Appendix C

Technical Notes: OSHA

Technical Note #Cl: Medical Surveillance Programs: Questions and Answers

In implementing medical surveillance programs a number of questions have arisen, including the following:

(1) What employees are covered by the medical surveillance provisions of OSHA standards?

As mentioned in chapter 7, some OSHA health standards require medical surveillance only for employees exposed at or above the action level specified in the standards. Other standards require medical surveillance for all employees exposed to any levels of the substance. Even these more stringent requirements have been upheld. In ***GAF Corp. v. OSHRC,***[1] the D.C. Circuit affirmed the Commission's holding that the employer was required to provide medical examinations for all employees exposed to asbestos, including employees whose exposures were below the PEL. In ***Duquesne Light Co.,2*** however, the Commission recently held that the asbestos standard did not require medical examinations of employees who were not regularly exposed, even though their sporadic exposures sometimes exceeded the standard. The coke oven, arsenic, and ethylene oxide standards require medical surveillance for employees exposed at least 30 days per year.

In formulating the ethylene oxide standard, OSHA rejected the recommendations of AFSCME and the AFL-CIO that medical surveillance should be provided to all formerly exposed employees as well as those presently exposed. According to OSHA, this recommendation was rejected because the present state of knowledge about ethylene oxide's long-term effects on humans is inadequate and only employees at a late stage of developing leukemia could be identified. The coke oven emissions standard, however, does require continued surveillance of previously exposed employees who have been reassigned by the same or a successor employer.[3]

(2) Are medical examinations mandatory?

Section 6(b)(7) of the Act provides that medical examinations shall '(be made available" to exposed employees. OSHA has interpreted this language to mean that the employer must offer the examination; the employee may refuse to take the examination.[4] The coke oven emissions standard contains a provision requiring employers to inform employees of the possible health consequences of refusing to take the examination and requiring a signecl statement by the employee that the consequences have been explained and understood .[5]

The detailed medical removal policy (MRP) and rate retention (RR) provisions of the lead standard were promulgated, in part, as an alternative to mandatory worker participation in the medical surveillance program. The preamble to the lead standard indicates that OSHA rejected the idea of making examinations mandatory because employees concerned about job security might be tempted to use chelating drugs as well as to conceal subjective symptoms of lead disease.[6] By contrast, with MRP and RR, workers would be encouraged to participate, but those who choose not to—because of privacy, religious, or other reasons–would not be required to participate.

The only time OSHA attempted to make medical surveillance mandatory was in the commercial diving standard, which was issued in 1977 and struck down by the Fifth Circuit in 197!3.[7] OSHA reasoned that the safety of other dive team members can depend on the health of an individual diver.[8] The multiple-physician review procedure, discussed in detail below, also was included in the diving staridard to ensure that divers would not be denied their employment on the basis of a single medical examination.

The preceding discussion of the "optional" nature of OSHA-required medical examinations does not mean that adverse consequences will not attach when an employee refuses to undergo examination. Simply because OSHA does not require participation does not mean that it protects a refusal to participate. Unless covered by the terms of a collective bargaining agreement, an employer may make cooperation with med-

[1] 561 F.2d 913 (D.C. Cir 1977).
[2] 11 () S.H Cas (BNA) 2033 (1984)
[3] 29 C F.R § 190, 1029(j)(3) (iii) (1984)

[4] B. Mintz, OSHA: History, Law, and Policy 134 (1984)
[5] 29 C F.R § 19101029 (j)(l) (ill) (1984).
[6] 43 Fed. Reg 52,952, 52,973.74 (19 78)
[7] Taylor Diving & Salvage Co v U ! S Dept of Labor 599 F 2d 622 (.5th Cir 1979).
[8] 42 Fed Reg 37,656-57 (1977)

ical examinations a valid condition of employment.[9] Thus, as a practical matter, most "optional" OSHA medical examination provisions may be, in fact, mandatory for employees if the employer chooses to make them so.

(3) What procedures are required?

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

Even without a separate health standard specifying the particulars of a medical surveillance program, OSHRC may impose an appropriate medical surveillance program as an alternative measure during the extended period of time request in a petition for modification of abatement (PMA). In *ITT* v. *Grinnell*,[10] the employer was cited for having excessive levels of silica dust. The employer filed a PMA to extend the abatement date, which the Commission granted conditioned on the employer's use of additional medical surveillance, including chest X-rays and pulmonary function tests.

Although OSHA prescribes the use of specific medical procedures, it should be emphasized that OSHA does not prohibit the use of any procedures. The only exception to this principle is the ban on the use of prophylactic chelation in the lead standard.[11]

(4) How are test results interpreted?

