

Chapter 1

Executive Summary

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Executive Summary

INTRODUCTION

Protecting the reproductive health and procreative capacity of working men and women is important for two basic reasons: 1) it safeguards the health of future generations, and 2) reproductive health and procreative capacity are fundamentally important to individual well-being.

Reproductive health hazards, for the purpose of this report, are defined as agents that cause reproductive impairment in adults and developmental impairment or death in the embryo/fetus¹ or child. The effects of reproductive impairment, which can include infertility, impotence, menstrual irregularities, spontaneous abortion, and damage to offspring, are difficult to measure and can result in damage to other, related systems of the body. Individuals also vary widely in susceptibility and extent of exposure to reproductive hazards.

What is known about reproductive health hazards is far outweighed by what is unknown: most commercial chemicals have not been thoroughly evaluated for their possible toxic effects on reproduction and development. Much of the information on suspected reproductive health hazards, as with other hazards, is derived from animal studies, which present problems of interpretation in extrapolating to effects in humans.

There are consequently no reliable estimates as yet of the basic measures of reproductive risk in the workplace—the number of workers exposed to such hazards, their levels of exposure, and the toxicity of the agents to which they are exposed.

There are a number of sophisticated technologies for assessing reproductive function, but none can fully assess fertility; the only true measure is the birth of a healthy infant. Because of these unknowns, the management of uncer-

tainty is the central issue in the protection of the reproductive health and procreative capacity of working men and women.

Most policy decisions regarding the management of occupationally related reproductive risk must be made within the context of two Federal statutes:

1. the Occupational Safety and Health Act (OSH Act), which gives the Federal Government the authority to protect workers to the extent feasible from exposure to substances that could damage their reproductive systems and general health; and
2. Title VII of the Civil Rights Act, which forbids employment discrimination on the basis of sex or pregnancy.

The OSH Act and the Civil Rights Act can usually be reconciled in cases where protection of the health of the embryo/fetus is of concern. An employer who employs in a nondiscriminatory manner and provides a place of employment that is free of recognized hazards violates neither law. When there is risk of exposure to recognized hazards in the workplace, the employer is obliged to take all reasonable nondiscriminatory steps to ameliorate the hazard. Employers who are nevertheless unable to provide a safe workplace to all employees may be legally permitted to resort to sex-based distinctions in removing individuals at risk if the employer meets certain stringent criteria established by the courts.

Three additional major statutes potentially apply to occupational reproductive risk—these are the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and the Atomic Energy Act (AEA).

A number of hazardous agents have been associated in varying degrees with impairment of male and female reproductive function and the health of the developing embryo/fetus. Their effects are mediated by genetic and environmental factors as well as by exposure.

¹Gestation is commonly divided into three stages: 1) the blastocyst, from conception until about 3 weeks; 2) the embryonic from 3 weeks to about 8 or 9 weeks; and 3) the fetal from 8 or 9 weeks until birth. The blastocyst stage is often subsumed within the embryonic stage in order to simplify terminology.

These agents include various chemicals; ionizing and nonionizing radiation; physical factors such as hot, cold, hyperbaric, or hypobaric environments, noise, and vibration; infectious agents; aspects of lifestyle such as tobacco and alcohol use; ingestion or absorption of certain drugs; and overexertion and stress.

Toxic agents are regulated for a range of health effects which until recently did not often include reproductive effects. However, toxic agents are unlikely to be regulated solely for their effects on reproductive health because toxic agents that affect reproductive health are likely to have other health effects as well. To date, four health hazards—ionizing radiation, lead, ethylene oxide (EtO), and dibromochloropropane (DBCP)—are regulated in part because of their effects on reproductive or procreative capacity.

Workers have two primary concerns related to reproductive health: exposure to substances that can endanger their reproductive health and procreative capacity, and exposure to substances that can endanger the health and development of their offspring. Workers are also concerned about employment opportunities and job security in this context. For example, employment opportunities for women workers may be affected by fetal protection policies instituted by employers who fear future liability for offspring harmed by workplace exposures. Opinions of workers regarding these policies differ, depending on their values and economic circumstances.

While policymakers and employers may never have complete information regarding the full extent of reproductive dysfunction and its causes, they must attempt to provide as safe a workplace as feasible. The primary means of protecting reproductive health in the workplace are adequate engineering and administrative controls to keep exposure at the lowest feasible levels; substitution of safer substances where feasible; and programs to educate workers concerning safe work practices and potential dangers.²

²See OTA'S report on *Preventing Illness and Injury in the Workplace*, OTA-H-256 (Washington, DC: U.S. Government Printing Office, April 1985).

The methods used to protect workers' reproductive health must meet minimum standards under the OSH Act and Title VII. Managers and policymakers often have different approaches to meeting minimum standards, depending on their personal philosophies. One view holds that all workers, even the hypersusceptible, must have equal access to job opportunities. In this view, justice cannot be served if employment is denied on the basis of immutable traits, such as sex, age, ethnic status, or genetic susceptibility. The workplace must therefore be made safe enough to protect the health of even the most vulnerable worker. A contrasting view holds that the hypersusceptible worker maybe denied equal access to job opportunities in situations where it is neither technically nor economically feasible to protect that worker. In this view, justice is served because the majority of workers have equal access and the employer can remain in business. Difficulties arise because the evidence that exposure to a substance causes harm is rarely conclusive, people cannot agree on the definition of "safe," and the definition and implications of hypersusceptibility can change, depending on the workplace situation. Thus, depending on philosophical viewpoint, justice can be interpreted to mean either equal opportunity for all or the greatest good for the greatest number.

If protective measures fail and workers are harmed, compensation becomes the issue. Under the laws of most States, reproductive impairment probably cannot be compensated within the workers' compensation system; moreover, workers are at present barred from bringing tort claims against their employers. Although lawsuits against third parties such as product suppliers and manufacturers may achieve redress, proving causation is often difficult. And, in some cases, third-party defendants cannot be identified.

Although it is difficult to identify the agents that are hazardous to reproductive health and the numbers of people who may be exposed, reproductive dysfunction is a significant health problem in the United States:

An estimated 2.4 million (8.4 percent) of U.S. couples in which the wife is of childbearing age are unintentionally infertile. In some cases this

inability to bear children appears to correct itself; in other cases the infertility persists.

Some congenital malformation is evident in 3 percent of all live births; an additional 3 percent of infants are found to have malformations by 1 year of age. The causes of congenital malformations are unknown in 60 to 70 percent of cases. (Rates of congenital malformation do not appear to be rising.)

The rates of other manifestations of reproductive and procreative dysfunction (e.g., depressed libido, impotence, contaminated breast milk, early menopause) are unknown.

Although the extent to which workplace exposure to chemical, physical, and biological agents may contribute to impairment of reproductive functioning is not known, the National Institute

for Occupational Safety and Health (NIOSH) ranks work-related reproductive impairment as sixth of the 10 leading work-related diseases and injuries. This ranking is based on numbers of workers exposed to known toxicants or substances suspected of being toxic to human reproductive capacity and levels of reproductive dysfunction in the population. Thus there is a clear need to elucidate the specific causes of reproductive dysfunction in order to reduce its overall incidence.

This report reviews the evidence for workplace-induced reproductive impairment. The options describe actions that might be taken to reduce the uncertainty surrounding its prevalence and causes, and to compensate those who may be harmed.

REPRODUCTIVE BIOLOGY AND MECHANISMS OF TOXIC EFFECTS

The complexity of the reproductive process is often masked by a focus on discrete components of procreation, such as the production of sperm or egg cells or development of the embryo/fetus. This narrow focus fails to encompass such aspects of reproductive function as overall adult health, sexual behavior, pregnancy, lactation, child health and development, puberty, and reproductive senescence. Failure to recognize the integral role of each of these components as part of reproductive function leads to an underestimate of the sensitivity of normal reproductive functioning to even minor disruptions.

The processes involved in the production of sperm and egg cells are different. Men produce sperm continuously from puberty throughout life. By contrast, women are born with a finite supply of egg cells which is steadily depleted from puberty through menopause.

Embryo loss is a part of the reproductive process. Only one-fourth to one-third of embryos conceived result in a live birth. Data on embryo loss are difficult to obtain and estimates vary because its incidence is particularly high in the early stages of pregnancy when the loss is least easily recognized.

Assessment of individual reproductive function cannot be limited to evaluation of reproductive organs and reproductive cells because the many indices of reproductive health are closely tied to other physiological systems. Indices of impaired reproductive functioning include abnormal pubertal development, depressed libido, impotence, and irregular menstrual cycles. Physical examination should thus include assessment of circulatory, endocrine, and neurologic function. Patient histories should cover a broad range of factors that may influence reproductive health, including personal and family medical history, lifestyle factors, and work history.

The complexity of reproduction and development is mirrored by the complexity of the biological mechanisms that underlie toxic effects. These mechanisms involve absorption, distribution within the body, metabolism (toxification and/or detoxification), excretion, and repair.

A toxicant, whether a chemical, physical, or biological agent, acts by interrupting the normal function of a cell, tissue, organ, or organism. Reproductive toxicants may act directly in two ways. They may be structurally similar to an endogenous compound (hormone or nutrient) and thus

mimic its action, or they may alter the structure of a hormone, causing it to vary in its activity. Toxicants may also act indirectly. Following metabolic conversion within the body, a secondary product acts on a tissue or organ of the reproductive system. Other toxicants act indirectly by altering the body's physiological control systems. Certain reproductive toxicants act in several ways simultaneously.

