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November 20, 19

TO: SOCMA OFFICIAL REPRESENTATIVES
AIHC DESIGNATED CONTACTS

LEGAL ISSUES - REPRODUCTIVE HEALTH HAZARDS

Gentlemen:

The American Conference of Governmental Industrial Hygienists held a Symposium in Tucson earlier this month dealing with "Protection of the Sensitive Worker." The Symposium dealt with a wide variety of issues involving the identification and protection of the sensitive worker but one of the most important papers presented during the meeting summarized the legal issues involved with protecting employees from reproductive health hazards.

The paper was prepared and presented by Mr. Robert C. Barnard of Cleary, Gottlieb, Steen & Hamilton and it will be included eventually in the official Proceedings of the Conference. However, we have received permission to distribute a pre-publication copy of the paper to our membership and we strongly encourage you to forward it to those in your company's Legal Department involved with this complicated issue.

Sincerely,

Ronald A. Lang
Executive Director

Encl.

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Protection of the Sensitive Worker

A Symposium

Co-Sponsored by

American Conference of Governmental
Industrial Hygienists

and

Arizona Center For Occupational
Safety and Health

Legal Issues: Reproductive Health Hazards

By

Robert C. Barnard

November 11, 1981

Legal Issues: Reproductive Health Hazards

The program for this symposium refers to the "sensitive" and, sometimes, to the "susceptible" worker. These are terms not defined in the law nor, indeed, in court decisions. I propose, therefore, to divide my discussion of the legal issues into three sections:

- who is an "employee" under the OSH Act,
- interaction of Title VII of the Civil Rights Act and the OSH Act,
- decisions or regulations under the OSH Act.

The Entities Involved

Discussion of reproductive health hazards must be based on a clear understanding of the entities involved. There are issues which concern the male or female worker. But it is important to remember that there is a third entity to be considered - the fetus. The fetus may be susceptible to hazards which also affect the parent but may also be harmed by exposure which does not overtly harm the parent.

Courts have upheld the right of a child to recover from injuries in utero. Cases have arisen primarily in the product liability area. It is important, therefore, in the discussion which follows to keep in mind the three entities concerned: the male worker, the female worker and the fetus.

Who is an "employee" under the OSH Act

Section 6(b)(5) of the OSH Act directs OSHA to develop standards for toxic or harmful agents that assure that "no employee will suffer material impairment of health or functional capacity..." The language appears sweeping, but is it reasonable to assume

that it means that the standards must protect against all sensitivities or susceptibilities?

Does the statute mean OSHA must adopt standards which will assure that a blind person driving a truck will suffer no impairment? Does a bridgeworker's job have to be made safe for those suffering from acrophobia? Does farm work in the sun belt have to be made safe for the person with xeroderma pigmentosa?

In order to construe the words of the OSH Act it is necessary first to look at the meaning of the term "sensitive worker." The term, which has come into both popular and regulatory use, appears nowhere in the statute, and the legislative history offers very little help in the definition.

I suggest that the term "sensitive" is easier to understand in the employment context if you translate the word as meaning "limitation." There are several kinds of limitations affecting workers:

- limitations voluntarily incurred -- e.g., increased risk of a smoker in relation to employment involving asbestos or radon daughters;
- genetic limitations - xeroderma pigmentosa is an example,
- physical limitations -- strength, height, eyesight, etc.

I believe it is generally accepted that it is legitimate for an employer to establish criteria for employment which fairly measure and predict the performance on the job so long as the criteria do not run afoul of the non-discrimination provisions of Title VII of the Civil Rights Act. Thus an employer can specify, for example, reading skill, strength, height, eyesight and manual skills for employee selection so long as the criteria are not discriminatory.

Employment criteria may be health oriented. For example, Johns Manville has established a rule against employing smokers in its asbestos plants. There can be little doubt that this employment criterion is designed to deal with the health problems caused by the synergistic interaction of smoking and asbestos; the cancer risk to smokers is increased by a factor of 8 or 9 over non smokers. The Johns Manville rule had two parts. One part involved smoking by existing employees; this included psychological guidance and forbidding smoking in the plant area with sanctions escalating to dismissal. Part two established no smoking criteria for hiring. The Court of Appeals upheld an arbitration decision that part one conflicted with the collective bargaining agreement 1/; part two of the policy has not been challenged by the union or the government.

In Boyce v. Reynolds Metals Co., 532 F.2d 638 (8th Cir. 1976) the court affirmed dismissal of a suit alleging discrimination on the grounds of race. The court found that the employee was dismissed because his asthma condition made it impossible for him to work in the chemical plant. No contention was made that the plaintiff's asthma condition was not a proper basis for dismissal. The record in Boyce indicated that the employer had taken reasonable steps to find another position for the plaintiff where he would not come in contact with the chemical fumes, but that none was available. Boyce supports

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1/ Johns-Manville Sales Corporation v. International Assoc. of Machinists, Local Lodge 1609, BNA Daily Labor Report (No. (145) D-1, July 25, 1980.

the proposition that termination of employment may be justified where the employer was unable to provide working conditions to enable the employee to maintain his health.