An accurate medical assessment often depends on a thorough history, clinical evaluation, and laboratory procedures. Although OSHA health standards promulgated after the asbestos standard (OSHA's first health standard promulgated by rulemaking) have contained appendixes with medical surveillance guidelines,[12] only the lead and cotton dust standards provide detailed guidance for physicians. The medical surveillance guidelines published with the proposed ethylene oxide standard recommended the use of cytogenetic monitoring of workers to detect chromosomal aberrations.[13] This recommendation was not included when the final version of the standard was promulgated.[14]

(5) Who selects the physician?

The Act does not specifically indicate whether the employer or employee has the right to select the physician who performs medical examinations. In promulgating the asbestos standard, OSHA determined that the employer should have the option of choosing the physician and should have access to the results of the examination.[15] The D.C. Circuit upheld OSHA's position[16] and this policy has been followed in subsequent health standards.

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

In *Taylor Diving & Salvage Co.* v. *U.S. Department of Labor*,[17] the Fifth Circuit struck down this provision. The court, citing its decision in *American Petroleum Institute* v. *OSHA*,[18] held that the standard was not "reasonably necessary or appropriate to provide safe or healthful workplaces." The court concluded that the standard imposed a mandatory job security provision controlled by the third physician. "[T]he employer has no control over the third doctor's fitness standards, so that the employer is prevented from setting higher health standards for employees than the secondary examining doctors choose to set."[19]

In *United Steelworkers of America* v. *Marshall*,[20] the D.C. Circuit reached the opposite result and upheld the multiple physician review procedure of the lead standard. According to the court, the provision is authorized by § 6(b)(7)'s broad mandate to require examinations that can "most effectively determine" a

[9] M. Rothstein, Medical Screening of Workers 88 (1984).

[10] 11 O.S.H. Cas. (BNA) 1464 (1983).

[11] 29 C.F.R. § 1910.1025(j)(4) (1984).

[12] Vinyl chloride, 29 C.F.R. § 1910.1017 App. A (1984); arsenic, 29 C.F.R. § 1910.1018 App. C (1984); lead, 29 C.F.R. § 1910.1025 App. C (1984); coke oven emissions, 29 C.F.R. § 1910.1029 App. B (1984); cotton dust, 29 C.F.R. § 1910.1043 Apps. B, C & D (1984); DBCP, 29 C.F.R. § 1910.1044 App. B (1984); acrylonitrile, 29 C.F.R. § 1910.1045 App. C (1984); ethylene oxide, 29 C.F.R. § 1910.1047 App. C (1984).

[13] 48 Fed. Reg. 17,315 (1983).

[14] 49 Fed. Reg. 25,734 (1984).

[15] B. Mintz, OSHA: History, Law, and Policy 136 (1984).

[16] Industrial Union Dept v. Hodgson, 499 F.2d 467, 485 (D.C. Cir. 1974).

[17] 599 F.2d 622 (5th Cir. 1979).

[18] 581 F.2d 493 (5th Cir. 1978), aff'd sub nom. Industrial Union Dept v. American Petrol. Inst., 448 U.S. 607 (1980).

[19] 599 F.2d at 625.

[20] 647 F.2d 1189 (D.C. Cir. 1980), cert. denied sub nom. Lead Indus. Assn., Inc. v. Donovan, 453, U.S. 913 (1981).

threat to worker health. In addition, the provision is reasonable in light of two findings supported by the record. First, lead diseases are often difficult to diagnose and multiple physician review increases the chances of a correct diagnosis. Second, some company physicians have engaged in the unsound and harmful practice of prophylactic chelation to reduce the blood-lead levels of employees. The court distinguished ***Taylor,*** where employees would seek multiple physician review to obtain a finding of fitness, thus forcing the employer to retain employees considered unfit by its own physician and standards. In the lead standard, the multiple physician review procedure was to prevent excess exposure of "leaded" employees and, together with the medical removal protection, the employer is not precluded from imposing more stringent health standards.

In the ethylene oxide standard, OSHA adopted the position taken by NIOSH that multiple physician review was unnecessary for ethylene oxide.

(6) Who pays for the examination?

Section 6(b)(7) of the act makes it clear that medical examinations shall be made available "by the employer or at his cost. " OSHA'S health standards have included language indicating that all costs for medical examinations must be borne by the employer. In ***Phelps Dodge Corp., 21 th Commission*** held that a provision in the inorganic arsenic standard providing that medical examinations be provided without cost required the employer to compensate employees for time spent taking the examination (outside normal working hours) and for extra transport at ion expenses. The Commission's decision was affirmed by the Ninth Circuit. [22]

(7) What personnel action may be taken as a result of the examination?

with the exception of medical removal protection and rate retention under some health standards, OSHA has not indicated what personnel actions may or may not be based on OSHA-mandated medical surveillance. Consequently, unless there is an applicable provision in a collective bargaining agreement or the personnel action otherwise violates some antidiscrimination law (e.g., handicap laws), an employer may discharge, reassign, lay off, or refuse to hire employees on the basis of medical surveillance. The problem of job security is one major reason why employees sometimes do not fully cooperate with medical surveillance programs .23

