 1975 the average salary for a woman worker was under \$7000 and that of a male over \$12,000. In part, these pay differences result from traditional channeling of women into low-paying, dead-end jobs.

The refusal to hire fertile women in certain industrial jobs could help to perpetuate the disparities between male and female earnings. For example, someone working in a lead battery plant might earn \$5-7 per hour, a bank teller or file clerk might earn \$3.50, and a waitress \$1.70 an hour plus tips.

Moreover, in certain areas where battery plants or smelters are located, there may be few industrial jobs available that don't involve lead exposure. For example, in Visalia, California, the Prestolite battery plant is one of the only industrial employers. If a woman wanted to work in the plant but was refused on the grounds of her sex and fertility, then she might not find another satisfactory job. Another job option in that location might be working in the fields -- a job not without hazards of its own.

In Kellogg, Idaho, one of the main employers is the Bunker Hill smelter. A woman who applied for a job there and was refused could easily remain unemployed or be forced to accept a lower-paying job -- a serious economic penalty for being a fertile woman.

Thus, evidence on the economic necessity for women to work, their lower earnings, and their unequal access to higher paying jobs, vividly demonstrates why a policy of excluding fertile women from jobs involving lead cannot be tolerated.

Unacceptable options for OSHA in standards-setting.

Section 6(b)(5) of the Occupational Safety and Health Act instructs the Labor Department to

"set that 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..." (emphasis added)

Few, if any, groups, be they government, industry, labor, or science, appear to dispute the fact that this requires OSHA to have a very definite role in protecting workers' sexual functions and abilities to conceive, father, and raise normal, healthy children. The question is how to implement this mandate when setting standards in order to protect the reproductive capabilities of men and women.

Several unacceptable alternatives to resolve this problem have been suggested to the Labor Department and some are already in practice by employers. Most of these "solutions" start from the assumption that having babies is a "woman's problem" and thus dismiss any suggestion that male workers need protection, too. But it takes a man and a woman to make a

baby and, as the evidence demonstrates, toxic chemicals don't discriminate.

Moreover, most of these "solutions" place the total responsibility for protection on the worker when, in fact, the legal responsibility rests with the employer.

Option No. 1 -- Fire all current female employees and refuse to hire other females unless they can prove they are no longer fertile.

The serious moral and legal pitfalls of this approach are obvious. First of all, it doesn't protect male workers from hazardous effects that exposure to lead may have on their reproductive systems.

Second, such a policy would require an employer to inquire into the fertility, sexual and birth control habits, and future child-bearing plans of a woman worker before she could begin or continue to work -- all of which would constitute a totally objectionable invasion of the woman's right to privacy.

Third, because many women do not have a choice about whether or not they want to work, this option could force women to be sterilized in order to get or keep a job -- a most disturbing departure from a woman's ethical right to keep her body whole.

Fourth, it violates the stated purpose of the Occupational Safety and Health Act, to "assure so far as possible every working man and woman in the National safe and healthful working conditions". The Act does not exclude fertile women from coverage.

Finally, this policy would appear to violate the principles of laws forbidding sex discrimination in employment, including Executive Order 11246, covering federal contractors, and Title VII of the 1964 Civil Rights Act. Section 703 (a)

of that Act provides that

"It shall be an unlawful employment practice for an employer:

- (1) to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's sex..." or
- (2) to limit, segregate, or classify employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's ... sex..."

Thus, setting standards which would ban fertile women from certain jobs would reduce employment opportunities for women and at the same time fail to protect men. Moreover, the effects of such standards would violate basic moral principles.

Finally, provisions in both the occupational health and sex discrimination laws would cast serious doubts on the validity of standards that were directed solely towards women, or subclasses of fertile or pregnant women.

Option No. 2 -- Fire, lay off, or transfer to a non-lead job a worker when she becomes pregnant without regard to seniority, fringe benefits, or wages.