The toxicology of reproductive and sexual functioning is generally divided into two types: 1) reproductive toxicity, and 2) developmental toxicity. A reproductive toxicant interferes with reproductive or sexual functioning of the adult from puberty through adulthood. The many ways in which a reproductive toxicant can manifest itself include depressed libido, impotence, irregular menstrual cycles, and infertility. A developmental toxicant produces an effect in the offspring from conception to puberty. Developmental toxicity has four principal manifestations: 1) death of the conceptus, 2) structural ab-

normality, 3) altered growth, and 4) functional deficiency in the offspring. Some toxicants may have both reproductive and developmental effects.

Developmental toxicants can cause functional teratogenesis (alterations or delays in the post-natal abilities of the individual or delays in growth and development of organ systems), structural malformation, or altered growth. Developmental toxicants can act during either the embryonic or fetal periods, and can kill the embryo or fetus. These toxicants may be equally toxic to both parents and the embryo/fetus. The evolution of the concept of developmental toxicity and teratogenicity has implications for the language of TSCA, which refers to these substances as "teratogens" thereby implying the exclusion of substances that may cause other developmental effects. Modifying this language to refer to "developmental toxicants" would clarify the existing statute with regard to contemporary understanding of the word teratogen, since a teratogenic effect is one of several developmental effects.

EVIDENCE FOR WORKPLACE HAZARDS TO REPRODUCTIVE FUNCTION

By present-day standards, there has been inadequate study of most suspected workplace hazards to reproductive function and pmcreative capacity in both men and women. This situation exists for a variety of reasons:

1. Testing for workplace-induced reproductive impairment is a relatively recent phenomenon, stimulated in part by the thalidomide tragedy. In past years, studies were neither required by government nor considered necessary by industry. Thus relatively few of the thousands of chemicals used in the workplace have been evaluated for their potential effects on the reproductive systems of either animals or humans.
2. The effects of some hazards have been examined only in men and/or women, or in the developing offspring, but not in all three.
3. Many substances that have been tested for their toxic effects in animals have never been studied for their effects in humans, and more reproductive endpoints have been studied in animals than in humans.

4. Many study findings, particularly those of human effects, are inconclusive because of methodological problems.
5. Methods for extrapolating observed reproductive and developmental effects in laboratory animals to possible similar effects in humans are only now being developed.
6. Data on human exposure levels and particular endpoints that indicate reproductive impairment are difficult to obtain.

The scientific literature from human epidemiological and animal toxicology studies was reviewed for evidence of reproductive effects from exposure to a selected list of chemical, physical, and biological hazards, and to stress. The substances that were reviewed are listed in table 1-1. With the exception of certain metals (e.g., lead, mercury) certain organic solvents and pesticides (e.g., DBCP, EtO), ionizing radiation, and certain biological agents (e.g., rubella, mumps), evidence linking particular agents with reproductive and/or developmental effects in humans is, for the most part, inconclusive. Some substances

Table 1-1.—Agents and Substances Reviewed for Reproductive Health Effects by OTA

Metals:	<i>Vinyl halides:</i>
Lead	Vinyl chloride
Boron	<i>Hormones</i>
Manganese	<i>Undefined industrial exposures:</i>
Mercury	Agricultural work
Cadmium	Laboratory work
Arsenic	Oil, chemical, and atomic work
Antimony	Pulp and paper work
Chemicals:	Textile work
<i>Agricultural chemicals:</i>	Physical factors:
Carbaryl	<i>Ionizing radiation:</i>
Dibromochloropropane (DBCP)	X-rays
DDT	Gamma rays
Kepon (Chlordecone)	<i>Nonionizing radiation:</i>
2,4,5-T, Dioxin (TCDD), and Agent Orange	Ultraviolet radiation
2,4-D	Visible light
<i>Polyhalogenated biphenyls:</i>	Infrared radiation
Polybrominated biphenyls (PBB)	Radiofrequency/microwave
Polychlorinated biphenyls (PCB)	Laser
<i>Organic solvents:</i>	Ultrasound
Carbon disulfide	Video display terminals
Styrene	Magnetic field
Benzene	Hyperbaric/hypobaric environments
Carbon tetrachloride	Hot environments
Trichlorethylene	Cold environments
<i>Anesthetic agents:</i>	Noise
Epichlorohydrin	Vibration
Ethylene dibromide (EDB)	Stress
Ethylene oxide (EtO)	Biological agents:
Formaldehyde	Rubella
<i>Rubber manufacturing:</i>	Cytomegalovirus
1,3-Butadiene	Hepatitis B
Chloroprene	Other infectious agents
Ethylene thiourea	Recombinant DNA

SOURCE: Office of Technology Assessment

have been studied more intensively than others, however. For example, anesthetic gases have been studied fairly extensively in humans, and major studies of the reproductive health effects of exposure to dioxin and prolonged use of video display terminals (VDTs) are currently in progress.

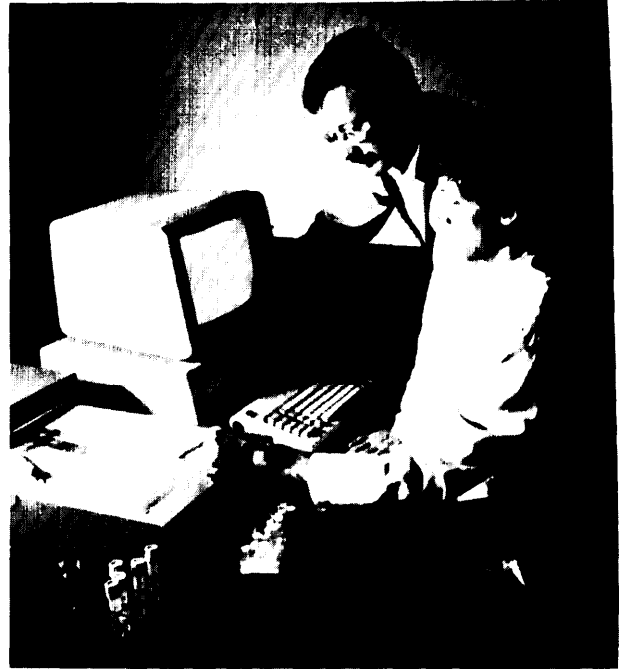


Photo credit: Pemina Meisels

Reports of reproduction system effects among users of the many video display terminals (VDTs) now in use in the Nation's workplaces have raised questions about the safety of prolonged VDT exposure. Comprehensive studies of these effects are now in progress.

REPRODUCTIVE RISK ASSESSMENT

Risk assessment is the use of scientific evidence to estimate the likelihood of adverse effects on the health of individuals or populations from exposure to hazardous materials and conditions. Risk assessment is often confused with risk management, although the two are distinct. Risk assessment evaluates the probability of biologically significant events, while risk management determines the possible actions that can or should be taken in response to an assessment that a substance or condition poses a significant risk.

Several Government agencies are charged with the regulation of harmful substances. Because

these agencies have different mandates based on the legislation underlying their authority and the types of substances and environments in their jurisdiction, the feasibility of centralizing risk assessment and management processes among them is uncertain. There is the potential, however, for establishing guidelines that can make these processes more explicit.

In risk assessment, no matter how clearcut the evidence for the hazard, there are always scientific unknowns. It is not possible to predict the likelihood of a particular health effect from given exposure without some degree of uncertainty re-

garding the specific number of people who may be affected. Scientific decisions regarding the use of particular models or dose-response curves may carry with them judgments that generate different assessments of risk, and thus result in different risk management policies.

There are four steps in risk assessment: hazard identification, dose-response assessment, exposure assessment, and risk characterization.

- Hazard identification is the qualitative analysis of all available experimental animal and human data to determine whether and at what dose an agent is likely to cause reproductive or developmental effects. Hazard identification determines the potential of an agent to do harm, not the probability that harm will, in fact, occur.
- Dose-response assessment determines the relationship between the magnitude of human exposure and the probability of human health effects. In this step the results of animal studies, during which high doses are often given, must be extrapolated to effects on humans, who are usually exposed to smaller doses and vary with respect to exposure, susceptibility, and lifestyle.
- Exposure assessment identifies the population segments potentially exposed to the agent, including their composition and size, as well as the magnitude, frequency, and duration of potential exposure to the agent. This information is difficult to obtain because exposure can occur in different time patterns (acute v. chronic), or by different routes (inhalation v. skin contact), and exposure information on worker populations is often unavailable.
- Risk characterization, the final step, summarizes information about the agent and evaluates it in order to estimate the risk. An important component of this phase is estimating the level of uncertainty in the conclusions.

Most agents for which risk assessment is necessary are chemicals. Most of the 5 million known chemicals are probably not harmful at typical exposure levels. Many chemicals are manufactured in small quantities or are used in small amounts in research laboratories. For example, of the more

than 48,000 chemicals* listed in the TSCA inventory (which lists substances in commerce but does not include pesticides, food additives, or cosmetics), only about 12,800 are manufactured in quantities of more than 1 million pounds per year, 13,900 are manufactured in quantities of less than 1 million pounds per year, and 21,700 are produced in unknown amounts. Workers are therefore unlikely to be exposed to more than a few of these chemicals in most workplaces. Because no publicly available toxicity information exists for more than 70 percent of the chemicals described in the TSCA inventory, it is currently impossible to evaluate their health effects.