Job criteria bearing on the subject of reproductive hazards have been upheld. In EEOC v. Olin Corporation, No. A-6-78-186 (W.D.N.C. December 29,1980), the Federal District Court upheld an employment policy under which women of childbearing capability were not allowed to occupy certain job classifications in the plant because of possible harmful effects of certain chemicals on the unborn fetus. 1/

The plant classified workplaces into three categories:

- "restricted areas" where there was exposure to abortifacient or teratogenic agents,
- "controlled areas" where the contact with agents is limited and the exposure lower, and
- areas of unrestricted jobs.

Under the policy, women of childbearing capability were barred from certain jobs in "restricted areas." Women were permitted to work in jobs in "controlled areas" after receiving counseling and upon promising to notify their supervisor if they became pregnant.

The policy provided for review of job category as Olin succeeded in reducing exposure and the Court found Olin was making a good faith effort to reduce exposure levels and to reclassify jobs.

Olin's policy did not exclude males from any jobs because of reproductive hazards. The Court found, however, that the Olin policy was legitimate (and nondiscriminatory) because

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1/ The case is pending on appeal by the EEOC.

the purpose of the policy was to protect the unborn and was based on sound medical knowledge.

The employment criteria may also be directed specifically at the protection of the fetus. B. F. Goodrich Company adopted a corporate policy for the protection of the fetus from transplacental carcinogenesis. Under that policy an unmarried female of childbearing age (under 50) was transferred from a job involving exposure to vinyl chloride to another position. Subsequent voluntary sterilization would not, under the policy, be the basis for reinstatement.

The transferred worker brought a sex discrimination suit and sought a preliminary injunction. Doerr v. B. F. Goodrich Co., 484 F. Supp. 320 (N.D. Ohio 1979). The court refused an injunction on the ground that no irreparable injury was shown (the employee was retained and paid the same wage in the transfer position). The court also discussed the question whether the complainant was likely to prevail on the merits at a trial and concluded that she would not. In reaching that conclusion the court

- noted the company's position on potential liability because the mother cannot waive the rights of a child born with defects because of maternal exposure;
- held that the policy was supported by medical and scientific avoidance which demonstrated little likelihood the complainant would prevail;
- rejected the claim that the policy was discriminatory because it did not deal with risks of male mutagenesis.

Doerr subsequently filed a complaint with the Ohio Civil Rights

Commission. In a decision dated August 13, 1980 the Commission found no probable cause of discrimination and dismissed the complaint. 1/

Similarly, the State of Wisconsin Equal Rights Division upheld as non-discriminatory a hiring policy of BASF Wyandotte which barred women of childbearing age from jobs involving exposure to mercury because of the potential damage to the fetus. 2/

It is also interesting to note that as a condition for the use of Ferriamicide against fire ants, EPA provided that women of childbearing age are prohibited from applying that pesticide. 44 Fed. Reg. 11,111, 11,117 (February 27, 1979). Deputy EPA Administrator Barbara Blum defended the prohibition as an essential "trade off", and noted that a woman could waive rights as to her own exposure but could not waive rights of a child who may be injured.

Finally, it is worth noting that both EPA and OSHA took action against the pesticide DBCP (dibromochloropropane) which, among other effects, caused male sterility. (EPA: Suspension Order and Notice of Intent to Cancel. 44 Fed. Reg. 65135 (November 9, 1979)); (OSHA DBCP final standard, 43 Fed. Reg. 11514 (March 17, 1978)). No issue of discrimination arose in those proceedings.

Based on this discussion, I suggest that the term "no employee" in the OSH Act should be interpreted to mean "no worker who satisfies reasonable criteria for employment or

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1/ Carol A. Doerr v. B.F.Goodrich Company (3)-1-08-27-79 (12395) 11-79; 052-79-2498.

2/ Wisconsin Dept. of Industry, Labor & Human Relations, ERD Case No. 7800624.

promotion." The interpretation I have offered suggests a reasonable meaning for the words "no employee" which might otherwise be so broad or vague as to raise a question of unlawful delegation of legislative authority by leaving too much to agency discretion.

Under this interpretation an employer can adopt reasonable criteria under which the employer can refuse to hire or promote workers, or can move or terminate workers, with certain limitations (or sensitivities). The job criteria must be soundly based and can include exclusion of women of childbearing age from certain jobs for medical reasons to protect the fetus.

Interaction of Title VII of the
Civil Rights Act and the OSH Act

Title VII of the Civil Rights Act (42 U.S.C. §2000e) forbids discrimination in employment on grounds of race, color, religion, sex or national origin. The obligations of employers not to discriminate are spelled out in "Uniform Guidelines On Employee Selection Procedures" published by the Equal Employment Opportunity Commission, 43 Fed. Reg. 38290 (August 25, 1978).

Both Title VII and the Uniform Guidelines leave intact the principles set out above regarding the legitimacy of hiring and promotion criteria based on sound medical or scientific grounds. They also leave intact the decisions which permit an employer for sound medical reasons to exclude a woman of childbearing age from certain jobs.

On February 1, 1980 the EEOC and the Department of Labor proposed Interpretative Guidelines on Employment Discrimination and Reproductive Hazards, 45 Fed. Reg. 7514. Those

guidelines proposed to establish the principle that discrimination on the basis of sex includes discrimination based on pregnancy or childbearing capacity. The proposed guidelines would have set up an elaborate structure of testing both male and female workers before an exclusion policy would be permitted and required an affirmative showing of no reproductive hazards to workers of the sex not excluded.

