# HUMAN MONITORING: SCIENTIFIC, LEGAL AND ETHICAL CONSIDERATIONS

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## INTRODUCTION

Human monitoring as a supplement to or replacement for environmental (ambient) monitoring of toxic substances in the workplace has recently become a major issue and has led to increased activity and discussion among those concerned with occupational health and safety. Congressional hearings[1] and an Office of Technology Assessment (OTA) study[2] have addressed problems associated with the genetic screening of workers. The Occupational Safety and Health Administration's (OSHA's) recently promulgated standard for occupational exposure to lead focuses on the biological monitoring of workers for lead uptake.[3] A conference in which the United States, the European Community and other countries participated addressed the problems arising from a variety

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Dedication: To Richard Severo of The New York Times, who raised our consciousness about the possible abuses of genetic testing and taught us the importance of a free press, but who lost his personal freedom in the process. Kupferberg, *Loyalty Test at The New York Times?*, COLUM. JOURNALISM REV., July-Aug. 1983, at 41.

1. *See generally Hearings on Genetic Screening of Workers Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st & 2d Sess. (1981–82).

2. OFFICE OF TECHNOLOGY ASSESSMENT, THE ROLE OF GENETIC TESTING IN THE PREVENTION OF OCCUPATIONAL DISEASE (Apr. 1983) [hereinafter cited as OTA REPORT].

3. 29 C.F.R. § 1910.1025 (1983).

of methods of monitoring and screening workers.[4] The American Conference of Governmental Industrial Hygienists (ACGIH) sponsored a symposium in 1981 on the protection of sensitive workers.[5] Finally, human monitoring was a topic of major concern at the last two annual meetings of the American Industrial Hygiene Association,[6] and at a two-day conference sponsored by the American Society of Law and Medicine in Washington.[7]

These discussions have revealed that the purposes of human monitoring are diverse and sometimes conflicting. One purpose is to reduce occupational disease or injury to the working population as a whole by providing indicators of *average* harm or risk of harm from exposure to toxic substances. The monitoring need not involve all workers, only a statistically informative sample, in order to ensure an adequate average level of toxic material control. Another purpose is to protect especially sensitive workers,[8] workers exposed to a toxic material by means other than inhalation, and workers for whom non-occupational sources may add to occupational exposure. An employer may institute human monitoring to remove workers from potentially harmful exposures, avoiding liability for increased worker compensation premiums and tort or products liability suits. Employers may also use human monitoring results to avoid increased worker demands for preventive technology or other health and safety measures.

This article fills an important gap in the literature on human monitoring. Previous writers have focused their attention on the problems of screening workers generally, rather than on the important distinctions among the several kinds of monitoring.[9] This article discusses additional scientific distinctions and their legal implications, for example, the differences between monitoring hypersensitive workers and monitoring

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4. Berlin, Yodaiken & Logan, *International Seminar on the Assessment of Toxic Agents at the Workplace: Roles of Ambient and Biological Monitoring*, 50 INT'L ARCHIVES OCCUPATIONAL & ENVTL. HEALTH 197 (1982) [hereinafter cited as Luxembourg Report].

5. ACGIH Symposium on Protection of the Sensitive Individual (Nov. 9–11, 1981) (Tucson, Ariz.).

6. The American Industrial Hygiene Association conducted its 1982 annual meeting in Cincinnati, Ohio, on June 6–11, 1982. The annual 1983 meeting was held in Philadelphia, Pennsylvania, on May 22–27, 1983.

7. The American Society of Law and Medicine and the Boston University Schools of Law, Medicine, and Public Health sponsored a conference in Washington, D.C., on Biological Monitoring and Genetic Screening in the Industrial Workplace on May 12–13, 1983.

8. The Occupational Safety and Health Act (OSHAct) authorizes the Secretary of Health and Human Services to require employers to address the problems of susceptible employees, 29 U.S.C. § 669(a)(5) (1982), and aging adults, 29 U.S.C. § 669(a)(7) (1982). For a description of sensitive populations in general under various environmental legislation, see R. FRIEDMAN, SENSITIVE POPULATIONS AND ENVIRONMENTAL STANDARDS (1981).

9. Rothstein, *Employee Selection Based on Susceptibility to Occupational Illness*, 81 MICH. L. REV. 1379 (1983); McGarity & Schroeder, *Risk-Oriented Employment Screening*, 59 TEX. L. REV. 999 (1981).

workers at high risk.[10] It places a broad proscriptive emphasis on protecting workers by integrating the employee's self-initiated right to refuse hazardous work with remedies available under the Occupational Safety and Health Act (OSHAct), the Toxic Substances Control Act (TSCA), and the National Labor Relations Act (NLRA) for the employer's misuse of monitoring results.

This article discusses:

(1) the scientific basis, appropriateness, and usefulness of various human monitoring activities;[11]

(2) the legal basis for OSHA monitoring requirements and for access to monitoring records provided under the OSHAct, TSCA, and NLRA;[12]

(3) the legal and ethical problems of conducting monitoring tests on workers and possible misuse of the results;[13] and,

(4) policy recommendations for the proper use of human monitoring in reducing occupational disease and injury.

## I. Definitions

At the outset, some important concepts that will appear throughout this discussion must be clarified. The general concept of monitoring encompasses five practices: medical surveillance, genetic monitoring, genetic screening, biological monitoring and environmental monitoring. The scientific and legal literature commonly uses "medical surveillance" and "biological monitoring" interchangeably, but the terms are not the same. This article employs the following definitions of these five concepts, consistent with regulations recently promulgated by OSHA.[14]

### *A. Medical Surveillance*

The first practice, medical surveillance,[15] is designed in an occupational setting to detect adverse health *effects* (or health status) resulting from hazardous exposures in the workplace. Medical surveillance testing serves to obtain certain types of information, such as the identification of workers who are suffering from an occupational injury or illness, epidemiological data on occupational disease, and general or specific data on categories or types of workers. These data are intended to aid in screening workers by monitoring specific organ systems that may be

10. *See infra* notes 258–263 and accompanying text.

11. *See infra* text accompanying notes 78–257.

12. *See infra* text accompanying notes 38–75, 369–475.

13. *See infra* text accompanying notes 319–368, 476–550.

14. *See, e.g.*, 29 C.F.R. § 1910.20(c) (1983).

15. The Luxembourg Report defines *health* surveillance as "the periodic medico-physiological examinations of exposed workers with the objective of protecting health and preventing occupationally related disease." Luxembourg Report, *supra* note 4, at 199. The authors prefer to use the term "medical" rather than "health" surveillance because the former more accurately describes the nature of the tests performed.

affected by exposure to workplace hazards. An employer may institute testing on its own initiative, in response to OSHA requirements, or at the request of employees or their unions.

Medical surveillance tests are generally diagnostic tools used in routine medical practice. They include chest x-rays, pulmonary function tests, routine blood analyses, serum liver function tests, serum kidney function tests and routine urinalyses.

The Luxembourg Report states that in some circumstances medical surveillance can prevent occupationally related disease.[16] Especially if a disease is *reversible* or *arrestable*, medical surveillance may be preventive insofar as it serves as a warning signal prompting timely action to avoid future exposures and continuing or progressive adverse health effects.

Pursuant to statute, OSHA can require employee medical surveillance.[17] The required medical surveillance provisions vary for the twenty-three OSHA health standards promulgated since 1972 (see Table 1), but generally they are routine diagnostic tests used in medical practice.[18] In January 1981, OSHA and the National Institute for Occupational Safety and Health (NIOSH) published the *Occupational Health Guidelines for Chemical Hazards*.[19] This volume includes a variety of information on approximately 450 substances for which OSHA adopted consensus standards under section 6(a) of the OSHAct.[20] The information for each substance usually includes chemical, toxicological and health hazard data, as well as recommendations for industrial hygiene and medical surveillance practices.[21]

Medical surveillance is most useful in three situations: (1) if compliance with the permissible exposure limits established by OSHA will not adequately ensure worker health; (2) if air measurement cannot sufficiently monitor worker exposure (e.g., if a significant route of entry is not inhalation); and (3) if high risk groups are exposed.[22] Medical removal may also be appropriate in these three situations.[23]

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16. Luxembourg Report, *supra* note 4, at 198.

17. *See infra* note 53 and accompanying text.

18. Although all OSHA health standards contain required medical surveillance provisions, the recently proposed ethylene oxide standard includes no such requirements. Rather, the agency has departed from giving specific medical guidance and opened up the possibility of unchecked discretion in testing by stating that "[t]he examining physician is free to prescribe the specific tests to be included in the medical surveillance program." 48 Fed. Reg. 17,315 (1983).

19. NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PUB. NO. 81-123, NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES FOR CHEMICAL HAZARDS (1981) (F. Mackison, R. Stricoff & L. Partridge eds.) [hereinafter cited as NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES].

20. Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(a) (1982).

21. *See infra* text accompanying notes 45–46.

22. D. Hattis, E. Rothenberg & N. Ashford, Some Considerations for the Design of OSHA Policy on Medical Surveillance and Removal Provisions in Occupational Health Standards 2 (Nov. 1979) (CPA/WP-79-9) (submitted to the U.S. Dep't of Labor by the Center for Policy Alternatives at the Massachusetts Institute of Technology) [hereinafter cited as CPA Medical Surveillance Report].

23. *See infra* note 64.

Table 1: Chemical Substances for which OSHA Has Promulgated Health Standards 1972–1980*

| | |
|---|---|
| 2-Acetylaminofluorene | 3, 3'-Dichlorobenzidine (and its salts) |
| Acrylonitrile | 4-Dimethylaminoazobenzene |
| 4-Aminodiphenyl | Etyleneimine |
| Arsenic (inorganic) | Lead (inorganic) |
| Asbestos | Methyl chloromethyl ether |
| Benzene[a] | 4, 4'-Methylene bis (2-chloroaniline)[b] |
| Benzidine | alpha-Naphthylamine |
| bis-Chloromethyl ether | beta-Naphthylamine |
| Coke oven emissions | 4-Nitrobiphenyl |
| Cotton dust | N-Nitrosodimethylamine |
| Cotton dust (in cotton gins) | beta-Propiolactone |
| Dibromochloropropane | Vinyl chloride |

a. Remanded to OSHA by the U.S. Supreme Court on July 2, 1980 for reconsideration of the permissible exposure level.
b. Deleted by the Third Circuit Court of Appeals on procedural grounds on August 20, 1976.

One particular type of medical surveillance that has received much attention is genetic monitoring. This type of monitoring includes the periodic testing of employees working with or possibly exposed to certain substances (such as known or suspected carcinogens) suspected to cause changes in chromosomes. Blood or other body fluid samples are collected for this monitoring. Generally, such monitoring is conducted in an attempt to determine if environmental exposures of a specific population (e.g., workers in the same job category) to particular substances causes changes in genetic material in statistically significant numbers above background levels.[24]

### *B. Other Human Monitoring Practices*

A third kind of human monitoring, genetic screening, is practiced on an employee only once, usually as part of a pre-employment or pre-placement exam.[25] This screening determines whether an *individual* possesses certain inherited genetic traits that may predispose him or her to an increased risk of disease if exposed to particular substances. Laboratory tests on body fluids, commonly blood, usually identify these traits.

*Adapted from NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19, at 31.

24. Proponents of genetic monitoring believe that the number of environmentally induced alterations in chromosomes (above background incidence) may cause a worker to be predisposed to certain occupational illnesses, particularly cancer. *See* Holden, *Looking at Genes in the Workplace*, 217 SCIENCE 336, 337 (1982); *see also* M. Legator, Genetic Toxicology: Relevant Studies with Animals and Humans 23–25 (June 24, 1983) (advance copy of paper delivered to the Royal Society of Medicine at the Anglo-American Conference on Pregnant Women at Work, London).

25. *See infra* text accompanying notes 237 & 240.

The fourth practice, biological monitoring, should be distinguished from medical surveillance. The former is a collection of activities designed to determine both whether a person has been exposed to and whether his or her body fluids or organs contain a particular substance or its metabolites.[26] The latter, in contrast, is used to determine the effects of exposure.[27] The Luxembourg Report defines biological monitoring as "the measurement and assessment of workplace agents or their metabolites either in tissues, secreta, excreta, expired air or any combination of these to evaluate *exposure and health risk* compared to an appropriate reference."[28] The analysis most commonly uses urine, breath and blood specimens, but sometimes hair, nails, tears, breast milk or perspiration, as well.

Some observers believe that the information obtained from biological monitoring can be used in conjunction with environmental monitoring results to determine whether ambient data predicts the true exposure of workers and thereby evaluate environmental control methods.[29] Others, however, believe that ambient environmental measurements cannot accurately be correlated with biological measurements because of individual pharmacokinetic and metabolic variability. One researcher states that "biological measurements reflect *uptake* and not *exposure* . . . there are numerous instances in which significant uptake of toxic materials have [sic] occurred in spite of low air-levels of the contaminant in question."[30]

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26. Ideally, the best indicator of risk would be a direct measure of the chemical or its metabolite at the target site, not the broad concept of "uptake." According to Professor Lauwerys,

> [a] direct measure [at the site of action] is not usually feasible because the sites of action are frequently located in tissues not accessible for sampling (e.g., brain acetylcholinesterase activity). The concentration of the pollutant or its metabolites in another body compartment (blood, urine) or the amount bound to another molecule may be used for this purpose if one has demonstrated that the latter parameter is in equilibrium with the amount at the site of action.

R. LAUWERYS, INDUSTRIAL CHEMICAL EXPOSURE: GUIDELINES FOR BIOLOGICAL MONITORING 5 (1983).

27. For example, medical surveillance (e.g., chest x-ray) would be an appropriate part of a pulmonary evaluation for a worker exposed to silica dust, as the x-ray would most likely show any *effects* due to such exposure. An x-ray, however, would not yield useful biological monitoring information in this situation, as it is impossible to assess the worker's *level of uptake* of silica dust. This observation is based on the professional experience of author Christine J. Spadafor as a registered nurse.

28. Luxembourg Report, *supra* note 4, at 199 (emphasis added).

29. H.J. Dunster, Monitoring as Part of Occupational Hygiene: The Regulatory Approach 4 (paper presented at the International Seminar on the Assessment of Toxic Agents at the Workplace: Roles of Ambient and Biological Monitoring, Luxembourg (Dec. 8–12, 1980) [hereinafter cited as Luxembourg Seminar]); Monroe, *The Role of Biological Monitoring in Medical and Environmental Surveillance*, in CHEMICAL HAZARDS IN THE WORKPLACE: MEASUREMENT AND CONTROL 5 (G. Choudhary ed. 1981) (American Chemical Society Symposium Series No. 149).