Results from both animal toxicology and human epidemiology studies are used in the risk assessment process. Toxicology studies have several advantages. The experimental situation can be controlled, animals can be given specific doses in controlled environments, and results can predict the possibility that an agent is a reproductive health hazard in a particular animal. Their principal disadvantage lies in the necessity for extrapolation to human health effects. Adequate mathematical models for extrapolating dose-response curves from animal toxicology studies to human effects have not been developed. In addition, there is some biological basis for the assumption of threshold effects in the developing embryo/fetus. Animal studies will continue to be necessary, however, as they provide essential information, and it is unethical to deliberately expose humans to potentially toxic substances.

Epidemiological studies may confirm an association between exposure to a hazard and reproductive impairment in humans. Unfortunately, once the effect is detected, the harm or damage has already been done. Epidemiology studies often suffer methodological problems because sample sizes of worker populations may be too small to significantly demonstrate effects on reproductive or developmental endpoints whose frequency is low in the overall population (e.g., congenital malformation). Many reproductive

*1982 total; this figure now exceeds 63,000.

The threshold concept assumes no harmful effects from exposure below a critical level at which no harmful effects are observed. By contrast, in cancer risk assessment, exposure to carcinogens is assumed always to present a risk, however low.

endpoints (e.g., spontaneous abortion, depressed libido) are difficult to measure. Some study designs have not controlled for the possibility of paternally mediated effects. Exposure is difficult to estimate and individuals may have lifestyle characteristics (alcohol, drug, or tobacco use) that confound study results. Moreover, workers, fearing loss of privacy, may be reluctant to cooperate in studies, and employers, fearing liability if results indicate evidence of harmful effects, may hesitate to conduct studies or to make data available to others for analysis.

Federal agencies are concerned to varying degrees with reproductive risk assessment. The National Institute of Occupational Safety and Health (NIOSH), as the research and information support agency for the Occupational Safety and Health Administration (OSHA), is carrying out research on reproductive impairment, and is in the beginning phases of reproductive risk assessment. The

Environmental Protection Agency (EPA) is carrying out research on reproductive impairment and is developing risk assessment guidelines on relevant topics. EPA's **Proposed Guidelines for Assessment of Developmental Toxicants** (in conjunction with three other proposed guidelines) has been published for comment in the Federal Register, and another, **Proposed Guidelines for Reproductive Risk**, will be completed in 1986. The EPA Developmental Toxicant guidelines assume the existence of thresholds and recommend the use of arbitrary safety factors for extrapolating safe exposure levels to humans until adequate mathematical models can be developed (see chapter 3). EPA is also completing Federal radiation protection guidelines that include recommendations for protection of workers from reproductive effects. The Nuclear Regulatory Commission (NRC) has also developed guidelines for protection of reproductive capacity.

REPRODUCTIVE RISK ASSESSMENT IN THE REGULATORY PROCESS

Occupational Safety and Health Administration

The OSH Act of 1970 gave the Federal Government responsibility for the occupational health of more than 75 million working Americans or some three-fourths of today's U.S. work force. OSHA, established by the Act, is the primary regulator of hazardous occupational exposures, including those that may cause reproductive effects.

OSHA has authority to regulate occupational health hazards in various ways. It may promulgate permanent or temporary standards, it may issue guidelines for employers when no standards exist, and it may enforce the general duty clause of the OSH Act.

- **Permanent Health Standards.** OSHA can promulgate permanent health standards for a single hazardous substance, for a group of specific substances, or even for a class of substances, but extensive and cumbersome rule-making proceedings may take several years to complete. OSHA has promulgated perma-

nent standards for three substances—DBCP, lead, and ethylene oxide—that include specific provisions for the protection of reproductive health.

- **Emergency Temporary Standards (ETSS).** OSHA may issue an ETS, effective immediately, if it determines that employees are exposed to a "(grave danger" from exposure to a health hazard. No court has decided whether reproductive health problems are grave dangers, although a recent Federal court of appeals decision suggests that only "incurable, permanent, or fatal" health consequences could support the issuance of an ETS. Since OSHA has lost several challenges to its ETSS in the courts of appeals, OSHA is unlikely to issue ETSS for known or suspected reproductive health hazards.
- **Guidelines for Employers.** Even where no temporary or permanent health standards apply, OSHA may issue guidelines to employers to follow as an interim measure to protect workers while a standard is being set.
- **General Duty Clause.** OSHA is empowered

to ensure that employers are fulfilling their general duty under the OSH Act to furnish working conditions free from "recognized hazards" that are likely to cause death or serious physical harm. Because a hazard is considered recognized only if it is common knowledge in the employer's industry or if the employer had actual or constructive knowledge of the hazard, OSHA may not be able to prove that newly documented or suspected reproductive health hazards are recognized. In any case, OSHA rarely enforces the general duty clause at present. The general duty clause is therefore unlikely to substitute for an ETS as an interim measure until a permanent standard is enacted.

OSHA may not have the authority to regulate employment policies that exclude women from jobs that entail exposure to suspected reproductive hazards. The Occupational Safety and Health Review Commission ruled that Congress intended a "hazard" to be a process or material that causes injury or disease by operating directly on employees as they engage in work. This decision suggests, for example, that OSHA does not have authority to issue a citation to an employer on the grounds that its fetal protection policy itself constitutes a hazard even though the policy may result in women submitting to surgical sterilization in order to keep their jobs. In 1984, the Commission's decision was affirmed by the Federal court of appeals for the District of Columbia.

Even if OSHA could expedite the permanent health standard procedures or enact ETSS without fear of being reversed in court, health standards for reproductive health hazards might not result. Harmful substances are difficult to identify and interagency cooperation with NIOSH has varied with the political philosophy of the Administration in power. Under the Carter Administration, OSHA and NIOSH developed a close working relationship, including personnel exchanges and various joint programs, though this resulted in criticism of NIOSH for allegedly abandoning its research neutrality. The Reagan Administration, which believes in the clear separation of research (risk assessment) from regulation (risk management), has discontinued some cooperative programs.

OSHA also has a shortage of the professional and technical staff needed to develop health standards. This staff shortage may result in insufficient technical expertise to evaluate NIOSH'S work and undertake appropriate regulatory actions.

Environmental Protection Agency

EPA has statutory authority under TSCA and FIFRA to regulate certain occupational exposures to reproductive health hazards, and under Executive Order No. 10831 to recommend Federal radiation protection guidance for workers. Like OSHA, EPA faces institutional and political uncertainties as well as scientific uncertainties that may constrain regulatory action.

EPA's administration of TSCA and FIFRA is constrained by data collection efforts that are not systematized enough to provide EPA with complete and consistent data for assessing reproductive effects of chemicals. Although TSCA requires companies to submit all available health effects data prior to manufacture of a toxic substance, testing rules do not address the full range of reproductive and developmental effects. New FIFRA regulations may begin to address a similar problem for pesticide manufacturers, who now, for the first time, are required to submit information on the potential reproductive effects of products regulated under FIFRA.

EPA has recently moved aggressively to take the regulatory lead from OSHA for substances that have potential health effects, including reproductive and developmental effects; e.g., benzene, ethylene oxide (EtO), formaldehyde, and glycol ethers. Public interest groups have persuaded EPA to yield to OSHA in regulating EtO, for example, because EPA does not have clear authority or resources to inspect or enforce EPA regulations in hospitals. EPA referrals to OSHA are likely to be made with increasing frequency.

EPA is, however, the primary governmental body regulating the hazardous exposure of farmworkers, whose working environment is very different from that of other workers. For example, unless drinking water is supplied, farmworkers may be forced to drink water from ditches or

other open sources that may be contaminated with pesticide and herbicide residues. A proposal to include children under 12 years of age within farmworker protection standards because of their special vulnerability and because they ‘(might be in the field at any time’ was dropped in 1974 after strong protests from growers and their associations. Although some pesticide manufacturers label products suspected of being hazardous to pregnant women, EPA standards do not discuss whether pregnant farmworkers require special precautions, nor do public comments to the 1974 proposal indicate that the potential for reproductive effects among pesticide applicators (male or female) has received adequate attention.

No single agency regulates radiation exposure; Federal responsibility is dispersed among five executive departments, one independent commission and two agencies, and by diverse statutory provisions. Federal responsibility operates under the unifying force of Federal radiation protection guidance administered by EPA. EPA is revising the existing (1960) Federal radiation protection guidelines for workers. The guidelines will include specific provisions for protection of reproductive health and the health of the embryo/fetus. The currently recommended exposure limit of 3 rems per quarter (3 months) whole-body dose equivalent limit is expected to be reduced. Officials believe the new limits will be sufficient to protect against the risk of cancer and genetic effects. The draft also recommends that the policy of conforming to the lower limiting value for the developing embryo/fetus should be achieved with-

out economic penalty or loss of job opportunity and security to the workers. The draft is to be transmitted to the President for approval in late 1985.

Nuclear Regulatory Commission

NRC regulations provide for some protection of reproductive health. The regulations provide for maximum exposure levels, including limitations on exposure to gonads and lifetime cumulative dose, and protection of the biological systems of minors. There are no provisions that deal with protection of the embryo/fetus or with pregnancy per se, although some expert groups have recommended reduction of exposure limits for fertile and pregnant workers. Other expert groups have argued for a gender neutral policy that protects male and female workers from mutagenic risks.

The nature of the regulations promotes the use of temporary employees. These workers generally receive higher doses over short intervals than do regular workers. Temporary workers constituted 35 percent of the work force in the nuclear power industry in 1977, but received an estimated 47.5 percent of the total work force radiation dose.