This is also an inappropriate approach. To begin with, it would require mandatory pregnancy testing, again an invasion of privacy. Moreover, although some pregnancy tests can now accurately determine pregnancy within the first week after conception, these are not yet widely used. Thus, a woman might not discover that she is pregnant until a month or more after conception. As a result, the transfer could decrease potential harm, but it might not always be effected soon enough to protect the developing child.

Second, if this approach were used as the sole solution instead of reducing air lead exposures, the mother might have a very high blood lead at the time of transfer. If her blood lead level was excessively high, it might not return to a safe level for the duration of pregnancy. Thus, the fetus could be potentially endangered even with the transfer.

Third, if a woman did not get equal pay on her new work assignment, or if she were laid off or fired, she might be forced to conceal her pregnancy from her employer because the economic penalties associated with a non-equitable transfer would be too great.

Fourth, the Equal Employment Opportunity Commission (EEOC) which enforces Title VII, has considered at least two cases involving employers' practices of effectively forcing radiation workers to resign when they become pregnant. In these situations, the EEOC ruled that the employers had to find "less discriminatory alternatives" that would accomplish the same objective of protecting the pregnant workers. (26)

Finally, the issues of seniority, fringe benefits, and equal pay upon transfer cannot reasonably be said to be issues only for labor-management decisions or collective bargaining. Fewer than one out of five women workers in the United States belongs to a labor union.

Option No. 3 -- Inform the female workforce and new female job applicants of the reproductive hazards of lead and let them decide if they want to keep or take the jobs.

Although informing workers of hazards is a vital component of any occupational disease prevention program, it cannot serve as the only protection for workers. The burden for worker protection is on the employer and cannot be shifted onto the individual.

This option, taken in lieu of providing any health protections against exposure does not allow for "informed consent" but only presents female workers with a Hobson's choice: the health of their future children or their livelihood.

Finally,

Option No. 4: Have separate and different lead standards for women and men workers.

For example, men would be allowed to work at any job where the air lead levels were under $100\text{ug}/\text{m}^3$, whereas women could be employed only in those workplaces where the levels were under $50\text{ug}/100\text{m}^3$. Obviously, such a policy would provide little incentive for industry to institute engineering and other controls necessary to lower exposures. It would be much more expedient for an employer to simply employ only male workers and avoid the expense of modifying the hazardous environment.

Again, a policy which differentiated between men and women on the basis of sex may well violate Title VII. Separate standards would be like a modern version of "protective legislation" for women that courts have consistently overturned under Title VII.

Such a policy would also totally ignore the data on potential reproductive hazards to males exposed to lead. Thus, the result of this alternative: women get fewer jobs and men get less protection.

An acceptable approach to protecting workers from the reproductive hazards of lead.

There is only one approach which is morally, ethically, and legally acceptably. OSHA must set a standard for lead exposure, based on the best available evidence, that will insure that both men and women can work safely without harming either's ability to conceive, father, and raise normal healthy children.

Some employers have said that this is impossible; that they cannot be expected to protect everyone in their plants; that it will cost too much money to institute controls, and that it is more sensible to just keep out "susceptible" groups of workers. Of course, in this case the "susceptible" group as defined by industry could potentially constitute two out of every three women seeking jobs which have lead exposure. (The fact that large numbers of women don't work in lead plants now is immaterial -- many of them have been kept out of industrial jobs by illegal discriminatory practices. The results of these past practices cannot now be used to justify further exclusion of women.)

Some employers imply or state outright that requiring a standard to protect against reproductive dangers to either sex or harm to the fetus is unrealistic and that those who propose it are not "living in the real world".

But if we examine a recent NIOSH recommendation on exposure to anesthetic gases, we find that the agency suggested this very same concept, i.e., setting a standard strict enough to protect the man, woman, and fetus. NIOSH's recommendation to OSHA was that the level of anesthetic gases in operating rooms be reduced to the lowest detectable level -- 2ppm.

