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Substantive and Procedural Obstacles to OSHA Rulemaking: Reproductive Hazards as an Example

Mark A. Rothstein

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SUBSTANTIVE AND PROCEDURAL OBSTACLES TO OSHA RULEMAKING: REPRODUCTIVE HAZARDS AS AN EXAMPLE

Mark A. Rothstein

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The human reproductive process is fragile; it is highly sensitive and, unfortunately, often works imperfectly. An estimated ten percent of couples attempting to parent children are infertile. For every 3,000,000 births per year in the United States there are 450,000 to 600,000 spontaneous abortions and 33,000 fetuses die in utero. Of live births, about ten percent are premature, approximately seven percent have a low birth weight, and another three to seven percent have congenital anomalies. The cause of the anomaly is unknown for sixty-five to seventy percent of the

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1 See L. SPEROFF, R. GLASS, & N. KASE, CLINICAL GYNECOLOGIC ENDOCRINOLOGY & INFERTILITY 467 (3d ed. 1983).


3 Fabro, supra note 2, at 291.

4 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH, UNITED STATES 356 (1983). “Of all infant deaths, two-thirds occur in those weighing less than 5.5 pounds (2500 grams) at birth. Infants below this weight are more than 20 times as likely to die within the first year. Low birth weight is sometimes associated with increased occurrence of mental retardation, birth defects, growth and development problems, blindness, autism, cerebral palsy and epilepsy.” U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, HEALTHY PEOPLE: THE SURGEON GENERAL’S REPORT ON HEALTH PROMOTION AND DISEASE PREVENTION 24 (1979).

5 Fabro, supra note 2, at 291.
cases. About 30,000 babies per year die during the neonatal period and at least 15,000 die in the first year.

Although environmental factors are known to be responsible for only a small percentage of congenital anomalies, there is overwhelming evidence that exposure to certain occupational hazards can result in a variety of negative reproductive effects. Among these effects are altered fertility, chromosomal abnormalities, spontaneous abortions, congenital malformations, behavioral disorders, and malignancies. Among the numerous substances and agents commonly in use in industry known to cause negative reproductive effects are arsenic, benzene, cadmium, formaldehyde, lead, mercury, radiation, and vinyl chloride.

Even though exposure to reproductive hazards by male as well as female employees may result in negative reproductive outcomes, some large companies have instituted policies excluding only fertile or pregnant women from employment where there is exposure. A major reason for these policies is the fear that a child born with birth defects might bring a tort action against the employer and, presumably, this is more likely where the exposed parent was the mother.

A great deal has been written about the legal issues surrounding claims of sex discrimination related to these exclusionary policies and about the possible tort actions that could be maintained against employers. Very little has been written, however,
about the legal issues involved in the regulation of reproductive hazards.

This Article will analyze current regulations governing reproductive hazards under the Occupational Safety and Health Act. It will also consider governmental research efforts and possible new regulations for dealing with reproductive hazards. Because the regulatory process involves numerous controversial policy choices, the Article includes interviews with current and former government officials.

Any new standards attempting to regulate occupational exposures to reproductive hazards must navigate the tortuous standards-promulgation process under the Occupational Safety and Health Act. The process is slow, difficult, and adversarial and the judicial review of new standards can further complicate the process. This Article analyzes the legal and political obstacles to effective regulation of reproductive hazards in the workplace. In so doing, it explores the broader problem of the need to simplify and expedite rulemaking under the Occupational Safety and Health Act.

II. CURRENT REGULATION OF REPRODUCTIVE HAZARDS UNDER OSHA

The first part of the Article discusses OSHA's present ability to regulate reproductive hazards. It begins with a discussion of the ways in which health hazards, in general, have been regulated. This is followed by a review of the current regulations specifically covering reproductive hazards. Finally, there is a discussion of the possible use of the general duty clause as a way of prohibiting harmful exposures to reproductive hazards in the absence of a specific OSHA standard.

A. General Requirements of OSHA Health Standards

Under Section 6(a) of the Act\(^4\) the Secretary was initially authorized to adopt “established federal standards”\(^5\) and “national consensus standards”\(^6\) without resort to the lengthy rulemaking procedures of Section 6(b)\(^7\) or the Administrative Procedure Act.\(^8\) This authority, which expired after two years (in 1973) was included in the Act to assure that workers would be protected as soon as possible after the Act’s effective date in 1971.

In 1971, pursuant to Section 6(a), OSHA adopted as standards the 450 threshold limit values (TLV’s),\(^9\) developed by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968 and which became “established federal standards” when they were previously adopted under the Walsh-Healey Act.\(^10\) The ACGIH set limits on the maximum concentrations for employee exposure to certain airborne contaminants, but did not otherwise specify monitoring or medical examinations.

For the most part, these standards have not been updated by OSHA. Pursuant to Section 6(b) rulemaking, however, twenty-two new health standards have been promulgated. These new health standards require employers to undertake a variety of preventive

\(^5\) Section 3(10), 29 U.S.C. § 652(10) (1976), defines “established federal standard” as “any occupational safety and health standard established by any agency of the United States and presently in effect, or contained in any Act of Congress in force on December 29, 1970.”
\(^6\) Section 3(9), 29 U.S.C. § 652(9) (1976), defines “national consensus standard” as any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope of provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.
\(^7\) 5 U.S.C. § 655(b) (1976). For a further discussion of § 6(b) rulemaking, see infra text and notes at notes 153-68.
\(^9\) A threshold limit value (TLV) represents the maximum time weighted average concentration to which a healthy worker may be exposed for a normal 40-hour week, up to eight hours a day, over a working lifetime (40-50 years) without becoming ill. See ACGIH, THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS IN THE WORK ENVIRONMENT AND BIOLOGICAL EXPOSURE INDICES WITH INTENDED CHANGES FOR 1984-85, at 2-3 (1984); Steinberg, ACGIH TLV’s and the Sensitive Worker, 3 ANNALS AM. CONF. GOVTL. INDUS. HYGIENISTS 77 (1982).
measures beyond simply specifying permissible exposure levels. Some of these requirements are set forth below.

1. Environmental Monitoring

The first responsibility of the employer is to conduct periodic atmospheric tests to determine the presence and concentration of hazardous substances. The standards differ on the required frequency of the testing, but even the most stringent requirements have been upheld. For example, in *Marshall v. Western Electric, Inc.*, the Second Circuit reversed the Occupational Safety and Health Review Commission (Commission) and held that an employer must monitor every operation in which vinyl chloride was released, regardless of the employer’s prediction that only negligible concentrations of the gas were released. In *Duquesne Light Co.*, the Commission held, however, in a highly questionable decision, that the asbestos standard does not require monitoring where employees are not regularly exposed during the course of work, even though their sporadic exposures sometimes exceeded the standard. In *Dunlop v. Rockwell International*, a citation was vacated because the employer had retained an independent testing laboratory to conduct atmospheric tests, even though those tests failed to discover the employer’s excess levels of asbestos fibers.

OSHA’s newer health standards have relied on the concept of an “action level.” For example, in the ethylene oxide standard OSHA established a one part per million (ppm) eight-hour time weighted average (TWA) as the exposure limit. The action level was set at 0.5 ppm. When initial monitoring reveals exposures below the action level, no further monitoring is required unless there is a change in production, process, or control. If exposures are above the action level, exposures must be monitored twice per year. (See Table 1). Monitoring may be discontinued, however, if there are two consecutive measurements, taken at least seven days apart, that show exposures below the action level.

The ethylene oxide standard’s preamble contains the following table indicating the environmental monitoring requirements.

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21 565 F.2d 240 (2d Cir. 1977).
22 11 OSHC 2033, 1984 OSHD ¶ 26,959 (1984). The holding may well lead to a lack of protection for construction, maintenance, and other employees whose exposures to toxic substances are not on a “regular” basis.
23 540 F.2d 1283 (6th Cir. 1976).
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TABLE 1.
FREQUENCY OF MONITORING REQUIRED UNDER THE ETHYLENE OXIDE STANDARD

<table>
<thead>
<tr>
<th>Exposure Scenario</th>
<th>Required Monitoring Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below the action level</td>
<td>No monitoring required</td>
</tr>
<tr>
<td>At or above the action level, but at or</td>
<td>Monitor exposures 2 times per year</td>
</tr>
<tr>
<td>below the TWA</td>
<td></td>
</tr>
<tr>
<td>Above the TWA</td>
<td>Monitor exposures 4 times per year</td>
</tr>
</tbody>
</table>

The action level attempts to provide a margin of safety, so that it is unlikely that a minor fluctuation in exposure would exceed the TWA. It requires employers to monitor exposures approaching the TWA to ensure that the TWA is not exceeded, while removing the burden of continuous environmental monitoring from employers with only slight exposure levels.

The main problem with the use of the action level concept is that it eliminates important protections for workers whose exposures are below the action level. For example, in *Industrial Union Department v. American Petroleum Institute*, the "benzene case," the United States Supreme Court was critical of OSHA for not requiring monitoring and medical testing of employees who were subject to exposures below the action level.

By doing so, it could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high. Moreover, in this way it could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage.

A similar problem exists under the lead standard, which established a permissible exposure limit (PEL) of fifty micrograms of lead per cubic meter of air averaged over an eight-hour work day and an action level of thirty micrograms. An employer must supply protective clothing, change rooms, showers, and other hygiene facilities only if the exposure level is above the action level. Thus, the children of workers exposed to levels of lead below the action level could be at risk from lead-contaminated clothing brought home by their parents.

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26 448 U.S. 607 (1980).
27 Id. at 658 (footnotes omitted).
28 29 C.F.R. § 1910.1025(g) and (i) (1984).
2. Biological Monitoring

Some OSHA health standards require the biological monitoring of exposed employees to measure the body’s uptake of toxic substances. For example, the lead standard requires that the employer provide blood sampling and analysis for lead and zinc protoporphyrin levels for each employee with lead exposure at or above the action level. This monitoring is required at least every six months.29

3. Medical Surveillance

OSHA health standards regulating toxic substances require a variety of medical procedures. In general, employers must conduct pre-placement examinations; the physician must furnish employers with a copy of the physician’s statement of suitability for employment in the regulated area; the employer must conduct periodic (usually annual) examinations; and in some instances, the employer must conduct examinations at termination of employment. The failure to conduct these required medical examinations may lead to the issuance of OSHA citations and the assessment of penalties. The following table contains a summary of the specific requirements.

<p>| TABLE 2. MEDICAL REQUIREMENTS OF OSHA HEALTH STANDARDS REGULATING TOXIC SUBSTANCES |
|----------------------------------|----------------------------------|----------------------------------|
| 29 C.F.R. Substance              | Primary Health Risks             | Required Medical Procedures      |
| 1910.1001 Asbestos               | 1. Asbestosis                    | 1. Pulmonary function tests       |
|                                 | 2. Mesothelioma                  | 2. Chest x-rays                   |
|                                 | 3. Lung Disorders                |                                  |
|                                 | 2. Bronchiogenic cancer          | 2. Consideration of reduced immunological competence of employees, those undergoing treatment with steroids or cytotoxic agents, pregnant women and cigarette smokers. |
|                                 | 3. Lung cancer                   |                                  |
|                                 | 4. Stomach cancer                |                                  |
|                                 | 5. Skin cancer                   |                                  |
|                                 | 6. Liver cancer                  |                                  |
|                                 | 7. Kidney cancer                 |                                  |
|                                 | 8. Pulmonary edema               |                                  |
|                                 | 9. Central necrosis              |                                  |
| 1910.1017 Vinyl chloride         | 1. Angiosarcoma                  | 1. Complete physical exam         |
|                                 | 2. Lung cancer                   | 2. Liver studies                  |</p>
<table>
<thead>
<tr>
<th>29 C.F.R.</th>
<th>Substance</th>
<th>Primary Health Risks</th>
<th>Required Medical Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1910.1045</td>
<td>Acrylonitrile</td>
<td>1. Asphyxia 2. Weakness</td>
<td>1. Complete medical history and exam, with particular attention to peripheral and central nervous system, gastrointestinal system, skin, and thyroid 2. Chest x-ray 3. Fecal occult blood screening for all workers over 40 years of age</td>
</tr>
</tbody>
</table>

*Source: Adapted from M. Rothstein, Medical Screening of Workers 20-21 (1984).*
OSHA medical surveillance programs have two primary purposes: (1) to give the employee notice of any adverse health effects that he or she may have suffered so that proper medical attention may be obtained and precautionary measures taken, and (2) to provide OSHA and NIOSH with data for research purposes. In implementing medical surveillance programs, the following questions have arisen:

a. What employees are covered by the medical surveillance provisions?

As mentioned earlier, some standards require medical surveillance only for employees exposed at or above the action level. Other standards require medical surveillance for all employees exposed to any levels of the substance. Even these more stringent requirements have been upheld. In GAF Corp. v. OSHRC, the D.C. Circuit Court affirmed the Commission's holding that the employer was required to provide medical examinations for all employees exposed to asbestos — including employees whose exposures were below the PEL. In Duquesne Light Co., however, the Commission held that the asbestos standard did not require medical examinations of employees who were not regularly exposed, even though their sporadic exposures sometimes exceeded the standard. The coke oven, arsenic, and ethylene oxide standards require medical surveillance for employees exposed at least thirty days per year.

In the ethylene oxide standard OSHA rejected the recommendation of the American Federation of State, County and Municipal Employees (AFSCME) and the AFL-CIO that medical surveillance should be provided to all formerly exposed employees as well as those presently exposed. According to OSHA, this recommendation was rejected because the present state of knowledge about ethylene oxide's long-term effects on humans is inadequate and that only employees at a late stage in developing leukemia could be identified. The coke oven emissions standard, however, does require continued surveillance of previously exposed employees who have been reassigned by the same or a successor employer.33

29 Id. § 1910.1025(j)(2).
31 561 F.2d 913 (D.C. Cir. 1977).
b. Are medical examinations mandatory?

Section 6(b)(7) of the Act provides that medical examinations shall “be made available” to exposed employees. OSHA has interpreted this language to mean that the employer must offer the examination; the employee may refuse to take the examination.\(^{34}\) The coke oven emissions standard contains a provision requiring employers to inform employees of the health consequences of refusing to take the examination and requiring a signed statement by the employee that the consequences have been explained and understood.\(^{35}\)

The detailed medical removal protection (MRP) and rate retention (RR) provisions of the lead standard were promulgated, in part, as an alternative to mandatory worker participation in the medical surveillance program.\(^{36}\) The preamble to the lead standard indicates that OSHA rejected the idea of making examinations mandatory because employees concerned about job security might be tempted to use chelating drugs and to conceal subjective symptoms of lead disease.\(^{37}\) By contrast, with MRP and RR, workers would be encouraged to participate, but those who chose not to — because of privacy or religious objections or for other reasons — would not be required.

The only time OSHA attempted to make medical surveillance mandatory was in the commercial diving standard, which was issued in 1977 and struck down two years later by the Fifth Circuit in *Taylor Diving & Salvage Co. v. United States Department of Labor.*\(^ {38}\) OSHA reasoned that the safety of other dive team members can depend on the health of an individual diver.\(^ {39}\) The multiple-physician review procedure, discussed in detail below, also was included in the diving standard to ensure that divers would not be denied their employment on the basis of a single medical examination mandated by OSHA.

The preceding discussion of the “optional” nature of OSHA-required medical examinations does not mean that adverse consequences will not attach when an employee refuses to undergo examination. Simply because OSHA does not require participa-

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\(^{34}\) B. Mintz, *supra* note 30, at 134.


\(^{36}\) For a further discussion, see *infra* text and notes at notes 295-309.


\(^{38}\) 599 F.2d 622 (5th Cir. 1979).

tion, however, does not mean that it protects a refusal to participate. Unless covered by the terms of a collective bargaining agreement, an employer may make cooperation with medical examinations a valid condition of employment. Thus, as a practical matter, most "optional" OSHA medical examination provisions are, in fact, mandatory for employees.

c. What procedures are required?