The proposed guidelines were based on two concepts:

- it is discriminatory to exclude workers of one sex from a known reproductive hazard until tests have shown that there are no reproductive hazards to workers of the other sex,
- the fetus was not recognized as a separate subject for protection. Hazards to female workers and to fetuses were assumed to be identical.

There was extensive public comment on the point that the proposal would have prevented protection from known hazards to one sex or to the fetus while tests went on concerning possible hazards to the other sex. The proposal was also based on a determination of questionable scientific validity: hazards to the fetus were not distinguished from hazards to the mother as a valid basis for occupational rules. The proposed policy ignored liability to a child injured by exposure, a liability the mother could not waive. The proposed guidelines were withdrawn January 16, 1981. 46 Fed. Reg. 3916.

Thus, a job criterion which is soundly based on protection of the fetus remains valid under Title VII. It follows also that a job criterion involving a validly demonstrated reproductive hazard to males only or to females only would also be valid.

Regulations and Decisions Under the OSH Act

In two recent cases the Supreme Court upheld the OSHA Cotton Dust [1] standard and refused to review the decision of the Court of Appeals upholding the OSHA Lead standard. [2] Each of these standards has provisions which have some bearing on the question of the protection of the sensitive worker. The Lead standard specifically addresses issues of reproductive hazards.

Unfortunately, the susceptible worker provisions in the Lead and Cotton Dust standards were not central issues in those cases. The decision of the Supreme Court in Cotton Dust and the decisions of the District of Columbia Circuit Court of Appeals on both standards only glanced at the question. [3] OSHA's authority to set standards covering susceptible workers will remain at least somewhat unclear until the Supreme Court or Congress speaks on this issue.

Cotton Dust. The standard required employers to grant to employees who could not wear a respirator the opportunity to transfer to another position if available. The standard

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1/ American Textile Mfgrs. Institute, Inc. v. Donovan, 49 U.S.L.W. 47206 (1981).

2/ United Steelworkers v. Marshall, 592 F.2d 893 (D.C. Cir. 1980) cert denied sub. nom Lead Industries Association, Inc. v. Donovan, 49 U.S.L.W. 3964 (1981).

3/ The Court of Appeals in a footnote rejected a contention by an amicus curiae that medical removal provisions are required by the OSH Act to prevent sex discrimination by exclusion of fertile women from certain jobs. The Court held that an OSHA proceeding is not the place to address hypothetical Title VII questions id. at p. 1238 n. 74.

also required the employer to guarantee no reduction in wages or benefits due to the transfer. 29 CFR § 1910.1043(f)(2)(v)(1980).

The transfer provisions were not challenged and neither the Court of Appeals nor the Supreme Court disturbed them. The Supreme Court did, however, strike down the wage guarantee because OSHA had failed to make the necessary findings justifying it as a safety or health measure.

The worker unable to wear a respirator is "susceptible" under the definition proposed above because the inability is a limitation. Neither the Court of Appeals nor the Supreme Court focussed on the scope of OSHA's authority under § 6(b)(5) to provide protection for susceptible workers or the employer's right to establish employment criteria excluding such workers.

It is interesting to note that in Questions and Answers published after the noise standard (29 C.F.R. § 1910.95 (1980)), OSHA in response to questions about an employee who could not wear protective equipment asserted without discussion that an employer may not expose the employee to excessive noise levels. OSHA did not answer the critical question whether an employer could dismiss such an employee if he could not provide working conditions to enable the worker to maintain his health. (Q's & A's to Part. 1910, OSHA 2095 (December 1973) reprinted in Empl. Saf. and Health Guide (CCH) §1119.69.)

Lead. In the rulemaking, OSHA concluded that exposure to lead has severe effects on the reproductive capabilities of males and females. OSHA identified genetic, gametotoxic, intrauterine and extrauterine effects from lead exposure. It concluded that the fetus and newborn are sensitive to lead; the

former through transplacental passage from the mother and the latter from lead in breast milk. (43 Fed. Reg. 52952, (November 14, 1978); Attachments to the Preamble to the Final Standard, 43 Fed. Reg. 54354, 54398, (November 21, 1978).)

Discussing its duty to deal with these adverse health effects, OSHA made the following statement:

> "OSHA must promulgate a standard which prevents occupational disease resulting from both acute and prolonged or chronic exposure to lead; it must likewise guard against the onset, progression or severity of chronic degenerative diseases of aging workers. The degree of protection to be provided must extend over the full span of a working life and must cover the more susceptible, as well as the more robust members of the exposed group." (43 Fed. Reg. 52963/3-52964/1) (Emphasis added.)

OSHA views of its authority to protect the fetus because damage to the fetus is an impairment of the female worker's health and its views on the limitations of its authority were further set out in the statement:

> "OSHA believes that damage to the fetus represents impairment of the reproductive capacity of the lead exposed parent. While OSHA believes that a standard should be set which protects all persons affected -- male and female workers, and the fetus -- the agency is limited by the requirement that a standard be feasible." (43 Fed. Reg. 52966/1) (Emphasis added.)