Their recommendation was based in large part on a nationwide study of anesthesiologists. The study revealed that when women working in operating rooms are compared with other female workers not exposed to waste anesthetic gases, the former group suffered from significantly more miscarriages, gave birth to more babies with defects, and had a higher incidence of liver disease and cancer.

The study also found that male workers and their children suffered adverse effects, too, although the results were not as significant statistically.

What was NIOSH's response to the discovery of these hazards? NOT that all fertile women be banned from the operating room. NOT that women be transferred out of the operating room when they became pregnant. Instead, NIOSH recommended that the necessary engineering controls -- in this case ventilation systems and scavenging devices -- be installed to remove the waste gases and thus reduce the levels of exposure as low as possible.

Similarly, when setting a standard for protection against exposure to lead, OSHA must consider the "best available scientific evidence". (Sec. 6(b)(5) of OSHAct.) Analysis of the evidence indicates that blood lead levels as low as 30 ug/10ml may exert harmful effects on reproductive processes or on the fetus. Thus, in order to protect against these and numerous other health effects of lead, OSHA must require a dramatic reduction in the allowable air lead exposures. This should be accomplished through engineering and other controls. To insure safety, reduction in air levels must result in a blood lead level for all exposed workers that does not exceed 30 ug/100ml.

Recommendations for the OSHA Standard.

The following suggestions concern only what the OSHA standard should contain with regard to special safeguards against the adverse effects of lead on reproduction.

1. The OSHA air lead level must be set to insure that no worker, male or female, has a blood lead level above 30ug/100ml.
2. If OSHA determines that this standard is not technologically feasible at this time, then it must set the lowest standard currently feasible and should develop interim protective procedures to be used until a reduction in air lead levels can be achieved. As an interim measure, the following transfer provisions to protect fertile workers must be included as part of the final lead standard (along with numbers 3-10, below):
 - a. Any worker employed in a lead area who is pregnant, breastfeeding, or seriously contemplating becoming a parent, shall be offered blood tests at least monthly to insure that blood lead levels do not exceed 30ug/100ml.
 - b. Any worker who is pregnant, breastfeeding, or seriously contemplating becoming a parent, and whose blood lead level is above 30ug/100ml, shall be immediately offered a temporary, voluntary transfer to a job without lead exposure, with retention of seniority, wages, and fringe benefits.
 - (1) In the event that such jobs do not exist, the employer shall devise some other administrative controls by which the employees at risk can continue to work with blood levels below 30ug/100ml. This might include shortened

shifts with make-up or "front" pay, rotation of employees, longer breaks, etc.

- (2) In plants or workplaces with collective bargaining agreements, the arrangements for such transfers, rotations, or other administrative controls shall be made with reference to existing local union contracts.

3. The air lead level must be the primary OSHA compliance tool, but during inspections OSHA compliance officers must also review the results of workers' lead tests to determine the adequacy of efforts to control exposure.
4. All workers exposed to lead must have an initial blood lead tests and medical examination after the standard goes into effect. Thereafter, they should be offered monthly blood tests whenever the air lead level is above the action level (one-half of the permissible exposure).

At the action level or below, workers should be offered blood lead exams at least every three months. In addition, workers should have the right to biological monitoring at any time that they suspect their lead exposure has increased.

Results of tests must be explained to workers in understandable language.

5. Employees (or job applicants) must not be forced by employers to answer questions about their fertility, sexual or birth control habits, or future plans for a family.

6. Free optional pregnancy testing and free sperm analysis must be offered to workers. Results of tests, with explanations, must be given to workers. This information should be considered part of the confidential medical record and not be disclosed without the prior written permission of the worker.
7. Workers should be encouraged to undergo medical examinations and biological monitoring, as well as to report pregnancies, but shall not suffer penalties for refusing to submit to such tests.
8. Employees (and job applicants) must be informed that excessive exposures to lead have resulted in reproductive difficulties, including fertility problems, menstrual disorders, stillbirths, and miscarriages, and other hazardous effects, so that they understand the significance of blood, sperm, and pregnancy testing. NIOSH shall develop a summary of such information in lay terms that employers will use in employee training and in pre-employment interviews.
9. Employers must be required to maintain records of the fertility and pregnancy experiences of employees and their spouses. Recorded information should include menstrual difficulties, difficulties conceiving, impotence, miscarriages, stillbirths, and birth defects or learning disabilities in children. This information shall be made available to the OSHA compliance officer, or NIOSH personnel, upon request. Again, workers shall be encouraged, but not forced, to supply this personal information. Wherever possible, spouses of