[21] 11 () S H Cas (BNA) 1441 (1983), aff 'd, 725 F 2d 1237 (9th Cir 1984)
[22] Phelps Dodge Corp v OSHRC, 725 F 2d 1237 [9th Cir 1984)
[23] M Rothstein Medical Screening of Workers 203.04" (t 984)

Technical Note #C.2: OSHA Priorities in Risk Assessment and Risk Management

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

In ***National Congress of Hispanic American Citizens v. Marshall, the*** D..C. Circuit reviewed OSHA'S priorities for development of health and safety standards. For health standards, OSHA considers the number of workers exposed, the severity of the hazards, the existence of research relevant to hazard identification and methods of control, N1OSH recommendations, citizen petitions, court decisions, and other factors. Using these criteria, OSHA generally has given its highest priority to carcinogenic substances.

Although White House priorities and congressional oversight and appropriations activity also affect standards promulgation, Congress has never spelled out its priorities for OSHA standards. According to OSHA'S health standards chief, "the Federal agencies are not doing a competent job of regulating chemicals and part of the blame rests with Congress." In his view, there is a need for congressional guidelines in developing criteria for priorities for regulation, such as the nature of the hazard and the level of exposure.

OSHA has developed an internal document, RUL.1, which provides a framework for dealing with severity, exposure, risk, feasibility, and similar issues. According to a Reagan Administration official, the potency of the substance and the current exposure levels are two key factors in establishing the need to regulate a hazardous substance. A former DOL official asserted that although priority should be given to the gravest health hazards, OSHA cannot afford to use all of its resources here. Another OSHA official observed that OSHA is required by law to apportion its resources between reviewing old standards and developing new ones.

The difficult scientific and policy questions of deciding what substances should be regulated, in what order, and in what manner are further complicated by political considerations. Most observers probably would agree with the OSHA official who stated that "the setting of OSHA'S priorities is, and always has been, highly politicized." A former OSHA chief under Ford and Carter commented that the priorities for standards-setting often depend on "who is making the

[24] 626 F.2d 882 (D.C. Cir. 1979)

most noise politically." In his view, this has been especially true during the Carter and Reagan Administrations. Another former OSHA chief and a current OSHA official contend that most of the pressure comes from the various interest groups rather than from the White House. Indeed, the degree of political pressure may be related to the type of regulation at issue. The former OSHA chief under Reagan stated that people are more reasonable in the safety area than in health. "Health issues involve politics at its lowest."

It is difficult to gauge the effects of such political maneuvering on the ultimate decisions of the agency. The former OSHA chief asserted that to be an effective head of OSHA "requires a strong-willed individual." Another former OSHA chief concurred that the "head of the agency must be strong enough to buck the political pressure."

Several of the individuals interviewed stated that political pressure is neither unanticipated nor totally undesirable. One official described attempts to influence OSHA policy as "helpful input." Another former OSHA chief under Reagan termed political pressure "a part of the game" and added that "it's the price we pay for having a free and open society." A former OSHA lawyer suggested that procedures established under the Act and the structure of our governmental system provide checks and balances on OSHA's decisionmaking.[25]

The way in which political considerations enter the decisionmaking process is also the cause of some concern. The director of OSHA's Office of Standards Review cautions that political pressure should influence only policy decisions, not the interpretation of scientific data. "If you don't want to regulate because of cost, say so. Don't prostitute the science."

Risk Assessment/Significant Risk

NIOSH Approach.—As a scientific and technical research agency, NIOSH approaches hazard control with the view of providing maximum protection for workers. Thus, although it need not determine whether a risk is "significant" in the legal sense, it does attempt to quantify the magnitude of risk. NIOSH's quantitative risk assessment attempts to identify hazards, assess exposure, evaluate possible dose-response relationships, and characterize risk. Unlike epidemiology, which is based solely on human data and observed levels of exposure, quantitative risk assessment considers data from animal studies as well and attempts to extrapolate risk estimates to lower levels than those observed in animals.

Because the courts require that OSHA standards contain increasingly detailed risk assessments, NIOSH has started more formal activities in quantitative risk assessment in the criteria documents division. A senior NIOSH epidemiologist who is leading this new effort says that NIOSH has little or no expertise in the field at present. Nevertheless, the agency is working with consultants to develop the capability to better quantify the need for standards. One of the goals of the new section is to develop working groups in various subject areas and, where needed, to use outside experts to assist with the risk assessments.