OSHA's health standards prescribe the specific medical procedures required during OSHA-mandated medical examinations. The argument has been made that broader latitude should be given to the examining physician by adopting more performance-oriented standards. This would allow physicians to change their practices quickly to comport with the latest medical developments. In rejecting this argument in the ethylene oxide standard, OSHA's preamble noted that mandatory requirements help smaller employers with less established medical departments to determine the appropriate examination protocols.

Even without a separate health standard specifying the particulars of a medical surveillance program, the Occupational Safety and Health Review Commission may impose an appropriate medical surveillance program as an alternative measure during the extended period of time requested in a petition for modification of abatement (PMA). In *ITT Grinnell*, the employer was cited for having excessive levels of silica dust. The employer filed a PMA to extend the abatement date, which the Commission granted conditioned on the employer's use of additional medical surveillance, including chest x-rays and pulmonary function tests.

Although OSHA prescribes the use of specific medical procedures, it should be emphasized that OSHA does not prohibit the use of any procedures. The only exception to this principle is the ban on the use of prophylactic chelation in the lead standard.

d. How are test results interpreted?

Accurate medical assessments often depend on thorough medical histories, clinical evaluations, and laboratory procedures. Although OSHA health standards promulgated after the asbestos

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40 M. Rothstein, *supra* note 11, at 88.
standard (OSHA's first health standard promulgated after rulemaking) have contained appendices with medical surveillance guidelines.43 only the lead standard and cotton dust standard provide detailed guidance for physicians. The medical surveillance guidelines published with the proposed ethylene oxide standard recommended the use of cytogenetic monitoring of workers to detect chromosomal aberrations.44 This recommendation was not included when the final version of the standard was promulgated.45

e. Who selects the physician?

The Act does not specifically indicate whether the employer or employee has the right to select a physician to perform medical examinations. In promulgating the asbestos standard OSHA determined that the employer should have the option of choosing the physician and should have access to the results of the examination.46 The D.C. Circuit upheld OSHA's position in *Industrial Union Department v. Hodgson.*47 This policy has been followed in subsequent health standards.

A notable exception concerns the “multiple physician review” procedure, first used in the commercial diving standard. The standard required medical examinations of employees who were to be exposed to hyperbaric conditions. If the employee was found to be unfit by the examining physician selected by the employer, the employee could seek a second opinion. If the first two physicians disagreed, a third physician was to be selected by the first two physicians and that physician's determination would be dispositive. All costs were to be borne by the employer.

In *Taylor,*48 the Fifth Circuit struck down this provision. The court, citing its decision in *American Petroleum Institute v. OSHA,*49 held that the standard was not “reasonably necessary or

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48 599 F.2d 822 (5th Cir. 1979).
appropriate to provide safe or healthful workplaces.” The court concluded that the standard imposed a mandatory job security provision controlled by the third physician. “[T]he employer has no control over the third doctor’s fitness standards, so that the employer is prevented from setting higher health standards for employees than the secondary examining doctors choose to set.”

In *United Steelworkers of America v. Marshall*, the D.C. Circuit reached the opposite result and upheld the multiple physician review procedure of the lead standard. According to the court, the provision is authorized by Section 6(b)(7)’s broad mandate to require examinations that can “most effectively determine” a threat to worker health. In addition, the provision is reasonable in light of two findings supported by the record. First, lead diseases are often difficult to diagnose and multiple physician review increases the chances of a correct diagnosis. Second, some company physicians have engaged in the unsound and harmful practice of prophylactic chelation to reduce the blood-lead levels of employees. The court distinguished *Taylor*, where employees would seek multiple physician review to obtain a finding of fitness, thus forcing the employer to retain employees considered unfit by its own physician and standards. In the lead standard, the multiple physician review procedure was to prevent excess exposure of “leaded” employees and, together with the medical removal protection, the employer is not precluded from imposing more stringent health standards.

In the ethylene oxide standard OSHA adopted the position taken by the National Institute for Occupational Safety and Health (NIOSH) that multiple physician review was unnecessary for ethylene oxide.

f. Who pays for the examination?

Section 6(b)(7) of the Act makes it clear that medical examinations shall be made available “by the employer or at his cost.” OSHA’s health standards have included language indicating that all costs for medical examinations must be borne by the employer. In *Phelps Dodge Corp.*, the Commission held that a provision in the inorganic arsenic standard providing that medical exam-

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50 599 F.2d at 625.
53 11 OSHC 1441, 1983 OSHD ¶ 26,552 (1983), aff’d, 725 F.2d 1237 (9th Cir. 1984).
inuations be provided without cost required the employer to compensate employees for time spent taking the examination (outside normal working hours) and for extra transportation expenses. The Commission’s decision was affirmed by the Ninth Circuit. 54

g. What personnel action may be taken as a result of the examination?

With the exception of medical removal protection and rate retention under some health standards, OSHA has not indicated what personnel actions may be based on OSHA-mandated medical surveillance. Consequently, unless there is an applicable provision in a collective bargaining agreement or the personnel action otherwise violates a statutory prohibition against discrimination, such as handicap laws, an employer may refuse to hire, reassign, lay off, or discharge employees on the basis of medical surveillance. The problem of job security is one major reason why some employees do not cooperate fully with medical surveillance programs. 55

4. Controls and Other Requirements

OSHA health standards attempt to reduce exposure through a variety of control strategies, such as engineering controls, work practice controls, personal protective equipment, and administrative controls. Depending on the working conditions, employers may have a wide range of other duties, such as providing showers and changing rooms, protective clothing, and laundry facilities. Employers also may be obligated to post warning signs and give detailed warnings to their employees. Finally, OSHA standards require that all health hazard emergencies be reported. For example, carcinogen exposure must be reported to OSHA within twenty-four hours. 56 Radiation exposure must be reported immediately by phone or telegram and a written report must be filed within fifteen days. 57

54 Phelps Dodge Corp. v. OSHRC, 725 F.2d 1237 (9th Cir. 1984).
55 M. Rothstein, supra note 11, at 203-04.
B. OSHA Standards Regulating Reproductive Hazards

1. DBCP

DBCP (1,2-dibromo-3-chloropropane) is a liquid pesticide. In July, 1977, workers at Occidental Chemical Company in Lathrop, California noticed a pattern of infertility at the plant. When tests were performed by the University of California it was discovered that fourteen of thirty-eight workers tested had significantly reduced sperm counts.58

On August 23, 1977, the union, the Oil, Chemical, and Atomic Workers (OCAW), petitioned OSHA to issue an emergency temporary standard (ETS) for DBCP with a PEL of one part per billion (ppb). At the time of the petition, no DBCP standard had been adopted by OSHA. On September 9, 1977, OSHA issued an ETS for DBCP, establishing an eight hour TWA of ten ppb and a fifteen minute ceiling level of fifty ppb.59 Based on evidence that DBCP was a carcinogen as well as a gametotoxin, on March 17, 1978, OSHA issued a permanent standard lowering the eight hour TWA to one ppb, with no ceiling limit.60 Neither the ETS nor the permanent standard was challenged in court.

In addition to regulating the permissible airborne concentration of DBCP, the standard also prohibits dermal and eye contact, requires exposure monitoring, establishes a respirator program, and provides for protective clothing, change rooms, and showers. The medical surveillance section of the standard provides for pre-placement and annual examinations, which must include at least the following:

1) A medical and occupational history including reproductive history;
2) A physical examination, including examination of the genito-urinary tract, testicle size and body habitus, including a determination of sperm count;
3) A serum specimen shall be obtained and the following determinations made by radioimmunoassay techniques utilizing National Institutes of Health (NIH) specific antigen or one of equivalent sensitivity: (a) Serum follicle stimulating hormone (FSH); (b) Serum luteinizing hormone (LH); and (c) Serum total estrogen (females);

The standard also provides for employee information and training as well as warning signs and product labels.

2. Lead

Unlike the DBCP standard, which was promulgated largely because of the negative reproductive consequences from exposure, the lead standard was promulgated mostly to prevent other health problems, such as neurological disorders. Indeed, as discussed previously, the standard as promulgated is not sufficient to ensure that there will be no reproductive damage caused by exposure to lead. The lead standard, however, does attempt to minimize reproductive harms in several additional ways.

The medical surveillance section of the standard requires the medical history to include reproductive problems. It also provides that if requested by an employee, medical examinations must include pregnancy testing or laboratory evaluation of male fertility. The standard further provides that the employer must furnish a medical examination or consultation if the employee notifies the employer of a desire to obtain advice concerning the effects of current or past exposure on his or her ability to procreate a healthy child. A final relevant provision of the standard, in the employee information and training section, requires the employer to inform all exposed employees about the medical surveillance program, "including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females)."

3. Ethylene Oxide

The preamble to OSHA's ethylene oxide standard indicated that ethylene oxide is not only a carcinogen, but a mutagen and abortifacient as well. OSHA therefore concluded that ethylene oxide exposure at the then-current level of fifty ppm posed a

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62 Id. § 1910.1025(j)(3)(ii).
63 Id.
64 Id. § 1910.1025(1)(v)(D).
significant risk to the reproductive health of both male and female workers.

The new standard not only lowered the PEL to one ppm, but included other measures designed to protect the reproductive health of workers. Some of these measures are identical to the lead standard's requirements, upon which they were based, and some are slightly different. As in the lead standard, employers must provide a medical examination or medical consultation for employees desiring information about the effects of current or past exposures on the ability to procreate a healthy child. As with lead, the medical history also includes a reproductive history. The physical examination, however, also must give particular attention to the reproductive system. Pregnancy and fertility testing also must be provided if the employee so requests, but only if the physician concurs in the need for testing. The preamble to the standard explains that the purpose of requiring the physician's concurrence for pregnancy or fertility testing is to avoid "abusive or frivolous" requests. OSHA cited no evidence, however, of such abuses under the lead standard.

The ethylene oxide standard contains a requirement that warning signs and labels must be used. The signs and labels must clearly note that ethylene oxide is a cancer hazard and a reproductive hazard. Employees also must be given information and training about ethylene oxide, including the potential for reproductive harm.

4. Other Reproductive Hazards

OSHA standards set PEL's for a number of other substances or physical agents which pose reproductive hazards. Some examples are benzene, cadmium, mercury, vinyl chloride, and ionizing radiation. For these latter hazards, however, there have been no efforts specifically addressed to preventing reproductive harms. The vinyl chloride standard, for example, was promulgated only after it was shown that vinyl chloride caused angiosarcoma, a rare cancer of the liver. Designed to reduce exposure to the lowest feasible limits, the standard would presumably protect against reproductive harms.

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65 Id. § 1910.1047(j)(2)(i)(E).
68 Id. § 1910.1047(j)(2)(ii)(B).
C. General Duty Clause

1. Overview

Section 5(a)(1) of the Act, the “general duty clause,” provides that each employer “shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.”

Section 5(a)(1) was enacted to cover serious hazards to which no specific standard applies. Because Section 5(a)(1) was designed to augment rather than supplant standards, citation under Section 5(a)(1) is improper where a specific standard is appropriate. During the first few years of the Act’s existence the general duty clause was used to prohibit hazardous conduct while specific standards were being promulgated or before a standard’s effective date. Subsequently, however, the general duty clause has been used for more peculiar violations, not covered by specific standards.

The most distinctive and significant element of Section 5(a)(1) violations is that they are limited to “recognized hazards.” The “recognition” requirement serves to ensure that cited employers at least have constructive knowledge of the existence of specific hazardous conditions. In this way, Congress sought to eliminate the unfairness of assessing first-instance civil penalties based on such a sweeping and broadly worded provision.

As with Section 5(a)(2) violations, the relevant inquiry for determining the existence of a violation is whether there are hazardous conditions and not whether there has been an accident. Also, “recognition” refers to knowledge of the hazard and not to recognition of the method of abatement.

American Smelting & Refining Co. v. OSHRC concerned the

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71 See American Smelting & Refining Co. v. OSHRC, 501 F.2d 504, 512 (8th Cir. 1974).
74 General Dynamics Corp. v. OSHRC, 599 F.2d 453, 464 (1st Cir. 1979).
75 501 F.2d 504 (8th Cir. 1974).
issue of whether recognized hazards are limited to those detectable through the senses or whether they extend to hazards only detectable through instrumentation. The Eighth Circuit reviewed the legislative history of Section 5(a)(1) and found compelling the fact that Congress changed the wording from “readily apparent hazards,” used in an earlier version of the bill, to “recognized hazards.” Moreover, the court pointed out that the ameliorative purpose of the Act would be subverted by a narrow construction of “recognized hazards.” “[T]o limit the general duty clause to dangers only detectable by the human senses seems to us to be a folly . . . . Where hazards are recognized but not detectable by the senses, common sense and prudence demand that instrumentation be utilized.”

A hazard is considered recognized if it is common knowledge in the employer’s industry or if the employer had knowledge of the hazardous condition. Thus, recognition may be established either objectively or subjectively.

In National Realty & Construction Co. v. OSHRC, the D.C. Circuit held that whether a hazard is recognized by an industry is determined by the “common knowledge of safety experts who are familiar with the circumstances of the industry or the activity in question.” The Commission has followed National Realty and also has held that the expert testimony of a compliance officer about industry practice may be used to show that a hazard was recognized.

In addition to expert testimony, the Commission and courts have held that other sources may be used to prove industry recognition. State and local laws, American National Standards Institute (ANSI) and National Fire Protection Association (NFPA) standards, industry publications, and manufacturers’

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76 Id. at 511.
77 489 F.2d 1257 (D.C. Cir. 1973).
78 Id. at 1265 n.32.
83 St. Joe Minerals Corp. v. OSHRC, 647 F.2d 840, 845 n.8 (8th Cir. 1981); Betten Processing Corp., 2 OSHC 1724, 1974-75 OSHD ¶ 19,481 (1975).
warnings, all have been used to demonstrate that a hazard was recognized by the employer’s industry. In proving industry recognition, it is essential that the referenced industry is the appropriate one. All industries do not necessarily recognize the same hazards and a citation may be vacated on this basis.

The second way in which a hazard may be recognized is if the employer has knowledge of the hazard. In Brennan v. OSHRC (Vylactos Laboratories, Inc.), the Eighth Circuit held that an employer’s personal knowledge of the existence of a hazard was sufficient to make the hazard “recognized.” This view has been followed by the Commission. It should be emphasized, however, that employer knowledge to show hazard recognition under Section 5(a)(1) refers to knowledge that a condition is hazardous, not knowledge that a condition exists.

An employer’s knowledge that a condition is hazardous does not depend on the occurrence of prior accidents. Moreover, employer knowledge encompasses both actual and constructive knowledge. Thus, employer knowledge has been found on the basis of correspondence, industry meetings, and publicized accidents; warnings given to supervisors by an independent engineering firm and at least one of its own employees; the employer’s use of fences, warning lights, and requiring passes to the area; and the employer’s taking some measures to protect exposed employees.

Some recent decisions of the Commission and courts of appeals have inferred employer knowledge from the obvious nature of the hazard. For example, in one case the Commission

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86 Young Sales Corp., 7 OSHC 1297, 1979 OSHD ¶ 23,768 (1979), aff’d mem. No. 79-1612 (D.C. Cir. 1980).
87 See R.L. Sanders Roofing Co. v. OSHRC, 620 F.2d 97 (5th Cir. 1980) (Commission erred in looking to construction industry rather than roofing industry.)
89 494 F.2d 460 (8th Cir. 1974).
91 St. Joe Minerals Corp. v. OSHRC, 647 F.2d 840, 845 n.7 (8th Cir. 1981). Cf. Magma Copper Co. v. Marshall, 608 F.2d 373 (9th Cir. 1979) (where recognition is based on employer knowledge the Secretary has the burden of demonstrating that the employer’s safety precautions were unacceptable in its industry).
92 Atlantic Sugar Ass’n, 4 OSHC 1355, 1976-77 OSHD ¶ 20,821 (1976).
93 St. Joe Minerals Corp. v. OSHRC, 647 F.2d 840, 845 (8th Cir. 1981).
97 489 F.2d at 1265, 1267.
98 Continental Oil Co. v. OSHRC, 630 F.2d 446 (6th Cir. 1980), cert. denied, 450 U.S. 965 (1981); Donovan v. Missouri Farmers Ass’n, 674 F.2d 690 (8th Cir. 1982).
found an "obvious" hazard where the employer refueled gasoline powered trucks indoors in the vicinity of open-flame heaters.