workers, with permission, should be interviewed in order to increase the accuracy of responses. Again, this information must be considered confidential.

This information on the outcome of pregnancy must be reviewed by NIOSH at five year intervals, starting five years after the effective date of the standard. It shall be analyzed thoroughly to determine any continued adverse effects of lead exposure on reproduction. If any effects are detected, NIOSH shall recommend that the lead standard be re-considered.

10. As outlined in the proposed standard, additional work practices must be implemented to lessen the possibility of accidentally taking lead home on the worker or his/her clothes, thereby endangering children and spouses. These practices should include required showers at the termination of the workday, provision and commercial laundering of work clothes, (regardless of the air lead levels), and clean change rooms.

When clothes are commercially laundered, the launderers must be advised of the hazards of lead and the precautions that are necessary to protect themselves.

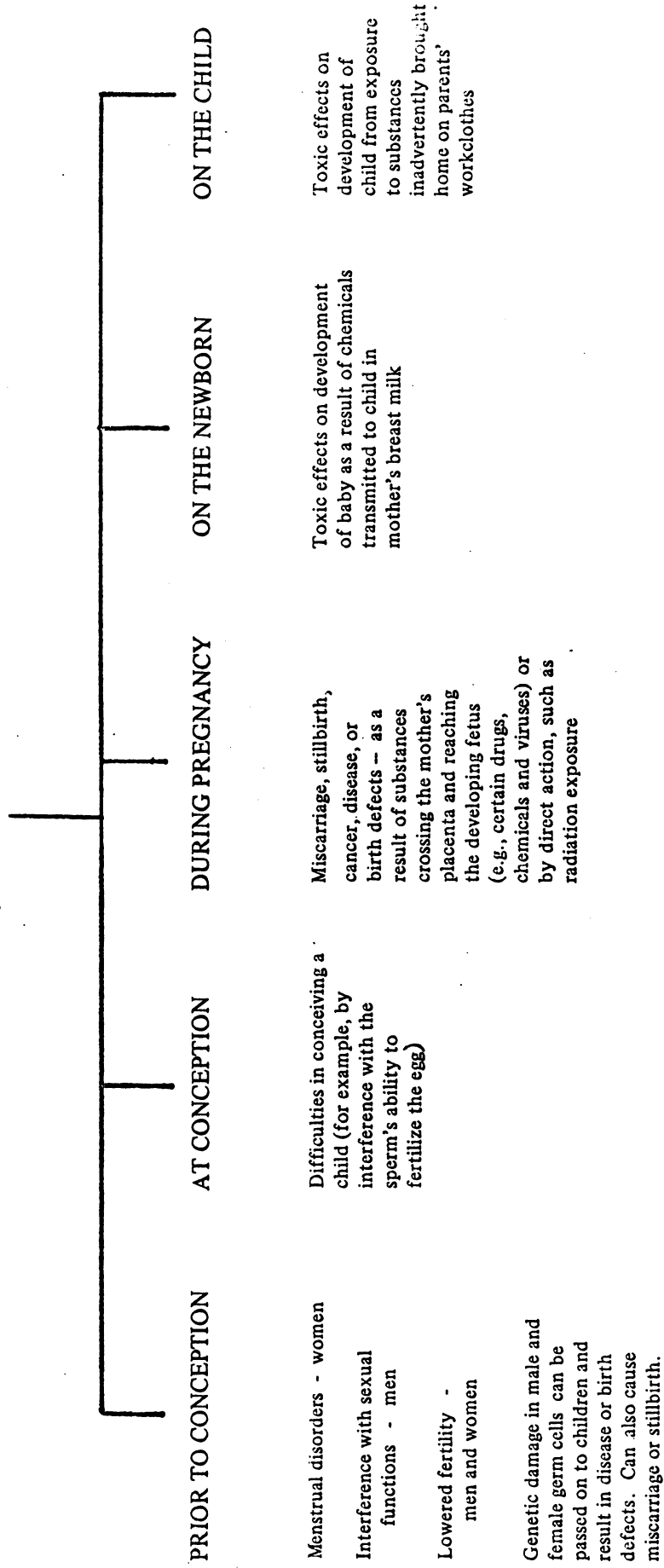
Conclusion.