OSHA Approach.—Any discussion of risk assessment under OSHA necessarily begins with the Supreme Court's 1980 decision in the Benzene case. In *Industrial Union Department* v. *American Petroleum Institute* (API),[26] the Supreme Court addressed several important substantive issues in ruling on the validity of OSHA's benzene standard. The Fifth Circuit had invalidated the standard because OSHA failed to provide a quantitative estimate of the benefits to be achieved by reducing the permissible exposure limit (PEL) from 10 ppm to 1 ppm.[27]

The Fifth Circuit based its decision on § 3(8)'s definition of an "occupational safety and health standard" as being "reasonably necessary or appropriate" for safe workplaces. From this language the court held that the Secretary must determine "whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard."[28] The court was, essentially, fashioning a three-part test:

1. whether substantial evidence supports the Secretary's estimate of expected benefits;
2. whether substantial evidence supports the Secretary's estimate of expected costs; and
3. whether the benefits bear a reasonable relationship to the costs.

Because there was inadequate evidence of expected benefits, the other issues were not decided.

The Supreme Court affirmed the decision of the Fifth Circuit, but the Court was sharply divided, and issued five separate opinions. Justice Stevens, writing for a plurality of four justices, rejected the Government's argument that § 3(8) is meaningless and is supplanted by § 6(b)(5), which details the requirements for standards dealing with toxic materials or harmful physical agents. According to the plurality opinion, § 3(8) must be satisfied before there can be any consideration of a standard under § 6(b)(5).[29] "[Section 3(8)]

[25] For a further discussion of how political factors influence OSHA, see [illegible] McCaffrey, OSHA and the Policies of Health Regulation (1981).

[26] 448 U.S. 607 (1980).

[27] American Petroleum Inst. v. OSHA, 581 F. 2d 493, 505 (5th Cir. 1978), aff'd, 448 U.S. 607 (1980).

[28] 581 F.2d at 503. The court relied on its prior construction, in Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission, 569 F. 2d 831 (5th Cir. 1978), of similar language in the Consumer Product Safety Act.

[29] Among the requirements of § 6(b)(5) is standard must be feasible

requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment In other words, "the burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material impairment. "[30]

In effect, the plurality added a fourth element to the Fifth Circuit's test that had to be satisfied before the other three factors could even be considered. This "significant risk" requirement is not just an analytical starting point, it is an important substantive limitation on OSHA'S rulemaking authority. According to the plurality, the Act "was not designed to require employers to provide absolutely risk-free workplaces, " but was only intended to require "the elimination, as far as possible, of significant risks of harm. "[32] The Fifth Circuit decision was affirmed because the Secretary failed to prove that there are significant risks associated with benzene exposure at the present limits.

Justice Marshall's dissenting opinion accused the plurality of fashioning a restrictive rule of law from a definitional section of the statute that was not intended to have such a profound effect. The result is to place "the burden of medical uncertainty squarely on the shoulders of the American worker, the intended beneficiary of the Occupational Safety and Health Act ."[33]

Significantly, of the two main points of the plurality opinion, the effect of $ 3(8) and the sufficiency of the evidence supporting the need for a new standard, neither are majority views of the Court .[34] Justice Rehnquist, concurring in the judgment, joined the four dissenters in concluding that ~ 3(8) was not intended to be a general check on the Secretary's authority under j 6(b)(5) .35 As to the sufficiency of the evidence supporting the need for a new standard, Justice Rehnquist did not address this question and Justice Powell, in a separate concurrence,[36] conceded that the question was close. The four dissenters argued that the Secretary had presented sufficient evidence of the need for the standard .37

Courts applying the API tests to other cases challenging OSHA standards have reached different results. In ***United Steelworkers of America v. Marshall,***[38] the D.C. Circuit, in upholding the validity of the lead standard, held that the Secretary had satisfied $ 3(8)'s requirement of proving "significant harm." Instead of relying on "categorical assumptions" about lead poisoning, the Secretary amassed voluminous data of the harmful effects of lead at various blood-lead levels and correlated these levels with various average air-lead levels.

In ***Texas Independent Ginners Association v. A!arshall,***[39] however, the Fifth Circuit struck down the cotton gin standard, finding that the Secretary failed to prove that cotton dust in cotton gins poses a significant health risk . OSHA simply assumed that because byssinosis results from high exposure levels in textile mills that byssinosis also results from the lower exposure levels in cotton gins. This assumption did not satisfy the $ 3(8) requirement of significant harm, especially in light of the seasonal nature of cotton gin operations.

An important part of risk assessment and "significant risk" is the quality of the scientific data on which the risk assessment is based. Section 6(b)(5) of the Act provides that standards dealing with toxic materials or harmful physical agents must be based on the "best available evidence. " While this language appears to be straightforward, the scientific evidence of the precise harmful effects of exposure to various substances is often inadequate, incomplete, inconclusive, or subject to dispute. At the same time, there may be clear evidence that exposure at some levels to these substances causes serious illness .40 This dilemma has raised two related questions in the context of $ 6(b)(5): 1) What constitutes the "best available evidence?" and 2) IS OSHA precluded from adopting new' standards until there is definitive, detailed, and indisputable scientific evidence?