30. Gompertz, *Solvents--The Relationship Between Biological Monitoring Strategies and Metabolic Handling: A Review*, 23 ANNALS OCCUPATIONAL HYGIENE 405, 410 (1980) (emphasis added) [hereinafter cited as *Solvents*].

Biological monitoring should not generally substitute for environmental monitoring. Rather, "environmental and biological monitoring are ways of investigating different problems and should be seen as complementary and not mutually exclusive procedures."[31] The substitution of biological monitoring in favor of environmental monitoring in order to determine compliance and control consistent with the OSHA standards is not appropriate for the following reasons:

> First, it is not clear whether OSHA has the authority to require workers to submit to biological monitoring procedures for determining compliance. Second, a biological standard may provide an incentive for employers to intervene in altering specific parameters in their workers.[32] Third, biological standards may reinforce a "blame the worker" attitude among employers with regard to specific employees, rather than focusing attention on the workplace.
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> In addition, in some cases, biological standards may involve greater risk of health damage due to possible delays between dangerous air exposure and the monitored biological response.[33]

One cannot, however, always define certain biochemical tests as either medical surveillance or biological monitoring. Certain tests are not only indicators of metabolic effects (medical surveillance), but also can be quantitatively linked to exposure (i.e., if a *biological* marker, though technically an effect, indicates exposure).[34]

The fifth practice, environmental monitoring, measures the concentration of harmful agents *in the workplace,* while the other types of monitoring involve tests performed *on the workers.* Environmental monitoring includes both ambient monitoring and personal monitoring.[35] The Luxembourg Report defines "ambient monitoring" as "the measurement and assessment of agents at the workplace and . . . [the evaluation of] ambient exposure and health risk compared to an appropriate reference."[36] Ambient (work area) monitoring is useful if the hazard is a

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31. *See* Gompertz, *Assessment of Risk by Biological Monitoring,* 38 BRITISH J. INDUS. MED. 198, 201 (1981) [hereinafter cited as *Assessment of Risk*].

32. An example is chelation therapy used in industrial settings to decrease worker blood lead levels.

33. *See* CPA Medical Surveillance Report, *supra* note 22, at 9.

34. Examples of these tests, cited in the Luxembourg Report, include zinc protoporphyrin (ZPP) and delta aminolaevulinic acid dehydrase (ALA-D). Luxembourg Report, *supra* note 4, at 199. Both are quantitatively related to lead exposure.

35. "Personal monitoring" is "a term designating the determination of the inhaled dose of an airborne toxic material or of an air-mediated hazardous physical force by the continuous collection of samples in the breathing or auditory zone, or other appropriate exposed body area, over a finite period of exposure time." 1 A.L. LINCH, EVALUATION OF AMBIENT AIR QUALITY BY PERSONNEL MONITORING at preface (2d ed. 1981). Personal monitors placed in the breathing zone (e.g., on shirt collars) are considered to provide a representative dose of inhaled air that transports any airborne hazardous agents. *Id.* The participants at the Luxembourg Seminar agreed that personal breathing zone sampling provides a better measure of an employee's daily exposure than area ambient sampling. Luxembourg Report, *supra* note 4, at 199.

36. *Id.* at 199.

specific one for which a permissible exposure limit is known (e.g., a consensus guideline or legal standard). An advantage is that it does not use the worker as a sampling device. This article does not treat environmental monitoring in any detail, but mentions it only in reference to the other four practices.

## II. Legal Authority for Human Monitoring

### *A. Agency Authority*

The OSHAct grants both OSHA and NIOSH the authority to promulgate regulations that require employers to conduct human monitoring, although it is not clear whether it authorizes either agency to force employees to submit to such monitoring. The authority granted to NIOSH is broader in scope than that vested in OSHA, but financial limitations on NIOSH in exercising that authority[37] give OSHA the greater practical grant of authority.

#### *1. OSHA*

OSHA may order biological monitoring under each of three sections of the OSHAct. Section 8(c)(1) provides general authority:

> Each employer shall make, keep and preserve . . . such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary or appropriate . . . *for developing information* regarding the causes and prevention of occupational accidents and illnesses. In order to carry out the provisions of this paragraph such regulations may include provisions requiring *employers to conduct periodic inspections*.[38]

Section 8(c)(3) contains a more specific mandate. It provides that OSHA "*shall* issue regulations requiring *employers to maintain accurate records* of employee exposures . . . which are required to be monitored or measured under Section 6."[39]

This section also requires employers to "promptly notify" employees if they have been exposed to any hazard in violation of "an applicable occupational safety and health standard promulgated under section 6."[40] The Senate deliberated over this provision while considering the OSHAct. Senator Peter H. Dominick (R-Colo.), who led an unsuccessful effort to pass a substitute Nixon Administration bill,[41] proposed

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37. *See infra* text accompanying note 75.
38. 29 U.S.C. § 657(c)(1) (1982) (emphasis added).
39. *Id.* § 657(c)(3) (emphasis added).
40. *Id.*
41. S. 4404, 91st Cong., 2d Sess. (1970).

an amendment that would have eliminated the provision.[42] In objecting to the language of section 8(c)(3), Sen. Dominick noted that it "indirectly requires excessive employer monitoring of his entire operation," and thus requires the employer "to be his own policeman, judge and jury."[43] The language of this section is broad as enacted. The fact that Congress chose to include it in the Act, rather than accepting the substitute bill deleting this language,[44] supports the proposition that the OSHAct requires employers to conduct biological or environmental monitoring or both for *any* exposure regulated under section 6.

Section 6 itself, however, casts some doubt on this interpretation. On the one hand, section 6(a) makes no mention of human monitoring, but merely requires OSHA to adopt previously existing health standards. Section 6(b), on the other hand, specifically discusses both biological monitoring and medical surveillance. Section 6(b)(7) mandates that, where "appropriate," a section 6(b) standard "*shall* provide for monitoring or measuring employee exposure . . . in such manner as may be necessary for the protection of employees."[45]

This provision raises an interesting issue. Unquestionably, section 8(c)(3) applies both to section 6(a) standards and section 6(b) standards, as both are occupational safety and health standards that require "employee exposures to be measured" within the meaning of section 8(c)(3). If section 8(c) grants broad power to order biological monitoring, then why does section 6(b) *also* grant such power? The solution may lie in the "accuracy" limitation of section 8(c).

Section 8(c)(3) requires only that employers maintain "accurate" records of employee exposures. For many exposures, accurate measurements may be possible without biological monitoring, i.e., by using environmental monitoring. Arguably, section 8 would not require biological monitoring in those situations. Under section 6(b), however, OSHA could still order biological monitoring if it were "necessary for the protection of the employees." This interpretation finds an implicit congressional attempt to balance the need for reliable information against the cost and inconvenience of a physically invasive monitoring procedure. Accordingly, potentially invasive monitoring would be subject to the specificity and increased scrutiny of the section 6(b) standard-setting procedure.

Biological monitoring results are included in an employee's exposure record.[46] The final OSHA rule states that this record must contain any

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42. S. 2193, 91st Cong., 2d Sess. (1970), *reprinted in* SUBCOMM. ON LABOR OF THE SENATE COMM. ON LABOR AND PUBLIC WELFARE, LEGISLATIVE HISTORY OF THE OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970, 92d Cong., 1st Sess. 368–69 (1971) [hereinafter cited as LEGISLATIVE HISTORY].

43. *Id.*

44. For a comparison of the Administration's substitute bill on this point with the Senate bill, and additional remarks by Senator Dominick, compare *id.* at 436–41 with 29 U.S.C. § 655(b)(7) (1982).

45. 29 U.S.C. § 655(b)(7) (emphasis added).

46. 45 Fed. Reg. 35,278 (1980).

information concerning "biological monitoring results which directly assess the absorption of a substance or agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.) but not including results which assess the biological effects of a substance or agent."[47] Biological monitoring results are also considered part of an employee's *medical* record under the same final rule. This OSHA definition of biological monitoring clearly distinguishes the results of these tests from the results of medical surveillance tests and is consistent with the definition in the Luxembourg Report.[48]

Currently, only the OSHA lead standard requires biological monitoring.[49] Some consensus health standards adopted under section 6(a) of the Act recommend biological monitoring for certain substances such as carbon monoxide, fluoride (inorganic) and pesticides, including endrin and parathion.[50]

Under the *NIOSH/OSHA Occupational Health Guidelines* mentioned earlier,[51] OSHA has issued biological monitoring guidelines for some consensus health standards adopted under section 6(a). These guidelines "provide a basis for promulgation of *new* occupational health regulations."[52] As these guidelines are not regulations, they probably will not be subject to judicial review.

Section 6(b)(7) specifies that, where appropriate, section 6(b) standards "*shall* prescribe the type and frequency of medical examinations or other tests which *shall* be made available, by the employer or at his cost, to employees exposed to [the regulated hazard] to most effectively determine whether the health of such employees is adversely affected by such exposure."[53] Further, if such examinations are "in the nature of research," NIOSH may provide the funding.[54] These provisions give clear authorization for OSHA to require medical surveillance to determine the health effects of hazards regulated under section 6(b), even if such surveillance is considered "research."

Results from medical surveillance tests become part of an employee's medical record.[55] According to OSHA's most recent ruling, an employee medical record must contain any information concerning the health status of the employee including "the results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including x-ray examinations . . . )."[56]

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47. *Id.*

48. Luxembourg Report, *supra* note 4, at 199.

49. 29 C.F.R. § 1910.1025 (1983).

50. 29 U.S.C. § 655(a). *See* NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19; *see also* text accompanying notes 167 & 192.

51. *See supra* note 19 and accompanying text.

52. NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19, at 1 (emphasis added).

53. 29 U.S.C. § 655(b)(7) (emphasis added).

54. *Id.*

55. 45 Fed. Reg. at 35,278.

56. *Id. See also infra* text and figure accompanying note 235.

Section 6(a) does not mention human monitoring. The *NIOSH/OSHA Occupational Health Guidelines*, however, contains extensive medical surveillance guidelines for approximately 450 substances.[57] Because the guidelines provide a basis for new regulations and do not constitute required practices, no one has yet decided the legality of adding medical surveillance requirements to existing section 6(a) standards.

A special kind of medical surveillance involving genetic testing of workers has caused some concern.[58] Standards that OSHA promulgated under section 6(b) and the proposed Cancer Policy for thirteen carcinogens require medical examinations to include a personal history of the employee, his family or both, including "genetic and environmental factors."[59] OSHA later issued a clarification, emphatically denying that the standards require genetic testing [60] of any employee.[61]

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57. It is important to note that these substances are accompanied by medical surveillance *guidelines* and not regulations. Therefore, industry has no legal responsibility for instituting the medical surveillance provisions suggested in the document, but may implement such medical guidelines voluntarily.

58. Severo, *59 Top U.S. Companies Plan Genetic Screening*, N.Y. Times, June 23, 1982, at A12, col. 4 (morn. ed.).

59. See paragraph (g)(1)(i) of each section in 29 C.F.R. §§ 1910.1003–.1016 (1983). *See also infra* note 61.

60. Genetic testing includes both genetic monitoring (cytogenetic and noncytogenetic, *see infra* note 94) and genetic screening.

61. Office of Information, U.S. Dep't of Labor, News 80-107 (Feb. 20, 1980). In February 1980, Dr. Eula Bingham, then the Assistant Secretary of Labor for OSHA, issued a news release responding to an article in the New York Times reporting that there was "a Government regulation mandating genetic screening in industry." Severo, *Federal Mandate for Gene Tests Disturbs U.S. Job Safety Official*, N.Y. Times, Feb. 6, 1980, at A1, col. 1 (last of a four article series entitled *The Genetic Barrier: Job Benefit or Job Bias?*). Dr. Bingham corrected this statement, which implied that genetic testing was a mandatory component of OSHA medical surveillance provisions, and commented that "there is absolutely no OSHA standard that requires genetic testing of any employee." U.S. Dep't of Labor, Office of Information, News 80-107 (Feb. 20, 1980). The OSHA Office of Compliance Programming followed this announcement by issuing an interpretive directive to the OSHA enforcement staff in August 1980. The interpretation applied to all OSHA standards that required a medical exam (including a personal history of the employee or his family or both, and occupational background, including genetic and environmental factors) as part of the medical surveillance provisions. OSHA Office of Compliance Programming, U.S. Dep't of Labor, OSHA Medical Surveillance Regulations — Genetic Testing (Aug. 22, 1980) (OSHA Instruction STD 1-23.4) [hereinafter cited as OSHA Medical Surveillance Regulations]. The standards affected by this interpretation included 29 C.F.R. § 1910.1003–.1016 (the 13 carcinogen standards), specifically paragraph (g)(1)(i) in each, and 29 C.F.R. § 1990.151 (the OSHA Cancer Policy — "model standard"). According to Dr. Bingham, such a personal history is "a routine part of standard medical practice. To read into [this] a 'mandate for genetic screening' is a gross distortion." N.Y. Times, Mar. 22, 1980, at 20, col. 3 (letter to the editor submitted by Dr. Bingham, then Assistant Secretary for Occupational Safety and Health). The directive specifically states that "these provisions do not require genetic testing of any employee." OSHA Medical Surveillance Regulations, *supra*.

Consistent with the agency's policy on genetic monitoring, OSHA has not authorized the use of genetic screening as part of any OSHA standard to date. There are hints, however, that OSHA currently is reconsidering its position on genetic testing. On April 21, 1983, the agency published in the *Federal Register* a proposed rule for ethylene oxide. "Screening for chromosome damage" is suggested in the proposal, but is not required. This

The OSHAct contains several sections authorizing environmental monitoring. Section 6(b)(7) states that "[a]ny standard promulgated under this subsection . . . shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees."[62] Section 6(a), addressing consensus standards, does not specifically require monitoring under section 6(a) as well as under section 6(b). Rather, section 8(c)(3) requires "employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section [6]."[63]

The OSHAct of 1970 does not contain specific language that expressly authorizes medical removal protection (MRP)[64] in occupational health standards. Various sections of the Act, however, indicate congressional intent to include MRP as part of the agency's rulemaking authority.[65] The mechanism of MRP is consistent with section 2(b) of the Act, requiring that "so far as possible every working man and woman in the nation [has] safe and healthful working conditions . . . ."[66] Section 2(b)(4)

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suggestion may be interpreted as recommending the practice of not only genetic screening but also genetic monitoring (periodic testing at the physician's discretion rather than one-time testing), for the proposal states "the employer is required to make any prescribed tests available *more often than specified* if recommended by the examining physician." 48 Fed. Reg. 17,315 (1983) (emphasis added).