OSHA did not address the separate issue of protection to the fetus as a separate entity.

In the Attachments to the Preamble published after the standard, OSHA referred to the effect of lead exposure on "particularly sensitive individuals" and identified those with sickle cell traits as one large subgroup of sensitive individuals. The effects on these individuals "must be considered" OSHA said "in the promulgation of this standard" (43 Fed. Reg. at 54361/2).

Based on this background of findings, OSHA established an across-the-board permissible exposure level (PEL) of 50 micrograms of lead per cubic meter of air (50 ug/m^3) averaged over an eight hour period. The Agency acknowledged that the PEL will not maintain blood levels which it had determined were necessary to protect pregnant women or workers planning pregnancies; a lower level (30 ug/m^3) was necessary to protect these workers but the agency found a standard at the lower level was not feasible. (43 Fed. Reg. at 52966/1). There was no discussion of levels necessary to protect sub groups of sensitive workers such as those with sickle cell traits.

The Agency maintained that despite the inadequacy of the standard to protect pregnant women or workers planning pregnancies, adverse reproductive affects on these workers would be minimized by the following provisions:

(1) biological and air monitoring above an action level of 30 ug/m^3

(2) medical surveillance and a medical removal program

(3) an education program for the workers.

(43 Fed. Reg. at 52966/1 and 2).

The Medical Removal Program (MRP) is the most radical plan OSHA has promulgated to deal with adverse medical effects and was regarded by OSHA as a precedent-setting regulatory experiment. Under the MRP, workers must be removed (not transferred when a position becomes available) where there is a medical determination that the employee has a "detected medical condition" that places him at "increased risk of material im-

pairment to health from exposure to lead." 29 C.F.R. §1910.1025(k)(1)(ii) (1980). The employer is required to maintain the employee's benefits and wages until the medical condition is cleared up for a maximum period of 18 months. These provisions apply, even if there is no job for the employee.

The Court of Appeals upheld the provisions of the standard including those relating to reproductive effects and medical removal. 1/ The Court concluded that the record supported OSHA's finding that lead exposure had reproductive effects on males and females and it accepted OSHA's contention that it had authority to protect "working mothers" since harm to fetuses "is a material impairment of the reproductive systems of parents." 2/ The Supreme Court refused to review the Lead case. 3/

Several points should be made about the Lead case:

(1) The Court of Appeals did not address hiring or promotion criteria;

(2) the Court of Appeals did not discuss sensitivity except as relates to male/female differentiation and the court did not distinguish the fetus as a separate entity;

(3) the Court of Appeals did not consider whether a single standard could be set if the record supported the conclusion that the level of significant risk is different for men than for women or fetuses. (OSHA rejected the contention that there was such a difference with respect to lead exposure and the Court upheld OSHA's finding.)

1/ United Steelworkers v. Marshall, 592 F.2d 893 (D.C. Cir. 1980) cert denied sub. nom Lead Industries Association, Inc. v. Donovan, 49 U.S.L.W. 3964 (1981).

2/ Id. at 1256.

3/ 49 U.S.L.W. 3964, June 30, 1981.

(4) neither OSHA nor the Court of Appeals tried to define the "increase" in risk necessary for medical removal. Removal is a case-by-case matter so the Court did not consider whether there must be a finding of significant increase in risk under the Supreme Court's Benzene decision. 1/

(5) nor did the Court of Appeals consider OSHA's assertion that the Medical Removal Program applied to workers planning a pregnancy. It is difficult to see how the necessary "detected medical condition" determination can be made with respect to an anticipation.

General Duty Clause. In addition to the duty to comply with standards, the OSH Act imposes a general duty on an employer to furnish "to each employee" a work place "free from recognized hazards that are causing or likely to cause death or serious physical harm to his employees." 29 U.S.C. § 654(a)(1). The impact of this clause on the employer's duty to employees susceptible to reproductive hazards has not been explored in any detail in the courts or by commentators. Two reasons can explain this omission:

(1) the legislative history made clear that the general duty clause is meant to be an extraordinary regulatory tool to be applied only where standards do not exist;

(2) application of the clause is appropriate only (a) where the hazard is recognized by the employer or generally recognized by the industry, and (b) feasible abatement measures are available.

A recent decision of the Occupational Safety and Health Review Commission dealt with reproductive hazards and

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1/ Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980). See also Pratt & Whitney Aircraft v. Secretary of Labor and OSAHRC, (9 O.S.H.C. 1554 at 1558-61, (2d Cir. 1981)(violation of a safety standard requires showing of "significant risk").

the general duty clause. 1/ Because decision of a different issue disposed of the case, the OSHRC had no occasion to consider the scope of the employer's obligation under the general duty clause.

That case involved an employer's policy of excluding from certain jobs women of childbearing age who had not been sterilized. The policy was adopted to protect fetuses from the teratogenic effects of lead, a protection which went beyond OSHA's lead standard and which the employer concluded was necessary to protect fetuses.

The Commission held that the general duty clause does not prohibit certain voluntary employer action to reduce reproductive hazards. The Commission rejected an argument that the policy was a health hazard because it pressured women employees to undergo sterilization which reduced their functional capacity. The statute applies to occupational hazards operating directly on the employee at work. The sterilization procedure, the Commission concluded, was external to the workplace and therefore could not be an occupational hazard.