In the ***Benzene*** case, the Secretary argued that because there is no absolutely safe level known for benzene, industry should have the burden of showring that a safe level exists. Any other approach, it was argued, would require OSHA to wait for deaths to occur before taking any action.

The plurality opinion specifically rejected this argument and, as discussed previously, held that OSHA had the burden of proving that it is at least more likely than not that long-term exposure to benzene at the present PEL presents a significant risk of material health impairment. According to the plurality, this

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[30] 448 U S. at 639 The court incorrectly paraphrased §3(8) as requiring a standard to be "reasonably necessary and appropriate." Actually, a standard need only be "reasonably necessary or appropriate

[31] 448 1' .S at 653

[32] Id.

[33] 448 U.S. at 690

[34] See generally Note, Plurality Decisions and Judicial Decisionmaking 94 Harv L. Rev 1127 (1981).

[35] 448 U' s at 681 L his view, § 6(b)(5) was too vague and therefore represented an unconstitutional delegation of legislative authority to the executive

[36] 448 U s, at 667 Justice Powell believed that the Secretary failed to prove tbe economic feasibility, of the standard.

[37] For criticism of the Court's decision, see M Rothstein, occupational Safety and Health Law 73-74 (2d ed. t 983); Rodgers, Judicial Review of Risk Benzene Decision, 1 t Envtl. 1.. 301 (1981)

[38] 647 F 2d 1 1119 (D C Cir 1980), cert denied sub nom Lead Indus Assn Inc v Donovan, 453 1'.S 913 (1981)

[39] 630 F 2d 398 (5th Cir. 1 980)

[40] See generally McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions Regulating Carcinogens in EPA and OSHA, 67 GeoL J. 729 (1979).

burden will not prevent OSHA from regulating carcinogens for the following reasons. First, it is OSHA's responsibility to determine, in the first instance, what it considers to be a significant risk. Although there is no duty to calculate the exact probability of harm, OSHA does have the obligation to determine whether a significant risk is present. Second, a standard need not be based on scientific certainty, and OSHA is free to risk error on the side of over-protection so long as the standard is supported by a body of reputable scientific thought. Third, the relative significance of risk can be quantified in a number of ways other than by epidemiological studies, such as by extrapolation of animal test data.[41]

In *Texas Independent Ginners Association* v. *Marshall*,[42] the Fifth Circuit held that the cotton gin standard was not based on the best available evidence. OSHA had based the standard on studies of ginning employees in Egypt, Uganda, Greece, and Sudan, rather than on a study of American gins, where there is reduced exposure due to the seasonal nature of the work. OSHA also overrelied on studies of byssinosis in the cotton manufacturing industry. Finally, OSHA failed to reopen the hearing record to consider a more recent study. On this final point, it is not clear what the practical limits should be for imposing an ongoing duty on OSHA to consider new evidence, inasmuch as new scientific information is being discovered on a continuing basis.

The *Benzene* decision has certainly caused OSHA to reevaluate the way in which scientific research is translated into regulatory action. Nevertheless, it has not viewed the decision as an insurmountable barrier, according to former Carter and Reagan OSHA Chiefs.

After the *Benzene* decision, the arsenic standard, which was pending before the Ninth Circuit, was remanded to OSHA for the completion of a risk assessment. In January 1983, OSHA published its final risk assessment for arsenic and in so doing set forth its general framework for evaluating the need for a standard.[43] In setting health standards OSHA uses a four-step approach:

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

Risk assessment, therefore, is the first step in the process of regulation. OSHA defines quantitative risk assessment as "an attempt to predict the degree of risk associated with a specific level of exposure. This is done either through direct observation or by extrapolation. . . ." Some important components of risk assessment are a description of the hazard, a description of the potential exposure and worker scenarios, a description of the dose-response relationship, and a quantitative determination of risk.[44]

According to some published reports, there is a danger in over-reliance on quantitative risk assessment. To begin with, the ability to generate detailed and precise mathematical models for hazards varies greatly. To require both detail and precision may be either impossible or so time-consuming that no action is taken on hazards clearly in need of regulatory action. (The court's recent decision on the asbestos ETS is an example). Thus, it has been argued that underlying policy questions should be addressed even without detailed quantitative models.[45]

Second, "risk assessment" should not be confused with "risk management," the latter being the process of evaluating alternative regulatory actions and selecting among them.[46] Risk assessment, quantitative or qualitative, cannot substitute for the value judgments and policy review essential to regulation. Administrative actions do not automatically result from risk assessment.

Third, there is a lack of uniformity in the way that Federal agencies conduct risk assessment.[47] Although there is widespread support for the use of a single methodology and interagency cooperation, there is disagreement about whether a single agency is needed to perform risk assessments.