The factual basis for NRC health regulations has not been adequately tested in the courts. Federal courts have repeatedly deferred to INRC expertise and discretion.

SEX DISCRIMINATION

Some companies and health care facilities have implemented, or are considering, policies that exclude women of childbearing age or capacity from jobs involving exposure to suspected reproductive or developmental hazards. Although it is impossible to determine how many companies have either written or unwritten exclusionary policies, at least 15 of the Fortune 500 as well as numerous hospitals are reported to exclude fertile and/or pregnant women from some jobs.

Company exclusionary policies vary greatly. Some are based on epidemiological and toxicological research findings with respect to particular substances; others are relatively speculative about suspected reproductive hazards. Some policies are carefully written and documented; others are unwritten, making them more flexible but also more ambiguous. In large manufacturing companies, policies are generally announced to employees and their unions, if applicable, prior to implemen-

tation; smaller organizations appear to formulate and apply policies as a perceived problem arises. Some policies recognize that a developmental hazard may be mediated through either male or female workers, while others apply only to women.

In some cases, these policies have faced court challenges on grounds of sex discrimination in violation of Federal law. Title VII of the Civil Rights Act of 1964 prohibits employment discrimination on the basis of sex, while the Pregnancy Discrimination Act of 1978, an amendment to Title VII, specifically forbids discrimination on the basis of pregnancy, childbirth, or related medical conditions. The amendment requires that women affected by these conditions be treated the same for all employment purposes as others not so affected but similar in their ability or inability to work.

While many of these cases are apparently settled out of court, some have been adjudicated and three have been reviewed by the Federal courts of appeals in the Fourth, Fifth, and Eleventh Circuits. XI three courts have held that the exclusion of fertile or pregnant women due to the existence of alleged hazards to the embryo/fetus is permissible if scientifically justified and if less discriminatory alternatives do not exist. In all other circumstances, such exclusionary policies constitute illegal sex discrimi-

nation. Although the three courts used different approaches, the following general principles can be extracted from these cases:

A fetal protection policy (FPP) that applies only to women is presumptively discriminatory. That is, the mere existence of an FPP will create Title VII liability for the employer in the absence of strongly supportive scientific evidence.

To overcome the presumption of discrimination, the employer must be able to present persuasive evidence that the body of scientific evidence supports legal findings that: 1) exposure at the level encountered in the workplace involves a significant risk of harm to the unborn children of women employees, 2) exposure at the level encountered in the workplace does not involve a similar risk of harm to the offspring of male employees, and 3) the FPP is effective in significantly reducing the risk. An employer's subjective but scientifically unsupported belief in the necessity of the policy is insufficient to defend it.

If the employer proves both points (embryo/fetal risk through maternal exposure and lack of embryo/fetal risk through paternal exposure), the plaintiff may nevertheless prevail by proving that an acceptable alternative policy would promote embryo/fetal health at least as well with a less adverse impact on one sex or by showing that the FPP is a pretext for discrimination.

WORKERS' COMPENSATION

The primary goal of workers' compensation is to provide relatively rapid and fair compensation for workplace-induced accidents or illnesses. Workers' compensation laws (and, to some extent, tort law) are also intended to deter hazardous conduct by employers through the use of economic disincentives, based on higher insurance costs and/or more frequent payments to injured workers. OSHA and other agencies with the authority to mandate workplace conditions were created in part as a response to the failure of workers' compensation laws to have a significant deterrent effect. Both the workers' compensation and tort liability systems fail to consistently provide compensation to the victims of occupationally induced reproductive impairment, though they sometimes result in some com-

pensation for some workers. Few workers seeking workers' compensation on the basis of reproductive impairment would be able to meet the following three criteria for eligibility, which state that the injury or disease must:

1. Be a "**personal**" injury or disease. This would preclude compensation for injuries or diseases suffered by others, such as the worker's spouse, fetus, child, or descendant.
2. Result in **job disability**. This requirement would prevent the award of disability benefits for most claims of reproductive injury or disease, since such harms do not usually disable the worker or prevent him or her from resuming work at the same job.
3. Be **caused** by a workplace accident or ex-

posure: Proving causation is difficult. Workers' compensation boards generally prefer medical evidence that a particular individual contracted a particular disease in a particular way to scientific evidence that shows how many, or even most, people contract the disease. The causation problem is endemic to occupational disease claims in general.

A few State systems utilize a "whole body" concept of disability that covers personal injuries that do not prevent a worker from returning to work. These States may allow reproductively impaired workers to collect a scheduled benefit, although only one State has considered the issue. The effects of the eligibility criteria on workers are summarized in table 1-2.

Because the "exclusivity of remedy" doctrine embedded in most workers' compensation sta-

tutes provides that an employee covered by such statutes cannot sue his or her employer at common law for any injury or disease subject to the worker's compensation statute, workers are often barred from seeking common law remedies. This bar to worker suits has generally been maintained by the courts *without regard to whether the worker's claim actual& resulted in the payment of benefits*.

If workplace exposure is determined to have adverse reproductive effects, workers presently have no remedies or, at most, inadequate remedies in the workers' compensation systems of most States. These victims of hazardous occupational exposures will, by default, bear the burden of their occupational exposures to reproductive health hazards.

Table 1-2.—Summary of Harms, Victims, Benefits Criteria, and Causation Problems in Workers' Compensation Systems

Circumstances of harm	Victim		
	Worker	Spouse	Embryo/fetus and offspring
1. Accidental injury to worker reproductive system or embryo/fetus resulting in injury or disease to a part of body covered by schedule or in loss of work	Personal injury: eligible for compensation for medical benefits in all States and loss of function and disfigurement in a few States. No disability unless earnings loss. No special causation problems	Not personal injury, therefore no compensation	Not personal injury, therefore no compensation
2. Acute or chronic exposure of worker, spouse, or embryo/fetus	If personal injury, will be eligible for compensation for medical benefits in all States and loss of function benefits in a few States. No disability benefits unless earnings loss. Special causation problems	Not personal injury, therefore no compensation	Not personal injury, therefore no compensation
3. "Side effect" cases where reproductive function impaired due to other diseases	Probably not applicable since other injury or disease will be primary personal injury for disability compensation, not the reproductive injury	NA	NA

NA—Not applicable.

SOURCE: Office of Technology Assessment.

TORT LIABILITY

The body of law governing personal injuries is known as tort law. Perhaps more than any other area of the common law, tort law is a battleground of evolving social theory.

Workers alleging reproductive injury may bring lawsuits against two primary types of defendants. First, they may try to sue their *employers* for alleged negligence, intentional tort, strict liability,

or product liability. Second, they may bring suit for negligence, strict liability, or product liability against the *manufacturers* of products used in the workplace that may have caused or contributed to the injury or disease.

Although the exclusivity rule operates to bar worker tort suits against their employers, two principal arguments have proven effective in convincing judges to allow suits against employers in some jurisdictions: the dual capacity exception and the intentional tort exception.

Dual capacity exists when the employer is also a manufacturer of the product that caused the worker's injury or provides medical services for the injury in a negligent fashion. Although some States allow an injured employee to sue a dual capacity employer, this exception has been opposed by industry and has been rejected in 23 States. Under the intentional tort exception, evidence that an employer's conduct manifested a deliberate attempt to injure a worker can also be used by the worker to overcome the exclusivity rule and bring a tort action against the employer. However, the fact that an employer's conduct is egregious is usually, in itself, insufficient to prove deliberate intent to cause injury. Therefore, for the most part, reproductively damaged workers have very limited access to redress against their employers through the courts.

Suits against employers or product manufacturers may be brought not only by the injured worker but also by others who may have been injured. One type of potentially injured party is especially relevant to reproductive health hazards: the embryo or fetus that has not been born, perhaps not even conceived, at the time the hazardous exposure occurs. The controversy over the rights of the affected child to recover for prenatal and pre-conception injuries has increased dramatically over the last 40 years. Where once there was complete denial of any rights, the courts now grant recovery in almost every situation resulting in injury to an embryo/fetus who is eventually born alive. Although these cases generally involve negligent medical treatment, the basis for liability to an embryo/fetus does not appear to be limited to medical malpractice. The extent of these legal rights varies greatly among jurisdictions, however, as courts struggle with the unique problems posed by the unresolved status of the embryo/fetus. Although all States now recognize the right to bring an action for prenatal injuries many jurisdictions will deny recovery unless the fetus has reached the stage of viability when it is injured. In these jurisdictions, lawsuits for many developmental effects, such as birth defects resulting from chromosomal aberrations or embryo toxicity, would not be permitted because the injury occurred prior to viability.

ETHICAL CONSIDERATIONS

The management of exposure to reproductive and developmental toxicants in the workplace presents ethical dilemmas because a course of action that may be justified by ethical principles can carry with it both desirable and undesirable consequences.

Reproductive health hazards in the workplace raise ethical issues in three areas. First, the management of suspected hazards often focuses on women workers, who traditionally have been discriminated against under the guise of protecting their reproductive health or the health of their offspring. Second, there is the equivocal status of an embryo/fetus who cannot consent to the

risks that may be involved. Third, reproduction is one of the most sensitive and intimate aspects of life, which raises issues of worker privacy.

The ethical principles most relevant to the issues of exposure to reproductive health hazards in the workplace are: 1) respect for persons, 2) beneficence, and 3) justice.