Conclusion

Both EPA and the NRC have had occasion to consider imposition of restrictions to protect women or fetuses (EPA pesticides, NRC radiation). However, the main developments have been under the OSH Act. The law on the subject of sensitive

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1/ American Cyanamid Co., OSARC Docket No. 79-5762, 9 OSHC 1596 (April 27, 1981), appeal docketed No. 81-1687 (D.C. Cir. July 1981).

workers and reproductive hazards is far from well developed.

However, certain conclusions seem possible.

- Criteria or policies which have the effect of excluding certain sensitive workers from the work place are nondiscriminatory if soundly based on medicine or science.

- An employer can dismiss a "sensitive" worker he cannot protect in the absence of a transfer provision such as that in Cotton Dust or the medical removal provision in Lead or restrictions in a collective bargaining agreement.

- A soundly based policy can be based on protection of the fetus as an entity; an employer can exclude women of childbearing capability from certain jobs where the objective is the protection of the fetus and the OSHA standard is not adequate to accomplish that objective.

- OSHA's assertion of authority to set a single standard has been upheld with respect to a male/female/fetus hazard where the record supported the OSHA finding of hazard to all above the exposure level allowed by the standard.

- The courts have not addressed OSHA's contention that a standard must protect a subgroup which is genetically or physically sensitive for reasons other than sex.

- The courts have not faced the question whether OSHA has authority to adopt a single standard if there is a difference in the level at which males, females or fetuses are significantly affected.

- OSHA acknowledges that its authority to set standards to protect the sensitive worker is limited by feasibility.

- The general duty clause has very limited application in dealing with potential harm to a fetus.

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Guidance for the Evaluation, Risk Assessment and Control of Chemical Embryo-Fetotoxins

Bruce W. Karrh, M.D.; Thomas W. Carmody; Robert M. Clyne, M.D.; Kenneth G. Gould, M.D., Ph.D.; Gloria Portela-Cubria, J.D.; Jerry M. Smith, Ph.D.; and Milton Freifeld

The recognition, evaluation, and control of embryotoxins in the workplace are toxicologically and administratively complex and present challenging circumstances to the occupational health professional and to the workplace manager. Accommodating the expectations of society and complying with existing laws and regulations make this complex problem even more difficult. By carefully applying the same toxicological considerations and control measures as are used for other chemicals which present different toxic hazards, exposures of susceptible persons to embryotoxins can be prevented or maintained at safe levels without unnecessary restriction of the opportunity for meaningful employment for any class of persons.

Concern for the unborn has generated tremendous pressure upon industry and regulatory agencies to provide effective control of potential chemical embryo-fetotoxins. The issue in regard to exposure to embryo-fetotoxic chemicals is protection of the susceptible embryo-fetus from chemical substances which can cross the placenta and cause damage to the embryo-fetus, almost always at concentrations which would have no adverse effect on the female or the male adult. It is not a matter of female employees being more susceptible than male employees or of female employees being at greater risk of adverse health effects from exposure. Nor is it an issue of sex discrimination against the female employee. The woman at work is involved only because she is capable, and uniquely so, of becoming pregnant and bearing children.

The determination of the intrinsic embryo-fetotoxic potential of a chemical and the estimation of risk from exposure are scientific endeavors, while the acceptability of an estimated embryo-fetotoxic risk for the unborn to a given exposure is a societal and regulatory decision.

Scope of the Problem

The discussion which follows will provide general guidance for evaluating the quality of data, assessing its significance, and controlling the degree of risk of exposure to embryo-fetotoxic chemicals. It will be neither all-inclusive nor specific, but will recognize the requirements for sound scientific judgment for each suspect chemical. It will not address either male or female gonadal toxins or mutagens, but will be concerned with the conceptus, embryo, or fetus. The importance of the legal considerations involved will also be summarized.

An embryo-fetotoxin is defined as a chemical which manifests an effect upon the conceptus during any of the stages of gestation, from fertilization until birth. It may induce death, structural malformations, metabolic or physiological dysfunction, growth retardation, or psychological and behavioral alteration which is manifest at birth or in the postnatal period. Death of the embryo, fetus, or newborn is included. The definition does not include in-utero induced carcinogenesis and abnormalities reflecting mutagenic effects. This definition is consistent with the Environmental Protection Agency definition of teratogen as contained in the Code of Federal Regulations.

In assessing the risk of exposure to embryo-fetotoxic chemicals two basic toxicological principles must be considered.

From E. I. duPont de Nemours & Co., Medical Division N-11400, Wilmington, DE 19898 (Dr. Karrh, Chairman); Union Carbide Corporation (Mr. Carmody); American Cyanamid Company (Dr. Clyne, Committee Liaison); International Paper Company (Dr. Gould); The Standard Oil Company of Indiana (Dr. Portela-Cubria); and Rohm and Haas Company (Dr. Smith).

Presented at the 1979 Joint Conference on Occupational Health, Sept. 27, 1979, Minneapolis, Minn.

1. Risk is a function of both the intrinsic embryo-fetotoxic potential of the chemical and the degree of exposure to the chemical.