In National Realty the D.C. Circuit outlined the Secretary of Labor's burden of proving a Section 5(a)(1) violation. The Secretary must prove (1) that the employer failed to render its workplace free of a hazard which was (2) recognized and (3) causing or likely to cause death or serious physical harm, and (4) that the citation has specified the particular steps the cited employer should have taken to avoid citation and that these measures are feasible and have a likely utility.99

2. Applicability to Reproductive Hazards

There are two possible ways in which Section 5(a)(1) may be relevant to reproductive hazards in the workplace. First, employers could be issued citations under Section 5(a)(1) and ordered to abate working conditions which are harmful to the reproductive health of workers or their offspring. The Secretary of Labor, however, would have two difficult hurdles to overcome in proving such a violation. To begin with, citation under Section 5(a)(1) requires the hazard to be recognized by the employer or its industry. For newly discovered or newly documented reproductive hazards, it may be difficult to prove that they were recognized. Thus, Section 5(a)(1) is unlikely to be a substitute for an emergency temporary standard under Section 6(c) or as an interim measure until Section 6(b) rulemaking is completed.

The other problem with using Section 5(a)(1) to cite employers for hazardous conditions is that Section 5(a)(1) can only be used if there is no applicable standard under Section 5(a)(2). For example, if a standard had a PEL of ten ppm and the data showed that there were still reproductive hazards at exposures below the PEL, Section 5(a)(1) could not be used. The Commission has held, in Daniel International, Inc.,100 that citation under Section 5(a)(1) is improper where the applicable standard is inadequate, because this would amount to a circumvention of the rulemaking process.

OSHA's enforcement guidelines101 also provide that Section 5(a)(1) may not be used to require an abatement method not set forth in a specific standard. For example, if a standard provides

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101 OSHA Instruction CPL 2.50 (1982).
for engineering controls but not medical surveillance, Section 5(a)(1) may not be cited to require medical surveillance.

The second possible use of Section 5(a)(1), to prohibit exclusionary employment practices, has already been attempted. In American Cyanamid Co., the Commission was faced with the question of whether the employer's policy, which excluded from certain employment women aged sixteen to fifty who had not been surgically sterilized, constituted a "hazard" under Section 5(a)(1). Five women employed in the lead pigments department submitted to surgical sterilization in order to retain their positions. A majority of the Commission held that "Congress did not intend the act to apply to every conceivable aspect of employer-employee relations and that due to its unique characteristics this condition of employment is not a hazard within the meaning of the general duty clause." "Hazard" was defined to mean processes and materials which cause injury and disease by operating directly upon employees as they engage in work or work-related activities.

Dissenting in American Cyanamid Co., Commissioner Cottine charged that the sterilizations resulted from a condition of employment imposed by the employer, and therefore should be considered a hazard subject to the general duty clause. Moreover, he cautioned that "[t]he exclusion of fertile women from certain employment invites employers to exclude other highly susceptible groups from employment when the effect varies among the exposed classes of individuals." The Commission's decision was affirmed by the D.C. Circuit.

Even if an employer's reproductive hazards policy were held to be within the purview of Section 5(a)(1), it is not clear that a violation could be found. As discussed earlier, citation under Section 5(a)(1) is inappropriate if a specific standard applies. An argument could be made that the "hazard" in American Cyanamid is not the employer's policy, but the exposure to lead. The employer's policy is simply the employer's attempt to deal with the hazard. Therefore, citation under Section 5(a)(1) is arguably precluded because of the existence of a standard dealing with lead.

Another question is whether the Secretary would be able to prove all the necessary elements of a general duty clause viola-

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103 741 F.2d 444 (D.C. Cir. 1984).
tion. Specifically, the Secretary must specify the particular steps
the cited employer should have taken to avoid citation and to
demonstrate the feasibility and likely utility of those measures.
Simply ordering the return of the women to the toxic environ­
ment will not correct the problem of reproductive hazards. Fi­
nally, an order directing the company to end its exclusionary
policies would be prospective only and would not help the women
who were already excluded or who had undergone sterilization.

III. HAZARD IDENTIFICATION AND RESEARCH

This section discusses the methods by which research on occu­
pational safety and health hazards are conducted and the way
that OSHA develops its priorities for promulgating new stan­
dards.

A. NIOSH and OSHA

Much of OSHA's inactivity in regulating reproductive hazards
in the workplace can be traced to a lack of research, both by the
scientific community generally and by OSHA and the National
Institute for Occupational Safety and Health (NIOSH). Dr. Peter
F. Infante, Director of OSHA's Office of Standards Review, has
observed that regulation of reproductive hazards is made more
difficult because there are relatively fewer studies on reproduc­
tive effects of substances found in the occupational setting than
there are on other effects, such as carcinogenicity. "We're no
better off today in terms of studying reproductive hazards than
we were in the 1950's. However, in terms of regulating hazards,
we're worse off because we've done little or nothing to contain
substances shown to be teratogenic to humans exposed in the
occupational setting."104

Section 22 of the Act105 established NIOSH within the Depart­
ment of Health and Human Services to be the "research arm" of
OSHA. Thus, NIOSH research is the logical starting point in
studying the regulatory process for reproductive hazards.

According to Dr. William Halperin,106 Chief of NIOSH's Indus­
trywide Studies Branch, NIOSH priorities for research are usu­
ally based on clusters of disease, toxicological studies, and public

104 Interview (July 3, 1984).
106 Interview (July 11, 1984).
concern. In terms of reproductive hazards, former NIOSH Director Dr. John F. Finkle\textsuperscript{107} stated that NIOSH, Public Health Service (PHS), and Environmental Protection Agency (EPA) have been too slow in recognizing the issue of reproductive hazards. Current NIOSH Director Dr. J. Donald Millar\textsuperscript{108} agrees that NIOSH has not paid adequate attention to reproductive hazards in the past and notes that there is a large gap in the scientific evidence needed for good regulation of hazardous substances.

Several administrative and technical problems have hampered NIOSH's efforts. Dr. Philip Landrigan,\textsuperscript{109} former Director of NIOSH's Division of Surveillance, Hazards Evaluation, and Field Studies, commented that prior attempts to study reproductive hazards suffered from budgetary and personnel problems. Dr. Jennifer Ratcliffe,\textsuperscript{110} Epidemiologist in NIOSH's Industrywide Studies Branch, remarked that NIOSH's small amount of research done on reproductive hazards is related mostly to understaffing and that more funding and a continuity of personnel are needed.

Technical problems also have interfered with NIOSH's work. Dr. Millar and Dr. Halperin pointed to generally weak methodologies in the reproductive hazards area. Identifying suitable cohorts and the problem of multiple exposures are just two of these technical problems. Dr. Ratcliffe added that studying the reproductive effects on women is even harder because of the difficulty in obtaining a good control group.

Table 3 indicates the status of NIOSH's current research on reproductive hazards. Several of the NIOSH criteria documents submitted to OSHA have identified reproductive hazards appropriate for regulatory action. These hazards include antimony,\textsuperscript{111} carbon disulfide,\textsuperscript{112} ethylene thiourea,\textsuperscript{113} polychlorinated biphenyls (PCB's),\textsuperscript{114} and nitrous oxide.\textsuperscript{115} Formaldehyde\textsuperscript{116} and EDB,\textsuperscript{117} the

\textsuperscript{107} Interview (July 6, 1984).
\textsuperscript{109} Interview (July 10, 1984).
\textsuperscript{110} Interview (July 26, 1984).
\textsuperscript{111} NIOSH No. 78-216.
\textsuperscript{112} NIOSH No. 78-166.
\textsuperscript{113} NIOSH No. 77-140.
\textsuperscript{114} NIOSH No. 77-156.
\textsuperscript{115} NIOSH No. 78-144.
\textsuperscript{116} NIOSH No. 77-225.
\textsuperscript{117} NIOSH No. 76-149.
### TABLE 3.
**NIOSH Reproductive Hazards Research**

<table>
<thead>
<tr>
<th>Suspected hazard</th>
<th>Workers studied</th>
<th>Status of research (as of 8/1/84)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. oryzalin</td>
<td>males</td>
<td>completed</td>
</tr>
<tr>
<td>2. carbon disulfide</td>
<td>males and male workers' wives</td>
<td>completed</td>
</tr>
<tr>
<td>3. organic compounds (waste water treatment workers)</td>
<td>males</td>
<td>completed</td>
</tr>
<tr>
<td>4. PCB's</td>
<td>females</td>
<td>completed</td>
</tr>
<tr>
<td>5. heavy metals (uranium workers)</td>
<td>male workers' wives</td>
<td>completed</td>
</tr>
<tr>
<td>6. DBCP</td>
<td>males</td>
<td>completed</td>
</tr>
<tr>
<td>7. pharmaceutical estrogen</td>
<td>males</td>
<td>completed</td>
</tr>
<tr>
<td>8. pharmaceutical lab workers</td>
<td>females</td>
<td>completed</td>
</tr>
<tr>
<td>9. EDB (2 studies)</td>
<td>males</td>
<td>1 completed/ 1 in progress</td>
</tr>
<tr>
<td>10. lead</td>
<td>males</td>
<td>nearly completed</td>
</tr>
<tr>
<td>11. chemotherapeutic drugs</td>
<td>females</td>
<td>1 study completed/ hazard alert in preparation</td>
</tr>
<tr>
<td>12. glycol ethers</td>
<td>males</td>
<td>field work completed, analysis in progress</td>
</tr>
<tr>
<td>13. VDT's</td>
<td>females</td>
<td>in progress</td>
</tr>
<tr>
<td>14. dioxin</td>
<td>males</td>
<td>development stage</td>
</tr>
<tr>
<td>15. ethylene oxide</td>
<td>males and females</td>
<td>proposed</td>
</tr>
<tr>
<td>16. organo-tin compounds</td>
<td>males</td>
<td>interested in</td>
</tr>
<tr>
<td>17. butadiene</td>
<td>males</td>
<td>interested in</td>
</tr>
<tr>
<td>18. radiofrequency</td>
<td>females</td>
<td>abandoned (problem with cohorts) but being reactivated</td>
</tr>
</tbody>
</table>

Note: This list excludes some reports of health hazard evaluations based on clusters of negative reproductive outcomes (e.g., spontaneous abortions).

Subjects of recent citizen petitions,\(^{118}\) also have been linked with reproductive harms.

The most common criticism of current OSHA-NIOSH relations involves the lack of technical personnel at OSHA resulting from personnel reductions. Dr. R. Leonard Vance, OSHA Director of Health Standards Development,\(^{119}\) has stated that because of a

\(^{118}\) For a further discussion of citizen petitions, see text and notes at notes 134-40.

\(^{119}\) Interview (July 3, 1984).
lack of technical personnel, OSHA is unable to review NIOSH's work in the depth that OSHA would like. The Directorate of Health Standards Programs has only one toxicologist, two epidemiologists, and no physicians, although the Directorate of Technical Support has additional personnel.

Dr. Eula Bingham, former Assistant Secretary of Labor for OSHA, agrees that the biggest problem now is OSHA's lack of expertise. According to Dr. Millar, OSHA needs an independent technical expertise. He was unaware of a shortage of professional staff in OSHA's Directory of Health Standards Development. Dr. Philip Landrigan concluded that current OSHA-NIOSH relations are "close to non-existent at the working level." He based this on a shortage of professional staff at OSHA. Dr. William Halperin, Chief of NIOSH's Industrywide Studies Branch, agreed that the staff at OSHA is "too small for the job at hand."

Dr. Ralph E. Yodaiken, Director of OSHA's Office of Occupational Medicine, disagreed with the notion that the chronic personnel shortages impair OSHA's ability to perform technical reviews. Although he is the only full-time occupational physician at OSHA, he notes that he is aided by in-house physicians on interagency assignments and by four residents who serve two to four month residencies at OSHA. In addition, he has ready access to the opinions of expert consultants when needed. Gary Strobel, Special Assistant to the Assistant Secretary of Labor for OSHA, acknowledged that NIOSH generates more technical material than OSHA can handle, but he doubts that more technical staff is the answer. In his view, this would require more lawyers, more administrators, and more staff "all the way up the line."

Both NIOSH and OSHA officials indicated disapproval of the priorities and policies of the other agency. On the NIOSH side, Dr. Finklea said it was difficult to get feedback from OSHA on the list

120 According to Joanne Linhard, Administrative Officer of OSHA's Directory of Health Standards, as of August 1, 1984, OSHA had 25 professionals in the Health Standards Directory (includes health scientists and industrial hygienists), compared to a high of 40 working there in March, 1981. There are presently two epidemiologists and one toxicologist; this compares with the 1979 high of five to six epidemiologists and one toxicologist. Interview (August 10, 1984).
121 Interview (July 11, 1984).
122 Interview (July 11, 1984).
123 Interview (July 11, 1984).
of NIOSH-proposed criteria documents so that NIOSH could better set its priorities for research. Dr. Robbins commented that NIOSH staff sometimes became frustrated by OSHA’s failure to implement NIOSH’s scientific recommendations. Dr. Millar stated that OSHA needs to reinstitute a policy of specifying its scientific needs.

On the OSHA side, Dr. Yodaiken and Deputy Assistant Secretary of Labor for OSHA Patrick R. Tyson explained that sometimes NIOSH research does not fit in with OSHA’s regulatory goals. Former Solicitor of Labor Carin A. Claus and former Associate Solicitor of Labor for OSHA Benjamin W. Mintz added that in some instances OSHA questioned the quality of NIOSH’s work.

The general framework for OSHA-NIOSH cooperative programs is set out in a 1979 interagency agreement. In broad terms the agreement sets out the responsibilities of each agency in development of health and safety criteria, development and revision of health and safety standards, health hazard evaluations and interactions with compliance, compliance assistance, technical information exchange, and other matters. Dr. Landriigan stated that the agreement provides a good framework, but as Dr. Robbins and Dr. Millar observed, it has not been followed. None of the current OSHA officials interviewed had ever heard of the agreement.

B. Standards Advisory Committees

Section 7(a) of the Act established a National Advisory Committee on Occupational Safety and Health (NACOSH) to advise the Secretary of Labor and Secretary of HHS on matters related to the Act. NACOSH is a permanent committee comprised of twelve members, four appointed by the Secretary of HHS and eight appointed by the Secretary of Labor. The membership is comprised of representatives of management, labor, the public, and the occupational safety and health professions. NACOSH’s basic purpose is to study all relevant material, consider possible alternatives, and weigh the feasibility of proposed standards.

125 Interview, July 25, 1984.
126 Interview, July 1, 1984.
127 Interview, July 12, 1984.
In accordance with Section 7(b), the Secretary may use advisory subcommittees in developing safety and health standards. An advisory subcommittee may be either standing or ad hoc. For example, the Construction Standards Committee is a standing committee that will stay in operation for years in order to address the many standards needed for that industry. On the other hand, the Asbestos Study Committee is an ad hoc committee created to tackle a single problem. A typical subcommittee has fifteen members and is composed of an equal number of employer and employee representatives, representatives of state agencies, professional representatives, one member appointed by the Secretary of HHS, and a federal agency representative if that agency is interested in the standard.

The legislative history and case law have recognized four purposes for advisory committee consultation: (1) to enable Labor Department officials to take advantage of the expertise of committee members; (2) to allow affected persons to participate in the promulgation of standards; (3) to enable affected persons to abide by the standards once promulgated; and (4) to facilitate better informed public comments on proposed standards.

Between 1971 and 1976, most of the major health standards proposals, such as asbestos and coke oven emissions, were based on advisory committee recommendations. Since 1977, advisory committees have not been used to make recommendations. This change was based on detailed requirements for advisory committees mandated by Office of Management and Budget (OMB) and the Carter administration's effort to reduce the number of advisory committees. Instead, OSHA has used consultants to assist in the research and drafting of various parts of OSHA standards.