Respect for Persons

The principle of respect for persons requires that individuals be treated as the focus of concern in their own right and not merely as the means to the achievement of other goals. This

principle has important applications both for workers exposed to reproductive hazards and for their offspring and potential offspring. Respect for persons requires informed and voluntary choices by individuals about matters that affect their well-being and life prospects. Informed choice by workers implies a duty on the part of employers and unions (and possibly the government) to disclose existing information about reproductive health hazards in the workplace. Voluntary choice based on accurate information allows workers to maintain their autonomy.

The principle of respect for persons offers little real guidance on the specific duties of employers towards workers' offspring and potential offspring. The difficulty lies in the fact that ethically and legally, fetuses, infants, and even young children have an equivocal status as "autonomous" beings. In general, the interests of fetuses, infants, and children fall more naturally under the principle of beneficence, since all persons and potential persons are entitled to benefits and protection from harm,

B e n e f i c e n c e

The principle of beneficence requires avoiding harms to others and maximizing the balance of benefits over harms. Beneficence is a consideration in at least three relationships in the workplace: employers' duty to workers, workers' duty to offspring, and employers' duty to offspring.

Employers' Duty to Workers

The specific and general legal duties specified under the OSH Act imply an ethical duty to avoid exposing workers to unreasonable risk of harm. The OSH Act may be a statutory codification of an evolving social conviction that the duty exists at the moral level. The Civil Rights Act implies a corresponding duty not to discriminate in the employment opportunities of individuals.

Workers' Duty to Their Offspring and Potential Offspring

Parents may have certain duties to the expected child even while it is an embryo/fetus. Such duties might equal but could not exceed the duties owed to newborn infants. This points up a limitation

to the duties owed embryo/fetuses: beneficence requires one to do what is best, on balance. It is not a duty to avoid any and all possible harms to the embryo/fetus when that same action might gain some benefits to the embryo/fetus and avoid other harms. From the standpoint of the management of exposure to reproductive health hazards, a parent who chooses to continue working in a mildly hazardous workplace is not necessarily **violating any** duty of beneficence to his or her embryo/fetus. For example, the benefits of working in a mildly hazardous situation might include improved prenatal health care, and better housing and food,

Employers' Duty to Workers' Offspring and Potential Offspring

The scope of employers' duty to their workers' embryo/fetuses is difficult to determine because of the lack of a clear relationship between employer and embryo/fetus, and ambiguities in the moral status of an embryo/fetus. While the worker-parent's exposure is to some degree voluntary, the fact that the embryo/fetus has not "(consented" to be exposed to hazards should not automatically lead to the implementation of a higher standard of protection for the embryo/fetus than for the worker-parent, unless the embryo/fetus is more susceptible.

This underscores the interaction of the principles of respect for persons and beneficence: the duty to protect certain persons or embryo/fetuses from harm may be in conflict with the duty to permit other persons maximum latitude for free and informed choice.

Justice

Justice is the fair and equal treatment of others. This principle is relevant to the management of reproductive health hazards in at least two ways: 1) the differential impact on male and female workers, and 2) the allocation of burdens.

Differential Impact on Male and Female Workers

The principle of justice requires that like cases be treated alike. Thus policies that have a heav-

ier negative impact on workers of one sex may not be just unless the cases are not alike. Fetal protection policies have typically been directed to women, who are much more likely than men to be removed from or denied jobs on the grounds that reproductive or developmental hazards exist. Unless such policies are based on relevant and important differences, they can be regarded as unjust.

Allocation of Burdens

There are two burdens to be allocated: financial burdens and health burdens. Generally, serious impairment to a person's health is perceived as a greater harm to that person's interest than are financial burdens, especially when financial burdens are spread over a large number of individuals, with little impact on each.

ISSUES AND OPTIONS

In many ways, reproductive health hazards are like other occupational health hazards. There is scientific uncertainty about the health effects of most occupational exposures. What should society's decisionmakers—employers, workers, regulatory agencies, courts, and legislators—do in the face of such uncertainty? What should be assumed about risk when it is unclear whether a substance is hazardous or not? What are the costs to the affected groups and to society in general? How can risks, expenses, and other burdens be apportioned fairly?

When these questions are asked in the context of the management of exposure to reproductive health hazards, however, it is important to consider this salient difference: men and women are physiologically distinct, especially with respect to reproduction. Are their biological differences of such nature and magnitude as to require differential treatment? Again, scientific uncertainty about the effects of chemical, physical, and biological exposures obscures the answer. Reproductive health hazards are also different because they can affect the offspring as well as the adult. This reality presents moral and legal questions about who is entitled to make certain decisions that may affect the health and well-being of future generations.

This discussion of the policy issues and options begins with an issue that is unique to reproductive health hazards in the workplace: the use of sex-based employment policies that exclude female workers from workplaces containing suspected reproductive and/or developmental hazards. Issues that are not confined to reproductive

health hazards, such as general occupational and environmental disease problems concerned with prevention, regulation, and compensation in the face of scientific uncertainty, are then summarized.

Sex Discrimination

Because of scientific uncertainty, it is difficult for an employer to meet the three criteria for justifying fetal protection policies (FPPs) that exclude only female (fertile or pregnant) workers from jobs involving exposure to suspected developmental health hazards. The mere existence of an FPP that applies only to women will, in the absence of strongly supportive scientific evidence, create liability for illegal sex discrimination under Title VII of the Civil Rights Act.

For those chemical, physical, and biological agents that have been researched for human reproductive effects, scientific evidence generally fails to confirm or disconfirm a need for differential exposure standards for men and women based on either reproductive effects on the adult or parentally mediated effects on future offspring. This is because most suspected hazards have not been thoroughly researched for their reproductive effects in both males and females and for developmental effects in the offspring.

ing the face of scientific uncertainty about many of the chemical, physical, and biological agents to which American workers are exposed, and with the great publicity given to substantial personal injury verdicts in product liability cases, employers feel obliged to take action to protect their

employees and their future offspring, and to defend their own economic interests.

The tort system provides incentives to employers to abate hazardous conduct. However, the employer's economic interests are much greater with respect to developmental hazards (those that affect the embryo or fetus due to parental exposure before conception or maternal exposure after conception) than they are for other reproductive hazards. For reproductive impairment, most State workers' compensation schemes both fail to provide compensation for the victims of occupationally induced reproductive and sexual impairment and prohibit employee personal injury lawsuits against employers. For developmental injuries, however, the offspring of exposed workers would not be covered by workers' compensation and therefore would have a right to sue the parent's employer. In addition, the harm that could be done to an embryo or fetus could be permanent and devastating, and could result in heavy liability, while effects on adult sexual or reproductive function, while potentially personally devastating or physically damaging, are unlikely to be physically or occupationally disabling and may be reversible.

Congress could consider whether the employer's greater economic incentive to prevent exposure to developmental hazards (as opposed to hazards to adult reproductive function) is justified by ethical or public health considerations: should the health of potential children be protected to a greater degree than the health and well-being of their parents?

Exposure to developmental hazards can occur either prior to conception or during pregnancy. Prior to conception, exposure may result in damage to a male worker's sperm cells or a female worker's egg cells. During pregnancy, exposure to a developmental hazard can be maternally mediated. There is also the possibility that an exposed man may transmit exposure to his pregnant wife who in turn exposes the embryo/fetus.

Officials in many companies believe that effects on future offspring are most likely to be caused by direct exposure of the pregnant woman, rather than by exposure of either parent prior to conception or by exposure of the sexual partner of a pregnant woman. This is, in part, true because

of the relative abundance of animal studies of developmental effects on the embryo/fetus due to exposure of pregnant females. There is a corresponding dearth of scientific information concerning possible male-mediated effects. Since companies anticipate being held financially and morally liable should fetal injury occur, many feel forced to employ only males in certain workplaces in order to avoid potential liability to a damaged infant. Since there are no records of any lawsuits brought by the children of exposed women workers, critics of industry policies suggest that fear of liability is speculative. To the extent that such liability might exist, some critics note that it could extend equally to the offspring of male workers.

Employers have a range of options, each with limitations. Further reducing exposure or eliminating the suspected hazard is the most effective and least discriminatory option, but may be the option with the highest cost and may not be economically or technologically feasible for particular employers or substances. In other cases reducing exposure to safe levels maybe impossible because too little is known about the hazard to establish a no-observed-effects-level (NOEL). Nevertheless, reducing exposure or eliminating the hazard may be cost-effective overall, when society's costs and benefits are added to those of the company.

Monitoring female workers for pregnancy, even if scientifically and legally defensible, would involve considerable intrusion on personal privacy and be difficult to implement. Monitoring is also likely to be only moderately effective because pregnancies are often not known or disclosed before exposure occurs and because no prevention of possible male-mediated effects would result. Voluntary medical removal policies for employees who are planning to parent children are less burdensome on workers and minimize differential treatment of men and women if applied to both sexes. However, if a pregnancy is unplanned, voluntary removal may not have occurred early enough to prevent injury.⁴

⁴Among women age 15 to 44 in the labor force in 1982, 33.6 percent of births in the previous 5 years were unplanned (7.6 percent were unwanted and 26.0 were mistimed). These data do not indicate whether these women were working at the time they became pregnant. (W. Pratt, personal communication, 1985, tabulations from the National Survey of Family Growth (NCHS), 1982).

The option of using sex-based distinctions in hiring and assigning workers, and then attempting to defend in court, is risky: the science and the law are in flux, and such exclusionary policies may be rejected due to corporate concerns about fairness or reputation. Nevertheless, sex-based distinctions may be less costly than other options for some employers, notwithstanding possible court challenges. Finally, various options involving personnel and medical counseling can be used to promote voluntary removal policies or coerce involuntary removal of female workers. An employer may find that one or more of these options protects his or her interests, though not necessarily those of his or her employees.