Important work needs to be done to accurately determine the risk of low level lead exposures. But enough is known at present about potential adverse health effects to justify -- and require -- reducing the permissible air limits to levels significantly lower than the $100\text{mg}/\text{M}^3$ limit proposed by OSHA.

OSHA should set a standard for lead exposure which will protect ALL workers, male and female, including fertile men and women, as well as pregnant workers. Any standard which will result in failure to protect large segments of the workforce or which will discriminate against certain workers on the basis of their sex or fertility does not serve the stated purpose of the Occupational Safety and Health Act -- "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions..."

Moreover, such a standard would violate the basic principles behind equal employment opportunity laws, as well as basic social and moral precepts.

CHRONOLOGY OF POTENTIAL ADVERSE EFFECTS OF
JOB EXPOSURES ON REPRODUCTION OR
ON THE ABILITY TO HAVE NORMAL,
HEALTHY CHILDREN



From: Working For Your Life -- A Woman's
Guide To Job Health Hazards

By: Andrea M. Hricko with
Melanie Brunt, p. C-4

SUMMARY OF SELECTED SCIENTIFIC STUDIES

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SELECTED STUDIES OF LEAD EXPOSURE'S EFFECTS ON REPRODUCTION
CONDUCTED DURING THE LAST TEN YEARS*

<u>Group I</u>	<u>Authors and Date</u>	<u>Subjects Studied</u>	<u>Lowest (or lowest mean) blood lead level where adverse effect seen</u>	<u>Selected Significant Findings & Comments</u>		
				<u>Reg. I</u>	<u>Reg. II</u>	
	Fahim, et al, 1976	Pregnant women not occupationally exposed	26 mg/100ml	96%	70%	Reg. I: did not live in "lead belt"
				Normal Pregnancy		
				3%	13%	Reg. II: lived in "lead belt"
				1%	17%	
				Preterms		
				Premature membrane rupture		
<u>Maternal Mean Blood Leads</u>						
				<u>Reg. I</u>	<u>Reg. II</u>	
				13 ug/100ml	14	
				Normal Pregnancy		
				26	29	
				Preterms		
				only	26	
				Premature membrane rupture	1 case	

Comments:In both regions, the blood lead levels of mothers with preterms or premature membrane ruptures were nearly twice as high as in normal pregnancies. (Average was under 30 ug/100ml)

Author does not offer explanation for the unexpectedly elevated blood leads in Reg. I. nor the unexpectedly low blood leads of some women in Reg. II.

* A few selected studies; not in any way intended as an exhaustive review.