Some present and former OSHA officials have differing views on the efficacy of advisory panels. Dr. Vance recommended amending the advisory panel language in the Act in order to replace the members representing various factions with independent and disinterested individuals. In his view, a panel of independent scientists could provide the peer review of technical documents needed by the agency. Dr. Corn conceded that NACOSH has been "under-used and too political," but he still believes

130 Id. § 656(b).
131 The Secretary's regulations on the composition and duties of § 7(b) advisory committees appear at 29 C.F.R. Part 1912 (1984).
133 B. Mintz, supra note 30, at 65.
that it could perform the peer review function if it was seriously regarded by the Assistant Secretary of Labor for OSHA. Dr. Bingham recognized the importance of advisory committees. In her view, the committees need not be non-political, and indeed benefit by having industry and employee representatives.

C. Citizen Petitions

Section 6(b)(1) of the Act contemplates that information about the need for a new standard may be presented by "an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision ...." The Secretary's regulations add that "any interested person may file ... a written petition for the promulgation, modification, or revocation of a standard."

Table 4 lists the citizen petitions for new standards and the status of the standards. The asbestos, vinyl chloride, diving, DBP, and acrylonitrile standards were the only petitions granted by OSHA. For the other standards, OSHA's refusal to issue an ETS or begin rulemaking on a permanent standard was sometimes followed by a court proceeding in which the petitioners sought to compel issuance of the standard. In some instances, such as pesticides, cotton dust, and labeling, the mere filing of the lawsuit may have been a substantial factor in issuing the standard more quickly. In other instances, protracted litigation was necessary and had a mixed record of success for the petitioners. After nine years of litigation, the field sanitation case was settled in 1982 and OSHA agreed to consider issuing a standard. A proposed standard was issued in March, 1984, but in April, 1985, OSHA made a final determination not to issue the standard. It is not clear when a final standard will be promulgated.

Regardless of the merits of a citizen petition, the courts are extremely reluctant to order the issuance of a standard, particularly an ETS. The decision to issue a standard commits the agency to a substantial expenditure of resources and is often at

135 B. Mintz, supra note 30, at 197.
### TABLE 4.
### Citizen Petitions for OSHA Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Year</th>
<th>Petitioner</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>asbestos (I)</td>
<td>1971</td>
<td>AFL-CIO</td>
<td>ETS issued, not challenged; permanent standard upheld</td>
</tr>
<tr>
<td>field sanitation</td>
<td>1972</td>
<td>National Congress of Hispanic American Citizens</td>
<td>Proposed standard withdrawn, 1984</td>
</tr>
<tr>
<td>organophosphorous pesticides</td>
<td>1972</td>
<td>Migrant Legal Action Program, Inc.</td>
<td>Petition denied, but ETS later issued. (subsequently vacated)</td>
</tr>
<tr>
<td>vinyl chloride</td>
<td>1974</td>
<td>AFL-CIO</td>
<td>ETS not challenged; permanent standard upheld</td>
</tr>
<tr>
<td>cotton dust</td>
<td>1975</td>
<td>Textile Workers Union</td>
<td>Petition denied, but permanent standard later issued</td>
</tr>
<tr>
<td>hyperbaric diving</td>
<td>1976</td>
<td>United Brotherhood of Carpenters</td>
<td>ETS struck down; part of permanent standard struck down</td>
</tr>
<tr>
<td>labeling</td>
<td>1976</td>
<td>Public Citizen Health Research Group</td>
<td>Petition denied, but proposed standard later issued and, after revision, final standard issued</td>
</tr>
<tr>
<td>DBCP</td>
<td>1977</td>
<td>Oil, Chemical, and Atomic Workers Union</td>
<td>ETS not challenged; permanent standard not challenged</td>
</tr>
<tr>
<td>acrylonitrile</td>
<td>1977</td>
<td>United Rubber Workers</td>
<td>ETS upheld; permanent standard not challenged</td>
</tr>
</tbody>
</table>

the expense of other, arguably more important, rulemaking. Thus, in *Public Citizen Health Research Group v. Auchter*, the D.C. Circuit held that the district court erred in ordering OSHA to issue an ETS for ethylene oxide. While ruling that the district court “impermissibly substituted its evaluation for that of OSHA” in ordering the issuance of an ETS within twenty days, the court ordered OSHA to expedite its rulemaking. In *UAW v. Donovan*, the district court, in refusing to order OSHA to issue an ETS on formaldehyde, stated: “Judicial review of an OSHA decision not to regulate is ‘extremely narrow.’ Reversal of OSHA’s

137 702 F.2d 1150 (D.C. Cir. 1983).
138 *Id.* at 1153.
decision here thus requires the exceptional to exist from both 'substantive' and 'judicial review' perspectives.\footnote{Id. at 751.}

\section*{D. OSHA Priorities}

Section 6(b)(1) of the Act directs the Secretary of Labor to promulgate standards “to serve the objectives of this Act . . . .” Section 6(g) sets forth two criteria for standards development: the urgency of the need for the standard (“worst-first”) and the recommendations from NIOSH.

In \textit{National Congress of Hispanic American Citizens v. Marshall},\footnote{626 F.2d 882 (D.C. Cir. 1979).} the D.C. Circuit reviewed OSHA’s priorities for development of health and safety standards. For health standards, OSHA considers the number of workers exposed, the severity of the hazards, the existence of research relevant to hazard identification and methods of control, NIOSH recommendations, citizen petitions, court decisions, and other factors.\footnote{Id. at 886.} Using these criteria, OSHA generally has given its highest priority to carcinogenic substances.\footnote{Id.}

Although White House priorities and congressional oversight and appropriations activity also affect standards promulgation,\footnote{Id. at 85.} Congress has never spelled out its priorities for OSHA standards. According to Dr. Vance, “the federal agencies are not doing a competent job of regulating chemicals and part of the blame rests with Congress.”\footnote{Interview (July 3, 1984).} In his view, there is a need for congressional guidelines in developing criteria for priorities for regulation, such as the nature of the hazard and the level of exposure.\footnote{Id.}

OSHA has developed an internal document, RUL.1, which provides a framework for dealing with severity, exposure, risk, feasibility, and similar issues. According to Mr. Tyson, the potency of the substance and the current exposure levels are two key factors in establishing the need to regulate a hazardous substance.\footnote{Interview (July 25, 1984).} Professor Claus asserted that although priority should be given to

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{140} \textit{Id.} at 751.
\item \textsuperscript{141} 626 F.2d 882 (D.C. Cir. 1979).
\item \textsuperscript{142} \textit{Id.} at 886.
\item \textsuperscript{143} “The priority treatment for cotton dust and lead was based on the severe hazards involved, the large number of employees at risk, and the excellent studies available on the hazards of cotton dust and lead.” B. Mintz, \textit{supra} note 30, at 84 (footnote omitted).
\item \textsuperscript{144} \textit{Id.} at 85.
\item \textsuperscript{145} Interview (July 3, 1984).
\item \textsuperscript{146} \textit{Id.}
\item \textsuperscript{147} Interview (July 25, 1984).
\end{enumerate}
\end{footnotesize}
the gravest health hazards, OSHA cannot afford to use all of its resources here. Dr. Vance observed that OSHA is required by law to apportion its resources between reviewing old standards and developing new ones.

The difficult scientific and policy questions of deciding what substances should be regulated, in what order, and in what manner are further complicated by political considerations. Most observers probably would agree with Dr. Vance that "the setting of OSHA's priorities is, and always has been, highly politicized." Dr. Corn commented that the priorities for standards-setting often depend on "who is making the most noise politically." In his view, this has been especially true during the Carter and Reagan administrations. Mr. Auchter and Mr. Tyson contend that most of the pressure comes from the various interest groups rather than from the White House. Indeed, the degree of political pressure may be related to the type of regulation at issue. Mr. Auchter related that people are more reasonable in the safety area than in health: "Health issues involve politics at its lowest." The way in which political considerations enter the decision-making process is also the cause of some concern. Dr. Infante cautions that political influences should be used only in policy decisions, not in the interpretation of scientific data: "If you don't want to regulate because of cost, say so. Don't prostitute the science."

IV. REGULATORY OPTIONS AND OBSTACLES

The following section discusses the problems in promulgating new health standards and, in particular, standards dealing with reproductive hazards. These difficulties can often be traced to the detailed procedural requirements of the Act, judicial interpretations of OSHA rulemaking, administrative and political factors, and scientific uncertainty.
A. Procedures for Promulgating Standards

1. Overview

Section 6(b) provides that any promulgation, modification, or revocation of OSHA standards must comply with specific rulemaking procedures.\(^{156}\) Pursuant to Section 6(b)(2), the Secretary is required to publish a notice of proposed rulemaking in the Federal Register and must allow thirty days after publication for interested parties to submit written data or comments. As a practical matter, OSHA usually allows at least ninety days for the submission of data or comments.\(^ {157}\)

OSHA usually schedules a public hearing when a proposal is issued, even though under Section 6(b)(3) a hearing is not required unless requested. Persons wishing to testify must indicate to OSHA the amount of time requested and the specific provisions to be addressed. Most of the testimony time is used to question witnesses.\(^ {158}\) OSHA also has its own witnesses and questions them.\(^ {159}\)

OSHA’s regulations provide that rulemaking proceedings shall be legislative in nature, but that fairness may require cross-examination on “crucial issues.”\(^ {160}\) In practice, however, OSHA has usually permitted cross-examination quite freely. The parties are often joined together (e.g., all employers, all unions) for the purpose of having a single individual question or cross-examine the witnesses.\(^ {161}\)

Hearings on proposed standards are of increasing importance, both in allowing interested persons an opportunity to present their views and in developing the record for subsequent judicial review. This may account for the growing length of the hearing. For example, OSHA’s first asbestos rulemaking hearing took four days and resulted in a record of 1100 pages. The hearing on OSHA’s carcinogens policy took two months and had a record of 250,000 pages.\(^ {162}\)

After the hearing is completed, the presiding ALJ usually gives


\(^{157}\) B. Mintz, supra note 30, at 63.

\(^{158}\) Id.

\(^{159}\) Id. at 64.


\(^{161}\) B. Mintz, supra note 30, at 65.

\(^{162}\) Id. at 62.
the parties thirty days to submit additional data and thirty days after that to submit post-hearing briefs. According to Section 6(b)(4), the final standard (or a determination that no new standard is needed) must be issued within sixty days after the end of the comment period. For a variety of reasons, OSHA has not been able to meet this deadline.

Courts have held that no mandatory timetable exists for promulgation of final standards under Section 6(b)(4). For example, in National Congress of Hispanic American Citizens v. Usery, the plaintiff sought an order requiring the Secretary to promulgate field sanitation, machinery guarding, and other agricultural standards. The district court granted summary judgment for the plaintiff and held that the timetable for promulgating standards in Section 6(b)(1) through (4) was mandatory. On appeal, the D.C. Circuit reversed. In an opinion by Justice Clark, the court held that the timetable was not mandatory because: (1) the Secretary was given discretion under Section 6(g) to “alter priorities and defer action due to legitimate statutory considerations;” and (2) inasmuch as the Secretary can decide not to issue a standard, “there is no sense in proceeding completely through the rulemaking process ... only to end up with the Secretary issuing a notice that the standard is not adopted.”

The final form of a standard may differ from the original proposal. Changes in a standard often reflect the comments and criticisms of interested parties as well as further agency deliberation and thus are to be encouraged. Nevertheless, the argument has been raised that where the final standard differs from the proposal, interested persons have been denied an opportunity to comment on the standard in its final form.

In Borg-Warner Corp., the Commission held that an asbestos
standard was not rendered invalid merely because it differed from the proposed standard. The notice of proposed rulemaking set forth the text of an emergency temporary standard (ETS) and announced the intent to adopt the ETS as a final standard, with or without changes after interested persons had an opportunity to comment on the proposal. Similarly, in Taylor Diving & Salvage Co. v. United States Department of Labor, the Fifth Circuit rejected a challenge to the employee-access-to-records provision of the commercial diving standard. According to the court, it is not necessary for the final form of a regulation to be republished in the Federal Register where the proposed regulation, in its initial form, gives sufficient notice to the interested parties of the Secretary's intentions.

Final OSHA standards typically contain detailed preambles, the standard itself, and any appendices. A common format is as follows:

1. An introductory discussion of the substance being regulated, its uses, and toxic properties.
2. A description of the background and history of the rulemaking proceeding.
3. A summary of the record and a discussion of the major issues raised by the proceeding. For health standards, this includes the extent of the risk upon exposure to the substance, the PEL, and economic and technological feasibility.
4. A discussion of the specific provisions of the standard, section-by-section, including an explanation why the particular provision was adopted and others were rejected.
5. A statement, as appropriate, on OSHA compliance with presidential executive orders on regulatory analysis, the National Environmental Policy Act, and the Regulatory Flexibility Act.
6. The text of the standard.

2. Possible Modifications

There is widespread agreement that the OSHA rulemaking process is slow, cumbersome, a drain on resources, and extremely

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167 599 F.2d 622, 626 (5th Cir. 1979). Accord, Daniel Int'l Corp. v. OSHRC, 656 F.2d 925 (4th Cir. 1981).
171 See, B. MINTZ, supra note 30, at 71.
adversarial. In an effort to expedite the process, in 1975 former Secretary of Labor John Dunlop attempted to use negotiations between the steel companies and unions to reach a consensus on a standard for coke oven emissions. As one commentator notes, "[t]his effort failed, and Dunlop's approach was greeted with considerable hostility."

In 1983 OSHA enlisted the services of neutral third-party mediators to facilitate a labor-industry agreement on revision of the existing benzene standard. Industry representatives from the Chemical Manufacturers Association, Rubber Manufacturers Association, American Iron and Steel Institute, and the American Petroleum Institute held a series of mediation sessions with union representatives from the AFL-CIO, United Steelworkers, Oil, Chemical, and Atomic Workers, and United Rubber Workers. Although mediation was unsuccessful in the benzene standard, the use of mediation has prompted a discussion of alternative dispute resolution techniques in OSHA rulemaking.

Deputy Assistant Secretary of Labor for OSHA, Patrick R. Tyson, and Special Assistant to the Assistant Secretary of Labor, Gary A. Strobel, were optimistic about mediation and thought that it could shorten the rulemaking process (both the hearing and comment period) and ease the resource drain of standards-setting. Dr. R. Leonard Vance, Director of OSHA Health Standards Programs, also was optimistic. He thought that the best chance for success might be with chemicals that had not been the subject of prior regulation and where the positions of the parties had not hardened. He favored mediation to reach a draft standard and then allow the public to comment. He asked for budget support for fiscal 1985 for this activity.

Other former OSHA officials are less sanguine about the prospects for mediation. Former Assistant Secretary of Labor for OSHA, Dr. Morton Corn, and former Associate Solicitor of

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172 See, e.g., COMPTROLLER GENERAL OF THE UNITED STATES, REPORT TO CONGRESS, DELAYS IN SETTING WORKPLACE STANDARDS FOR CANCER CAUSING AND OTHER DANGEROUS SUBSTANCES (1977); GENERAL ACCOUNTING OFFICE, REPORT TO THE SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE: SLOW PROGRESS LIKELY IN DEVELOPMENT OF STANDARDS FOR TOXIC SUBSTANCES AND HARMFUL PHYSICAL AGENTS FOUND IN WORKPLACES (1973).

173 B. Mintz, supra note 29, at 88 (footnote omitted).

174 Interview (July 25, 1984).

175 Interview (July 25, 1984).

176 Interview (July 3, 1984).

177 Interview (July 3, 1984).
Labor for OSHA, Benjamin W. Mintz, were "skeptical" about mediation, perhaps as a result of OSHA's experience in 1975. Former Assistant Secretary of Labor for OSHA, Dr. Eula Bingham, also expressed reservations. Dr. Bingham cautioned that it would be inappropriate to have the mediation take place too far along in the rulemaking process. Former Solicitor of Labor Carin A. Claus, while agreeing that consensus is important, questioned whether OSHA can or should delegate its statutory responsibility to protect the public interest. Specifically, she questioned whether the unions can be expected to represent the views of all workers, including non-union employees. Mr. Strobel countered this argument by asserting that the regular comment period protects against this danger and permits comments by all concerned individuals.