Risk Acceptability

In the *Benzene* case, the Supreme Court's plurality opinion stated:

> [T]he [OSHA] statute was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so. . . . There are many activities that we engage in every

[41] 448 U.S. 607, 656-58 (1980).
[42] 630 F.2d 398 (5th Cir. 1980)
[43] 48 Fed. Reg. 1864 (1983).
[44] See generally Congression - Research Service, A Review **ot Risk** Assessment Methodologies, House Subcommittee **on** Science, **Research,** and Technology **98th** Cong , **1st** sess (Comm **Print 1** 983)
[45] See **('r-door** Epidemiology and Procedura] Protections for Workplace **Health** In **the Aftermath of the** Benzene Case 5 Indus Rel L J 372 (1983)
[46] National Acade my of Scie nces. Risk Assessment in the Federal Govern - ment Managing the' Process 18 (1983)
[47] Id at 4-7

day—such as driving a car or even breathing city air—that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities "unsafe. " Similarly, a workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm.[48]*

The above quote indicates that only significant risks are appropriate for regulation and that the presence of some degree of risk in the workplace is inevitable and thus "acceptable. "[49]

It is difficult to define or quantify what is an acceptable risk. The acceptability of a risk depends on the nature of the risk, its severity, the level of exposure, the economic consequences, the alternatives, the views of the decisionmaker and, perhaps most importantly, the question of acceptable to whom? It may be that it is unnecessary to define what risks are acceptable, at least in the regulatory context. OSHA has not said what is acceptable, only what is not.

The specific question of what is an acceptable risk under OSHA has, apparently, not yet materialized. Two OSHA officials indicated that because of recent court decisions, OSHA must be particularly concerned about the issues of significant risk and feasibility before it takes regulatory action. A third added, however, that the notion of acceptable risk is "inherent in decisionmaking" and that it influences decisions in practical ways.

There is also some concern that the concept of "acceptable risk" is used by those who argue, in effect, that some jobs are inherently unsafe or unhealthful and that the government is misguided in its attempts to eliminate all of these risks. A Carter OSHA Chief charged that "acceptable risk" is a "non-issue in OSHA. Nobody is suggesting that it is possible to have zero risk in the workplace. " Moreover, she asserted that this "phony issue" is raised by those individuals opposed to any regulation of the workplace.

Technical Note #C.3: Technological Feasibility of OSHA Health Standards

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

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

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

In ***Society of the Plastics Industry, Inc. v. OSHA ,***[50] the Second Circuit indicated that a defense based on technological infeasibilit,y requires showing that a standard is "clearly impossible of attainment. " The court stated that OSHA may require improvements in existing technologies or the development of new technologies. l

Similar reasoning was used by the Third Circuit in ***AFL- CIO v. Brennan,***[52] although it reached the opposite result. In ruling on the feasibility of a mechanical power press standard, the court declared that "at least to a limited extent, OSHA is to be viewed as a technology-forcing piece of legislation. "[53] Nevertheless, the court found that compliance with the standard was not technologically feasihle "in the near future. "sq

Decisions of the courts of appeals have attempted to clarify this '(technology-forcing" language. In ***American Iron & Steel Institule v. OSHA ,***[55] the Third Circuit indicated that even though the Secretary may require an employer "to implement technology 'looming on today's horizon, ' . . . the statute does not permit the Secretary to place an nffirrnative duty on each employer to research and develop new technology."s' According to the court, lhis is especially true when the research and development provisions are specula -

[48] Industrial Union Dept v. American Petrol. Inst , 448 U.S. GOT/ 641-4.2 (1980)

[49] See Dinman. Occupational Health and the Reality of Risk—An Eternal Dilemma of Tragic Choices, 22 J Occup. Med. 153 (1980)

[50] 509 F.2d 1301 (2d Cir. 1975). See generally Doniger, Federal Regulation of Vinyl Chloride: A Short Course in the Law and Policy of Toxic Substances Control, 7 Ecology L.Q. 497 (1978).

[51] 509 F 2d at 1309.

[52] 530 F 2d 109 (3d Cir. 1975).

[53] Id at 12 1 (footnote omitted).

[54] Id. at 122. See Industrial Union Dept. v. Hodgson, 499 F.2d 467, 479-80 (D.C. Cir 1974).

[55] 577 F 2d 825 (3d Cir. 1978), cert. dismissed sub nom. Republic Steel Corp. v OSHA, 448 U.S. 917 (1980)(coke oven emissions standard),

[56] 577 F.2d at 838, See 47 Cin 1.. Rev. 477 (1978)

tive and render any assessment of feasibility practically impossible.