2. A dose-response relationship holds for each embryo-fetotoxic response and there exists a threshold exposure level (dose) for each chemical below which no effect is to be expected.

Medical Issues

Recent surveys indicate that up to 7.5% of all delivered infants have developmental abnormalities that interfere with their survival or result in clinical disease. Selective elimination of many malformed human ova, embryos, and fetuses occurs either soon after conception (between the second and seventeenth days) or by spontaneous abortion of the fetus before the twenty-second week of gestation. More than one-third of all embryos die before recognition of pregnancy, and about 15% of recognized pregnancies abort spontaneously. It has been estimated that about 40% of those lost embroyos and fetuses would have been malformed had they survived. Historically, lead has been used as an abortifacient. At the turn of the century women workers in the lead industries were known to have decreased fertility and an increased abortion rate, along with symptoms of lead poisoning. This led to the widespread enactment early in the twentieth century of labor codes forbidding the employment of women in industries involving a lead hazard.

In 1956 Minamata disease was described and by 1959 its cause had been proven. The expectant mother with this disease could not have become pregnant if her methyl mercury intake was so great that she became acutely ill. At a lower dose, the woman might have become pregnant and the child might have been spontaneously aborted or born dead. At even lower doses, the child might have been born with congenital Minamata disease, evidenced by neurologic symptoms.

Maternal alcoholism is thought to be the leading known cause of teratogenic effects in humans but the full extent of its effects is unkown. Twenty percent of all birth defects are estimated to have been caused by known genetic transmission. Chromosomal aberrations cause 3 to 5% of such defects and radiation, both therapeutic and nuclear, accounts for less than 1%. Infections, including rubella, cytomegalic inclusion disease, herpes simplex, toxoplasmosis, and syphilis, account for 2 to 3%. Maternal metabolic imbalances, such as endemic cretinism, diabetes, phenylketonuria, and virilizing tumors, account for 1 to 2%. Drugs and environmental chemicals, including androgenic hormones, folic acid antagonists, thalidomide, organic mercury, some hypoglycemics and some anticonvulsants, account for 2 to 3%. Causes of the remaining 65 to 70% are unknown.

The thalidomide experience of the 1950s aroused much interest in teratogenicity and increased the determination to identify teratogens in advance in order to prevent similar experiences in the future. For instance, the FDA now requires animal teratogenicity studies on all new drugs and the EPA requires these tests on agrichemicals if "the product use may reasonably be expected to result in exposure to human females, or if use may result in residues in food or feed."

The human embryo is most sensitive to teratogens during the period of organogenesis (eighteenth through 60th day of gestation). The most critical period is during early differentiation (eighteenth through thirtieth day). At this time, the woman usually does not know that she is pregnant, for there is no reliable method for ascertaining human pregnancies earlier than three weeks after conception. Severe injuries during the first 17 days after fertilization will usually result in death of the fertilized ovum. Lower-level exposures to some substances for longer periods of time may produce abnormalities which are not obvious at birth but which may be noted months or years after delivery. During the period of advanced differentiation (after 60 days) the susceptibility of the fetus to teratogenic agents affecting structure lessens rapidly.

Assessment of Intrinsic Embryo-Fetotoxic Potential

The intrinsic embryo-fetotoxic potential of a chemical for a given species is dependent upon the toxic properties of the chemical and of its metabolites. The response may be modified by the defense mechanisms of the host and of the target embryo. The assessment of the intrinsic embryo-fetotoxic potential of a chemical requires sound scientific data and the judgment of scientists who have appropriate training and experience.

After reliable data are developed, their relevancy must be scientifically evaluated. The numerous factors to be considered include the following.

1. Response
   a. Type (e.g., structural, biochemical, functional)
   b. Severity (e.g., life threatening, incapacitating, reversible)
   c. Relativity (e.g., ratio to other toxicity, primary or secondary effect)
2. Dose-Response
   a. Threshold exposure level
   b. Slope of the dose-response curve
   c. Critical time of dosing
3. Route of Exposure
   a. Inhalation
   b. Dermal
   c. Oral
4. Biological Variation
   a. Biochemical toxicology
   b. Target site
   c. Species (strain)
   d. Type of placenta
5. Biochemical Toxicology
   a. Absorption
   b. Distribution
   c. Biotransformation
   d. Excretion
6. Biometrics
   a. Sensitivity of study
   b. Limitation of study
7. Host Response
   a. Biochemical
   b. Physiologic
   c. Pharmacologic
   d. Pathologic
   e. Immunologic
   f. Tissue and biochemical repair
8. Replication of results
9. Number of species involved

Assessment of Human Exposure

Human exposure in the workplace is controllable. Understanding the degree and nature of the potential exposure permits some measure of control of risks associated with a chemical which has intrinsic embryo-fetotoxic potential. Assessment of the exposure includes evaluation of the following.