Even those individuals who have doubts about mediation emphasize the need for labor-management cooperation. Dr. Bingham recommends that labor and management attempt to reach agreement on key issues. Professor Mintz notes that joint statements, stipulations of fact, and other agreements help the rulemaking process, but he adds that such agreements are difficult to reach within the present rulemaking framework.

3. Judicial review

The validity of OSHA standards may be reviewed by the courts in two ways. First, any party adversely affected by a standard may obtain pre-enforcement review by filing a petition for review within sixty days of a standard's promulgation. Pursuant to Section 6(f), these petitions may be filed in the United States court of appeals for the circuit in which the party resides or has its principal place of business. A copy of the petition must be forwarded to the Secretary by the clerk of the court.

The second method of review, available to any person "adversely affected or aggrieved" by a final order of the Commission, is filing a petition for review pursuant to Section 11(a). Petitions

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178 Interview (July 12, 1984).
179 Telephone interview (July 23, 1984).
179 Interview (July 1, 1984).
180 Interview (July 25, 1984).
181 Telephone interview (July 23, 1984).
182 Interview (July 12, 1984).
183 The discussion of judicial review is based largely upon M. ROTHSTEIN, supra note 168, at 89-97.
for review under Section 11(a) must also be filed within sixty days in a United States court of appeals for the circuit in which the violation is alleged to have occurred, for the circuit in which the employer has its principal office, or in the District of Columbia Circuit.

Filing a petition for judicial review under Section 6(f) does not stay the effective date of a standard, nor does a Section 11(a) petition stay a final order of the Commission. A reviewing court, however, may grant a stay. In judicial review under either section of the Act, the Secretary's determinations in promulgating a standard are conclusive if supported by "substantial evidence" in the record considered as a whole.

Section 6(f) specifically provides for judicial review of standards in the United States courts of appeals. Section 8(g), which authorizes OSHA to promulgate necessary rules and regulations, is silent on the issue of judicial review. Therefore, under the Administrative Procedure Act, the district courts are the proper forum for initial review of regulations. Consequently, it is important to determine whether the Secretary has promulgated a "standard" or a "regulation."

In Louisiana Chemical Association v. Bingham,\(^1\) the Fifth Circuit held that although the promulgating agency's characterization of a rule is a relevant factor, it is not necessarily determinative. According to the court, Congress conceived of Section 6 OSHA standards as remedial measures addressed to specific and already identified hazards, not as purely administrative efforts designed to uncover violations of the Act and discover unknown dangers. Applying this test, the access to exposure and medical records rule is a regulation aimed primarily at possible detection of significant risks not yet covered by standards. Therefore, it is a regulation reviewable in district court rather than a standard reviewable in the court of appeals.

Section 6(f) permits the party challenging the standard to choose to file for judicial review in the United States court of appeals for the circuit in which it resides or has its principle place of business. Considering the national scope of OSHA standards and the number of parties adversely affected by a standard, there is ample opportunity for forum shopping. Indeed, the ability of affected industries to obtain judicial review in a sympathetic court is one of the major impediments to OSHA rulemaking ac-

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\(^1\) 657 F.2d 777 (5th Cir. 1981).
cording to a number of individuals interviewed, including Dr. Bingham and Dr. Vance.186

A second, related problem concerns the “race to the courthouse” that invariably occurs when two or more parties are seeking review in different circuits. Under 28 U.S.C. Section 2112(a), if there are two or more filings in different courts of appeals to review the same administrative order, venue will lie in the court of the first filing.

In *Industrial Union Department v. Bingham*,187 the court held that a petition to review the benzene standard was timely filed in the D.C. Circuit after the standard was disclosed to industry and labor representatives, but before the standard was filed with the Federal Register. Nevertheless, “in the interest of justice,” the court ordered the case transferred to the Fifth Circuit, where “the first petition was filed subsequent to the disclosure of the agency decision to the public.”188

After the decision in *Industrial Union Department*, OSHA promulgated a regulation that indicated that standards are “issued” when they are filed with the Federal Register.189 Although the regulation gave all parties the same starting time, it did not end the “race to the courthouse.” Indeed, even with a uniform starting time, problems of varying sorts have arisen. For example, in *United Steelworkers of America v. Marshall*,190 a conflict developed involving two challenges to OSHA’s lead standard. When OSHA “issued” its standard on November 13, 1978, the Steelworkers immediately filed a petition for judicial review in the Third Circuit at 8:45 a.m. EST. At precisely the same time, 7:45 a.m. CST, the Lead Industries Association filed a petition in the Fifth Circuit. In ruling on the venue question, the Third Circuit refused to go beyond the official notations of the time of filing to determine if one petition had been filed seconds before the other petition. The court declared that “unlike race tracks, . . . courts are not equipped with photoelectric timers, and we decline the invitation to speculate which nose would show as first in a photo finish.”191

186 Dr. Vance added that “activists” also may obtain review in a sympathetic court and induce the court to determine OSHA’s regulatory priorities. Interview with Dr. R. Leonard Vance, Director of OSHA Health Standards Development (July 3, 1984).
187 570 F.2d 965 (D.C. Cir. 1977).
188 Id. at 972.
190 592 F.2d 693 (3d Cir. 1979).
191 Id. at 695.
court then ordered that the proceedings be transferred to the D.C. Circuit, which was deemed "obviously a convenient forum" because a petition to review an EPA lead standard had recently been filed by the industry in that court. 

Section 6(f) grants the right to seek judicial review to "any person who may be adversely affected by a standard." There have been no OSHA cases decided on the issue of how adversely affected a person must be in order to challenge a standard. In Fire Equipment Manufacturers' Association v. Marshall, however, the Seventh Circuit held that a trade association and manufacturers of fire protection equipment did not have standing to challenge an amendment to OSHA's fire protection standard. The industry petitioners claimed they were "adversely affected" because the new standard would result in a decline of profits and competitive disadvantage. In rejecting the argument, the court held that "[t]he profits of manufacturers of fire fighting equipment are not within the zone-of-interests protected or regulated by the Act." 

Section 6(f) provides that in judicial review of new OSHA standards "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." Thus, although the substantial evidence test is generally used in adjudicatory proceedings or formal rulemaking it applies to OSHA standards promulgation, which is informal rulemaking. The Act's anomalous use of the substantial evidence test resulted from a legislative compromise. The Senate bill provided for informal rulemaking, while the House version required formal rulemaking and the use of the substantial evidence test. 

The courts have had considerable difficulty in applying the substantial evidence test in reviewing OSHA standards. In Asso-
ciated Industries v. United States Department of Labor, the Second Circuit held that the substantial evidence test must be applied to policy determinations as well as findings of fact. The court suggested, however, that the difference between the substantial evidence test and the "arbitrary and capricious" test may be largely semantic.200 This view has been shared by the Fifth Circuit.201

The D.C. Circuit has taken a somewhat different approach and considers that the substantial evidence test provides for "more rigorous scrutiny" than the arbitrary and capricious test.202 In Industrial Union Department v. Hodgson,203 the D.C. Circuit found it "impossible" to apply the substantial evidence test to the Secretary's policy determinations. The court indicated it would analyze the Secretary's rulemaking to determine whether it had been performed "in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future."204

In AFL-CIO v. Marshall,205 the D.C. Circuit set out the scope of its review function.

The tasks of this reviewing court are thus to ensure that the agency has: (1) acted within the scope of its authority; (2) followed procedures required by statute and by its own regulations; (3) explicated the bases for its decisions; (4) adduced substantial evidence in the record to support its determinations.206

The most detailed standard of review was formulated by the Third Circuit in Synthetic Organic Chemical Manufacturers As-

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199 487 F.2d 342 (2d Cir. 1973).
200 Id. at 349-50.
201 See American Petrol. Inst. v. OSHA, 581 F.2d 493, 497 (5th Cir. 1978), aff'd sub nom. Industrial Union Dep't v. American Petrol. Inst., 448 U.S. 607 (1980); Florida Peach Growers Ass'n v. United States Dep't of Labor, 489 F.2d 120, 128-29 (5th Cir. 1974). See also Texas Indep. Ginners Ass'n v. Marshall, 630 F.2d 398, 404 n.22 (5th Cir. 1980) (rejecting assertion that substantial evidence test can be used only for factual determinations and noting that use of this test for policy considerations is practicable).
203 499 F.2d 467 (D.C. Cir. 1974).
204 Id. at 475 (quoting Automotive Parts & Accessories Ass'n v. Boyd, 407 F.2d 330, 338 (D.C. Cir. 1969)). See Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1304 (2d Cir. 1975).
206 617 F.2d at 650 (footnotes omitted).
According to the court, judicial review of any standard promulgated under Section 6 is a five-step process, consisting of the following:

1. determining whether the Secretary’s notice of proposed rulemaking adequately informed interested persons of the action taken;
2. determining whether the Secretary’s promulgation adequately sets forth reasons for his action;
3. determining whether the statement of reasons reflects consideration of factors relevant under the statute;
4. determining whether presently available alternatives were at least considered; and
5. if the Secretary’s determination is based in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination.

Despite these slightly different tests, the courts of appeals have been in agreement on the general standards of review of policy decisions. Judicial review of policy decisions will be limited to determining whether the Secretary’s action is consistent with the statutory language and purpose, whether the policy judgment is reasonably related to factual matters supported by substantial evidence, and whether there are adequate explanations of the assumptions underlying predictions or extrapolations and of the bases for resolving conflicts and ambiguities. A standard will be remanded only if there are “nagging questions” about the reason and rationale for the Secretary’s particular choices.

The Supreme Court also has been troubled in its search for the most appropriate standard by which to review the complex scientific and policy issues involved in OSHA rulemaking. It has

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208 503 F.2d at 1160.
210 Texas Indep. Ginners Ass’n v. Marshall, 630 F.2d 398, 405 (5th Cir. 1980).
213 See Industrial Union Dep’t v. American Petrol. Inst., 448 U.S. 607, 695 & n.9, 705-06
indicated, however, that it will give deference to the courts of appeals' determinations of whether there is substantial evidence.

In *American Textile Manufacturers Institute, Inc. v. Donovan*, the Supreme Court held that, because the Act places responsibility for determining substantial evidence questions in the courts of appeals, the Supreme Court will intervene only in the rare instance when the substantial evidence standard was mis apprehended or grossly misapplied by the court of appeals.

Our inquiry is not to determine whether we, in the first instance, would find OSHA's findings supported by substantial evidence. Instead, we turn to OSHA's findings and the record upon which they were based to decide whether the Court of Appeals "misapprehended or grossly misapplied" the substantial evidence test. 

4. Emergency Temporary Standards

Section 6(c)(1) provides that if the Secretary determines that employees are "exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards," an emergency temporary standard (ETS) may be issued. These standards are effective immediately upon publication in the Federal Register without any detailed rulemaking requirements. Under Section 6(c)(3) an ETS may remain in effect for only six months; thereafter, the Secretary must promulgate a permanent standard under Section 6(b). In this event the ETS serves as the proposed rule.

Although emergency temporary standards need not be promulgated in accordance with the detailed procedures of Section 6(b), there are certain procedural requirements. One of these requirements is a statement of reasons. In *Dry Color Manufacturers Association v. Department of Labor*, the Secretary at-


215 Id. at 523.
220 486 F.2d 98 (3d Cir. 1973).
tempted to promulgate an ETS concerning exposure to fourteen chemicals said to be carcinogens. The only statement of reasons was a conclusion, finding the chemicals to be carcinogens and reciting the need for a standard based on the language of Section 6(c)(1). The Third Circuit held that the statement of reasons was inadequate to satisfy Section 6(e). According to the court, an ETS statement of reasons must indicate: (1) what data in the record are being principally relied on; (2) why those data suffice to show that the substances covered by the standard are harmful and pose a grave danger of exposure to employees; and (3) why the particular standard is necessary for the protection of employees.\footnote{Id. at 106-07; see Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 506 F.2d 385 (3d Cir. 1974), cert. denied, 420 U.S. 973 (1975); Florida Peach Growers Ass'n v. United States Dep't of Labor, 489 F.2d 120 (5th Cir. 1974); Associated Indus. v. United States Dep't of Labor, 487 F.2d 342 (2d Cir. 1973).}

The dissent in \textit{Dry Color}, however, argued that preparing an exhaustive statement of reasons would be time-consuming and render the ETS mechanism ineffective. Thus, it was suggested, all that should be required is notice of the Secretary’s reason for issuing the ETS and access to the scientific data upon which the Secretary relied.\footnote{486 F.2d at 110 (dissenting opinion).}

In \textit{Florida Peach Growers Association v. United States Department of Labor},\footnote{489 F.2d 120 (5th Cir. 1974).} organizations representing farmworkers contended that the Secretary exceeded his authority by summarily amending an ETS without using the modification procedures of Section 6(b). The Fifth Circuit disagreed and held that an ETS may be amended in the same manner as it was originally issued under Section 6(c). The court observed that adherence to Section 6(b) procedures could easily consume all of the six month life of the ETS.\footnote{Id. at 127.}

The final function of an ETS may be to serve as a proposed rule for the issuance of a permanent standard. In \textit{Synthetic Organic Chemical Manufacturers Association v. Brennan},\footnote{506 F.2d 385 (3d Cir. 1974), cert. denied, 420 U.S. 973 (1975).} the Secretary formed an advisory committee, after an ETS was issued, to help draft a permanent standard. Section 6(b), however, provides that a proposed rule may not be published until sixty days after the submission of an advisory committee’s report.\footnote{29 U.S.C. § 655(b).} The Third Circuit
rejected the Secretary's assertion that the apparent conflict between Sections 6(b) and 6(c) should be resolved by exempting ETS promulgation from this procedural requirement of Section 6(b). The court held that the language of Section 6(b) prevails and that an ETS may not be used "as a technique for avoiding the procedural safeguards of public comment and hearings required by subsection 6(b)." Thus, the Secretary must either appoint the committee well in advance of issuing an ETS or promulgate a permanent standard based on an ETS without using an advisory committee.

An emergency temporary standard must be based on the existence of a grave danger and the need for a standard to protect workers from the danger. The first element, therefore, is proving that there is a grave danger. According to the Third Circuit in *Dry Color Manufacturers Association v. Department of Labor*, the Act does not require an absolute certainty of the deleterious effect of a substance, but there must be evidence showing "more than some possibility" of a grave danger. The dissent, however, contended that the purpose of the Act would be best effectuated by holding that even a scintilla of evidence can support an ETS.

In *Florida Peach Growers Association v. United States Department of Labor*, the Fifth Circuit rejected the suggestion that deaths must occur before the issuance of an ETS. Nevertheless, the court held that there must be a danger of "incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health . . . ."

In many instances the only scientific research on a hazardous substance before promulgating an ETS will be animal studies. The application to humans of data extrapolated from animal studies of carcinogens, however, was specifically accepted by the Third Circuit in *Dry Color and Synthetic Organic Chemical Manufacturers Association v. Brennan*.

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227 506 F.2d at 389 (quoting *Dry Color Mfrs. Ass'n v. Department of Labor*, 486 F.2d 98, 104-05 n.9a (3d Cir. 1973)).
228 486 F.2d 98 (3d Cir. 1973).
229 Id. at 104.
230 Id. at 110 (dissenting opinion).
231 489 F.2d 120 (5th Cir. 1974).
232 Id. at 132.
The second element of an ETS is the need to protect workers from the danger. In Dry Color the court noted that the purpose of Section 6(c)(1), to provide immediate protection, allows the Secretary to assume that employee exposure is occurring at any workplace containing the proscribed hazardous substance and where the corrective measures required by the ETS are not in effect. If the workplace is as safe and healthful without compliance with the letter of the ETS, the employer must resort to the variance procedures of Section 6(d).