In *United Steelworkers of America* v. *Marshall*,[57] the D.C. Circuit delineated OSHA's burden of proving technological feasibility. "OSHA's duty is to show that modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting."[58] The court's limited role in deciding whether this burden has been met was set out in the D.C. Circuit's opinion in *AFL-CIO* v. *Marshall*:[59]

> Judging the technological feasibility of a particular agency goal is beyond the expertise of the judiciary especially where the assessment involves predictions of technological changes. Instead, our task on review is to find whether the agency sufficiently supported its feasibility determination with material in the record.[60]

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

In *American Textile Manufacturers Institute, Inc.* v. *Donovan*, [61] the Supreme Court addressed the issue of whether the Act requires the Secretary, in promulgating a standard under § 6(b)(5), to determine that the costs of the standard bear a reasonable relationship to its benefits. The Fifth Circuit, in the *Benzene* case,[62] had imposed such a requirement. The D.C. Circuit, however, in the cotton dust[63] and lead[64] cases had rejected this view.[65]

In a five-to-three decision,[66] the Court rejected the argument that the Act requires the use of cost-benefit analysis. Relying on the plain meaning of the word "feasible" as "capable of being done," the Court ruled that imposing a cost-benefit requirement would be inconsistent with the mandate of Congress:

> Congress itself defined the basic relationship between costs and benefits, by placing the "benefit" of worker health above all other considerations save those making attainment of this "benefit" unachievable. . . . Thus, cost-benefit analysis by OSHA is not required by the statute because feasibility analysis is.[67]

The Court observed that when Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such an intent on the face of the statute.[68] Neither the language of OSHA nor its legislative history indicate such a congressional intent.

According to the majority opinion of Justice Brennan, "feasible" as used in § 6(b)(5) includes economic feasibility. After reviewing the record, the Court concluded that the D.C. Circuit did not err in holding that the Secretary's finding that compliance with the cotton dust standard was economically feasible was supported by substantial evidence. Even though no specific economic studies were performed on the final standard, there were studies that showed that compliance with a stricter and more costly standard was feasible.[69]

Two further points relative to the *ATMI* case are worthy of mention. First, the holding is limited to § 6(b)(5) standards; the Court did not address the issue of whether cost-benefit analysis is required in promulgating other types of standards.[70] Second, despite assertions to the contrary,[71] the Secretary is not even permitted to engage in cost-benefit analysis in promulgating standards pursuant to § 6(b)(5). Besides feasibility analysis, "Congress did not contemplate any further balancing by the agency for toxic material and harmful physical agents standards. . . ."[72]

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

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[57]647 F.2d 1189 (D.C. Cir. 1980), cert. denied sub nom. Lead Indus. Assn., Inc. v. Donovan, 453 U.S. 913 (1981).

[58]647 F.2d 1189.

[59]617 F.2d 636 (D.C. Cir. 1979), aff'd sub nom. American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981)(cotton dust standard).

[60]617 F.2d at 656.

[61]452 U.S. 490 (1981).

[62]American Petrol. Inst. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978), aff'd on other grounds sub nom. Industrial Union Dept. v. American Petrol. Inst., 448 U.S. 607 (1980).

[63]AFL-CIO v. Marshall, 617 F.2d 636, 664 (D.C. Cir. 1979), aff'd sub nom. American Textile Mfrs. Assn., Inc. v. Donovan, 452 U.S. 490 (1981).

[64]United Steelworkers of America v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied sub nom. Lead Indus. Assn., Inc. v. Donovan, 453 U.S. 913 (1981).

[65]See also American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 836 (3d Cir. 1978) (upholding validity of coke oven emissions standard despite an annual compliance cost of $240 million), cert. dismissed sub nom. Republic Steel Corp. v. OSHA, 448 U.S. 917 (1980).

[66]Justice Powell took no part in the decision, but in his concurring opinion in the API case, he indicated that he would require cost-benefit analysis. Thus, as to this issue, it would appear that the Court is divided five-to-four. Justice Stewart, since replaced by Justice O'Connor, voted with the dissent in ATMI.

[67]452 U.S. at 509 (footnote omitted).

[68]Id. at 510.

[69]Id. at 522-36.

[70]Id. at 509 n. 29.

[71]Id. at 544 (Rehnquist, J., dissenting).

[72]Id. at 513.