62. 29 U.S.C. § 655(b)(7) (1982).

63. *Id.* § 657(c)(3).

64. As with the definitions of medical surveillance and biological monitoring, the terms *medical removal* and *medical removal protection* (MRP) are used inconsistently. Because of the apparent state of confusion of these and the related term *rate retention*, the authors offer the following definitions, which again are consistent with OSHA standards.

According to OSHA,

> MRP is a protective, preventive health mechanism integrated with the medical surveillance provisions [which include biological monitoring] of the final [lead] standard. [It] provides temporary medical removals for workers discovered through medical surveillance to be at risk of sustaining material impairment to health from continued exposure . . . . [It] also provides *temporary economic protection* for those removed.

43 Fed. Reg. 52,972 (1978) (emphasis added). Medical removal benefits include the maintenance of "the earnings, seniority and other employment rights and benefits of a worker as though the worker had not been removed or otherwise limited." *Id.* at 52,976. Under MRP, earnings include base wage, overtime, shift differentials, incentives and other compensation regularly earned while working. 29 C.F.R. § 1910.1025, app. B, ¶ (K) (1982). This maintenance of economic benefits is sometimes also referred to as *rate retention*. The authors view MRP as an entire package that includes temporary removal with accompanying continuation of economic and employment benefits. Rate retention, therefore, is a standard condition in MRP. This definition is consistent with the OSHA lead standard.

*Medical removal*, to be distinguished from MRP, involves removing the worker from exposure without regard for earnings, seniority and other employment benefits.

65. The agency considers MRP to be a protective, preventive health mechanism for the purposes of: (1) maximizing meaningful participation in a medical surveillance program under the standard; (2) facilitating the use of temporary medical removals; and (3) appropriately allocating the costs of temporary medical removals. *See* 43 Fed. Reg. 52,972–73 (1978).

66. 29 U.S.C. § 651(b) (1982).

asks that employers protect worker health "by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions,"[67] and section 2(b)(5) that employers provide healthful working conditions "by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems."[68]

Sections 3(8) and 6(b)(5) grant the statutory authority for including MRP in occupational health standards. Section 3(8) states that a standard can require "the adoption or use of one or more practices, means, methods, operations or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[69] MRP meets the definitional criteria of section 3(8). Section 6(b)(5) requires OSHA to base occupational health standards on "experience gained under this and other health and safety laws."[70] Section 6(b)(7) specifies that an OSHA standard shall prescribe such control procedures "as may be necessary for the protection of employees."[71] The general rulemaking authority of section 8(g)(2) provides additional authority for the agency to include MRP in a health standard. It states that "[t]he Secretary . . . shall . . . prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under this chapter . . . ."[72]

After promulgating the final lead standard in 1976, OSHA considered the merits of developing a generic standard for medical removal protection.[73] To date the agency has not taken any further action on issuing a generic MRP rule.

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67. *Id.* As stated in the preamble of the final lead standard, "OSHA's adoption of MRP is a direct result of the proven value of this protective mechanism, and by adopting MRP, OSHA is following the Congressional mandate in section (b)(4) . . . ." 43 Fed. Reg. 52,977 (1978).

68. 29 U.S.C. § 651(b)(5).

69. *Id.* § 652(8).

70. *Id.* § 655(b)(5). Medical removal provisions and economic provisions are provided in the Black Lung Medical Surveillance and Transfer Program, part of the Federal Coal Mine Health and Safety Act of 1969. Although the Supreme Court has not yet spoken directly on the issue, OSHA's authority to include a mandatory MRP provision in a section 6(b) standard has been upheld by the Court of Appeals for the District of Columbia Circuit. The court upheld OSHA's general authority to require MRP programs in appropriate circumstances, and specifically approved the MRP provision in the lead standard. United Steelworkers of Am. v. Marshall, 647 F.2d 1189, 1230 (D.C. Cir.), *cert. denied*, 453 U.S. 913 (1980). Pending the denial of certiorari, the Supreme Court stayed all portions of the lead standard *except* the MRP provision. In American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981), the Supreme Court invalidated an MRP provision for cotton dust, noting that OSHA had failed to make a record for the connection between such a provision and a "safe and healthful working environment." *Id.* at 520. Nonetheless, the Court noted that justification for an MRP program "very well may" exist. *Id.* at 539. In dicta, the Court noted that one such justification may be the usefulness of an MRP provision as an inducement to employees to cooperate with human monitoring programs. *Id.* The D.C. Circuit also cited this rationale in upholding the MRP provisions in the lead standard. United Steelworkers of Am. v. Marshall, 647 F.2d at 1228.

71. 29 U.S.C. § 655(b)(7).

72. *Id.* § 657(g)(2).

73. *See generally* CPA Medical Surveillance Report, *supra* note 22 (discussion of the usefulness of a generic MRP standard).

*2. NIOSH*

In its capacity as a research agency, NIOSH has broad power to order human monitoring. Inherent authority to do so is granted in sections 20(a)(1), 20(a)(4) and 20(a)(7) of the OSHAct, all of which include mandates to NIOSH to conduct various studies pertaining to occupational health. Section 20(a)(5) gives specific authority to order both biological monitoring and medical surveillance. It states that NIOSH may

> prescribe regulations requiring employers to measure, record, and make reports on the *exposure* of employees to substances or physical agents which [NIOSH] reasonably believes may endanger the health or safety of employees . . . [and] establish such programs of *medical examinations* and tests as may be necessary for determining the incidence of occupational illnesses and the *susceptibility* of employees to such illnesses.[74]

This section envisions collecting information for extensive epidemiological studies. It is not limited to hazards already regulated under section 6. Therefore, its potential scope is much broader than that pertaining to OSHA. Section 20(a)(5), however, also directs NIOSH to "furnish full financial or other assistance" to "any employer who is required to measure and record exposure of employees . . . under this subsection," to defray "any additional expense" the employer incurs in fulfilling those requirements.[75] Budgetary limitations thus place a decided constraint on NIOSH's ability to impose biological monitoring requirements. The reimbursement provision does not appear to apply to medical surveillance.

### *B. Employer Authority Absent Agency Directive*

In general, employers have the authority at common law to gather information regarding the health, fitness, and physical and mental capabilities of their employees. This authority grows out of the employer's right to set reasonable conditions of employment that will protect his or her interest in having work performed in an efficient and socially acceptable fashion. A recent decision of the Kansas Court of Appeals stated the rationale for this right:

> As a matter of public policy, employers must have the right to establish reasonable standards of physical fitness for their employees to insure insofar as possible that work is performed by employees who will not endanger themselves, their fellow employees, or the public at large.[76]

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74. 29 U.S.C. § 669(a)(5) (emphasis added).

75. *Id.*

76. Cussimanio v. Kansas City S. Ry., 5 Kan. App. 2d 379, 383–84, 617 P.2d 107, 112 (1980).

As human monitoring is one method by which an employer can obtain the information necessary to determine whether an employee meets "reasonable standards of physical fitness," employers have the general authority to implement human monitoring programs even without state or federal regulation directing them to do so.

## III. Scientific and Technical Concerns in Human Monitoring

### *A. Testing Principles and the Adequacy of the Tests*

Conducting any or all of the four types of human monitoring tests is certain to be a complex activity. Before deciding how to interpret the results of the tests and what possible action to take, one must assess the goodness of the tests. To determine whether a test reliably detects a certain disease or abnormality, one must consider the test's sensitivity, specificity and predictive value, the frequency of the condition within a population, and the reproducibility of the results.[77]

The *sensitivity* of a test is a measure of how accurately the test identifies those people with the disease or abnormality, who will correctly test positive. *Specificity* is a measure of how accurately the test identifies people without the disease or abnormality, who will correctly test negative. A test's *predictive value* is the accuracy of the test in eliminating people with false results. For example, among all people who test positive for having the disease or abnormality, the "predictive value positive" is the proportion of those who truly have the condition. Merely because someone tests positive does not necessarily mean that he or she actually has the condition for which he or she has been screened.

The *frequency* of the disease or abnormality within the test population is an important but commonly overlooked factor that can dramatically influence the test's predictive value.[78] *Unless one knows the frequency of the condition in the population to be screened, one cannot*

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77. See Table 2 for a mathematical definition of sensitivity, specificity and predictive value.

78. Vecchio, *Predictive Value of a Single Diagnostic Test in Unselected Populations*, 274 New Eng. J. Med. 1171, 1173 (1966). When applying diagnostic test results to unselected populations, false-positive errors may be magnified due to the relatively low prevalences of disease in the general population. The terms "prevalence" and "incidence" are epidemiologic terms related to the frequency of disease in a population. *Point prevalence* is the frequency of the disease at a designated time. The *incidence* of a disease is the number of cases of the disease that come into being during a specified period of time. *See* B. MacMahon & T. Pugh, Epidemiology: Principles and Methods 60–61 (1970).

An example from Dr. Paul Rockey of the U.S. Public Health Service can be used to illustrate the importance of this factor:

> An electrocardiogram (EKG) taken during exercise . . . is about 95% sensitive and 95% specific for coronary artery disease. If this test is given to 1000 patients with angina pectoris (chest pain), . . . and the frequency of coronary artery disease (in the group) is 80%, of the 800 persons with disease, 95% or 760 persons will have positive exercise tests. Of the 200 persons without

*estimate the test's predictive value.* Few frequencies are in fact known for conditions related to work environments.

*Reproducibility* of results is also an important component in any testing program. One or more laboratories should repeat a test often enough to ensure the reliability of the results. Comparability of test results also depends on the standardization of techniques and methods. Currently, however, little data exists to compare the testing methods used in various occupational health studies.[79] Along with the standardization of techniques, laboratory quality assurance and control are essential.[80]

### *B. Limitations of the Tests Used in Human Monitoring*

This section addresses the specific types of tests used to conduct medical surveillance, genetic monitoring, genetic screening and biological

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the disease, 95% or 190 persons will have negative exercise tests, but 10 will have positive tests. Therefore, . . . the positive predictive value of the test is

$$\frac{760}{(760 + 10)} = 98.7\%$$

*Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology,* 97th Cong., 1st Sess. 126–28 (1981) (Statement of Dr. Paul Rockey, U.S. Public Health Service, Transcript No. 53).

This percentage indicates that of all those who tested positive for coronary artery disease (total of 770), 98.7% or 760 persons actually have the disease. Conversely, if the same EKG test were given to healthy job applicants (e.g., 18 to 30 years old), a group in which the frequency of coronary artery disease is 2%, one would see very different results in the predictive value. If 1000 applicants were tested, then of the 20 persons with the disease, (20 x .95) or 19 persons would have positive tests and one would have a false negative test. Of the 980 applicants without the disease, (980 x .95) or 931 persons would have negative tests, but 49 would have false positive results. Therefore, the predictive value positive of the test is

$$\frac{19}{(19 + 49)} = 28\%$$

The predictive value positive of 28% means that of those who tested positive (total of 68), only 28% or 19 persons actually have coronary artery disease. The other 72% or 49 persons in fact have no coronary disease.

This example demonstrates a major problem with the use of certain diagnostic tests, particularly in an occupational setting for pre-employment exams. Individuals free of disease falsely tested positive, and if such a test were to be conducted on a similar population as a condition of employment, 72% might wrongly be denied work based on the misclassified test results. Not only may false positive results cause denial of employment, but they may cause persons without the disease to undergo further testing. This second level of testing may subject the person to more risky diagnostic procedures and cause unnecessary social costs associated with testing people who are in fact free of disease.

79. P. Hughes, Biological Monitoring 9 (paper presented at the Luxembourg Seminar, *supra* note 29).

80. S. Crisp & H. Egan, Standardisation, Good Laboratory Practice and Quality Control: Exchange of Information and International Co-operation 7 (paper presented at the Luxembourg Seminar, *supra* note 29).

Table 2: Sensitivity, Specificity, and Predictive Value of a Test*

| | | Disease | | |
|---|---|---|---|---|
| | | Present | Absent | Total |
| Test Outcome | *Positive* | a (true positives) | b (false positives) | (a + b) |
| | *Negative* | c (false negatives) | d (true negatives) | (c + d) |
| | TOTAL | (a + c) | (b + d) | |

| | | |
|---|---|---|
| Sensitivity | $= \frac{a}{(a + c)}$ | $= \frac{\text{true positives}}{\text{true positives + false negatives}}$ |
| Specificity | $= \frac{d}{(b + d)}$ | $= \frac{\text{true negatives}}{\text{false positives + true negatives}}$ |
| Predicted Value Positive | $= \frac{a}{(a + b)}$ | $= \frac{\text{true positives}}{\text{true positives + false positives}}$ |
| Predicted Value Negative | $= \frac{d}{(c + d)}$ | $= \frac{\text{true negatives}}{\text{false negatives + true negatives}}$ |

monitoring,[81] discussing certain limitations severely affecting test interpretation and use of the results.

*1. Medical Surveillance*

The limitations of medical surveillance tests in an occupational setting include nonspecificity, nonselectivity, and the fact that they may detect a disease or abnormality *after* possibly serious and irreversible adverse health effects have occurred. The frequency of false positive and false negative results in routine tests depends on where the "normal" limits of the test are set.[82] (Limits are related also to determining the frequency of the occurrence of the condition in the population under scrutiny.) For continuous variables, such as serum measurements, it is difficult to define the "normal" range because of individual variability. In fact, what may be "normal" for one person may be a disease state for another. (See the shaded area in Figure 1.)[83]

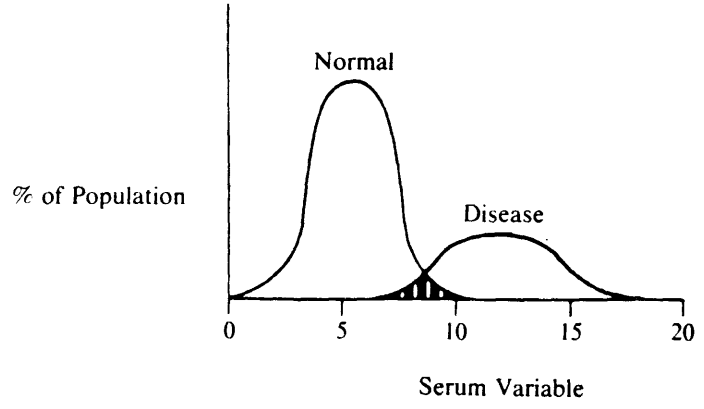
*Adapted from Thorner & Remein, *Principles and Procedures in the Evolution of Screening for Disease*, 67 PUB. HEALTH MONOGRAPH 1–24 (1967); Vecchio, *Predictive Value of a Single Diagnostic Test in Unselected Populations*, 274 NEW ENG. J. MED. 1171 (1966); Cole & Morrison, *Basic Issues in Population Screening for Cancer*, 64 J. NAT'L CANCER INST. 1263 (1980).