As the following table demonstrates, OSHA has had a difficult time in the courts of appeals in challenges to its ETS's. This is particularly true in the Fifth Circuit, which has refused to

<table>
<thead>
<tr>
<th>Standard</th>
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<th>Result</th>
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<td>1971</td>
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<td>12 Upheld</td>
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<td>2 Vacated</td>
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<td>1974</td>
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<td>Taylor Diving &amp; Salvage Co. v. Department of Labor, 537 F.2d 819 (5th Cir. 1976)</td>
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<td>benzene</td>
<td>1977</td>
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<tr>
<td>DBCP</td>
<td>1977</td>
<td>Not challenged</td>
<td>—</td>
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<td>1983</td>
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<td>Asbestos Info. Ass'n v. OSHA, 727 F.2d 415 (5th Cir. 1984)</td>
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234 486 F.2d at 102-03 n.3.

235 Id. Cf. Taylor Diving & Salvage Co. v. United States Dep't of Labor, 537 F.2d 819 (5th Cir. 1976) (stay of ETS granted where there was probability of success on merits of attack on standard and the likelihood of issuance of variance too uncertain to eliminate possibility of irreparable injury).
uphold the ETS for pesticides, commercial diving, or asbestos. The most devastating blow to the use of emergency standards by OSHA was the Fifth Circuit's recent decision relating to asbestos.

In 1983 OSHA promulgated an ETS for asbestos, lowering the PEL from 2.0 fibers per cubic centimeter (fcc) to 0.5 fcc. The ETS was based on a new quantitative risk assessment showing that reducing the PEL for six months would save forty to eighty lives. A group of asbestos products manufacturers sought judicial review of the ETS in the Fifth Circuit.

In Asbestos Information Association/North America v. OSHA, the Fifth Circuit held that the ETS was invalid and stayed its enforcement. The central theme of the court's analysis focuses on whether OSHA had proven the need to adopt an ETS for asbestos rather than modifying the existing standard after notice and comment rulemaking. The court pointed out that Section 6(b) rulemaking can be completed within one year regardless of an ETS and therefore "the practical effects of our decision on the regulations enforced in the workplace will endure only a short time." It further added that "the plain wording of the statute limits as to assessing the harm likely to accrue, or the grave danger that the ETS may alleviate, during the six-month period that is the life of the standard."

One reason for publishing the ETS, according to OSHA, was to set in motion the process of promulgating a new permanent asbestos standard. The court was wary of permitting Section 6(c) rulemaking to substitute for Section 6(b) rulemaking:

[A]s its legislative history makes clear, the ETS statute is not to be used merely as an interim relief measure, but treated as an extraordinary power to be used only in "limited situations" in which grave danger exists, and then, to be "delicately exercised." The Agency cannot use its ETS powers as a stop-gap measure. This would allow it to displace its clear obligations to promulgate rules after public notice and opportunity for comment in any case, not just in those in which an ETS is necessary to avert grave danger.

The court rejected the asbestos manufacturers' argument that an ETS may not be issued unless it is based on new information. A "heightened awareness" based on new extrapolations certainly could justify the Secretary's action. Nevertheless, the benefits

236 727 F.2d 415 (5th Cir. 1984).
237 Id. at 420.
238 Id. at 422.
239 Id. (citations omitted).
240 Id. at 423.
of the ETS must outweigh its costs.\textsuperscript{241} While it rejected the industry argument that the costs were excessive, the court was unconvinced of the accuracy of OSHA's estimate of the benefits.

OSHA performed a detailed quantitative risk assessment and developed a dose-response curve from epidemiological studies of exposed workers rather than by relying on animal data. This assessment was made specifically to satisfy the "significant risk" requirement of the Supreme Court's \textit{benzene} decision\textsuperscript{242} and the "grave danger" language of Section 6(c). The Fifth Circuit was troubled by the possibility of inaccuracy in using risk assessment for a six-month exposure period.

\textit{[A]lthough risk assessment analysis is an extremely useful tool, especially when used to project lifetime consequences of exposure, the results of its application to a small slice of time are speculative because the underlying data-base projects only long term risks . . . . Applying the risk assessment process to a period of six months, one-ninetieth of OSHA's estimated working lifetime, only magnifies those inherent uncertainties.}\textsuperscript{243}

Moreover, as the court had previously noted, the mathematical extrapolations had not been the subject of "peer reviews." "Precisely because the data has not been scrutinized, however, the court has particular interest in having access to both favorable and unfavorable peer reviews."\textsuperscript{244}

Finally, the court held that, even assuming OSHA's projected benefits would accrue from the ETS, OSHA failed to prove that an ETS — the "most dramatic weapon in its enforcement arsenal\textsuperscript{245} — is necessary to achieve the projected benefits.\textsuperscript{246} Specifically, OSHA had failed to enforce its current standard and could reduce exposures through enforcement and expeditious Section 6(b) rulemaking.\textsuperscript{247}

The court's opinion is subject to a variety of criticisms. Simply stated, the court is requiring OSHA to do the impossible. If the ETS were not accompanied by quantitative risk assessment of the expected benefits, undoubtedly the court would have held the ETS to be invalid. OSHA, however, performed a detailed risk

\begin{itemize}
  \item \textsuperscript{241} \textit{Id.} at 423-24.
  \item \textsuperscript{242} \textit{Industrial Union Dep't v. American Petrol. Inst.}, 448 U.S. 607 (1980).
  \item \textsuperscript{243} \textit{727 F.2d} at 425-26.
  \item \textsuperscript{244} \textit{Id.} at 421 n.15.
  \item \textsuperscript{245} \textit{Id.}
  \item \textsuperscript{246} \textit{Id.} at 426.
  \item \textsuperscript{247} \textit{Id.} at 427.
\end{itemize}
assessment based on epidemiological evidence and calculated the number of lives expected to be saved. Differences of opinion over mathematical models should not obscure the fact that under any model a substantial number of lives would be saved by the ETS. It is never possible to predict precisely the effects of exposure on thousands of workers — nor is such evidence required. As the Supreme Court stated in the benzene case:

OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence, ... a reviewing court [is required] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge. 248

Furthermore, the court's discounting of numerous reputable studies because of a lack of opportunity for public comment is antithetical to the express purpose of Section 6(c).

Not surprisingly, many present and former OSHA officials were dismayed by the court's decision and its implications. Former Assistant Secretary of Labor for OSHA, Thorne G. Auchter, stated: "You can kiss ETS's goodbuy. They are not a viable option for the foreseeable future." 249 Former Assistant Secretary of Labor for OSHA, Dr. Eula Bingham, did not agree that emergency standards are dead, citing the standard DBCP, but cautioned that unless there were "hot new data" it would be best to use an ETS only for new hazards. 250 Former Solicitor of Labor, Carin A. Claus, 251 and former Associate Solicitor of Labor for OSHA, Benjamin W. Mintz, 252 observed the problem of trying to persuade a reviewing court to uphold OSHA's use of an ETS to lower the PEL of a current standard. Former Assistant Secretary of Labor for OSHA, Dr. Morton Corn, 253 pointed out, however, that even emergency standards for new hazards, such as hyperbaric diving, had been struck down.

The individuals interviewed stated that the record overwhelmingly supported issuance of the asbestos standard. According to Dr. R. Leonard Vance, Director of OSHA Health Standards Development: "If there is no grave danger for asbestos, there is no

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249 Telephone interview (July 30, 1984).
250 Telephone interview (July 23, 1984).
251 Interview (July 1, 1984).
252 Interview (July 12, 1984).
253 Interview (July 3, 1984).
grave danger for anything. The health effects of asbestos are ten times worse than the rest of the substances combined.”254 He further added that, other than tobacco smoke, there was more epidemiological data on asbestos than any other substance of which he was aware. Mr. Auchter expressed a similar view: “The asbestos ETS was the best piece of work the agency had ever done — by far.”255

Professor Claus reasoned that ETS challenges are difficult cases for the courts to decide on an emergency basis and that they are reluctant to order any capital expenditures when the life of the standard is only six months. In her view, Congress would need to amend Section 6(c)’s “grave danger” language to make the ETS provision effective.256 In the meantime, both Dr. Corn and Mr. Auchter agree that pursuing an ETS now would be a waste of the agency’s limited resources in the sense of its very limited probability of being upheld.

5. Generic Standards

As discussed in this section, the promulgation of new OSHA standards is a long, costly, and difficult process. In reviewing OSHA standards the courts insist on procedural regularity, a showing of significant risk, the use of the “best available evidence,” proof of material impairment, demonstration of technological and economic feasibility, and substantial evidence of other crucial elements. These requirements, budget and personnel problems, legal challenges, policy shifts at OSHA, and other factors have resulted in very few new standards being promulgated.

There have been only ten successful permanent rulemaking actions since 1971, resulting in 22 health standards. The bulk of OSHA health standards remain the outdated 1968 ACGIH TLV’s adopted in 1971. The standards contain mostly PEL’s, without any requirements for environmental monitoring, biological monitoring, or medical surveillance. While hundreds of new chemicals are being introduced into industry each year, only a few new standards are promulgated. As a result, the agency is always “playing catch-up.” For example, in 1977 OSHA lowered the PEL for the pesticide DBCP when it was shown that DBCP was a gametotoxin and carcinogen.257 The pesticide often used as a sub-

254 Interview (July 3, 1984).
255 Id.
256 Interview (July 1, 1984).
stitute for DBCP is ethylene dibromide (EDB), a potent carcinogen which also has been linked to a variety of reproductive harms. It is not clear when OSHA will tighten restrictions on exposure to EDB.

Under the leadership of Dr. Morton Corn, OSHA attempted to promulgate health standards on a "generic" basis. That is, OSHA sought to establish a regulatory framework for rulemaking on an entire class of substances or hazards at a single time. It was hoped that such an approach would result in the more efficient and expeditious promulgation of standards. The "standards completion project," begun in 1974, was a generic rulemaking project that attempted to update the original health standards package. The generic carcinogen policy developed criteria and procedures for regulating carcinogenic substances. Both efforts failed. The standards completion project was abandoned. The generic carcinogen policy was challenged in the Fifth Circuit, and the court is holding in abeyance its decision pending OSHA reconsideration. It has not been followed. Although generic-type rulemaking has produced the access to employee exposure and medical records standard and the hazard communication standard, there have been no further efforts to promulgate generic standards for specific harmful substances.

With such a broad array of reproductive hazards to be regulated, the question has been raised whether it would be possible or desirable to promulgate a generic reproductive hazards standard. Dr. Corn said that it would be possible. He recommended coordinating various regulatory agencies such as OSHA, Mine Safety and Health Administration (MSHA), Consumer Product Safety Administration (CPSC), EPA, and Food and Drug Administration (FDA), and also starting with a less controversial generic standard before moving to reproductive hazards. Dr. Finklea agreed with the idea of beginning with a simpler generic standard, such as skin irritants. He pointed out, however, that the problem with proposing a generic standard for reproductive hazards is the paucity of information. Dr. Bingham, Dr. Infante, and Dr. Robbins also supported the idea of a generic approach to reproductive hazards.

One of the key issues in using such an approach is deciding what quantity and quality of data are needed before specific

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258 Interview (July 3, 1984).
259 Telephone interview (July 6, 1984).
standards are issued. Dr. Halperin stated that “we need to protect workers on the basis of toxicological studies, rather than waiting for epidemiological data.” Dr. Ratcliffe expressed some reservations about the specifics of a generic standard. She questioned whether we know enough about the physiological processes of reproductive harms. In addition, the extrapolation techniques used to convert animal data to humans is not as well developed for reproductive hazards as it is in other areas, such as in cancer studies. She concluded, however, that a generic approach is “certainly theoretically possible for the future.”

B. Risk Assessment and “Significant Risk”

Any discussion of risk assessment under OSHA necessarily begins with the Supreme Court’s 1980 decision in Industrial Union Department v. American Petroleum Institute. There, the Supreme Court addressed several important substantive issues in ruling on the validity of OSHA’s benzene standard. The Fifth Circuit had invalidated the standard because OSHA failed to provide a quantitative estimate of the benefits to be achieved by reducing the permissible exposure limit (PEL) from ten ppm to one ppm.

The Fifth Circuit based its decision on Section 3(8)’s definition of “occupational safety and health standard” as being “reasonably necessary or appropriate” for safe workplaces. From this language the court held that the Secretary must determine “whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard.” The court was, essentially, fashioning a three-part test: (1) whether substantial evidence supports the Secretary’s estimate of expected benefits; (2) whether substantial evidence supports the Secretary’s estimate of expected costs; and (3) whether the benefits bear a reasonable relationship to the costs. Because there

260 Interview (July 11, 1984).
261 Telephone interview (July 26, 1984).
262 448 U.S. 607 (1980).
263 This discussion is taken from M. ROTHSTEIN, supra note 168, at 71-76.
265 Id. at 503. The court relied on its prior construction, in Aqua Slide ‘N’ Dive Corp. v. Consumer Product Safety Commission, 569 F.2d 831 (5th Cir. 1978), of similar language in the Consumer Product Safety Act.
was inadequate evidence of expected benefits, the other issues were not reached.

The Supreme Court affirmed the decision of the Fifth Circuit but was sharply divided and issued five separate opinions. Justice Stevens, writing for a plurality of four justices, rejected the government's argument that Section 3(8) is meaningless and is supplanted by Section 6(b)(5), which details the requirements for standards dealing with toxic materials or harmful physical agents. According to the plurality opinion, Section 3(8) must be satisfied before there can be any consideration of a standard under Section 6(b)(5). "[Section 3(8)] requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment." In other words, "the burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material impairment."

In effect, the plurality added a fourth element to the Fifth Circuit's test that had to be satisfied before the other three factors could even be considered. This "significant risk" requirement is not just an analytical starting point; it is an important substantive limitation on OSHA rulemaking authority. According to the plurality, the Act "was not designed to require employers to provide absolutely risk-free workplaces," but was only intended to require "the elimination, as far as possible, of significant risks of harm." Therefore, the Fifth Circuit was affirmed because the Secretary failed to prove that there are significant risks associated with benzene exposure at the present limits.

Justice Marshall's dissenting opinion accused the plurality of fashioning a restrictive rule of law from a definitional section of the statute which was not intended to have such a profound effect. The result is to place, "the burden of medical uncertainty squarely on the shoulders of the American worker, the intended beneficiary of the Occupational Safety and Health Act."

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266 448 U.S. at 608.
267 Among the requirements of § 6(b)(5), a standard must be "feasible."
268 448 U.S. at 639. The court incorrectly paraphrased § 3(8) as requiring a standard to be "reasonably necessary and appropriate." Actually, a standard need only be "reasonably necessary or appropriate."
269 448 U.S. at 653.
270 Id.
271 Id. at 690.
Significantly, of the two main points of the plurality opinion, the effect of Section 3(8) and the sufficiency of the evidence of the need for a new standard, neither are majority views of the Court. Justice Rehnquist, who concurred in the judgment, joined with the four dissenters in concluding that Section 3(8) was not intended to be a general check on the Secretary's authority under Section 6(b)(5). As to the sufficiency of the evidence of the need for a new standard, Justice Rehnquist did not address this question and Justice Powell, who wrote a separate concurrence, conceded that the question was close. The four dissenters argued that the Secretary had presented sufficient evidence of the need for the standard.

Courts applying the API tests to other cases challenging OSHA standards have reached different results. In United Steelworkers of America v. Marshall, the D.C. Circuit, in upholding the validity of the lead standard, held that the Secretary had satisfied Section 3(8)'s requirement of proving "significant harm." Instead of relying on "categorical assumptions" about lead poisoning, the Secretary amassed voluminous data of the harmful effects of lead at various blood-lead levels and correlated these levels with various average air-lead levels.

In Texas Independent Ginners Association v. Marshall, however, the Fifth Circuit struck down the cotton gin standard, finding that the Secretary failed to prove that cotton dust poses a significant health risk in cotton gins. OSHA simply assumed that because byssinosis results from high exposure levels in textile mills that byssinosis also results from the lower exposure levels in cotton gins. This assumption did not satisfy the Section 3(8) requirement of significant harm, especially in light of the seasonal nature of cotton gin operations.