1. Physical Properties of the Chemical
   a. Solid
   b. Liquid
   c. Gas
   d. Aerosol
   e. Dust
   f. Vapor pressure
   g. Melting point
   h. Boiling point
   i. Solubility
2. Route of Exposure
   a. Respiratory (inhalation)
   b. Percutaneous (dermal)
   c. Gastrointestinal (oral)
3. Dose
   a. Concentration
   b. Volume
4. Characteristics of Exposure
   a. Frequency
   b. Continuous
   c. Intermittent
   d. Duration
   e. Details of the process
5. Population at Risk
   a. Age
   b. Sex
   c. Health
   d. Occupation
   e. Number

Assessment of Risk

Following the evaluation of the intrinsic embryo-fetotoxic potential of a chemical, an assessment of risk based on scientific principles must be made. Most critical to this judgment are the following questions.

1. Does the embryo-fetotoxic response occur in more than one species?
2. Does the embryo-fetotoxic response occur at exposures substantially below exposures which produce other, nonteratogenic toxic effects?
3. Do the data indicate a dose-response relationship?
4. Has the test been done in the most appropriate animal model for the class of chemical evaluated and in an exposure route applicable to man?
5. What are the threshold and the no-observable-effect levels of exposure for the animal model?
6. What populations are at risk (exposed) and what characterizes the exposures?

Estimation of Acceptable Exposure Levels

Following assessment of the embryo-fetotoxic potential of the chemical, the potential for human exposure, and the risk, an acceptable exposure level should be estimated, taking into consideration the degree of confidence in the data and the variability and nature of the population at risk.

Where acceptable exposure levels can be estimated, they should be accompanied by documentation and statements of rationale.

Control of Chemicals Posing a Potential Embryo-Fetotoxic Risk

When it has been determined that a substance presents a risk of embryo-fetotoxicity, the following actions should be considered.

1. Employees who may be affected should be informed of the possible consequences of exposure to such substances and appropriate safe handling procedures should be established and communicated.
2. Engineering controls should be used to the extent practical to reduce and to maintain at acceptable levels exposure to embryo-fetotoxins. Such controls should be augmented by administrative controls as appropriate.
3. Whenever further engineering and administrative controls are not practical to keep exposures at or below acceptable levels, the use of personal protective equipment should be required where appropriate. Employees who are required to use such equipment should be adequately trained in its proper use.
4. Where there is potential for exposure to an embryo-fetotoxin for which an acceptable exposure level cannot be set due to inadequate data, women of reproductive potential should be excluded from the work area.
5. Where engineering and administrative controls, augmented as appropriate by personal protective equipment, are determined to be inadequate to ensure acceptable levels of exposure to an embryo-fetotoxic compound, women of reproductive potential should be excluded from the work areas.

Legal Issues

Many legal issues in various specialized areas are involved in the evaluation, risk assessment, and control of embryo-fetotoxins. For example, there are a number of equal employment opportunity matters to be considered when a company concludes that it must exclude women of reproductive potential from workplace areas as a means of controlling exposure.

The company may be called upon to demonstrate that the embryo-fetotoxic effect is due to exposure of the embryo or fetus during gestation and not due to toxic effects on the mother due to the exposure during pregnancy. If only women of reproductive potential are excluded, the employer may have to demonstrate that the toxic effects result only from in-utero exposure of the embryo or fetus and not from preconception exposure by either parent. Consideration must be given to what constitutes suitable alternate assignments and compensation for employees excluded from certain jobs because of potential exposures. Company counsel should be sought at an early date on these and all other legal issues which may be involved.

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Donald L. Norwood

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To R. E. Lehmkuhl
D. A. Kuhn
~~J. J. Hall~~
~~R. D. Gamblin~~
J. A. DeBernardi
J. Friend
C. L. Miller

~~File~~ 1 file copy for hazards

Date 03-18-81

Attached for your information.

DLN:nng

SAL 000045926

Order 11246, and subsequent orders pursuant thereto, and are not required by Title VII of the 1964 Civil Rights Act.

[14] 72. There was testimony at the trial that Olin did not achieve its goals set forth in the affirmative action plans. While such testimony is some evidence of discrimination it falls far short of establishing such discrimination since there was no showing by the Commission that sufficient vacancies existed which would have allowed the Company to achieve the goals, that sufficient numbers of qualified applicants applied or were otherwise available for the jobs for which the goals were set and there was no testimony concerning the qualifications of persons who were selected for such vacancies as did exist. A bald showing that the affirmative action goals were not met does not establish discrimination.

[SPECIAL AGREEMENT]

73. In 1973 Olin and the Union entered into a Special Agreement in compliance with Revised Order No. 4 of the Office of Federal Contract Compliance for the purpose of resolving any question as to whether Olin has taken sufficient action to cure the present effects of any past discrimination against blacks or females. In September 1972, the General Services Administration conducted an audit of Olin's facilities at Pisgah Forest. At the conclusion of the examination, Olin was told by G.S.A. that it would in the near future ask it to (1) determine whether or not it had an affected class or classes of employees, and (2) to propose a remedial seniority program for eliminating the effects of past discrimination in those affected classes, if any. In response to this representation, Olin, without any further communication from G.S.A., voluntarily undertook to examine its operations to determine whether in fact it did have affected class employees. At that time, the Endless Belt Department was made up almost entirely of female employees. In addition the blacks hired after 1963 were dispersed in various jobs throughout the departments, a disproportionate number of long term black employees had remained in janitorial jobs.