Technical Note #C.4: Coverage of Employees, Employers, and Chemicals Under The Hazard Communication Standard

Employees

Of the 25 million workers "potentially exposed" to chemical health hazards, approximately 15 million are covered by the hazard communication standard .73 OSHA'S standard applies only to manufacturers, importers, and distributors of "hazardous chemicals," and is limited to firms in certain standard industrial classification (SIC) codes .74 Furthermore, the standard does not cover nonmanufacturing personnel (e.g., office workers), though they may work in the chemical manufacturing sector and may be exposed to toxic chemicals. Also unprotected by the regulation are commercial, nonmanufacturing "downstream" users of chemicals, agricultural workers, and public employees. OSHA'S rationale for limiting coverage to selected employees of chemical manufacturers in SIC codes 20-39 results from the desire to create a cost-effective rule. The agency based the regulation on data indicating that half of "chemical source" illnesses and injuries occur at these worksites.[75]

Most State "right-to-know" laws provide coverage to a larger worker population than does OSHA. The Iaws are seldom limited to persons engaged in the manufacture of hazardous chemicals, and most include all employees who will come in contact with hazardous chemicals at the workplace, though domestic workers are expressly excluded from coverage in several States. Furthermore, several State laws expressly cover public employees.

Employers

OSHA'S standard applies to a selective, albeit large, portion of chemical manufacturers and importers .7' To avoid interagency jurisdictional disputes, OSHA has exempted from coverage pesticides and hazardous wastes (subject to EPA regulations), food additives (regulated by FDA), distilled spirits (controlled by BATF), and consumer products (subject to CPSC regulations) .77 Similarly, miners are exempt due to coverage by the Mine Safety and Health Act.

As discussed earlier, most State "right-to-know" laws cover all employees exposed to chemical hazards in the workplace. Some States, however, such as West Virginia, exclude certain industries. 's

Hazardous Chemicals

OSHA'S hazard communication standard requires chemical manufacturers and importers to assess the hazards of chemicals they produce or import to which workers may be exposed .79 Certain chemicals are not subject to this requirement, and chemicals produced and used in laboratories are subject to less stringent regulations. Information about chemicals determined to be hazardous must be communicated to workers.

Chemical exposures which result in acute or chronic health effects are considered health hazards .60 The determination of hazardness is to be based on "evidence that is statistically significant and that is based on at least one positive study conducted in accordance with established scientific principles. "8[1] In determining whether a chemical poses a health hazard, an employer may consult a list of "available data sources" provided by OSHA.[82] It is important to recognize, however, that use of these sources is advisory, not mandatory. One of the chief (riticisms of the OSHA regulation is the advisory nature of the source lists. Some argue that employers are granted too much discretion in determining whether a chemical poses a hazard, [83] And some observers contend that employers may not report all that is known about a chemical's hazards. [84]

Another criticism of the regulation concerns the concentration levels established by OSHA. The standard requires disclosure of substances that contain 0.1 percent (or more) of carcinogens, or that contain **1** percent (or more) of chemicals otherwise identified as hazardous.[85] Critics maintain that the concentration levels set by OSHA are arbitrary, and do not provide adequate safeguards to protect worker health.[8']

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[7] 'See Preamble to final OSHA Standard on Workplace Hazard Communication, () S H Rep (BNA) 700, 748 (Dec 1, 1983); Workers' "Right-to-Know" OS}{ V's Hazard Communication Rule Issue Brief IB84 103, The Library of Congress Congressional Research Service 2 (1984)

[74] 29 CFR §19101200(b) (1984) OSHA officials have, since the promulgation of the Hazard Communication Standard, undertaken a review of the limited coverage of the regulation At the present time, OSHA is considering expanding the scope of the standard to include all employers. OSH Rep (BNA) 761 763 (Mar 7, 198.5 I

[75] See Preamble to final OSH A Standard on Workplace Hazard (on] munication, () S I I Rep (BNA) 700, 748 (Dec 1, 1 983)

[76] I(1 at 705-07

[77] 29 C.FR §§ 1910. 12 00(b)(4), (5) (1984)

[78] W Va Code § 21-3A 8(C) (198 1)

[79] 29 C F R § 1910.100, (d)(i (1984)

[80] Id at § 1910 1200(C)

[81] Id at § 1910 1 200(d)(2)

[82] Id at § 19 1 o 1200 (app C)

[83] Workers' "Right-to-Know": OSHA's Hazard Communication Rule, Issue Brief IB84 103, The Library of Congress Congressional Research Service 2, 4 (1984)

[84] Id

[85] 29 C.F.R § 19101 200(d)(5)

[86] Workers' "Right 40-Know" OSH A's Hazard Communication Rule, Issue Brief IB84 103, The Library of Congress Congressional Research Service 2, 3 (1984)

States regulating this area have taken an active role in determining the substances for which an employer must provide information to workers. Most States (rather than the manufacturers) determine which chemicals are subject to their right-to-know laws. This ensures a greater likelihood of compliance with the statutory requirements (by removing uncertainty as to the substances regulated), and provides for enhanced effectiveness in reaching statutory goals.

Furthermore, many States define a "hazardous" chemical more broadly than does OSHA. New Jersey, for example, lists nearly 2,00(1 substances as "hazardous" chemicals. [87]

[87] "Chemical Right-to-Know Requirements Federal and State Laws and Regulations on Disclosure, Special Report (BNA) 3 11 984)