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273 448 U.S. at 681. In his view, § 6(b)(5) was too vague and therefore represented an unconstitutional delegation of legislative authority to the executive.
274 448 U.S. at 667. Justice Powell believed that the Secretary failed to prove the economic feasibility of the standard.
277 630 F.2d 398 (5th Cir. 1980).
An important part of risk assessment and "significant risk" is the quality of the scientific data upon which the risk assessment is based. Section 6(b)(5) of the Act provides that standards dealing with toxic materials or harmful physical agents must be based on the "best available evidence." While this language appears to be straightforward, the scientific evidence of the precise harmful effects of exposure to various substances is often inadequate, incomplete, inconclusive, or subject to dispute. At the same time, there may be clear evidence that exposure at some levels to these substances causes serious illness. This dilemma has raised two related questions in the context of Section 6(b)(5): (1) What constitutes the "best available evidence?"; and (2) Is OSHA precluded from adopting new standards until there is definitive, detailed, and indisputable scientific evidence?

In the benzene case, the Secretary argued that because there is no absolutely safe level known for benzene, the burden should be on the industry to show that there is a safe level for benzene exposure. Any other approach, it was argued, would require OSHA to wait for deaths to occur before taking any action.

The plurality opinion specifically rejected this argument and, as discussed previously, held that OSHA had the burden of proving that it is at least more likely than not that long term exposure to benzene at the present PEL presents a significant risk of material health impairment. According to the plurality, this burden will not prevent OSHA from regulating carcinogens for the following reasons. First, it is OSHA's responsibility to determine, in the first instance, what it considers to be a significant risk. Although there is no duty to calculate the exact probability of harm, it does have the obligation to find that a significant risk is present. Second, a standard need not be based on scientific certainty and OSHA is free to risk error on the side of over-protection so long as the standard is supported by a body of reputable scientific thought. Third, the relative significance of risk can be quantified in a number of ways other than epidemiological studies, such as by extrapolation of animal test data.

280 448 U.S. at 652.
281 448 U.S. at 656-58.
In *Texas Independent Ginters Association v. Marshall*, the Fifth Circuit held that the cotton gin standard was not based on the best available evidence. OSHA based the standard on foreign studies of ginning employees in Egypt, Uganda, Greece, and Sudan, rather than on a study of American gins, where there is reduced exposure due to the seasonal nature of the work. OSHA also overrelied on studies of byssinosis in the cotton manufacturing industry. Finally, OSHA failed to reopen the hearing record to consider a more recent study. On this final point, it is not clear what the practical limits should be for imposing an ongoing duty on OSHA to consider new evidence, inasmuch as new scientific information is being discovered on a continuing basis.

The *benzene* decision certainly caused OSHA to reevaluate the way in which scientific research is translated into regulatory action. Nevertheless, it is not viewed as an insurmountable barrier. Dr. Bingham termed the decision, "not an extraordinary impediment." Mr. Auchter referred to the risk assessment requirement as "nothing but using good judgment."

After the *benzene* decision, the arsenic standard, which was pending before the Ninth Circuit, was remanded to OSHA for the completion of a risk assessment. In January 1983, OSHA published its final risk assessment for arsenic and in so doing set forth its general framework for evaluating the need for a standard. In setting health standards OSHA uses a four step approach:

1. Risk assessments are performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers.
2. OSHA considers which, if any, of the proposed standards being considered for that substance will substantially reduce the risk.
3. OSHA looks at the best available data to set the most protective exposure limit necessary to reduce significant risk that is both technologically and economically feasible.
4. OSHA considers the most cost-effective way to achieve the objective.

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282 620 F.2d 398 (5th Cir. 1980).
283 Telephone interview (July 23, 1984).
284 Telephone interview (July 30, 1984).
285 The standard was subsequently upheld. See *ASARCO, Inc. v. OSHA*, 746 F.2d 483 (9th Cir. 1984).
287 *Id.*
Risk assessment, therefore, is the first step in the process of regulation. OSHA defines quantitative risk assessment as “an attempt to predict the degree of risk associated with a specific level of exposure. This is done either through direct observation or by extrapolation . . . .” Some important components of risk assessment are a description of the hazard, the potential exposure and worker scenarios, the dose-response relationship, and a quantitative determination of risk.

According to some published reports, there is a danger in over-reliance on quantitative risk assessment. To begin with, the ability to generate detailed and precise mathematical models for hazards varies greatly. To require both detail and precision may be either impossible or so time-consuming that no action is taken on hazards clearly in need of regulatory action. (The court’s recent decision on the asbestos ETS is an example.) Thus, it has been argued that underlying policy questions should be addressed even without detailed quantitative models.

Second, “risk assessment” should not be confused with “risk management,” the latter being the process of evaluating alternative regulatory actions and selecting among them. Risk assessment, quantitative or qualitative, cannot substitute for the value judgments and policy review essential to regulation. Administrative actions do not hatch automatically from risk assessment eggs.

C. Strategies for Control

1. Engineering Controls and Personel Protective Equipment

In its report, Preventing Illness and Injury in the Workplace, the Congressional Office of Technology Assessment (OTA) examined the concept of “hierarchy of controls.” The basic tenet of the hierarchy of controls is to control the hazard as close to the source as possible.

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291 OFFICE OF TECHNOLOGY ASSESSMENT, PREVENTING ILLNESS AND INJURY IN THE WORKPLACE ch. 9 (1985).
In general, the order [of controls] is described as: engineering controls, work practice controls, and personal protective equipment (p.p.e.). Sometimes administrative controls are included at the same order as either engineering controls or work practice controls. But in all cases, personal protective equipment is listed as the control of last resort.\textsuperscript{292}

According to the OTA report, personal protective equipment is a last line of defense when engineering controls are infeasible, insufficiently protective, or not yet installed.

The problems of p.p.e. arise out of (1) limitations in performance, (2) difficulties in evaluating their performance, and (3) problems and burdens associated with their use, and the physical burdens they create.\textsuperscript{293}

Engineering controls have the advantage of being easier to monitor to determine performance, are more reliable, enhance the development of new control and production technology, and do not create employee burdens. The main advantage of personal protective equipment is that it is usually significantly less expensive than engineering controls.

In February 1983, OSHA issued an advance notice of proposed rule making, stating its intention to reexamine its policy of giving priority to engineering controls.\textsuperscript{294} Specifically, OSHA stated its four objectives as follows:

1. To explore whether a revised policy will allow employers to institute more cost-effective compliance strategies.
2. To investigate whether advances in respirator design, technology and applications may permit increased reliance on respirators.
3. To attempt to identify processes, operations and circumstances appropriate for particular compliance strategies.
4. To assess actual workplace conditions and employee health in industries and operations employing different compliance strategies.\textsuperscript{295}

In comments submitted to OSHA, employers and trade associations supported a change in OSHA policy to allow for personal protective equipment to substitute for engineering controls. Comments from NIOSH, health and safety professionals working for universities and government agencies, and labor unions sup-
ported a continuation of OSHA’s preference for engineering controls. In the preamble to the ethylene oxide standard OSHA specifically restated the agency’s policy of favoring the hierarchy of controls approach.

2. Medical Removal Protection

OSHA’s statutory authority to use medical removal protection (MRP) as a strategy for control was discussed previously. Assuming such authority exists, the next question is whether MRP is a viable strategy for control of reproductive hazards.

The starting point for considering this issue is OSHA’s lead standard. The standard set a PEL of fifty micrograms per cubic meter of air averaged over an eight-hour period and an action level of thirty micrograms. In addition, employees with blood-lead levels at or above fifty micrograms per one-hundred grams of whole blood (or who had symptoms of lead disease) are subject to medical removal.

In its preamble to the final lead standard, OSHA indicated that:

To minimize the risk of genetic damage, menstrual disorders, interference with sexual function, lowered fertility, difficulties in conception, damage to the fetus during pregnancy, spontaneous miscarriage, stillbirth, toxic effects on the newborn, and problems with the development of the newborn or developing child, blood-lead levels should be kept below 30ug/100g in both males and females exposed to lead who wish to plan pregnancies.

Despite this language, the standard’s PEL and MRP requirements contemplate that when full compliance is achieved the average blood-lead levels of workers will be thirty-five ug. The Act’s feasibility requirement, however, prevented OSHA from promulgating a stricter standard. Reproductive effects were to be minimized, according to OSHA, by the thirty ug/m³ action level, medical surveillance, and employee education. Moreover, the standard’s medical surveillance guidelines suggests that “the physician might recommend special protective measures or medi-

296 29 C.F.R. § 1910.1025(c).
297 Id. § 1910.1025(k).
299 Id. at 52,966.
300 Id.
301 Id.
cal removal for an employee who is pregnant or who is planning to conceive a child . . . . 302

Can optional MRP under the lead standard prevent reproductive harms? Is optional or mandatory MRP for pregnant workers or male and female workers attempting to parent children a feasible control strategy? The experts interviewed were doubtful about MRP for a variety of reasons.

In many ways, lead is one of the best substances for medical removal because the effects of lead are largely reversible with a discontinuation of exposure. But, MRP as a reproductive hazards control strategy, even for lead, is not entirely satisfactory. Dr. Ratcliffe points out that there is a "rebound effect" of blood-lead levels after removal or chelation, where the levels will often go back up without further exposure after an initial drop. In addition, because of low calcium levels during pregnancy, lead stored in bones and other tissues may reenter the bloodstream. Finally, MRP would not prevent the mutagenic effects that already had occurred.303

Some individuals interviewed said that, in some situations, MRP could be a valuable strategy to use for substances other than lead. Dr. Bingham suggested that MRP might be a feasible strategy, but it would depend on the substance and whether there is irreversible damage.304 Dr. Halperin said that MRP is feasible, but only for certain hazards, such as nurses exposed to rubella.305 Dr. Robbins commented that, at best, MRP is an interim measure to be used while engineering controls are being developed. He added that it may be useful specifically because it is an expensive measure and therefore creates an incentive to implement controls.306

Other individuals interviewed expressed even greater reluctance to use MRP, mostly because of a lack of research on reproductive hazards. Dr. Yodaiken said that he would be "very reluctant" to use MRP on a universal basis. In his view, "it may be inappropriate because of a lack of good scientific evidence."307 Dr. Landrigan agreed that MRP "is not the way to go" and "it is better to clean up the workplace." He stated that "to justify [MRP] we would need to undertake a great deal of additional

303 Telephone interview (July 26, 1984).
304 Telephone interview (July 23, 1984).
305 Interview (July 11, 1984).
306 Interview (July 25, 1984).
307 Interview (July 11, 1984).
research on reproductive effects." Dr. Finklea also expressed his personal view that we do not know enough now to use this approach. Finally, Dr. Infante stated that MRP would be valuable only where the effects were transplacental. Moreover, he added that mutagenicity has been very poorly studied and that a fair number of teratogens are also mutagens. He concluded that "containment is a better strategy."

D. Feasibility

1. Technological

The congressional purpose of the Act, to assure safe and healthful workplaces, is qualified by the phrase "so far as possible." This language indicates that the Secretary must promulgate standards that are technologically achievable. Even before a standard is proposed, OSHA considers whether it is feasible, and in so doing may modify an "absolute" standard recommended by NIOSH or another body. Nevertheless, a standard may be promulgated that contemplates vast improvements in safety and health technology.

Section 6(b)(5), which applies to new standards regulating toxic substances or harmful physical agents, contains two references to the requirement of feasibility. First, in promulgating standards under Section 6(b)(5), the Secretary "shall set the standard which most adequately assures, to the extent feasible, ... that no employee will suffer material impairment of health ...." Second, in addition to the attainment of the highest degree of protection for employees, "other considerations shall be ... the feasibility of the standards ... ."

In Society of the Plastics Industry, Inc. v. OSHA, the manufacturers of vinyl chloride and vinyl chloride products contended that compliance with the required exposure level of the vinyl chloride standard was not technologically feasible. The Second Circuit rejected this contention and indicated that the defense of

308 Interview (July 10, 1984).
309 Telephone interview (July 6, 1984).
310 Interview (July 3, 1984).
311 29 U.S.C. § 651(b).
312 Id. § 655(b)(5).
313 Id.
technological infeasibility requires the showing that a standard is “clearly impossible of attainment.” The court stated that “the Secretary is not restricted by the status quo. He may raise standards which require the improvements in existing technologies or which require the development of new technology . . . .”

Similar reasoning was used by the Third Circuit in AFL-CIO v. Brennan, although the court reached the opposite result. In ruling on the feasibility of a mechanical power press standard, the court declared that “at least to a limited extent, OSHA is to be viewed as a technology-forcing piece of legislation.” Nevertheless, the court found that compliance with the standard was not technologically feasible “in the near future.”

Decisions of the courts of appeals have attempted to clarify the “technology-forcing” language first used in AFL-CIO v. Brennan. In American Iron & Steel Institute v. OSHA, the Third Circuit indicated that even though the Secretary may require an employer “to implement technology ‘looming on today’s horizon,’ . . . the statute does not permit the Secretary to place an affirmative duty on each employer to research and develop new technology.” According to the court, this is especially true when the research and development provisions are speculative and render any assessment of feasibility practically impossible.

In United Steelworkers of America v. Marshall, the D.C. Circuit delineated OSHA’s burden of proving technological feasibility. “OSHA’s duty is to show that modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.” The court’s limited role in deciding whether this burden has been met was set out in the D.C. Circuit’s opinion in AFL-CIO v. Marshall:

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315 509 F.2d at 1309.
316 530 F.2d 109 (3d Cir. 1975).
317 Id. at 121 (footnote omitted).
318 Id. at 122. See Industrial Union Dep’t v. Hodgson, 499 F.2d 467, 479-80 (D.C. Cir. 1974).
322 Id.
Judging the technological feasibility of a particular agency goal is beyond the expertise of the judiciary especially where the assessment involves predictions of technological changes. Instead, our task on review is to find whether the agency sufficiently supported its feasibility determination with material in the record.\footnote{324}

The issue of technological feasibility could arise if OSHA attempted to require the use of engineering controls to reduce exposure to levels that would not be harmful to the reproductive health of any workers or their offspring. Because of evidence suggesting that extremely low levels of exposure could be harmful, it might be asserted that it is technologically infeasible to achieve the required reductions in exposure levels.

2. Economic

A related argument that is likely to be raised is that it is economically infeasible to reduce exposures to the levels where no reproductive harms would occur.

In American Textile Manufacturers Institute, Inc. v. Donovan (ATMI),\footnote{325} the Supreme Court addressed the issue of whether the Act requires the Secretary, in promulgating a standard under Section 6(b)(5), to determine that the costs of the standard bear a reasonable relationship to its benefits. The Fifth Circuit, in the benzene case,\footnote{326} had imposed such a requirement. The D.C. Circuit, however, in the cotton dust\footnote{327} and lead\footnote{328} cases had rejected this view.\footnote{329}

In a five-to-three decision,\footnote{330} the Court rejected the argument that the Act requires the use of cost-benefit analysis. Relying on the plain meaning of the word “feasible” as “capable of being

\footnote{324} 617 F.2d at 656.
\footnote{325} 452 U.S. 490 (1981).
\footnote{329} See also American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 836 (3d Cir. 1978), cert. dismissed, 448 U.S. 917 (1980) (upholding validity of coke oven emissions standard despite an annual compliance cost of $240 million).
\footnote{330} Justice Powell took no part in the decision, but in his concurring opinion in the benzene case, he indicated that he would require cost-benefit analysis. Thus, as to this issue, it would appear that the Court is divided five-to-four. Justice Stewart, since replaced by Justice O'Connor, voted with the dissent in cotton dust.
done,“ the Court ruled that imposing a cost-benefit requirement would be inconsistent with the mandate of Congress.