These options may be viewed as falling on a continuum from being more protective of embryo/fetal health and less protective of employment rights to less protective of embryo/fetal health and more protective of employment rights. In many cases, this is an oversimplification, since options that protect against paternally mediated effects may increase protection of the embryo/fetus while spreading the burdens more evenly between men and women. Nevertheless, most options can be classified as either overprotective or underprotective, and the issue is whether the price of either is too high.

OPTION 1:

Congress could maintain the status quo.

Congressional inaction would effectively continue the existing system of employer flexibility in tailoring fetal protection programs to existing scientific information concerning risk. As discussed above, the courts have set guidelines under which certain sex-based employment distinctions are permissible under Title VII when risks to the embryo/fetus are involved. If the status quo is maintained, any evolution of the law in this area would take place in the courts.

Maintaining the status quo also maintains the financial incentives: an employer might anticipate that the expense of losing a sex discrimination lawsuit would be smaller than the verdict in a single lawsuit brought by the offspring of a worker for personal injuries sustained in utero. This suggests that, notwithstanding Title VII's prohibition, sex-based distinctions may be the favored alter-

native in some cases, even where they are not scientifically supportable.

OPTION 2:

Congress could amend Title VII so as to prohibit FPPs that apply only to women unless scientific evidence exists showing that there are no paternally mediated effects.

Research on reproductive health effects of various substances has focused on female-mediated developmental effects in human and animal populations and generally overlooked the possibility of male-mediated developmental effects or other reproductive effects. This bias may be reflected in employment policies that exclude women from the workplace based on scientific data but allow men to remain exposed because of a lack of data concerning male reproductive health effects. Current scientific evidence is in most cases inadequate to determine the extent to which a substance that is hazardous to one sex may or may not be hazardous to the other.

Congress could therefore provide greater protection to the future children of exposed men and perhaps, over time, even reverse this research bias by amending Title VII to create a legal presumption concerning the scientific data in Title VII sex discrimination suits. The law could provide that any substance proven or suspected of being a hazard to one sex (or its future offspring) for the purpose of an exclusionary policy will be legally presumed to be a hazard to the other sex (and its future offspring) at similar exposure levels until substantial scientific evidence demonstrates the contrary to be true. This approach would help ensure that women's employment rights are not easily overridden. It would provide greater protection to men and their future offspring in cases where a substance is known to be harmful to women and their future offspring but where the evidence concerning men is not yet available. It would also encourage employers to undertake more scientific research on both male and female reproductive and developmental risk so as to be able to scientifically support a single-sex exclusionary policy. Finally, it would enable Congress to articulate how much scientific justification is necessary to support an employment policy that discriminates between men and women.

This option could make exposing both men and women economically preferable to excluding both, however, especially for small companies that cannot afford the research that would be required to overcome the legal presumption of similar effects on both sexes. An unpredictable number of embryo/fetuses could be exposed to hazards that are real but insufficiently documented to be the subject of a legal FPP that applies only to one sex.

This option might also discourage employers from engaging in any research at all if the result is likely to be the exclusion of men as well as women, or only men. Employers might decide to take the chance that a substance is harmful and could injure a worker's offspring rather than pay for research that might result in the expense of redesigning a workplace that would otherwise pose significant risks to both sexes.

While the current system may also result in an unpredictable number of paternally mediated developmental effects, this option could result in an unpredictable number of paternally *and* maternally mediated developmental effects. A similar proposal by the Equal Employment Opportunity Commission (EEOC) and Office of Federal Contract Compliance Programs (OFCCP) was withdrawn in 1981 due to these concerns,

In addition, Congress could make sex-based distinctions a less attractive employer option by providing an additional financial disincentive, such as recovery of punitive or treble damages by losing defendants in sex discrimination lawsuits. Such disincentives would also make it easier for employees who have been discriminated against to find lawyers willing to handle their cases.

OPTION 3:

Congress could require that employers with unproven but suspected developmental hazards in their facilities fully inform workers and allow individual employees to decide whether or not to continue in jobs involving such exposures. Employees would then be responsible for the consequences of exposures to which they consented.

An employer disclosure requirement could be coupled with employer immunity from personal

injury suits should injury to an employee or his or her offspring result from the employee's informed consent to the exposure. Because it appears that a worker cannot legally waive his or her offspring's legal right to avoid injuries caused by developmental hazards, employers are generally unwilling to accept a worker's attempted waiver of the future offspring's rights. Under this option, if an employee were to decide to continue in a job involving exposure to a suspected but unproven developmental hazard, the employee would be legally, financially, and morally responsible for injury to his or her offspring. A possible suboption would grant employees the right to temporarily and voluntarily work at another job.

The major beneficiaries of such a policy would be employers, workers who do not parent children during the period of exposure or bioaccumulation (e.g., workers who practice sexual abstinence or who have undergone sterilization), and workers who parent healthy children because speculation about a suspected hazard was incorrect. Employers would benefit because they could avoid the economic burdens associated with the other options, as well as the potential expense of compensating damaged children. Workers who cannot or choose not to parent children would be free to expose themselves to suspected developmental toxins rather than be excluded from the workplace on the assumption that they might parent children.

There are several problems inherent in this option. The public health problem is that some employees may assume the risk, either because of scientific uncertainty, because they mistakenly believe the exposure will not hurt them, or because they are not planning parenthood, and produce injured children as a result. While workers intending to reproduce might not intentionally expose themselves to suspected developmental hazards, accidental pregnancies could have serious consequences for the health of the offspring. In these cases, this option may force a worker and his or her partner to choose between an abortion and an injured child. The public health problem could in fact extend beyond the injured children themselves and, in the case of genetic mutations, affect the health of future generations.

It is also questionable whether full disclosure or true informed consent can really be made in

such circumstances. Technical information that is disclosed but not fully understood may lead to misinterpretation of the extent of risk. Furthermore, the prospect of unemployment or a wage decrease may leave the worker with little choice but to continue employment in a potentially hazardous workplace. These situations cast doubt on the concept of freely given consent. In addition, many people believe that shifting the burden for workplace risks to the employee is never ethical.

There is also an ethical issue as to whether a worker should be permitted to waive the rights of future offspring to be uninjured (or, if prevention fails, to be compensated for a job-induced injury), so that the worker can pursue his or her employment in a particular job and facility. Moreover, while it may seem fair to eliminate the employer's liability to the child of a worker who consents to exposure, the worker may not be financially able to assume the consequences of his or her decision, in which case this burden falls on society.

The financial benefit to employers may be minimal. Because of the scientific uncertainty involved, an employer's disclosure and an employee's consent will often be less than fully informed. In these cases, the worker and his or her injured offspring may attempt to bring a personal injury suit against the employer and have the worker's consent declared legally ineffective. Thus, employers may be subjected to the same legal battles and expenses that accompany the prophylactic use of exclusionary fetal protection policies.

SUBOPTION:

Congress could allow workers to temporarily and voluntarily remove themselves from jobs involving exposure to suspected reproductive health hazards.

OSHA provisions allow medical removal for employees exposed to some health hazards, such as lead.

In cases where the employee's uptake of the hazard can be easily measured, an employee could consent to be regularly monitored for his or her uptake of workplace substances until the concentration of suspected or known hazards was sufficiently elevated to warrant the employee's removal from that job. This monitoring could

be limited to those who are trying to parent children or could be extended to all workers with reproductive capability. In cases where the employee's uptake cannot be measured easily, an employee who is trying to parent a child could voluntarily remove himself or herself from a job involving a potentially hazardous exposure. In many cases, however, measurement of exposure levels or safety levels cannot be accurately determined.

Upon removal from the job and its risks, the employee could be temporarily placed in a job without exposure to suspected reproductive or developmental hazards, either retaining the former wage rate or assuming the generally lower wage rate of the less hazardous job.

In cases where the employer could not economically justify placing the employee in another, non-hazardous position (e.g., where all such positions are filled, or where they require extensive training or education), the employee could be permitted to take a paid or unpaid leave of absence without losing seniority, health benefits, and/or eligibility for unemployment insurance or workers' compensation coverage during or after the period of absence. This option may not be realistic for many small businesses.

In a Pennsylvania case, involuntary removal from a job to protect worker health, including reproductive health, from further absorption of lead, and subsequent placement of the workers by the employer in different, lower paying jobs resulted in a successful claim for partial disability benefits. In reversing the Pennsylvania board's order denying benefits, the Pennsylvania Supreme Court stated:

It would be barbaric to require an employee to continue in a position where he is exposed to a toxic substance until he is so ill that he is physically incapable of performing his job. We have held that . . . the word disability is to be regarded as synonymous with loss of earning power.⁵

Conceivably, this view could be extended to situations from which the employee voluntarily withdraws to avoid a reproductive health hazard with compensation to be provided for any resulting decrease in earnings. This policy would be

⁵Lash v. Workmen's Comp. App. Bd., 420 A.2d 1325 (Pa. 1980).

comparable to cases of voluntary removal from health risks where the worker was not barred from securing unemployment benefits.

After the voluntarily rotated or absent employee has parented a child (or determined that he or she is not able to parent a child), within a maximum timeframe designed to protect the employer, the employee could be allowed to resume his or her former responsibilities without penalty.

OPTION 4:

Congress could amend Title VII to explicitly permit FPPs that treat male and female workers differently when scientific information supporting differential treatment is inconclusive.