Group I (cont.)	<u>Authors and Date</u>	<u>Subjects Studied</u>	Lowest (or lowest mean) blood lead level where adverse effect seen	<u>Selected Significant Findings & Comments</u>				
				Blood lead levels (ug/100ml)				
	Lancranjan, et al, 1975	Male storage battery workers, sperm analy- sis and study of sexual dynamics	41±12 (S.D.) ug/100ml	74±26	53±21	41±12	23±14	
				% with altered spermatogenesis	93	68	63	28
				% with teratospermia	86	58	31*	16
				% with asthenospermia	50	51	42	24
				% with hypospermia	50	44	42	28
				* not significant				
				<u>Comment:</u>				
				Even slightly increased lead exposure (41ug/100ml ± 12) is associated with sperm problems. As Zielhuis has pointed out, there are some statistical problems due to overlapping groups, large standard deviations, and no matched controls. Dose-response relationship seen for difficulties with erections/5				
				<u>Definitions:</u> teratospermia = malformed sperm hypospermia = decreased number asthenospermia = decreased motility				
	Varma, et al, 1974	Male mice, fed 2% lead sub-acetate		Pregnancy rate in mates: 27.6% when mice lead- exposed; 52.7% in controls.				
				Fertility of treated males reduced by 50%. Increased number of early fetal deaths in offspring of treated group.				

Group I (cont.)	<u>Authors and Date</u>	<u>Subjects Studied</u>	<u>Lowest (or lowest mean) blood lead level where adverse effect seen</u>	<u>Selected Significant Findings & Comments</u>		
				Paternal exposure only	Maternal exposure only	Both parents exposed
Group I (cont.)	Hilderbrand, et al, 1973	Male and Female rats, varying doses	30 ug/100ml	<p>Males: At 50 ug/100ml (4 rats), spermatogenic activity halted; testes damaged. At 30, increased prostate weight; Impotence--refusal to copulate with estrus females; Less sperm motility. At 19, no effects seen.</p> <p>Females: At 53 ug/100ml PbB (blood lead), persistent vaginal estrus. Ovarian cysts developed. Reduction in corpora lutea. At 30, irregular estrus cycles. At 14, no adverse effects noted.</p> <p><u>Author's Comment:</u> Females were adversely affected by lower doses of lead than male animals, possibly due to different enzyme activity in the liver.</p>		
	Stowe, et al, 1971	Male and Female rats, fed lead acetate; 2nd generation observed		<p>% with reduced # of offspring per litter* 15% 26%[†] 35%[†]</p> <p>% with reduced birth weight 12%[†] 19%[†] 29%[†]</p> <p>% with reduced pup survival 18% 41% 67%[†]</p> <p>* percentage increase over controls † significant increase</p> <p><u>Author's Comment:</u> Conclude that paternal effect is due to lead-toxic spermatozoa which fertilize the normal ova. Paternal effects included reduced birth weight and reduced number of weaned pups per litter. Gameto toxic effects have additive male and female components.</p>		

Authors and Date	Subjects Studied	Lowest (or lowest mean) blood lead level where adverse effect seen	Selected Significant Findings & Comments
Group II			
Forni, et al, 1972	Lead-exposed male workers in storage battery plants, foundries, etc., and workers previous- ly poisoned but not exposed for last 18 months. Study of chromosomal changes	56 ug/100ml + 17 (S.D.)	<p>Workers with clinical symptoms showed highly significant increase of chromosomal changes over controls.</p> <p>Workers with preclinical lead intoxication with no symptoms of disease (78± 25ug/100ml mean) showed a significant increase of chromosomal changes.</p> <p>Those previously poisoned but who had no exposure to lead in 18 months showed no significant increase in chromosome changes over controls.</p> <p><u>Author's Comment:</u></p> <p>The rate of chromosomal changes seems to reduce in a number of months or years after workers leave lead exposure.</p>
<p><u>Note:</u> A number of chromosome studies have been positive and a number have been negative.</p>			
Group III			
Hubermont, et al, 1976	Pregnant rats, lead in drinking water	Above 32 ug/100ml but under 65	<p>At 10ppm administered to mothers before and during pregnancy and also while nursing, offspring had increased blood and kidney lead concentrations.</p> <p>Associated with a decrease in ALAD activity* in blood of offspring. Not seen in mothers.</p> <p>With administration of 1ppm lead (resultant blood lead level = 32 ug/100ml), no effect seen in offspring</p> <p>* ALAD is an enzyme inhibited by high blood lead levels. If significant inhibition occurs, it can lead to overt changes in the blood, such as anemia.</p> <p>(A 1970 study -- found a correlation between brain and blood ALAD activity in suckling rats.)</p>