81. For the background and uses of these types of monitoring, see *supra* text accompanying notes 15–34.

82. A. HARVEY, J. BORDLEY & J. BARONDESS, DIFFERENTIAL DIAGNOSIS: THE INTERPRETATION OF CLINICAL EVIDENCE 11 (3d ed. 1979).

83. For example, the accepted range of blood urea nitrogen (BUN) is considered to be 10–20 milligrams per 100 milliliters of whole blood (mg/100 ml). HARRISON'S PRINCIPLES

Figure 1: False Positives and False Negatives Relative to "Normal" Limits*




Reprinted with permission from: Cutler, P.: *Problem Solving in Clinical Medicine: From Data to Diagnosis*, © (1979), the Williams & Wilkins Co., Baltimore.

Exposure to noise and resulting hearing loss is an example of a different difficulty in determining "normal" levels. Figure 2 serves as an illustration.

Figure 2 demonstrates how the definition of "normal" can obscure the full impact of exposure to an occupational hazard. Curve I represents the hearing loss in a population that has not been exposed to noise. Curve II represents the hearing loss in an exposed population. The vertical line, called a "fence," separates the population with "normal" hearing acuity from the population with impaired hearing. The "fence" is placed somewhat arbitrarily. Persons with impaired hearing lie to the right of the fence on both curves. When the entire population is exposed to noise, the population's hearing shifts. The handicaps of those with impaired hearing before noise exposure increase after the population shift. They are not counted, however, as an increase in the number of impaired persons because they were impaired from the start. Other persons who had no hearing impairment initially crossed the fence after exposure to noise. They are considered newly impaired. Finally, a sizable number of

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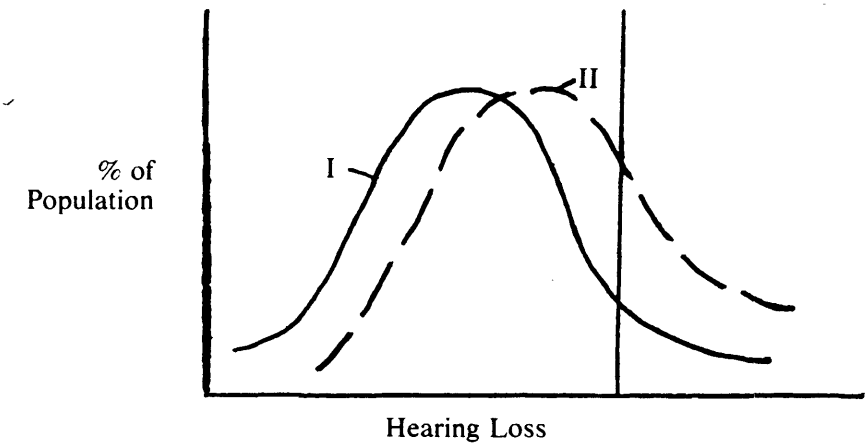
OF INTERNAL MEDICINE A-4 (R. Petersdorf, R. Adams, E. Braunwald, K. Isslebacher, J. Martin & J. Wilson 10th ed. 1983). A person who is initially monitored as having a BUN of 10 mg/100 ml and then increases to 19 mg/100 ml still falls within accepted limits, even though that individual's kidney function may have been impaired. In this situation, the diseased individual has a serum level that may also be exhibited by non-diseased individuals. Therefore, the false negative result occurs because the serum measurement is not a perfect predictor of disease.

*Adapted from P. CUTLER, PROBLEM SOLVING IN CLINICAL MEDICINE: FROM DATA TO DIAGNOSIS 16 (1979).

Figure 2: Shifts in Hearing Acuity with the Addition of Noise*




persons who do not cross the fence, and who therefore are not considered impaired, nonetheless suffer a significant loss in hearing acuity.

Another problem with the results of routine medical surveillance tests is that they may be nonselective in that they do not identify a particular pollutant (or agent) as the cause for disease. The health effects observed may be due to any one of several factors (both occupational and non-occupational) other than the one for which the worker is being considered for treatment or removal. Cutler points out that

> . . . when new tests are first discovered many are thought to be specific for certain diseases . . . . Subsequent studies showed these tests [e.g., rheumatoid factor for rheumatoid arthritis, SGOT-SGPT for acute myocardial infarction or liver cell necrosis] to be nonspecific and positive in other diseases which were either closely related or not related at all.[84]

Cutler cites pulmonary function tests, which medical surveillance programs frequently use, as an example. He observes that "[p]ulmonary function tests tell only the physiologic derangement, not the cause of disease."[85]

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*Adapted from N. ASHFORD, D. HATTIS, E. ZOLT, J. KATZ & G. HEATON, ECONOMIC AND SOCIAL IMPACTS OF OCCUPATIONAL NOISE EXPOSURE REGULATIONS 5-2 (1976) (Office of Noise Abatement and Control, U.S. Envtl. Protection Agency, EPA Pub. No. EPA550/9-77-352).

84. P. CUTLER, PROBLEM SOLVING IN CLINICAL MEDICINE: FROM DATA TO DIAGNOSIS 16 (1979).

85. *Id.* at 164. Another illustration of the inability of a routine medical surveillance test to identify the cause of a disease can be made by again using BUN as an example. The OSHA lead standard requires that BUN analysis be conducted on all employees who are or may be exposed to lead concentrations above 30 micrograms per cubic meter of air,

The interpretation of medical surveillance results also provides an opportunity for abuse. Employers may attribute elevated blood urea nitrogen (BUN) levels, detected in workers exposed to lead, to other causes such as physical stress and water depletion. Thinking that those two factors rather than lead exposure are the cause for elevated BUN levels, an employer may incorrectly believe that he need not impose further controls on lead in the workplace.

Another limitation on many routine medical surveillance tests is that they may detect a disease or abnormality only after adverse health effects, sometimes serious and irreversible, have occurred. For example, tests will detect an elevated BUN level in workers who have nephrotoxicity because of lead exposure only after 66% of kidney function is lost or when symptoms of renal failure are present.[86]

*2. Genetic Monitoring*

One controversial type of medical surveillance is *genetic monitoring:* the periodic testing of blood and body fluids of employees working with or possibly exposed to substances that may cause alterations in chromosomes. As pointed out earlier, such monitoring attempts to determine whether environmental exposures to particular substances cause statistically significant changes in genetic material.[87] Genetic monitoring is usually used to determine the mutagenicity (ability to cause a permanent change in the genetic make-up, other than one brought about by new associations of genes from different parents)[88] or clastogenicity (ability to act as a chromosome-damaging agent)[89] of a chemical or ionizing radiation. It is also used to identify or monitor exposure to substances suspected of causing chromosomal changes.[90]

It has been proposed that such monitoring techniques might also identify those individuals susceptible to certain agents and serve as an "early warning system" to identify those at risk before clinical signs

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averaged over an eight hour period for more than 30 days per year. 43 Fed. Reg. 53,010 (1978). This measurement is required because BUN levels serve as an indicator of renal function, and exposure to lead causes known adverse effects to the renal system. Although exposure to lead may cause an increase in the BUN measurement, an increase in BUN levels may also be seen from other causes, such as impaired kidney function, stress and any other cause of decreased renal blood flow like salt and water depletion or decreased fluid intake. J. WALLACH, INTERPRETATION OF DIAGNOSTIC TESTS: A HANDBOOK SYNOPSIS OF LABORATORY MEDICINE 40 (3d ed. 1978). Therefore, if testing for elevated BUN levels were conducted in a foundry where there was some exposure to lead, a number of workers might test positive for BUN elevation, not necessarily because of exposure to lead that affected the kidneys, but because of physical stress and sweating (causing salt and water depletion).

86. *See* 43 Fed. Reg. 52,965 (1978).

87. *See supra* note 24 and accompanying text.

88. THE COMM. ON CHEMICAL ENVTL. MUTAGENS OF THE NAT'L RESEARCH COUNCIL BD. ON TOXICOLOGY AND ENVTL. HEALTH HAZARDS, IDENTIFYING AND ESTIMATING THE GENETIC IMPACTS OF CHEMICAL MUTAGENS 245 (1983).

89. OTA REPORT, *supra* note 2, at ix.

90. *Id.* at 67.

become apparent.[91] One researcher maintains that these tests may serve as "advanced warning procedures" for *populations*, but cautions that interpretation of test results on an *individual* basis is unjustifiable because environmental factors and inter-individual and temporal variation may confound the results.[92] The same researcher suggests testing populations with a statistically appropriate number of subjects to compensate for expected individual variability.[93]

There are two types of genetic monitoring — cytogenetic and noncytogenetic. The cytogenetic technique, which is considered the more reliable method, detects major changes in the gross structure of chromosomes. Noncytogenetic techniques detect actual damage to deoxyribonucleic acid (DNA).[94] Chromosomal aberrations and sister chromatid exchanges (SCE)[95] are commonly the markers or endpoints in quantifying abnormalities in cytogenetic monitoring. Both types of cytogenetic monitoring commonly use peripheral blood lymphocytes and sometimes bone marrow. The endpoints for noncytogenetic monitoring techniques include the detection of mutagens in body fluids (urine, blood, feces), germ cell damage (sperm), and somatic cell damage.[96]

*a. Cytogenetic Monitoring*

Four common problems arise in using cytogenetic techniques for monitoring purposes. First, the population's background frequency of both chromosomal aberrations and SCEs fluctuates greatly, giving highly variable baseline data.[97] The occurrence of SCEs presumably involves

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91. *See generally* Dabney, *The Role of Human Genetic Monitoring in the Workplace*, 23 J. OCCUPATIONAL MED. 626 (1981) (discussion of this proposal).

92. M. Legator, *supra* note 24, at 24.

93. *Id.* at 25.

94. *See* OTA REPORT, *supra* note 2, at 10.

95. A *chromosomal aberration* is an "abnormal chromosomal complement resulting from the loss, duplication, or rearrangement of genetic material." R. KING, A DICTIONARY OF GENETICS 51 (2d ed. 1974). A *sister chromatid exchange* (SCE) is an exchange at one locus between sister chromatids of a chromosome, not resulting in an alteration of overall chromosomal structure. *See* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 126 (J. Doull, C. Klaassen & M. Amdur eds. 2d ed. 1980) [hereinafter cited as CASARETT AND DOULL'S TOXICOLOGY]. These two changes are commonly quantified in the attempt to determine a "safe" exposure level to a certain substance in the practice of genetic monitoring.

96. Some believe that chromosomal aberrations may be early signals of adverse health effects, *see* Holden, *supra* note 24, at 337, and may mean that exposure to a hazardous substance is too high. Conversely, others believe that one cannot distinguish between the background number of chromosomal aberrations and the aberrations caused by chemicals. See the discussion in West, *Genetic Testing on the Job*, SCIENCE 82, Sept. 1982, at 16. This view also holds that there is not a definite link between chromosome breakage and cancer, *see also infra* note 100; Holden, *supra* note 24, at 337 ("not a shred of evidence that directly links chromosome damage to any disease").

97. Carrano, Minkler, Stetka & Moore, *Variation in the Baseline Sister Chromatid Exchange Frequency in Human Lymphocytes*, 2 ENVTL. MUTAGENESIS 325 (1980) [hereinafter cited as Carrano]; GUIDELINES FOR STUDIES OF HUMAN POPULATIONS EXPOSED TO

the breakage and reunion of DNA, although the exact mechanism for SCE formation remains unknown.[98] Cell-to-cell differences in the mean SCE frequency of single individuals are probably the primary source of highly varying background SCE frequencies.[99]

Next, the state-of-the-art of such testing is not developed to the point that scientists know the meaning of "positive" findings (a statistically significant increase in the number of abnormal chromosomes relative to an appropriate control group). Although such findings are not widely accepted as an indicator of an increased risk of cancer,[100] some researchers believe that chromosomal aberrations are related to the occurrence of cancer.[101]

SCE frequency is easier and quicker to detect under laboratory conditions than are chromosomal aberrations,[102] and the practice is widely advocated as an indicator of potential genetic or carcinogenic hazard.[103] Some researchers believe that SCE techniques may be valuable in identifying exposures to genotoxins and recommend their use, especially if available experimental data indicate the SCE-inducing capacity of the agent in question.[104] The relation of the presence of SCEs to disease

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MUTAGENIC AND REPRODUCTIVE HAZARDS 4 (A. Bloom ed. 1981) [hereinafter cited as Bloom]; OTA REPORT, *supra* note 2, at 70. Fluctuations due to intra-individual and inter-individual variations make cytogenetic monitoring results very difficult to interpret, give them limited utility, and make it particularly difficult to define either a "normal" or "biologically significant" range for testing results.

98. Latt, Schreck, Loveday, Dougherty & Shuler, *Sister Chromatid Exchanges*, 10 ADVANCES HUMAN GENETICS 283 (1980) [hereinafter cited as *Chromatid Exchanges*]; Carrano, *supra* note 97, at 326.

99. Carrano, *supra* note 97, at 325. The results are necessarily limited by the number of individuals examined (eight) but the variation would not be much different even with a larger population.

100. Bloom states that

> in human populations, no associations have been definitely drawn between those individuals with induced breakage and subsequent development of cancer . . . although the presence of the chromosomal breakage in the lymphocytes of mutagen-exposed persons is at times a marker of exposure, it is not by definition a harbinger of cancer for the carrier individual.

Bloom, *supra* note 97, at 31.

101. For example, Legator believes that there is in fact a link between chromosomal abnormalities and cancer. He states that "[a]ll carcinogens that have been thoroughly tested have been found to induce some kind of chromosomal rearrangement . . . ." The detection of chromosome abnormalities indicates that the chemical is in all likelihood a human carcinogen-mutagen. M. Legator, *supra* note 24, at 24.