This protective public health approach offers greater protection to the embryo/fetus than some of the other options. It assumes that the embryo/fetus is more susceptible to workplace health hazards than are adults. This option also assumes that most injuries are maternally mediated during pregnancy and overlooks the possibility of damage due to pre-conception exposure of either father or mother.

Unfortunately, this option could permit unnecessary discrimination against female workers. In any given year, only 1 of 15 women aged 16 to 44 gives birth to a live child,⁶ though all 15 might be subject to exclusionary policies that deny them their jobs or encourage them to submit to surgical sterilization due to speculation about risk of developmental effects. Furthermore, it is reasonable to assume that some of the substances for which scientific evidence is inconclusive are not in fact harmful to the embryo/fetus at the level of exposure encountered in the workplace. The level of protection to the embryo/fetus provided by this option would not reduce the risk of paternally mediated effects and could come at a substantial cost to female employment opportunities.

⁶On average, less than 1 of the other 14 women will have a pregnancy that fails to result in a live birth. Fetal loss may be attributable to exposure to occupational and/or other health hazards. In addition, some of these women will be exposed to hazards that are not manifested until a pregnancy 1 or more years later.

Regulation

Regulation in the Face of Uncertainty

Regulatory agencies such as OSHA, EPA, and NRC often face scientific uncertainty about whether a particular exposure constitutes a hazard to reproductive health. This problem exists for all areas of health regulation. Activities in the face of scientific uncertainty vary among Government agencies. Due to differing statutory mandates, OSHA, EPA, and NRC have developed their own procedures for corporate notification of new evidence concerning adverse health effects and agency response to toxicity information.

Should an agency regulate exposures when scant evidence suggests a possible health hazard, on the premise that worker health should be protected from all suspected hazards despite the substantial cost of such protection? Or should an agency only regulate when “all the evidence is in”—i.e., when there is a preponderance of evidence that a substance is harmful? OSHA, the agency charged with protecting occupational health, currently declines to regulate unless there is a preponderance of scientific evidence demonstrating the existence of a significant health risk.

OPTION 1:

Congress could maintain the status quo.

Agencies could continue to regulate exposures only after substantial evidence supports reducing exposure limits because of the finding of significant risk, even though this may result in more harmful exposures than might otherwise be the case. Regulating only when supported by substantial evidence would nevertheless serve to protect society from well-documented hazards while avoiding the costs associated with regulating suspected substances that later prove to be non-hazardous.

OPTION 2:

Congress could instruct the regulatory agencies to be more willing to assume that an exposure is dangerous when only a small number of studies suggest *this*.

Such an option would probably require a legislative amendment to the OSH Act specifying that an OSHA determination as to risk is conclusive

if some evidence of risk exists. Such determinations might concern whether an observed health effect is occupationally induced or not, or whether evidence demonstrates an effect on animals but is only suggestive in humans. This would better enable OSHA to regulate when the scientific evidence is not substantial. Presently, a court can strike down OSHA regulations if the court believes there is not “substantial evidence” to support the standard.

This option may result in great costs for “protection” from substances that are later shown not to be harmful at levels encountered in the workplace, but it could also protect some workers from exposure to a substance that is later, more conclusively, proven to be harmful.

Private Right of Action

OSHA is enforced solely by the Federal Government, except where States have federally approved State plans. Individual workers have no explicit right to go to court to force OSHA to issue citations to particular employers who are **violating** the Act. Thus, even if an employee has evidence that his or her employer is exposing him or her to a known reproductive (or other) health hazard, the employee probably cannot force OSHA to cite the employer either for violating an OSHA health standard or for violating the general duty clause.

OPTION 1:

Congress could maintain the status quo.

Congress may use its oversight and appropriations authority to maintain a level of OSH Act enforcement that is satisfactory to the Congress.

OPTION 2:

Congress could amend the OSH Act to grant employees the right to force OSHA to take action against employers who may be violating either an OSHA standard or the general duty clause.

This would enable workers to force OSHA to inspect a facility if there are reasonable grounds for concern about workplace health and safety hazards and to issue a citation if a workplace is found to be unhealthful or unsafe. Unless OSHA is provided additional funding and manpower for

responding to worker petitions, however, the agency’s resources may be diverted from other matters identified by administrative and scientific personnel as having higher priority.

Additional Relationships Between OSHA and NIOSH

Congressional action might help to protect workers from potential occupational health hazards by creating additional relationships between OSHA and NIOSH that enable or encourage OSHA to act on NIOSH-generated data about reproductive health hazards.

OPTION 1:

Congress could maintain the current relationship between OSHA and NIOSH.

Though the two agencies have common goals—the protection of occupational health in America’s workplaces—their separation in the bureaucracy may sometimes result in lack of communication and thus a lack of compatible research and regulatory priorities.

OPTION 2:

Congress could join OSHA and NIOSH organizationally.

Although creating a single agency from the two might enhance communication and cooperation in risk assessment and risk management activities, either agency’s removal from its current parent agency might compromise the quality of those activities. NIOSH’S relationship with the Centers for Disease Control enables it to play an important role in the Federal Government’s public health effort, while OSHA’S relationship with the Department of Labor may make the agency more politically responsive than NIOSH. OSHA’S Chief reports to a member of the President’s Cabinet while NIOSH’S does not; this may or may not affect agency interactions. The fact that different subcommittees of Congress oversee the activities of the two agencies does not help to increase coordination of priorities.

OPTION 3:

Congress could give NIOSH the power to force OSHA to respond to NIOSH recommendations concerning reproductive and other occupational health hazard~

When NIOSH evaluates suspected health hazards and makes recommendations to OSHA concerning regulation, OSHA is not presently required to respond. Congress could force OSHA to respond to NIOSH research and recommendations by requiring OSHA to act within a fixed time limit after receiving NIOSH research results and recommendations and either proceed as recommended or publish an explanation in the Federal Register of why such action would be inappropriate. This would place a burden on OSHA to articulate its reasons for failing to adopt health standards recommended by NIOSH.

The disadvantage of this option is that requiring OSHA to respond to NIOSH recommendations may dilute its personnel resources and prevent OSHA from attending to matters it considers more pressing. For example, a NIOSH study that finds that a particular substance may cause transitory infertility and that results in a NIOSH recommendation for regulatory action could require a formal OSHA response based on scientific, economic, and other data. Given OSHA's small technical staff, the legally mandated response to NIOSH and the public could prevent OSHA from investigating other suspected hazards that, while not yet the subject of completed NIOSH research, appear to be more hazardous. In addition, forcing OSHA to respond to NIOSH recommendations might dilute OSHA's ability to enforce existing standards.

Emergency Temporary Standards

Even when the evidence appears to strongly support a health standard, OSHA may not promulgate an emergency temporary standard (ETS) unless a "grave danger" exists. The Fifth Circuit Court of Appeals interprets this language to mean a danger of "incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health." Given this definition, some reproductive health hazards might be categorized as grave dangers, while others might not. It is unclear, for example, whether temporary infertility would be considered to be a grave danger, even though it could have a permanent effect on an employee's ability to reproduce, particularly if the female of the couple is approaching 40 years of age. In the ab-

sence of a grave danger, however, OSHA must promulgate a permanent standard, which may take more than a year to produce, thus allowing some workers to be exposed to the hazard in the interim.

Even where a grave danger exists, the ETS procedure has been held by a Federal appeals court to require an exhaustive statement of reasons, indicating on which data OSHA is relying, why those data are sufficient to show the existence of a grave danger, and why the particular standard is necessary for the protection of employees. Preparing such an exhaustive statement of reasons could be sufficiently time-consuming to render the ETS mechanism ineffective for reproductive health hazards.

OPTION 1:

Congress could maintain the status quo.

This would probably result in OSHA refusal to issue ETSS for hazards that produce certain reproductive health effects (e.g., temporary infertility) that may not be considered grave dangers by the courts. In addition, the requirement of an exhaustive statement of reasons means that ETSS are less likely to be promulgated quickly when a genuine public health emergency occurs.

OPTION 2:

Congress could amend the "grave danger" language of the OSH Act.

This would allow OSHA to respond quickly to public health concerns, including reproductive health hazards, that are not incurable, permanent, or fatal, without fear that a court will require the agency to proceed by way of the cumbersome and time-consuming formal rulemaking process. The disadvantage of this option was recognized by Congress when the grave danger language was adopted. Emergency temporary standards can result in substantial compliance costs to an affected employer, yet they are effective only for 6 months and generally require less supporting evidence than do permanent standards. Congress wanted to spare employers the expense of complying with temporary standards unless a substantial workplace danger warranted the regulation.

OPTION 3:

Congress could amend the OSH Act so that all that is required when an ETS is issued is notice of OSHA'S reason for issuing the standard and access to the scientific data on which it relied.

This would allow an ETS to be issued for an agent that is reasonably suspected, though not yet proven, to be hazardous.

Compensation for Job-Induced Reproductive Harm

Even when there is full cooperation among labor, industry, and government, prevention of occupational disease may not always be successful. In some cases, a substance may not be recognized as hazardous until some workers are injured. Even in cases where the hazard is recognized and exposure avoided, accidents occur. A manufacturing or design flaw may make engineering controls or personal protective equipment malfunction. A human error by an employee may result in release of a substance. Exposure to multiple substances both inside and outside the workplace, as well as personal lifestyle and medical factors, may yield unanticipated interactions. All of these scenarios have two things in common: they are **unpredictable** events leading to injury and they will probably continue to occur with uncertain frequency in spite of all preventive efforts.