<u>Group IV</u>	<u>Authors and Date</u>	<u>Subjects Studied</u>	<u>Lowest (or lowest mean) blood lead level where adverse effect seen</u>	<u>Selected Significant Findings & Comments</u>
	Carson, et al, 1974	Pregnant ewes, fed lead throughout gestation	34 ug/100ml	<p>Controls: 4ug/100ml Low exposure: 18 Higher exposure: 34</p> <p>} Maternal levels during gestation</p> <p>Lambs, ages 10-15 months, prenatally exposed to maternal blood levels of 34ug/100ml required more days to learn visual discrimination task than controls. Time among group with 18ug/100ml maternal blood levels did not differ from controls.</p> <p><u>Author's Comment:</u> There may be too few animals at PbB of 18 to show effects OR there could be a threshold between 18 and 34ug/100ml. Study supports government guidelines that pregnant women's blood leads not exceed 30ug/100ml.</p> <p><u>Comment:</u> Unknown how closely correlated sheep and human blood leads would be.⁶</p>
	Brady, et al, 1974	Rats: one or both parents, or neither, had received lead acetate		<p>The three lead-exposed groups of offspring made more errors on a black-white discrimination water T-maze than did controls. The groups with both parents exposed had longer swimming times than single-exposed parent.</p> <p>Exposure of either parent yields a learning deficit in offspring of about equal dimensions.</p>

<u>Group V</u>	<u>Authors and Date</u>	<u>Subjects Studied</u>	<u>Lowest (or lowest mean) blood lead level where adverse effect seen</u>	<u>Selected Significant Findings & Comments</u>
	Garshani, et al, 1974	Pregnant women, not occupationally exposed, and their newborn babies		High level of correlation between mean blood lead in mothers (10.3ug/100ml) and that in corresponding infants (10.1). Newborn babies have blood levels comparable to the maternal levels.
	Barltrop, et al, 1969	Maternal and cord blood lead levels at term. Also, study of aborted fetuses.		Correlation found between maternal and fetal cord blood leads: Maternal: 13.9ug/100ml Fetal: 10.8ug/100ml In fetuses studied, lead transfer across placenta was first detected at about 14th week of pregnancy.
	<u>Note:</u> Some studies show high correlation between maternal and fetal blood lead levels; others (e.g. Fahim) show variations in levels. At least one study -- shows higher blood lead levels in fetus than mother. ⁴			
<u>Group VI</u>	Gilani, et al, 1973	2 day old chick embryos administered lead acetate		Most common anomalies were high incidence of neck abnormalities, malformed limbs, and retarded growth. Increasing doses caused increased number of malformations.
	McClain, et al, 1970	Pregnant rats and mice, lead injected	30 ± 6ug/100ml	At 50mg/kg of lead, the mean blood lead level of rats was 50 ± 7ug/100ml. For mice at same dose: 30 ± 6ug/100ml. Defects seen at this dose: Mice: Increased incidence of cleft palate Rats and mice: Non-ossification of cervical centri (i.e. failure in normal bone development)
	<u>Note:</u> Authors state that there was limited placental transfer of lead in these animals.			

<u>Group VI</u> (cont.)	<u>Authors and Date</u>	<u>Subjects Studied</u>	<u>Lowest (or lowest mean) blood lead level where adverse effect seen</u>	<u>Selected Significant Findings & Comments</u>
	Ferm, et al, 1967	Pregnant hamsters, injected with lead salts, during days 7-9 of gestation.		High incidence of skeletal (sacral and tail) malformations in embryos.
<u>Group VII</u>	Kostial, et al, 1974	Pregnant and lactating rats.		Lead was administered during gestation, on 4th day of lactation, and at day 15 of lactation. More lead was transported to offspring during late stages of breast-feeding than as a result of transplacental passage or earlier stage of lactation.

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