102. Wolff, *Cytogenetic Analyses at Chemical Disposal Sites: Problems and Prospects*, in ASSESSMENT OF HEALTH EFFECTS AT CHEMICAL DISPOSAL SITES 70 (W. Lowrance ed. 1981) (proceedings of a symposium held June 1–2 at the Rockefeller University in New York City).

103. Bloom, *supra* note 97, at 5.

104. Vainio, Sorsa & Hemminki, *Biological Monitoring in Surveillance of Exposure to Genotoxicants*, 4 AM. J. INDUS. MED. 87–103 (1983) [hereinafter cited as Vainio]. These authors believe that many agents in the environment are not known to be genotoxic. Therefore, monitoring for genotoxic effects, such as SCEs, may be useful in determining a hazard potential, as genotoxic manifestations are usually delayed a number of years after

or illness, however, is more uncertain even than that of chromosomal aberrations.[105]

A third problem is that external variables other than the suspected agent may affect the outcome of the results. For instance, chromosomal aberrations may not necessarily result from exposure to the substance in question, but also from a viral infection, exposure to ionizing radiation, or previous or simultaneous exposure to another chemical.[106] Substances other than the one suspected in monitoring may similarly induce SCEs. For example, agents that strongly tend to cause SCEs include viral infections, saccharin, x-rays, and chlorambucil (a chemotherapeutic agent).[107]

Finally, flaws in study design and interpretation of results, lack of proper validation, and lack of standardization of methods and statistical analysis have frequently clouded the results of cytogenetic monitoring studies in well-defined industrial settings.[108] The timing of genetic monitoring may be crucial.

Differences in longevity of aberrations found in lymph cells[109] have important implications for when a worker is monitored. For instance, workers with intermittent vinyl chloride exposure would need to be tested more frequently than benzene workers because the chromosomal marker disappears more rapidly for vinyl chloride.[110] Without more frequent testing, the chromosomal aberrations from vinyl chloride exposure would not be detected.

In addition, according to the OTA, studies do not show whether monitoring will detect endpoints at chronic, low-levels of exposure.[111] These uncertainties led OTA to conclude that "the appropriateness of chromosomal endpoints for occupational monitoring needs to be determined on a case-by-case basis for each chemical."[112]

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exposure. Because conducting epidemiological studies can take a long time, they believe it is necessary to identify genotoxic exposure as early as possible and thereby probably prevent some of the long-term health hazards.

105. Wolff, *supra* note 102, at 71; *Chromatid Exchanges*, *supra* note 98, at 267. A complete, detailed discussion of SCEs is provided in the Gene-Tox Program Report of the Environmental Protection Agency.

106. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 166.

107. *Chromatid Exchanges*, *supra* note 98, at 282–83.

108. Dabney, *supra* note 91, at 626–31.

109. *See infra* note 115.

110. OTA REPORT, *supra* note 2, at 74.

111. *Id.*

112. *Id.* In occupational settings, an increase in SCEs has been detected only for effective alkylating agents, such as ethylene oxide. *See* Vainio, *supra* note 104, at 92. Recently the Committee on Science, Engineering and Public Policy (a joint committee of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine) identified the need for developing "[a]nalyses of chromosomal alterations to detect genetic damage in peripheral blood cells (lymphocytes) of large exposed populations" because of the "little information available to measure or verify actual human exposure" to chemicals. *See* Comm. on Sci., Engineering and Public Policy, Report of the Research Briefing Panel on Human Health Effects of Hazardous Chemical Exposures 106–07 (1983). This research recommendation is contained in one of the seven research briefings prepared

Analysis of the four problems that SCEs have in common with chromosomal aberrations leads to the conclusion that occupational monitoring for SCEs is highly experimental[113] at this time. Without quantitative data directly linking SCE occurrence to the onset of disease, scientific commentaries on the application of this test as a worker surveillance tool have suggested SCE studies are still in their formative stages. Accordingly, test results must be interpreted with caution when making assessments of the risk to workers from exposure to occupational hazards.[114]

Occupational studies investigating the occurrence of chromosomal aberrations and exposure to certain chemicals have been conducted.[115] An increase in chromosomal aberrations associated with exposure to ionizing radiation is a finding that is widely accepted.[116] There is no similar wide acceptance, however, of such an association of chromosomal aberrations and exposure to workplace carcinogens and mutagens.

The literature that discusses cytogenetic monitoring as a method of determining the adverse health effects of occupational hazards suggests much uncertainty in performing such an activity routinely on a worker population.[117] The large variability of baseline levels, the unknown clinical relevance of "positive" findings, other variables influencing the testing results, and the lack of standardization of methods and analysis indicate that these tests currently are not practical for general use. The scientific recommendation that these tests not be used in routine medical

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by the committee in response to a request from the White House to "identify those research areas . . . likely to return the highest scientific dividends as a result of incremental federal investments . . . ." *Id.* at v.

113. Dabney, *supra* note 91, at 627.

114. Bloom, *supra* note 97, at 33.

115. For example, related occupational studies have been conducted for benzene, Forni, Cappellini, Pacifido & Vigliani, *Chromosome Changes and Their Evolution in Subjects with Past Exposure to Benzene*, 23 ARCHIVES ENVTL. HEALTH 385–91 (1971); Picciano, *Cytogenetic Study of Workers Exposed to Benzene*, 19 ENVTL. RESEARCH 33–38 (1979), and vinyl chloride, Kucerova, Polivkova & Batora, *Comparative Evaluation of the Frequency of Chromosomal Aberrations and the Sister Chromatid Exchange Numbers in Peripheral Lymphocytes of Workers Occupationally Exposed to Vinyl Chloride Monomer*, 67 MUTATION RESEARCH 97–100 (1979); Anderson, Richardson, Weight, Purchase & Adams, *Chromosomal Analysis in Vinyl Chloride Exposed Workers, Results from Analysis 18 and 42 Months After an Initial Sampling*, 79 MUTATION RESEARCH 151–62 (1980). Dabney has critically reviewed three of the four studies (Forni, Picciano, Kucerova). Dabney, *supra* note 91, at 626–31. The aberrations detected in the benzene studies remained in peripheral lymphocytes for longer periods than the aberrations detected in workers exposed to vinyl chloride. The aberrations among those with vinyl chloride exposure disappeared quickly after exposure was reduced. These results indicate that perhaps chromosomal aberrations from vinyl chloride exposure could be used to document *recent* exposure and those from benzene exposure could be used to document *cumulative* exposure. OTA REPORT, *supra* note 2, at 74.

116. Bloom, *supra* note 97, at 4–5; Wolff, *supra* note 102, at 75–76.

117. For a discussion of the latest research in the field of cytogenetic monitoring, see Donahue, Essigmann & Wogan, *Aflatoxin-DNA Adduct Detection in Urine as a Dosimeter of Exposure*, in INDICATORS OF GENOTOXIC EXPOSURE, BANBURY REPORT 13, at 221–230 (B. Bridges, B. Butterworth & I. Weinstein eds. 1982).

surveillance programs[118] is consistent with OSHA policy to date that medical surveillance "provisions do not require genetic testing of any employee."[119]

The OTA recently completed an assessment of the role of genetic testing. Regarding cytogenetic monitoring, the OTA report stated that a review of epidemiologic studies discussing the cytogenetic technique did not establish a dose-response relationship between worker exposure and the chromosomal aberrations. The OTA found that the studies generally did not account for other possible causes of chromosomal aberrations, such as age, nutritional status, and the presence of disease.[120] The report also found that: "[n]o occupational studies relate positive findings for any chromosomal endpoint with increased risk for any disease. Therefore, the clinical significance of a positive occupational cytogenetic study is unknown; nor is it known whether cytogenetic monitoring can be used to determine 'safe' levels of exposure."[121]

*b. Noncytogenetic Monitoring*

Noncytogenetic monitoring techniques detect directly or indirectly the presence of mutagens or DNA damage resulting from the presence of mutagens.[122] The tests commonly identify: (1) mutagens in body fluids, (2) somatic cell damage, and (3) germ cell (sperm) damage. The possible methods for evaluating populations exposed to mutagenic hazards for each of these three testing schemes lies beyond the scope of this article.[123]

This type of testing uses urine, feces, and blood as test materials in bacterial or *in vitro* cell culture mutagenicity assays. Primarily urine is analyzed for the presence of mutagens and therefore it will receive more discussion in this section than the other two body fluids.

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118. Dabney, *supra* note 91, at 626. It is interesting to note that in the same issue of the *Journal of Occupational Medicine* another article reached opposite conclusions, *see* Fabricant & Legator, *Etiology, Role and Detection of Chromosomal Aberrations in Man*, 23 J. OCCUPATIONAL MED. 617, 624 (1981). The Dabney article states that the genetic monitoring tests are still research tools not to be used for routine medical surveillance and that the predictive value of these short-term genetic tests has not been established. In contrast, the Fabricant and Legator article states that "[i]ndustrial cytogenetic monitoring, as a form of preventive medicine, is now possible . . . . Chromosomal studies are now considered to be the best method for examining genetic damage in routine industrial medical surveillance." Fabricant & Legtor, *supra*, at 624. The authors of this second article also conclude that genetic monitoring provides a reliable and objective method for evaluating genetic change in the worker population.

119. *See supra* note 61 and accompanying text.

120. OTA REPORT, *supra* note 2.

121. *Id.* at 74.

122. *Id.* at 75.

123. Details and reviews of these numerous methods are available elsewhere in the literature. *See, e.g.*, Green & Auletta, *Editorial Introduction to the Reports of "The Gene-Tox Program,"* 76 MUTATION RESEARCH 165–68 (1980); Waters & Auletta, *The GENE-TOX Program: Genetic Activity Evaluation*, 21 J. CHEMICAL INFORMATION & COMPUTER SCI. 35 (1981); Bloom, *supra* note 97, at 123–25.

The urine analysis method is now believed to be readily applicable to human monitoring situations.[124] There are limitations, however, to the use of urine analysis in detecting the presence of mutagens. For example, "only recent exposures can be measured" and "the presence of mutagens in urine has not been translated into a known risk to the individual."[125] One must know the metabolic fate of the mutagen in order to know when to test and how to interpret the results properly.[126] In general, the body fluid analysis tests are limited in that they do not measure cumulative exposure nor do they translate the results into quantitative risks for either individuals or populations.[127]

Somatic cell damage usually involves the analysis of hemoglobin, lymphocytes, or chemically damaged DNA. While these tests may show promise in reliably identifying mutations, there are presently technical and theoretical (e.g., variables that may affect the results) limitations that must be resolved before such testing can be considered useful in an occupational setting.[128]

Germ cell tests use sperm for mutation analysis. As with somatic cell testing, studies using germ cell analysis show promise. Germ cell tests, however, need further development. The endpoints of the sperm test have not been shown to be associated with heritable disease states and, until fully validated, the tests should be regarded as experimental.[129]

Noncytogenetic techniques are considered to be in a developmental phase. In sum, to date these tests have not

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124. Analytical methods for urine are readily applicable to human monitoring in the workplace because:

> 1) Preliminary studies in humans have demonstrated that mutagens can be detected in the urine of humans exposed to various therapeutic drugs [citations omitted]. Because results were obtained from only a single patient, conclusions may not be appropriate for general application. Mutagens can also be detected in the urine of humans exposed to industrial chemicals and cigarette smoke [citations omitted];
> 2) the collection of urine samples is noninvasive and easy to obtain from males and females on a regular schedule;
> 3) multiple analyses can be performed simultaneously from a single urine sample; and
> 4) costs and performance time associated with this approach are amenable to large-scale sampling studies.

Bloom, *supra* note 97, at 127.

125. OTA REPORT, *supra* note 2, at 76.

126. For example, the presence of mutagens in the urine may indicate exposure to a mutagenic agent or an agent that forms a mutagenic metabolite. Excretion of the mutagen may work as a protective process. Conversely, the absence of mutagens in the urine of those exposed may give a false sense of security. In fact, the mutagen may not be excreted because it is bound to cellular molecules, possibly posing a hazard. Bloom, *supra* note 97, at 127.

127. *Id.* at 128. According to Dabney, "[f]urther research and comparison with other tests need to be completed before any judgment can be made on the general utility of body fluid analysis." Dabney, *supra* note 91, at 627.

128. OTA REPORT, *supra* note 2, at 77–80.

129. Dabney, *supra* note 91, at 627.

> been established as a reliable technique for monitoring human populations . . . . At present, there is not enough research experience using humans for most noncytogenetic techniques to determine accurately their usefulness in workplace monitoring situations . . . . The most obvious deficiency in these tests is the lack of the availability of the normal baseline response.[130]

Although many of these tests hold promise in the identification of mutations, "extrapolations of these test results to human health is difficult . . . . Given our limited understanding of, and experience with, direct laboratory tests for mutations in man, current use of these tests should be limited largely to studies aimed at evaluating the *tests* rather than evaluating exposed human populations."[131]

*3. Genetic Screening*

An employee undergoes genetic screening *only once*, usually as part of a pre-employment or pre-placement exam, to determine individual risk from exposure to a certain workplace substance or substances because of an inherited genetic defect. This practice should not be confused with *genetic monitoring* described above, which is conducted periodically to determine risk to a group of employees who may exhibit chromosomal changes that are not inherited but due possibly to exposure to certain substances in the workplace.

There are numerous human traits for which screening can determine genetic predisposition to occupational disease. OTA reviewed only a small percentage of the traits,[132] and this article does not discuss them in detail. The general findings of OTA regarding these screening techniques are that "while the biological foundations of the concept of genetic screening to identify predisposition to occupational disease are sound,"[133] more epidemiologic investigation is needed. OTA also concluded that factors other than genetic status may cause the response, and the

> identification of genetic factors that may contribute to the occurrence of job-related disease is a science truly in its infancy . . . . [G]enetic differences may in part explain the variability of responses to chemicals in the workplace. What percentage of the total variability may be explained by genetic factors is uncertain.[134]

Geoffrey M. Karny of OTA testified before a congressional subcommittee that "few data" presently "support the correlation between any of these traits and an increased risk for disease from occupational exposure,

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130. *Id.* at 75.
131. Bloom, *supra* note 97, at 118 (emphasis added).
132. OTA REPORT, *supra* note 2, at 89–105.
133. *Id.* at 99.
134. *Id.* at 98–99.

mainly because of serious flaws in study design."[135] As with genetic monitoring, genetic screening methods are neither adequately specific nor sufficiently developed for current use in monitoring incidences of occupational disease.[136]

Much controversy surrounds the practice of genetic screening, particularly because fifty-nine corporations informed OTA that they plan to begin genetic screening programs of their workers in the next five years,[137] even though the usefulness of such tests has not been confirmed.[138] Genetic factors do not exist in isolation. Nutritional status, age, pre-existing disease and the interactions of various medications may affect an individual's susceptibility to toxic substances.[139] The overall state-of-the-art for genetic screening has not been developed broadly enough to distinguish genetic factors from these other variables that may

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135. *Genetic Screening in the Workplace: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. 21 (1982) (statement of Geoffrey M. Karney, Project Director, Biological Applications Program, OTA) (discussing traits for glucose-6-phosphate dehydrogenase (G-6-PD) deficiency, sickle cell, and alpha and beta thalassemias).