Congress itself defined the basic relationship between costs and benefits, by placing the “benefit” of worker health above all other considerations save those making attainment of this “benefit” unachievable . . . . Thus, cost-benefit analysis by OSHA is not required by the statute because feasibility analysis is.331

The Court observed that when Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such an intent on the face of the statute.332 Neither the language of OSHA nor its legislative history indicate such a congressional intent. Moreover, the general definitional language of Section 3(8) cannot be used to impose a cost-benefit requirement and thereby “eviscerate” the “to the extent feasible” language of Section 6(b)(5).333

According to the majority opinion of Justice Brennan, “feasible” as used in Section 6(b)(5), includes economic feasibility. After reviewing the record, the Court concluded that the D.C. Circuit did not err in holding that the Secretary’s findings that compliance with the cotton dust standard was economically feasible was supported by substantial evidence. Even though no specific economic studies were performed on the final standard, there were studies that showed that compliance with a stricter and more costly standard was feasible.334

In a separate dissent, Justice Stewart argued that OSHA failed to justify its estimate of the costs of the cotton dust standard because it did not have any estimates of the cost of the final version of the standard.335 Justice Rehnquist, joined by Chief Justice Burger, reiterated his view from the benzene case that Section 6(b)(5) represents an unconstitutional delegation of legislative authority to the executive.336

Two further points relative to the cotton dust case are worthy of mention. First, the holding is limited to Section 6(b)(5) standards; the Court did not address the issue of whether cost-benefit analysis is required in promulgating other types of standards.337 Second,
despite assertions to the contrary, the Secretary is not even permitted to engage in cost-benefit analysis in promulgating standards pursuant to Section 6(b)(5). Besides feasibility analysis, "Congress did not contemplate any further balancing by the agency for toxic material and harmful physical agents standards . . . ."339

After the cotton dust decision, OSHA indicated that it would not engage in cost-benefit analysis, but that it would use cost-effectiveness analysis. While the former would consider whether the benefits of a regulation are sufficient to outweigh its costs, the latter is concerned with the most efficient way of attaining a certain level of protection.

E. Jurisdictional Problems

One possible way of addressing the problem of reproductive hazards in the workplace is for OSHA to attempt to regulate the permissible range of an employer's options relating to employee exposure. For example, OSHA might promulgate a standard prohibiting an employer from excluding women from areas where there is exposure to known or suspected abortifacient, mutagenic, teratogenic, or embryofetotoxic substances. The promulgation of such a regulation would raise the legal issue of whether OSHA had exceeded its statutory authority.

Although the courts have not addressed the issue of OSHA's authority to promulgate a standard prohibiting exclusionary employment practices, some analogous issues have arisen in cases involving medical removal protection (MRP) and rate retention (RR). MRP is simply the removal of employees from further hazardous exposure to a toxic substance until it is medically advisable to return. RR requires that the removed employee's wages and benefits be maintained during the period of removal.

MRP and RR provisions in OSHA health standards have become increasingly stringent. For example, the vinyl chloride standard (promulgated in 1974) provides for MRP, but not RR.340 The asbestos standard (promulgated in 1972) provides for MRP of employees for whom respirators are ineffective, but RR is required only if there is an available position.341 The cotton dust

338 Id. at 544 (Rehnquist, J., dissenting).
339 Id. at 513.
341 Id. § 1910.1001(d)(2)(iv)(c).
standard (promulgated in 1978), however, squarely raised the issue of OSHA authority.

The cotton dust standard placed heavy reliance on the use of respirators to protect employees from exposure to cotton dust, particularly during the four-year interim period given employers to install engineering controls. One part of the respirator provision requires employers to give employees unable to wear a respirator — because of facial irritation, severe discomfort, or impaired breathing — the opportunity to transfer to another position, if available, where the dust level meets the standard's permissible exposure limit (PEL). When such a transfer occurs the employer must guarantee that the employee's wages and benefits are maintained.

In American Textile Manufacturer's Institute, Inc. v. Donovan, the Supreme Court, without deciding the issue of whether OSHA could impose MRP and RR requirements at all, struck down this RR provision because OSHA "failed to make the necessary determination or statement of reasons that its wage guarantee requirement is related to the achievement of a safe and healthful work environment." Rather than explaining the RR provision as being essential in ensuring that workers would seek needed MRP, OSHA had stated that the "goal of this provision is to minimize any adverse economic impact on the employee by virtue of the inability to wear a respirator." The Court dismissed OSHA's statement of the importance of encouraging employees to disclose symptoms of disease — expressed in its brief before the Court — as unacceptable "post-hoc rationalizations."

The Court's most instructive statement on the permissible scope of OSHA rulemaking is the following:

Because the Act in no way authorizes OSHA to repair general unfairness to employees that is unrelated to achievement of health and safety goals, we conclude that OSHA acted beyond statutory authority when it issued the wage guarantee regulation.

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342 Id. § 1910.1043.
344 Id.
346 Id. at 537-38.
347 Id. at 538 (quoting 43 Fed. Reg. 27,387, col. 3 (1978)).
348 Id. at 539.
349 Id. at 540 (footnote omitted).
When OSHA subsequently promulgated its new lead standard in 1978, it included an even broader MRP and RR provision. Employees with blood-lead levels above the specified limit and those employees showing symptoms of lead disease must be removed until their blood-lead has returned to an acceptable level. The employer may transfer the employee to a non-lead plant, low-lead area of a plant, or may keep the employee in a high-lead area for a shorter work week. When an employee is removed in any way the employee retains his or her earnings rate, seniority, and benefit levels for up to eighteen months and upon return must be restored to his or her original job status.350

Unlike its statement of reasons accompanying the cotton dust standard, the lead standard contained detailed findings of the need for RR. OSHA found “that unless workers were guaranteed all their wage and seniority rights upon removal, they would resist cooperating with the medical surveillance program that determined the need for removal, since they reasonably might fear being fired or sent to lower-paying jobs if they revealed dangerously high blood-lead levels.”351

In United Steelworkers of America v. Marshall,352 the D.C. Circuit upheld the validity of the MRP and RR provision. The lead industry argued that Congress did not intend to have MRP and RR under OSHA because the Act is silent on this subject,353 while the Coal Mine Health and Safety Act of 1969 (CMHSA),354 passed the year before OSHA, contained an MRP provision. The court rejected this argument, noting that the CMHSA covered a single industry and was drafted with much greater specificity than OSHA.355 The lead industry next argued that the provision violated Section 4(b)(4)’s prohibition on OSHA interfering with workers’ compensation. Although acknowledging the “seriousness” of this argument, the court noted the limited duration and scope (for example, there is no payment for medical expenses) of RR benefits, and indicated that the group of workers to benefit from this provision will become increasingly smaller as the PEL is lowered.356 "We conclude that though MRP may indeed have a great

350 29 C.F.R. § 1910.1025 (k)(1).
353 Id.
354 Id.
355 Id. at 1232.
356 Id. at 1234.
practical effect on workmen's compensation claims, it leaves the state schemes wholly intact as a legal matter, and so does not violate Section 4(b)(4). Finally, the court rejected the argument that MRP with RR violates the national labor policy of allowing all substantive provisions of labor management relations to be left to collective bargaining. Simply because earnings protection is a mandatory subject of bargaining and could be adopted through collective bargaining does not mean OSHA has no authority to mandate such a program.

The D.C. Circuit's opinion contains a footnote with particular relevance to the issue of MRP and reproductive hazards:

Amici representing public interest law organizations and California state labor agencies have argued that MRP is not only legally valid under the OSH Act, but is legally required by Title VII of the Civil Rights Act of 1964, 42 U.S.C. Section 2000e et seq. (1976 & Supp. II 1978). They argue that without MRP employers will discriminate against fertile women — to whom lead exposure poses an even greater threat than it does to other workers — by excluding them from all lead-exposed jobs at the outset. A review of an OSHA proceeding, however, is not the place to address hypothetical Title VII questions, and in any event we think fertile women can find statutory protection from such discrimination in the OSH Act's own requirement that OSHA standards ensure that "no employee will suffer material impairment of health ***." 29 U.S.C. Section 655(b)(5) (1976) (emphasis added).

When read together, the cotton dust and lead cases suggest the following about OSHA regulation of reproductive hazards:

1. OSHA has the statutory authority to protect male workers, female workers, and fetuses.
2. OSHA could promulgate a standard setting exposure levels where male workers, female workers, and fetuses would not suffer harm, so long as the standard met all of the requirements of Sections 3(8) and 6(b)(5), such as "significant risk," and technological and economic feasibility.
3. OSHA might well be precluded from promulgating a regulation prohibiting the exclusion of all women from exposure to reproductive hazards. Such rulemaking may be held to be preempted by Title VII, or might be held to be an

357 Id. at 1236.
358 Id.
359 Id. at 1238 n.74 (emphasis in original).
360 Id. at 1256 n.96.
attempt "to repair general unfairness unrelated to achievement of health and safety goals."\textsuperscript{361}

4. OSHA probably would \textit{not} be precluded from promulgating a regulation prohibiting an employer from making sterilization of current employees (male employees, female employees, or all employees) a condition of continued employment. Valid health and safety goals would seem to include prohibiting both exposure to sterilizing agents and "voluntary" sterilization in order to retain employment. Note: An employer policy requiring that all employees be sterilized might not violate Title VII. It is not clear whether OSHA has the authority to promulgate a regulation prohibiting an employer from hiring only employees who had been sterilized or were otherwise incapable of reproduction. Such a regulation might be upheld based on the same considerations as are applicable to current employees.

5. The promulgation of an OSHA standard prohibiting an employer from refusing to hire fertile women would entail elements of both considerations 3 and 4. The legality of such rulemaking may ultimately turn on the state of the factual record developed at the rulemaking, including evidence whether prohibiting the employment of fertile women causes women to become sterilized.

The purely employment discrimination aspects of reproductive hazards are beyond the scope of this Article. OSHA's attempts to regulate reproductive hazards, however, invariably have raised employment discrimination issues. For example, the \textit{American Cyanamid} case, in which OSHA attempted to use Section 5(a)(1) to prohibit an employer's policy of excluding all fertile women from working where there was exposure to lead, was discussed earlier.

In 1980 the Equal Employment Opportunity Commission (EEOC) and the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) issued joint Proposed Interpretive Guidelines on Employment Discrimination and Reproductive Hazards.\textsuperscript{362} The Guidelines, issued pursuant to Title VII of the Civil Rights Act of 1964 and Executive Order 11246, were proposed to address the fact that an "increasing number of employers and contractors . . . are initiating policies excluding all women of childbearing capacity from certain jobs because of exposure to hazardous substances or conditions."\textsuperscript{363}

\textsuperscript{361} 452 U.S. at 541.
\textsuperscript{363} \textit{Id}. 
The Guidelines permit the "temporary emergency exclusion" of employees of only one sex or of pregnant employees under limited circumstances, including where there is proof of a hazard to one sex or the fetus, but not to the other sex. The Guidelines do not address the issue, however, of how the emergency exclusion is triggered. For example, there is no discussion of whether an employer may require women employees to take periodic pregnancy tests.

The Guidelines prohibit altogether any reproductive hazards policies applicable to only one sex. Facially neutral policies that adversely impact one sex must be justified "in accordance with relevant legal principles." (Presumably, this means establishing a business necessity or job-relatedness defense.) The Guidelines do not give any examples of such neutral policies.

The proposal was met with numerous comments and great controversy. On January 13, 1981, the Proposed Guidelines were withdrawn. According to Eleanor Holmes Norton, former chair of EEOC, one of the main problems with the reproductive hazards rulemaking, which ultimately led to the withdrawal of the joint proposal of EEOC and OFCCP, was the lack of a consensus in the scientific evidence received in response to the proposal. Without such a consensus it was considered to be virtually impossible to issue a final regulation dealing with this complex and controversial subject.

The Proposed Guidelines contemplated an active role for OSHA in "consultation and coordination" with EEOC and OFCCP. NIOSH and OSHA research also was contemplated. Former OSHA administrators Dr. Morton Corn and Thorne Auchter had considerable reservations about such OSHA involvement. They asserted that OSHA lacked the statutory authority, resources, or expertise to become involved in discrimination claims. Dr. Eula Bingham, who as head of OSHA, was instrumental in getting the Proposed Guidelines issued, disagreed. In her view, OSHA has "inherent responsibility" in this area; OSHA should lend technical support and assistance to EEOC and NIOSH. Neither OSHA, EEOC, nor OFCCP, however, have any current plans to reconsider rulemaking in this area.

365 Id. at 7516.
367 Interview (July 1, 1984).
368 Telephone interview (July 23, 1984).
V. CONCLUSION

Promulgating any new OSHA health standard is extremely difficult. It depends on a good working relationship between NIOSH and OSHA, adequate budgets and personnel for each agency, and insulation of the decision makers from the political pressures that invariably arise when new regulations are proposed. The rulemaking process is protracted, detailed, cumbersome, resource draining, and adversarial. The reviewing courts have required detailed analyses of significant risk and technological and economic feasibility. The courts also have shown a reluctance to uphold the validity of emergency temporary standards, and have required, at times, a precise and an almost cataclysmic showing of "grave danger."

Only three current OSHA health standards, those for DBCP, lead, and ethylene oxide, specifically attempt to protect workers from reproductive hazards. The prospects are unclear for new standards or more stringent modifications of existing standards to protect reproductive health. A number of problems exist. There is a lack of scientific research presently available on reproductive hazards in the workplace, in part because of an historical lack of interest in this field at OSHA, NIOSH, the Centers for Disease Control (CDC), and the Public Health Service (PHS). There are also problems with methodologies for new studies, such as the need to develop better models for extrapolating animal data to humans and the ongoing problem of cohort selection.

With so many unregulated reproductive hazards and the prospect of new substances being introduced at a faster rate than regulations can be issued at the present pace, the question has been raised whether a generic reproductive hazards standard is possible. Such a policy would establish the framework for regulating a variety of substances and would, presumably, allow for more efficient and expeditious standards promulgation. Although many individuals interviewed supported the idea in principle, there are potential scientific, legal, and political stumbling blocks.

Another problem with reproductive hazards standards is that the fetus and the reproductive systems of both males and females are often affected by relatively low exposure levels — well below that which would otherwise harm an adult. Reducing exposure levels to protect such sensitive individuals and fetuses may, arguably, be technologically or economically infeasible.

An additional strategy for dealing with reproductive hazards is
the medical removal of workers who were attempting to parent children or who were pregnant. Scientifically, this approach would be valuable for only a limited number of hazards, primarily where the only effects were transplacental. Moreover, an expansive use of medical removal, especially if used to protect employment rights generally and not just worker health, would raise a number of difficult legal problems.

The prospects for regulating reproductive hazards under OSHA, however, should not be viewed as totally bleak. Our scientific understanding of the toxicology, physiology, teratology and other important disciplines affecting reproduction is expanding. Our capabilities to implement increasingly effective and efficient controls are growing. The awareness of reproductive hazards as an important occupational health problem is heightening. New regulatory strategies could be developed to bring about reasonable, effective regulation of reproductive hazards under OSHA. These new strategies also are essential if there is to be effective regulation of the numerous other kinds of occupational safety and health hazards.
APPENDIX— LIST OF PERSONS INTERVIEWED

1. Thorne G. Auchter
   former Assistant Secretary of Labor for OSHA
2. Edward J. Baier
   Director of Technical Support, OSHA
3. Dr. Eula Bingham
   former Assistant Secretary of Labor for OSHA
4. Carin A. Claus
   former Solicitor of Labor
5. Dr. Morton Corn
   former Assistant Secretary of Labor for OSHA
6. Dr. John F. Finklea
   former Director of NIOSH
7. Dr. William Halperin
   Chief, Industrywide Studies Branch, NIOSH
8. Dr. Peter F. Infante
   Director, Office of Standards Review, OSHA
9. Dr. Philip Landrigan
   Former Director, Division of Surveillance, Hazards and Evaluation and Field Studies, NIOSH
10. Dr. Theodore J. Meinhardt
    Senior Review Epidemiologist, Division of Standards Development and Technology Transfer, NIOSH
11. Dr. J. Donald Millar
    Director of NIOSH
12. Benjamin W. Mintz
    former Associate Solicitor of Labor for OSHA
13. Eleanor Holmes Norton
    former Chair, EEOC
14. Dr. Jennifer Ratcliffe
    Epidemiologist, Industrywide Studies Branch, NIOSH
15. Dr. Anthony Robbins
    former Director of NIOSH
16. Gary A. Strobel
    Special Assistant to the Assistant Secretary of Labor for OSHA
17. Patrick R. Tyson
    Deputy Assistant Secretary of Labor for OSHA
18. Dr. R. Leonard Vance
    Director of Health Standards Development, OSHA
19. Dr. Ralph E. Yodaiken
    Director, Office of Occupational Medicine, OSHA