The provisions of the Special Agreement provided a means whereby an affected class member could use all of his or her seniorities in accord with the provisions of the existing labor agreement, rather than establish a separate agreement which set up black versus white, or male versus female considerations when, and if, a particular job opening, transfer, promotion, etc., was being co- dered, as was the case in other remedial seniority agreements Olin had reviewed. Its basic effect was to give credit for plant seniority which would, by the use of the procedures set forth in the agreement, create other meaningful seniority dates which fitted into the seniority system agreed to by the Union and the Company, and would forever continue and perpetuate the effectiveness of those dates without requiring a separate agreement to be administered. (See JI Stip. No. 37).

74. The Special Agreement was fully explained to all persons whom it affected, that is, blacks hired prior to June 1, 1963, and females hired prior to November 1, 1966, and all such employees were given an opportunity to take advantage of its provisions. The agreement was not an admission by Olin and the Union that past unlawful practices had occurred or that they were being perpetuated by the seniority system.

75. In light of the Court's finding that the seniority system is a bona fide system, the Special Agreement was not necessary in order to cure any alleged perpetuation of past discrimination. If discrimination had occurred, the Special Agreement afforded complete and full relief to cure any alleged discrimination against persons covered by the agreement.

Olin's Policy on Fetal Vulnerability

[15] 76. The parties stipulated that Olin has had in effect since March 1978, a policy under which women of childbearing capability have not been allowed to occupy certain job classifications at its Pisgah Forest facility because of possible harmful effects of certain chemicals upon the unborn fetus. The policy bars women of childbearing capability from certain jobs in areas known as "restricted" areas where there is exposure to known or suspected abortifacient or teratogenic agents. In areas where the nature of the work requires very limited contact with such agents and the level of exposure is lower, such areas being known as "controlled" areas, non-pregnant females are permitted to work at such jobs after receiving counseling and with the understanding they will notify their supervisor when they become pregnant. The policy provides that pregnant females who are moved from "controlled jobs" have their seniority protected. Other jobs are classified as "unrestricted" jobs, these areas being areas where exposure to chemicals and physical agents does not constitute a hazard to the unborn fetus.

77. The policy provides for downgrading of jobs from "restricted" to "controlled" to "unrestricted," depending upon Olin's ability to reduce levels of exposure in the different areas and Olin is making a reasonable, good-faith effort, to reduce the chemical exposure level at the plant. The medical witnesses testified that Olin uses a sophisticated system for daily monitoring of chemical exposure levels.

78. Olin does not have a policy which excludes males or females from certain areas because of possible damage to their reproductive organs. The Commission's contentions that these policies discriminate against females and therefore constitute violations of Title VII are without merit.

79. Dr. O'Connell, Dr. Ryan and Mr. Roberts testified in detail about the policy and why they deemed it necessary. The Court finds that the policy was instituted for sound medical and humane reasons and is based upon sound medical knowledge and research and years of monitoring of levels of chemical exposure at Olin's plant. The Court further finds that it was not instituted or maintained with the intent or purpose to discriminate against females because of their sex. The evidence shows that the purpose of the policy is to protect the unborn fetus at a time when it is most vulnerable to exposure to harmful chemicals. The policy has been conducted in a reasonble manner, and the Company has counselled with females who have indicated their desire to enter restricted or controlled areas. The record shows that very few female employees have indicated a desire to work in the "restricted" areas. No female employee has filed a charge of discrimination with the Commission alleging that this policy discriminates against females because of sex.

Maintenance Apprenticeship Program

80. Olin has had a maintenance Apprenticeship Program at the Pisgah Forest facility since approximately 1966. In 1977 Olin voluntarily registered its program with the United States Department of Labor, Bureau of Apprenticeship and Training at the request of certain employees who desired to obtain veterans benefits. Entry into the program has been through open bidding after posting throughout the plant. Employees have been selected for entry into such program through a formalized selection system which has included since 1977 a joint committee consisting of management and Union officials.

[16] 81. Prior to 1980, the selection criteria for entry into the Maintenance Apprenticeship Program included

plant seniority and craft- ence and/or schooling those persons who signe program. Beginning in 19 ed separate "pools" for males, and females to inso and females are represent gram.

82. On the basis of th rate of blacks and female gram, they have been rec program on a proportion testimony of Bohan and (11d). The Court finds tha has been administered on non-discriminatory basis, who has applied for the filed a charge with the Co tending that he or she cluded from the progra race or sex.

Contracting Out Custodi

83. Prior to 1979 the c at the Olin plant had be by Olin employees. In 1 tracted the work to an ou tor. The Union grieved th contract out the work a violation, but not as a rac tion. An impartial arbi mined that Olin contrac work for legitimate busi which were permissible u tract. The Court finds t dence that the purpose of was an effort to effect a n ings and to attempt to ob quality of cleaning than h before. Such reasons con mate business purposes.

[17] 84. The effect of t contract out the custodial fall disproportionately o ployees since the custodi at the time was appro black and 50% white, and pay and seniority were pr lowing them to move to e the Transfer Pool by usin seniority. There is no evid was a factor in the Compa enter the contract.

85. Olin later determ minate the contract wit contractor and to continu own employees to perform al work. Olin than gav custodial employees the main in their current job to their former custodi Court finds that there wa discriminate against black ing out the custodial work

Step 2 Finishing Operator