136. This statement is supported by the fact that the DuPont Corporation, which had conducted G-6-PD testing at its Deepwater, New Jersey, plant until mid-1980, discontinued giving the tests to both blacks and white workers of Mediterranean ancestry. The company determined that the test did not have good predictive capability and was not helpful "in [its] attempt to place people in jobs where there would be no unusual health risk." Hess, *Is Genetic Screening a Chemical Industry Ploy?*, CHEMICAL BUS., CHEMICAL MARKETING REP., Dec. 14, 1981, at 42; *see also infra* note 245.

137. Severo, *supra* note 58, at A12, col. 4; OTA REPORT, *supra* note 2, at 9. Proponents of genetic screening believe that employees with particular genetic traits may be more "susceptible" to certain illnesses than employees without the trait when both groups are exposed to the same substance. For example, a deficiency of G-6-PD, a component of red blood cells, is believed by some to cause affected individuals to become anemic when exposed to certain substances, such as oxidizing agents. *See infra* note 267. By preventing workers with certain genetic traits from performing jobs where exposure to particular substances may occur, advocates believe that such screening serves a function in reducing the incidence of occupational disease and acts as a means of protecting employees, particularly the "hypersusceptibles," from workplace hazards, as it is not economically feasible to provide an environment that is risk-free for all workers.

The critics' arguments against the use of genetic screening include scientific uncertainty, its use as a tool for discriminatory practices, and its use as an alternative to cleaning up the workplace. As far as the scientific community is concerned, "there appears to be very little support at present for biochemical genetic screening . . . . The tests are regarded as arbitrary and, although valid, not very predictive." Holden, *supra* note 24, at 336. *See supra* note 136 and accompanying text.

138. The information supplied to OTA was disclosed at a hearing before Congress on June 22, 1982. *Genetic Screening of Workers: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. 7–38 (1982). On October 14 and 15, 1981, this same subcommittee had conducted hearings on screening research into human variation and the application of that research to occupational settings. *Genetic Screening and the Handling of High-Risk Groups in the Workplace: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981).

139. E. Calabrese, Predicting Susceptibility to Occupational Diseases via Genetic Markers 2 (March 1982) (report submitted to the Office of Technology Assessment).

cause a response to a toxic substance. For example, during World War I, it was speculated that TNT-induced adverse effects were intensified by inadequate diets.[140]

A substantial amount of evidence exists to support the proposition that some individuals have a genetic predisposition to industrially related disease (e.g., G-6-PD deficiency related to an increased risk of hemolytic anemia[141]). The principal problem, however, is that the levels of exposure required to cause the response are not usually documented. Therefore, it is difficult to estimate risk or to determine the adequacy of established workplace exposure standards in protecting worker health.

Because of this obvious gap in the scientific data and the inability to distinguish genetic factors from other variables, screening for the purposes of pre-employment testing, pre-placement testing, job denial or job transfer seems misguided and unjustified at this time.[142] Speculation on its use as an accurate and reliable tool in the future is difficult, as workers are exposed to thousands of chemicals in industry. One would need to test each of those chemicals for adverse effects in those with heritable traits, take into consideration other variables, and perform statistical analyses on the data before one could ascertain the goodness of the tests.

Those who favor the practice of genetic screening believe that it serves to reduce occupational disease by protecting the employees, particularly the "hypersusceptibles," from workplace hazards.[143] It may be difficult, however, to determine which workers are actually "hypersusceptible" as a result of genetic predisposition. This difficulty is reflected by the fact that of the ninety-two human disorders for which a genetically determined specific enzyme deficiency has been identified, only five meet the prerequisite for a different job assignment.[144]

The U.S. National Cancer Institute recently awarded a Canadian scientist a contract to "perfect a simple test for identifying cancer-prone individuals."[145] Such a test has serious potential for misuse. From a

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140. 1 E. CALABRESE, NUTRITION AND ENVIRONMENTAL HEALTH 379 (1980).

141. E. Calabrese, *supra* note 139, at 79.

142. Regarding the general application of genetic screening, OTA concluded that the "biological foundations of the concept of genetic screening to identify predispositions to occupational diseases are sound." OTA REPORT, *supra* note 2, at 99. OTA also stated, however, that the predictive value of the test is low in the general population so epidemiologic studies using genetic screening tests could be "seriously flawed." *Id.* at 11. Based on these facts, OTA indicated that more research on tests identifying traits in the general population and epidemiologic studies need to be conducted. This recommendation is consistent with OTA's conclusion on the overall state-of-the-art, that presently "[n]one of the current genetic tests evaluated by OTA meets established scientific criteria for routine use in an occupational setting." *Id.* at 9.

143. N. ASHFORD, CRISIS IN THE WORKPLACE: OCCUPATIONAL DISEASE AND INJURY 118 (1976). *See also* Stokinger & Scheel, *Hypersusceptibility and Genetic Problems in Occupational Medicine — A Consensus Report*, 15 J. OCCUPATIONAL MED. 564, 572–73 (1973).

144. N. ASHFORD, *supra* note 143, at 118.

145. *A Test for Cancer-Prone People*, CHEMICAL WEEK, Aug. 18, 1982, at 23. The recipient of the contract stated that the test could be used in industries where "workers

scientific point of view, the test would have to demonstrate acceptable sensitivity, specificity, predictive value, and reliability. Individual biological variation must be factored in along with variables like age, nutritional status and pre-existing disease. The test must also include appropriate markers that identify disease with certainty and be subject to verification by appropriate statistical analysis and epidemiologic evidence. To date, the state-of-the-art for genetic screening has not achieved this.[146]

Some critics contend that genetic screening may lead to discriminatory employment practices[147] against certain ethnic and racial groups by industry.[148] Opponents of genetic screening also contend that such screening practices shift the focus from cleaning up the workplace so that all workers are protected as much as possible from harmful exposures to a "blame the worker" attitude resulting in the removal of workers. This removal may create a false sense of security that *all* of those who will develop cancer have been identified and removed, as well as encourage the employer to divert attention from the detection and removal of chemical and physical workplace hazards that pose a continuing threat to those workers who remain.

Results from genetic screening tests may be interpreted wrongly to mean that some workers will experience responses from exposures to certain chemicals. Such workers, who exhibit what is in fact normal variation, are inappropriately categorized as "hypersusceptible."[149]

*4. Biological Monitoring*

Biological monitoring determines both the occurrence of exposure and the uptake (or presence) of a particular substance or its metabolites in body fluids or organs. It may complement medical surveillance and environmental monitoring.

Biological monitoring may be an important tool when inhalation is not the only significant route of exposure. It detects *total uptake* from all routes (inhalation, ingestion, skin absorption) and estimates individual health risk as well by measuring or approximating internal exposure. It can take account of the individual differences in uptake, metabolism, and response, and thereby reflect the risk for an individual worker.[150]

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are exposed to radiation or carcinogenic chemicals, allowing employers to *screen out workers with a high susceptibility to cancer* — perhaps 2–3% of the population." *Id.* (emphasis added). The test could be as "simple as 'detecting VD'" and would be marketed as a "simple kit." *Id.* It is likely that industries that use carcinogens in the workplace would use the screening technique.

146. OTA REPORT, *supra* note 2, at 9, 89, 100.

147. *See infra* text accompanying notes 489–549.

148. Regarding screening as a general practice for sickle cell trait, a genetic characteristic particular mostly to blacks, Marc Rothstein, professor of law at West Virginia University, stated that "[b]ecause certain biochemical genetic tests have a marked impact along racial lines, any differentiation based on such a test would establish a prima facie case of discrimination." Severo, *supra* note 58. *See also* Rothstein, *supra* note 9, at 1389–91.

149. *See infra* note 260 and accompanying text.

150. *Assessment of Risk*, *supra* note 31, at 201.

Results from biological monitoring procedures may in some instances provide indications of a medical disorder much earlier than those of medical surveillance. Biological monitoring serves as an indicator that exposure and uptake have occurred, although harm may not yet have.[151] Medical surveillance results, by contrast, show possible adverse effects from such exposure, indicating that harm, sometimes irreversible, has already occurred.

In conducting biological monitoring tests, one must assess the appropriateness of the biological parameter under consideration and the goodness of the test being used. Stated another way, one must question whether a change in the parameter being observed (e.g., a metabolite of the exposure substance) is an indicator of the actual or potential health damage that is the endpoint. If, in fact, the observed change does indicate an actual or potential adverse health effect, one must then determine how well the test monitors that change. In selecting a biological test, one must consider the predictive value, specificity, sensitivity, and occurrence of false positives and false negatives[152] as well as other factors.[153]

The frequency with which biological monitoring should be conducted "does not follow any general rule, [but] depends on the variability and the intensity of exposure, the toxicity of the agent, and the pharmacokinetic properties [such as] short versus long biological half-time[s]" of residence in the body.[154] In general, monitoring should take place more frequently if the substance is suspected of producing irreversible changes in the body, if it is highly volatile, if the level of exposure is high, and at each change in production technology.[155]

The first limitation of biological monitoring is that few reliable tests are available.[156] In addition, some of the tests available (e.g., for blood

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151. R. LAUWERYS, *supra* note 26, at 1.

152. *See supra* Table 2 and accompanying text.

153. Factors to take into account in the choice of biological tests include: (1) the test should measure or evaluate absorption of an agent in a reproducible manner; (2) the analytical error and biological variability should be small; (3) the test should be quantitatively reliable for the relevant range of occupational exposure; (4) convenience and risk factors (associated with obtaining a specimen) should be considered; (5) the concentrations of the agent measured in the body media should be quantitatively relatable to a health effect; and (6) the test should provide useful information over and above that obtained by ambient monitoring. *See* Luxembourg Report, *supra* note 4, at 206.

154. Zielhuis, *Biological Monitoring*, 4 SCANDINAVIAN J. WORK, ENV'T & HEALTH 1, 13 (1978) (guest lecture delivered at the 26th Nordic Symposium on Industrial Hygiene in Helsinki, Finland, October 1977).

155. Bardodej, *Biological Monitoring of Exposure to Chemical Pollutants; Exposure Tests, Biological Limits and Methods of Analysis: A Review*, 8 DEVELOPMENTS IN TOXICOLOGY & ENVTL. SCI. 335, 338 (1980).

156. Of those available, "[o]nly a few have well-established predictive validity . . . ." P. Hughes, *supra* note 29, at 7.

> Considering biologic tests in general, many score high in sensitivity, but unfortunately, rather low in specificity. The results are then difficult to interpret . . . . So while the search goes on for chemical tests relatively simple to perform, yet of a high degree of specificity, the results of which may be interpreted with reasonable confidence, there are not very many such tests at hand today.

*Id.* at 11–12.

analyses) are invasive,[157] and an invasive technique may deter workers from participating in monitoring activities.

A second limitation is that it is difficult to establish whether the exposure substance in question causes any observed changes in the biological parameter. This limitation makes it difficult to pinpoint a cause-effect relationship. Cells and tissues generally respond in a limited number of ways to a wide variety of stresses, and the changes observed are often not specific. Frequently, workers are exposed simultaneously to multiple substances, so one must also consider whether a different substance or a combination of substances caused the observed changes in the parameter of interest. Another complicating factor in ferreting out a cause-effect relationship is non-occupational exposures that may cause the observed effects.

A third limitation involves variability of response. Multiple factors can cause biological variations in response among workers exposed to the same substance. Numerous factors must be considered in developing, applying and interpreting biological analyses.[158] Realizing that multiple factors can cause such variability in response, it is difficult to determine the "normal" response for an individual. This makes the interpretation of results difficult, even when they are accurate. Apparently healthy individuals with the same biological monitoring results may differ greatly in sensitivity.

A fourth limitation is that the parameter of interest for biological monitoring can be altered artificially (e.g., by prophylactic chelation),[159]

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157. *See infra* text accompanying notes 189–90.

158. General factors to consider include:

(1) rate of metabolism, *see infra* note 264a:
  (a) individual variations in enzyme complement,
  (b) diet,
  (c) stimulation or inhibition of enzymes in the metabolic sequences,
  (d) dose of the exposure chemical, and
  (e) competition for the necessary enzyme;
(2) the ratio of bound to free chemical in the blood;
(3) special situations in which excreted levels of the index chemical do not indicate current exposure levels;
(4) concentration changes due to volume changes in the bioassay material;
(5) non-workplace occurrence of the index chemical in the body and the resulting natural variations in concentration;
(6) age of the worker;
(7) disease;
(8) sex of the worker;
(9) normal range of the index chemical to be expected in the bioassay material;
(10) time required for the index chemical to appear in the bioassay material;
(11) analytical methodology, *see supra* notes 79 & 80; and
(12) route of exposure.

*See* Waritz, *Biological Indicators of Chemical Dosage and Burden*, in 3 PATTY'S INDUSTRIAL HYGIENE AND TOXICOLOGY 257, 263, 265 (L.J. Cralley & L.V. Cralley 3d ed. 1978); *see also infra* text accompanying notes 258–318.

159. Blood lead levels are commonly used to assess lead body burden. These levels can be artificially decreased by a chelating agent, which is a substance that chemically

and this limitation may carry with it associated health risks. The practice of prophylactic chelation has the potential for serious misuse. Chelating the workers would keep their blood lead levels below the removal trigger level,[160] so employers might also realize an economic advantage in not having to remove workers. For employers who expose employees to lead levels above the permissible OSHA standard, such a practice would be more cost-effective than installing expensive engineering controls to bring ambient lead levels within the regulated level. The installation of engineering controls may not then seem necessary because of the "acceptable" blood lead levels of the employees. This response is inconsistent with the OSHA policy that requires altering the workplace via engineering controls rather than altering the worker to control lead exposure in the workplace.