The issue that remains, therefore, concerns the personal and financial costs of occupational disease in general and reproductive health hazards in particular. While the *persona* cost of reproductive, sexual, or developmental injuries must ultimately be borne by the affected individuals and their families, these individuals may be morally entitled to place some or all of the financial burden on other parties associated with the injurious workplace situation.

Most workers cannot collect compensation for their reproductive injuries. As discussed previously, not only do most workers' compensation systems fail to provide remedies for job-induced reproductive failure, they also deny workers access to court-awarded relief. (Since injured offspring are not covered by workers' compensation statutes, they may press their claims in court.)

Should compensation for a worker's reproductive or procreative injury be provided? If so, should it be provided through court-awarded remedies under State tort law or through workers' compensation schemes, either at the State or Federal level? Since a workers' compensation award is generally the only remedy available to compensate a worker with nonreproductive occupational injuries, it may be rational to extend coverage to job-induced reproductive injuries. Historically, the underlying theory of compensation law is to award benefits only for those injuries that cause a diminution in earning capacity. Workers' compensation can be viewed as being designed to protect the worker from economic insecurity and not as a form of "damages" in the sense of relieving the victim from all of the effects of the injury. Yet the exclusivity rule prevents injured employees from seeking compensatory damages in court, even when the employer is negligent. Since it limits the worker's ability to collect damages, workers' compensation can also be viewed as a form of limited restitution. Because of this conflict, a policy choice is presented in which legislators must weigh the relative interests of the employer, the public, the injured worker, and the integrity of the workers' compensation system.

Several theories underlie the responses of State courts, legislatures, and compensation boards to reproductive harm claims made pursuant to workers' compensation statutes. The narrowest theory is the view that actual wage loss is required for any benefits other than medical. A potentially broader view requires evidence of loss of earning capacity, though not necessarily actual wage loss. The most generous theory, adopted by only a handful of States, claims that the health and functions of the whole man or woman should be used as the standard for measuring the validity of a claim and its compensability. Reproductive or procreative impairment maybe covered under such theories because it may have life-shattering effects without negative economic implications.

Virtually all State workers' compensation systems follow one of the two narrower theories, thereby providing a remedy for reproductive injuries only when they affect earning capacity. It is a justifiable option to limit the scope of State

compensation plans to the occupationally disabled. But no one claims that it is justifiable to base denial of a tort remedy on the fact that the reproductive injury was job-related if the case falls outside the State system for compensating occupational injuries.

Regardless of whether compensation is provided through the workers' compensation system or the tort system, the problem of assigning moral, legal, and financial responsibility is complicated by uncertainty concerning the relationship between a particular workplace exposure and a particular injury. Scientifically conclusive evidence that a particular workplace exposure caused or contributed to an injury is rare. Test results showing the effects of a substance on animal reproductive or procreative capacity, or on embryo/fetal development, must be interpreted with caution, and research on human exposure presents a number of moral and pragmatic constraints that may confuse the assignment of causation. Furthermore, determination of whether there is a statistically significant relationship between workplace exposure and a medical condition may require study of large numbers of exposed employees; in some cases, the number of workers exposed to the suspected hazard may be smaller than the number of subjects needed for ensuring valid and reliable results. In any event, a court of law or a workers' compensation board may be unwilling to rely solely, or even substantially, on the results of epidemiologic or toxicologic investigations to support claims for compensation.

Given the scientific uncertainty as to causation of most reproductive dysfunction, compensation boards and courts are faced with a choice between compensating too few and compensating too many. If the court or compensation board requires a high degree of scientific certainty, then the tribunal can be relatively certain that it has not paid on fraudulent or erroneous claims, but some genuine cases of job-induced reproductive impairment will go uncompensated due to lack of sufficient proof. If the tribunal accepts less scientific evidence to support claims, fewer meritorious cases will go uncompensated but more erroneous claims will result in a windfall to the claimant. The expense of paying the erroneous

claims will fail directly on industry, which funds the workers' compensation program, and ultimately on the consumers of that industry's products. The question therefore arises as to how the burden of scientific uncertainty should be allocated among the various concerned parties.

OPTION 1:

Congress could enact a Federal statute, or State legislatures could add specific provisions to State workers' compensation statutes, to cover loss of reproductive and procreative function even when nondisabling.

Workers' compensation schemes already provide scheduled benefits for some types of injuries in the absence of wage loss (e.g., for loss of an eye, limb, or digit). If coverage for reproductive injuries is adopted, the amount of compensation should be the value that the legislature places on the reproductive impairment; when a worker suffers reproductive or procreative impairment without a wage loss, there is no justification for tying the cash benefit to an existing wage level.

Proposals for occupational disease compensation at the Federal level have generally used job disability or earnings loss as a criterion for compensability. Such legislation would fail to result in compensation for most reproductively injured workers.

OPTION 2:

A Federal statute could be enacted or State legislatures could amend their workers' compensation laws to provide workers with the right to pursue a tort remedy for injuries falling outside the workers' compensation law.

If legislators do not want to extend workers' compensation coverage to nondisabling reproductive injuries, they could adopt this option so that injured workers can sue employers who are allegedly responsible for their injuries.

Adopting this option would probably result in an increase in liability actions. A comparison of the costs of compensating individuals with occupationally caused asbestosis suggests that moving occupational disease cases into the tort system will result in higher awards to injured

workers, as well as higher legal expenses, than does placing these cases under the umbrella of workers' compensation. Court proceedings may also take longer than those for workers' compensation; and court proceedings are generally less likely to result in compensation due to the more stringent evidentiary standards that they apply.

OPTION 3:

Reproductive impairment claims could be carefully disaggregate into those suitable for the compensation system and those suitable for the tort system.

This would necessitate variations on the legislative actions suggested above for the first and second options. For example, physical impairment of a worker's reproductive system may be determined to be suitable for the State compensation system (with the necessary amendment and benefits schedule), whereas harms to other members of the worker's family may be determined to be suitable for the tort liability system (as they are at present).

***Reducing Uncertainty:
Issues in Research***

Given the existing level of reproductive dysfunction, it is difficult to know whether the level of risk now tolerated represents the inevitable and irreducible consequence of life in the 20th century, or whether it represents an excessive and reducible risk to the reproductive health of workers and their potential offspring. Additional research on reproductive health hazards can reduce the degree of uncertainty.

From the point of view of workers, increased funding for research is intimately linked to their "right to know" about the substances to which they are exposed. Only informed workers can make informed choices. From the point of view of employers, more research could lead to better understanding of the actions necessary to both protect workers and inform them of potential risks. From the point of view of society, more research could reduce scientific uncertainties and lead to more reasoned consideration of policies to protect the reproductive health of working men and women.

There are practical considerations to be weighed, however. How much research is enough? How should resources be allocated among the various agencies and between basic and applied research? The results of basic research are often not immediately applicable and their impact is difficult to measure. It might be possible to place a monetary value on a new in-vitro assay that reliably and validly tests for specific developmental effects, but how can a monetary value be placed on the prospect of reducing the incidence of spontaneous abortion?

Several types of studies, from research at the molecular level to epidemiological studies on human populations, are necessary to elucidate the causes and consequences of suspected reproductive health hazards. This effort includes basic research to better understand the physiology of reproduction and the mechanisms of action of toxicants. More efficient techniques need to be developed to assay reproductive and developmental effects. Mathematical models for accurately extrapolating dose-response effects from animals to humans are needed. The reproductive endpoints in animals that reliably predict concordant effects in humans need to be clarified. Human populations need to be better monitored and more studies need to be done in the workplace.

The workplace is the laboratory for occupational health research. Occupational health research and monitoring activities are currently carried out by the larger firms, and both toxicology and epidemiology research efforts are sponsored by trade associations. However, some researchers report difficulty in gaining access to industrial settings in order to carry out research on workplace-related health effects. Companies are in a difficult position because they fear liability for injured workers could result from such studies. Congress might limit corporate liability in the case of companies that cooperate with researchers in order to provide an incentive to cooperate. However, this option could place an unnecessary burden on injured workers by denying them full compensation for their injuries.

In a period of budget-tightening, congressional oversight to ensure adequate review of research priorities and scientific standards may be in or-

der. In addition, some measures could improve the quality of data inexpensively. For example; such low-cost options as recording the occupations of both parents on birth records could provide information on whether birth defects are correlated with occupation. Occupational histories of both parents could also be added to the Birth Defects Monitoring Program (CDC survey), and the NCHS National Health and Nutrition Examination Survey (HANES).

Most basic research on human reproductive physiology is carried out in university laboratories sponsored by the National Institutes of Health (NIH) or the National Science Foundation (NSF). Basic research in toxicology is carried out in universities as well as by the National Institute for Environmental Health Sciences (NIEHS), the National Toxicology Program (NTP), EPA, the Food

and Drug Administration (FDA), and NIOSH. Work on improved methods of risk assessment, including use of new assays and development of mathematical models for extrapolation from animal data, is being carried out by these same agencies. The Centers for Disease Control is carrying out several surveillance efforts to monitor levels of reproductive impairment in the population. Both EPA and NIOSH are also conducting epidemiology studies. NIOSH can have a positive impact on the quality of epidemiology studies done in industry through its Health Hazard Evaluations. These studies can increase knowledge of human effects, and can be used to further cooperative efforts between government and industry. Congress, through its appropriations and oversight functions, could assign priority to particular types of research and improve its quality.