Changes in a biochemical parameter of interest for an individual worker may be nonspecific and variable. A trend for a cause-effect relationship is possible, however, if results of a working population (with baseline parameter determinations) are properly analyzed along with a comparable control population.

Understanding the rate of metabolism relative to the type of specimen is particularly important in timing biological monitoring. For example, some substances are excreted in the urine very rapidly after exposure (e.g., the metabolite trichloroethanol from trichloroethylene exposure), while others have a longer retention time once exposure has been discontinued (e.g., lead). To best determine the occurrence of exposure or uptake for trichloroethylene, the workers should be monitored one to three hours after exposure.[161] Conversely, lead is excreted so slowly via the kidneys that the level of lead found in the urine is not informative as to uptake at any particular time.

The most reliable way to quantify the presence of a substance or its metabolite in the body would be to measure the concentration in the

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binds lead and makes the lead biochemically and toxicologically inactive or unavailable. 43 Fed. Reg. 53,001 (1978). Workers engaging in prophylactic chelation therapy would, therefore, have lower blood lead levels than they would otherwise. The workers then might not need to be removed from the workplace because their blood lead levels would be within the limits required by OSHA. *See infra* text accompanying note 321. The potential risks of this practice differ according to the different chelating agents but generally include nervousness, feelings of pressure in the chest, transient rise in blood pressure, kidney problems, aplastic anemia and possible increases in the absorption of lead from the gastrointestinal tract if lead exposure continues. 43 Fed. Reg. 53,001–02 (1978).

The OSHA lead standard does not authorize the use of prophylactic chelation as an alternative to controlling employee exposure. However, diagnostic or therapeutic chelation in situations of acute overexposure to lead is approved so long as the employer assures "that it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence." *Id.* at 53,011.

160. *See infra* text accompanying note 321.

161. Ogata, Takatsuka & Tomokuni, *Excretion of Organic Chlorine Compounds in the Urine of Persons Exposed to Vapours of Trichloroethylene and Tetrachloroethylene*, 28 BRITISH J. INDUS. MED. 390 (1971) [hereinafter cited as Ogata].

adversely affected organ (e.g., biopsy). This certainly is not a practical large-scale testing scheme for a working population. As a surrogate, biological monitoring usually involves the collection and analysis of urine, blood, and expired air. Other specimens less commonly used are biopsied fat, saliva, breast milk, hair, nails, and feces.[162] Although these specimens may be useful for certain analyses, they produce associated problems of collection, storage, and analysis.[163] A discussion of the three more commonly used specimens follows.

Urine is one of the most frequently used biological monitoring specimens. Samples are easy to collect and collection is noninvasive. Analysis usually involves measuring a metabolite of the substance of concern (e.g., measurement of urinary phenol resulting from benzene exposure). Criteria have been established for the reliability of urine analysis for a particular organic index chemical.[164]

OSHA has promulgated no standards to date that require urinary biological monitoring. The OSHA benzene standard, however, which was remanded to the agency by the Supreme Court,[165] did contain a provision

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162. R. BASELT, BIOLOGICAL MONITORING METHODS FOR INDUSTRIAL CHEMICALS 3 (1980).

163. *Id.*

164. Studies indicate that urine analysis for a particular organic index chemical will be most reliable if:

(1) the index chemical has no non-workplace progenitors;
(2) the slope of the dose-response curve is fairly steep;
(3) the time needed to eliminate half of the substance from the body (half-life) is no longer than eight hours and preferably no greater than four hours;
(4) the method of analysis is *specific* for the exposure substance;
(5) the method of analysis is validated in humans at the highest exposure level of interest (dose-response curves should not be extrapolated beyond the highest experimental level);
(6) urine collection times are consistent and appropriate for the excretion half-life time;
(7) urine samples are analyzed shortly after collection;
(8) the method and determination of the concentration of the index chemical are first validated for the group of workers of interest before routine application;
(9) the worker is not on a diet, has no pre-existing disease, and is not taking any medicine that could interfere with the kinetics of the reaction of interest or any procedures;
(10) the worker is not being exposed off-the-job to the index chemical or another progenitor of the index chemical;
(11) the urinary level of the index chemical is relatable to the amount of exposure chemical absorbed by all routes;
(12) the dose-response equations are shown to apply to both men and women, or separate ones are developed and applied to each sex; and
(13) the workdays of the group of interest and the group used to derive the concentration of the index chemical in the urine are the same, if the half-life of elimination is much greater than eight hours.

Waritz, *supra* note 158, at 294–95.

It is also customary laboratory practice in the United States to correct urine samples to a specific gravity ("the measured mass of a substance compared with that of an equal volume of another taken as a standard," BLAKISTON'S GOULD MEDICAL DICTIONARY 1271 (4th ed. 1979)) of 1.024 for comparability, Elkins, Pagnotto & Smith, *Concentration Adjustments in Urinalysis*, 35 AM. INDUS. HYGIENE ASS'N J. 559, 565 (1974), although some investigators have used values of 1.016 and 1.018. R. BASELT, *supra* note 162, at 2.

165. Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607 (1980).

in the medical surveillance section for urinary phenol levels. Phenol is one of the principle urinary benzene metabolites. The urinary phenol levels were to be monitored only in emergency situations, not on a routine basis.[166]

NIOSH recommended in 1975 that urinary fluoride analyses be conducted at least every three months among a select group of workers, using post-shift urine samples.[167] A pre-shift urinary fluoride sample would serve as a baseline reference.[168] NIOSH's analysis suggested diet as part of the evaluation.[169]

The *NIOSH/OSHA Occupational Health Guidelines* also makes recommendations for urinary biological monitoring for some substances, although it does not provide trigger levels and guidance on steps to take if the substance (or metabolite) is found. For example, the medical guidelines for inorganic mercury, tellurium and manganese state that urinary determinations of the substances "may be helpful" in assessing absorption or exposure.[170]

In view of the previously mentioned factors that must be taken into account in interpreting urinary biological monitoring results, published scientific reports on occupational biological applications give widely varying conclusions. For example, some researchers believe that the measurement of urinary phenol is unreliable as an indicator of benzene exposure,[171] while others believe it to be a good index of workplace

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166. That part of the remanded standard states that "[i]f the employee is exposed to benzene in an emergency situation, the employer shall provide the employee with a urinary phenol test at the end of the employee's shift." Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607 (1980). The biological trigger level was 75 milligrams of phenol per liter of urine (mg. phenol/L). If the urine level was lower than 75 mg. phenol/L, no further testing would be required. If higher, then the employer was to provide additional hematology tests as soon as practicable, to be repeated in one month.

167. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, PUB. NO. 76-103, CRITERIA FOR A RECOMMENDED STANDARD . . . OCCUPATIONAL EXPOSURE TO INORGANIC FLUORIDES 3 (1975) [hereinafter cited as FLUORIDE CRITERIA DOCUMENT].

168. If the preshift sample has a fluoride level of 4.0 mg./L. or the postshift sample has a level of 7.0 mg./L., "steps shall be taken to evaluate *dietary sources*, personal hygiene, basic work practices, and environmental controls." *Id.* (emphasis added).

169. Note that diet is a variable to be considered in evaluating the results of biological monitoring tests. *See supra* notes 158 & 168.

170. NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19.

171. Even though the OSHA benzene standard provided for urinary phenol determinations, researchers have reported that individual determinations may be unreliable because of inter-individual variability in metabolism of benzene and differences in nutritional status. Docter & Zielhuis, *Phenol as a Measure of Benzene Exposure*, 10 ANNALS OCCUPATIONAL HYGIENE 318, 323 (1967). Others conclude that urinary phenol levels do not serve as reliable indicators of benzene exposure if such exposure is less than eight hours at five parts of benzene per million parts of air (ppm). Roush & Ott, *A Study of Benzene Exposure Versus Urinary Phenol Levels*, 38 AM. INDUS. HYGIENE ASS'N J. 67, 74 (1977). The current average eight hour permissible exposure level for benzene is ten ppm. AM. CONFERENCE OF GOVTL. INDUS. HYGIENISTS, TLVs®: THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS IN THE WORK ENVIRONMENT WITH INTENDED CHANGES FOR 1983–1984 11 (1983) [hereinafter cited as THRESHOLD LIMIT

exposure.[172] Urinary biological monitoring is also used to discover any uptake of organics like toluene and styrene, as well as metals like lead and cadmium.[173]

Analyzing contaminants in expired air is a biological monitoring technique that is increasing in application.[174] Generally, this type of analysis has been limited to chlorinated hydrocarbon solvents like methylene chloride, carbon tetrachloride and trichloroethylene.[175] The chemicals enter the body via the lungs (although some may be absorbed through the skin), then enter the vascular system, equilibrate with the body, and are later excreted in exhaled air. Equilibrium of the contaminants between the body and respired air can be used as "an indication of the concentra-

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VALUES]. So in workplaces where benzene exposure is less than five ppm averaged over eight hours, some may consider urinary phenol measurements inappropriate or useless. In addition, ingestion of the recommended dosages of over-the-counter medicinals such as Pepto-Bismol[R] and Chloraseptic[R] has been reported to cause urinary phenol levels in excess of 75 mg. phenol/L without exposure to benzene. Fishbeck, Langner & Kociba, *Elevated Urinary Phenol Levels Not Related to Benzene Exposure*, 36 AM. INDUS. HYGIENE ASS'N J. 820, 824 (1975). The results of the Fishbeck study must be interpreted and generalized with caution, as only one worker who used over-the-counter medicinals was sampled. Also note that this study disapproves of the practice of adjusting urine specific gravity to 1.024, as the authors believe that it does not accurately reflect the average specific gravity for urine. *See supra* note 164.

172. Except in those cases in which medicines cause elevated urinary phenol levels, other researchers believe that urinary phenol is probably a good index of workplace exposure to phenol or benzene. Waritz, *supra* note 158, at 286–87; Ohtsuji & Ikeda, *Quantitative Relationship Between Atmospheric Phenol Vapour and Phenol in the Urine of Workers in Bakelite Factories*, 29 BRITISH J. INDUS. MED. 70 (1972). Results of the Ohtsuji study are necessarily limited by its small sample size (seven). Although the measurement of urinary phenol may be nonspecific and insensitive for individual assessments of exposure to low levels of benzene in the air, Luxembourg Report, *supra* note 4, at 201, such monitoring conducted among a statistically significant sample of workers may indicate the potential risk for the exposed working population as a whole.

173. "Excessive exposure to cadmium is most likely to occur in the workplace." H. Perry & E. Perry, Evaluation of Cadmium as a Biological Hazard 11 (paper presented at the Luxembourg Seminar, *supra* note 29). Concern about worker exposure to cadmium and its known toxic effects on the kidney has prompted the practice of urinary cadmium monitoring. *See* NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, PUB. NO. 77-181, OCCUPATIONAL DISEASES: A GUIDE TO THEIR RECOGNITION 347 (M. Key, A. Henschel, J. Butler, R. Ligo, I. Tabershaw & L. Ede eds. 1977) [hereinafter cited as OCCUPATIONAL DISEASES].

As with benzene, the goodness of this testing to determine the body burden of cadmium has been disputed. Some researchers believe that "cadmium . . . in urine . . . may be used for estimating the internal dosage of cadmium and hence the risk of health impairment." R. Lauwerys, Cadmium 11 (paper presented at the Luxembourg Seminar, *supra* note 29). The Luxembourg Report concurs. Luxembourg Report, *supra* note 4, at 201. Still, others believe that the "body burden of cadmium can be estimated with certainty only by measuring the renal and/or hepatic cadmium concentrations with biopsy or at autopsy . . . . Urinary cadmium concentration may provide some measure of cadmium exposure; however at present, the evidence is only indirect . . . ." H. Perry & E. Perry, *supra*, at 11–12.

174. Soule, *Industrial Hygiene and Sampling Analysis*, in 1 PATTY'S INDUSTRIAL HYGIENE AND TOXICOLOGY 762, 765 (G. Clayton & F. Clayton 3d ed. 1978).

175. *Id.* at 765–67.

tion of the contaminant in the workroom air to which the individual has been exposed."[176] Experimental inhalation studies also have shown "a good correlation between concentration decrease of the index chemical in post-exposure exhaled air and prior exposure."[177] The concentration of chemicals in the exhaled air decreases exponentially with time, not only when the chemical is inhaled, but also when it is absorbed via the skin and ultimately exhaled unchanged.[178]

In addition, the expired air samples are easily obtained through a comfortable procedure. As a result, worker acceptance for this type of monitoring may be greater than for urine or blood sampling, for all the employee need do is take several deep breaths and force expired air through a tube into a container.

According to one researcher, "[i]f the concentration of the exposure chemical in exhaled air varies in some regular fashion with body burden, regardless of route of absorption, this would provide a very desirable method for measuring industrial exposure."[179] This type of monitoring would have further advantages over other methods of monitoring, in addition to the already mentioned positive aspects,[180] but also some limitations.

The first limitation of expired air analysis is that its use is limited to those substances that are sufficiently volatile to be exhaled in measurable amounts.[181] This limitation is crucial to the issue of the timing of the test.[182] A second limitation is that although exhaled air is ideally repre-

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176. *Id.* at 765.

177. Waritz, *supra* note 158, at 299.

178. *Id.* at 295.

179. *Id.*

180. Advantages of expired air analyses over other monitoring methods include the following factors:

(1) Metabolism usually would not be involved, so all metabolic factors that can affect the rate of appearance of the index chemical would not affect the analysis.

(2) The index chemical appears rapidly in exhaled air. Therefore, it is not necessary to wait hours or weeks for the index chemical to appear in the bioassay material.

(3) The analysis would be amenable to gas-chromatographic techniques, which can be made quite specific, thereby eliminating interference from non-index chemicals. This technique also makes it possible to analyze several chemicals at the same time.

(4) Several samples can be taken in rapid succession.

(5) Usually the subject can be observed while providing the sample, to assure he or she follows instructions.

(6) Very few non-workplace progenitors exist for the index chemical. Therefore, the excreted material is more likely to represent workplace exposure than in the analyses of other biological materials (e.g., urine).

(7) The technique is noninvasive.

(8) The technique measures individual exposure without the bother of a personal monitoring device.

*Id.* at 295–96.

181. R. BASELT, *supra* note 162, at 2.

182. For example, if a substance is highly volatile, the exposed worker needs to be tested shortly after exposure. This limitation may impose inconvenient testing times, depending on the time of the worker's last exposure relative to when the employee is, for example, to go to lunch or to go home.

sentative of the average exposure, some data suggest that samples taken shortly after exposure represent the latest exposure level and not an average.[183] Also, because chemicals are excreted at different rates, decay curves need to be developed for all chemicals for which exhaled air analysis will be conducted. There is a related need to gather accurate data on exposure time, as that measurement is necessary to calculate exposure from the developed decay curves.[184] Finally, problems remain in determining the appropriate time to sample as well as in developing satisfactory sampling and analytical methods.[185]

Physiological factors like blood concentration and solubility of the index chemical in tissues and fat may affect exhaled air levels of the exposure chemical. This article does not discuss the fundamental physiological concepts related to post-exposure air concentrations.[186] There are also non-physiological factors that can affect the index chemical concentration in exhaled air, causing variability in results.[187]

To date, OSHA has promulgated no standards requiring expired air analysis as part of a biological monitoring scheme. Even though the analysis has been used as a biological monitor for benzene,[188] the remanded OSHA benzene standard did not provide for it.

Collecting blood samples is another biological monitoring practice conducted to determine toxic chemical exposure to a particular substance. Most commonly, this analysis has been employed to measure carbon monoxide exposure, using carboxyhemoglobin levels as an index, or pesticide exposure, using cholinesterase levels as an index, and to test directly for metals such as lead and cadmium.

The principal limitation on this type of biological monitoring is that the procedure for obtaining a specimen is an invasive one.[189] This can make it difficult to obtain full worker participation and to acquire speci-

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183. Stewart, Hake & Peterson, *Use of Breath Analysis to Monitor Trichloroethylene Exposures*, 29 ARCHIVES ENVTL. HEALTH 6, 6 (1974).

184. Waritz, *supra* note 158, at 302.

185. *Solvents*, *supra* note 30, at 408.

186. For a discussion of these concepts, see Waritz, *supra* note 158, at 296.

187. Non-physiological factors that can cause variability in the concentration of index chemicals in expired air include:

(1) non-workplace progenitors of the index chemical (e.g., perhaps the chemical entered the bloodstream prior to workplace inhalation; also, it is not possible to detect if the breath sample of the chemical came from the bloodstream or the mouth);

(2) respiratory rate — until the chemical is in equilibrium in the body, respiratory rate can affect the rate of uptake (e.g., increased uptake with increased respiration when body compartments are not saturated);

(3) sex — males and females are reported to have different absorption coefficients; and

(4) skin absorption of the exposure chemical — kinetics in the lung for some solvents may differ between skin absorption exposure and exposure via inhalation.

*See id.* at 297.

188. L. Lave & E. Callison, An Economic View of Biological Monitoring in the Workplace 11 (paper presented at the Luxembourg Seminar, *supra* note 29).

189. *See supra* text accompanying note 157.

mens frequently. In addition, blood containers and collection devices must usually be selected for a *specific* application.[190]

The OSHA lead standard is the only health standard that requires blood analysis as a biological monitoring tool. A blood lead level determination for workers who are or may be exposed to more than thirty micrograms of lead per cubic foot of air, averaged over eight hours, is a component of the medical surveillance provisions.[191] The *NIOSH/OSHA Occupational Health Guidelines* recommends biological monitoring blood analysis for substances like carbon monoxide and pesticides like endrin and parathion.[192] Blood analysis as a biological monitoring technique for cadmium also has been studied, but there is no consensus about the goodness of the test.[193]

In addition to the need to develop analyses for chromosomal alterations,[194] the Committee on Science, Engineering and Public Policy, a joint committee of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, has identified a further need to develop analyses of expired air, blood, and urine as a means for evaluating exposure.[195] Potential applications for these indicators include use to increase the power of epidemiologic studies[196] and use as a tool to assess the consequences of human exposure in industrial settings.[197]

The terms "biologic threshold limit values"[198] and "biological permissible limits" (BLVs)[199] refer to the concept of measuring levels of the

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190. R. BASELT, *supra* note 162, at 2. For example, some anticoagulants present in collection tubes interfere with the determination of the substance to be measured (e.g., fluoride is a good anticoagulant but it has been observed to inhibit enzymes such as cholinesterase).

191. 43 Fed. Reg. 53,010 (1978); 29 C.F.R. § 1910.1025(j)(1)(i) (1983).

192. NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19.

193. Some observers believe that "in occupationally exposed persons, cadmium levels in blood is [sic] a good indicator of the average intake during recent months but not of body burden nor of the most recent exposure." R. Lauwerys, *supra* note 173, at 11–12. Others agree that cadmium in the blood is a poor index of body burden but hold that blood concentrations reflect recent exposure. H. Perry & E. Perry, *supra* note 173, at 11. The Luxembourg Report concludes that cadmium in the blood is a good biological indicator for estimating both the body burden of cadmium and the risk of health impairment. Luxembourg Report, *supra* note 4, at 201.

194. *See supra* note 112.

195. COMM. ON SCI., ENGINEERING AND PUBLIC POLICY, *supra* note 112, at 7. The Committee believes that the "development and validation of techniques of high sensitivity and specificity . . . [*see supra* text accompanying note 78] would be powerful tools for direct evaluation of human exposure to environmental chemicals and its impact on human health." The Committee cited the lack of available information to measure or verify actual human exposure as one rationale for the recommended research. According to the Committee, "[s]pecific *biologic markers* of human exposure (as an adjunct to *environmental monitoring*) [*see supra* text accompanying note 31] . . . offer a great opportunity to improve the ability to assess the effects of chemicals . . . ." *Id.* (emphasis added).

196. *See infra* text accompanying notes 226–227.

197. COMM. ON SCI., ENGINEERING AND PUBLIC POLICY, *supra* note 112, at 7.

198. Elkins, *Excretory and Biologic Threshold Limits*, 28 AM. INDUS. HYGIENE ASS'N J. 305, 307 (1967).

199. Zielhuis, *supra* note 154, at 13.

exposure chemical or its metabolites or both in biological specimens that correspond to the permissible air limits of exposure. The American Conference of Governmental Industrial Hygienists (ACGIH) defines BLVs as values representing "limiting amounts of substances (or their effects) to which the worker may be exposed without hazard to health or well-being as determined in *his* tissues and fluids or in *his* exhaled breath."[200] According to the ACGIH, the BLVs and their associated compliance procedures "should thus be regarded as an effective means of providing health surveillance of the worker."[201]

The ambient analogue of BLVs is the familiar threshold limit values (TLVs), which are "the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect."[202] The ACGIH states that BLVs may be used as an adjunct to or *in place of* TLVs.[203] The rationale for the adoption of BLVs is that

> there are situations where air analyses, in combination with the atmospheric TLV, are not adequate to evaluate precisely the peril of the hazard, since the amount absorbed cannot be predicted from the data obtained by such determinations. In such situations, it is highly desirable to have other means of estimating exposure. With many substances this can be done by analyzing suitable biologic specimens or excretion products for the toxic agent or a metabolite derived therefrom.[204]

Scientists are in widespread agreement as to the need to develop biologically permissible levels for toxic substances.[205] As a result, some are undertaking efforts to develop such levels. For example, participants at the Luxembourg Seminar identified the need for consistent international biological indicator levels.[206] In a survey of nine European countries, conducted in 1980, the seven governments that responded answered

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200. THRESHOLD LIMIT VALUES, *supra* note 171, at 8.

201. According to the ACGIH, biologic measurements on which the BLVs are based can furnish two kinds of information useful in the control of worker exposure:

(1) Measuring the individual worker's overall exposure. This measurement can be obtained by: (a) determining in blood, urine, hair, nails, body tissues and fluids, the amount of the substance to which the worker was exposed; (b) determining the amount of the metabolite(s) of the substance in tissues and fluids; and (c) determining the amount of the substance in the exhaled air.

(2) Measuring the worker's individual and characteristic response. These measurements provide a good assessment of the physiologic status of the worker and include: (a) changes in the amount of some critical biochemical constituent; (b) changes in activity of a critical enzyme; and (c) changes in some physiologic function.

*See id.* at 8–9.

202. *Id.* at 3.

203. *Id.* at 9.

204. Elkins, *supra* note 198, at 306–07.

205. Zielhuis, *supra* note 154, at 13.

206. Otherwise, they reported, "it would be highly detrimental to workers' faith in occupational health and safety programs designed to protect worker health, if [they] varied

affirmatively the question: "Does your department consider to introduce [sic] in the future *biological 'standards'* for some agents, which will have in your country about the same significance as standards for concentration in air (e.g., mean air concentration, TLV)?"[207] Biological threshold limit values have been established for nineteen cyanogenic chemicals[208] and suggested for three pesticide absorption and response levels.[209]

Although enthusiasm for developing BLVs is growing, some serious issues regarding the development and use of BLVs must be addressed. First, what is a "normal" limit?[210] "Normal" may be considered to be a "statistical expression [of a distribution] of a large number of individual responses."[211] Comparing an individual value to general norms, however, may result in false negative results.[212] Alternatively, a BLV could be set high enough to eliminate all "normal" values, but then some overexposed workers might never reach it.[213] The limit could also be set at a level that included many people who had not been overexposed to the workplace chemical, but this option would require later confirmation that elevated levels were in fact due to workplace exposure.[214]

The problem lies in trying to devise a single value (or fence) as the dividing line between normal and abnormal test results. Attempts to do so are usually flawed methodologically. In addition, one researcher has found that clinical studies on the relationship between uptake and quantitative changes in the proposed biological parameter are still insufficient, making definition of meaningful BLVs not yet possible.[215]

Two other important considerations involve the goodness of the tests and individual variability. Before any BLVs are determined, the ability of the test to provide accurate, reproducible results with adequate sensitivity, specificity and predictive value must be demonstrated.[216] Many factors may cause variability of response to a given substance including

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with place of employment or when crossing national boundaries." Luxembourg Report, *supra* note 4, at 202. "Where the threshold limit values in air are well documented and the absorption balance, biotransformation pathways and elimination kinetics of [the] pollutant and its metabolic products are known, then the biological limit can be derived from the experimentally established relationship between pollutant concentrations in air and in biological material." Bardodej, *supra* note 155, at 338.

207. Zielhuis, *supra* note 154, at 5–6. The seven European governments that provided positive responses were Denmark, France, the Federal Republic of Germany, Great Britain, Ireland, Italy and the Netherlands.

208. Linch, *Biological Monitoring for Industrial Exposure to Cyanogenic Aromatic Nitro and Amino Compounds*, 35 AM. INDUS. HYGIENE ASS'N J. 426, 430 (1974).

209. Zielhuis, *supra* note 154, at 15.

210. *See supra* note 82 and accompanying text.

211. E. CALABRESE, METHODOLOGICAL APPROACHES TO DERIVING ENVIRONMENTAL AND OCCUPATIONAL HEALTH STANDARDS 243 (1978).

212. *Id.*

213. Waritz, *supra* note 158, at 287.

214. *Id.*

215. R. LAUWERYS, *supra* note 26, at 4.

216. *See supra* Table 2 and accompanying text.

pre-existing disease, nutritional status and prior exposures.[217] Furthermore, many workplace substances are not suitable for biological threshold limit determinations.[218]

To date, OSHA's lead standard is the only standard that requires adherence to a biological threshold limit value.[219] The biologically permissible limit for lead in the blood is fifty micrograms of lead per 100 grams of blood. The remanded OSHA benzene standard provided for a urinary BLV of seventy-five milligrams of phenol per liter of urine.[220] In addition, NIOSH has recommended a urinary BLV for fluoride.[221]

Although the idea of establishing BLVs is attractive, the seriousness of the limitations of the concept cannot be ignored. If BLVs are eventually established, based on reliable and accurate tests, then they should be used as an adjunct to medical surveillance testing and environmental monitoring, but certainly *not* in place of either one.

### *C. Frequency and Timing of Exams*

The decision as to when to administer tests to workers in the employment cycle is usually determined by OSHA regulations, by management alone, or as a result of an agreement between management and labor. Tests most commonly conducted in the employment cycle include:

— pre-employment
— pre-placement
— periodic
— post-illness or injury
— episodic
— termination or retirement

The twenty-three OSHA health standards provide for testing on some of these occasions, and the *NIOSH/OSHA Occupational Health Guidelines* provides substance-by-substance recommendations on when to test.[222] Table 3 provides categories for the general application of the tests relative to the four types of human monitoring.

The decision as to when to conduct testing should be considered on a substance-by-substance basis. The rate of metabolism of the

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217. *See infra* text accompanying notes 258–318. Various environmental and biological factors may modify the concentration of the chemical or its metabolite in biological media. Accordingly, these factors must be considered when interpreting results. R. LAUWERYS, *supra* note 26, at 5.

218. Elkins, *supra* note 198, at 307–09.

219. 29 C.F.R. § 1910.1025(k)(1)(i)(D) (1983).

220. Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607 (1980).

221. FLUORIDE CRITERIA DOCUMENT, *supra* note 167, at 3.

222. NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19.

Table 3: Temporal Characteristics of Tests for the Four Types of Human Monitoring

| | Medical Surveillance | Genetic Monitoring | Genetic Screening | Biological Monitoring |
|---|---|---|---|---|
| Pre-Employment | X | | X | X |
| Pre-Placement | X | X | X | X |
| Periodic | X | X | | X |
| Post-Illness or Injury | X | | | X |
| Episodic | X | X | | X |
| Termination/Retirement | X | | | |

substance[223] and the natural history of the disease caused by exposure to that substance[224] must be factored into the decision.

From 1972 to 1974, data were collected from 5000 U.S. workplaces for the first NIOSH National Occupational Health Survey. The survey included workplaces representing a range of plant sizes and industry types. It provided information on the percentage of workers in the study population receiving pre-employment, pre-placement, periodic, post-illness and termination exams.[225] What is done with the information gathered during these procedures? So far, the data obtained from screening workers has not been well coordinated or analyzed, either in isolation or in conjunction with other worker information (e.g., exposure data).[226]

223. Metabolic rates for chemicals vary from individual to individual and from substance to substance. The time between exposure to a certain agent and the appearance of the agent or its metabolite in the urine may vary from a few hours to days. For example, not until 42 to 69 hours after exposure to trichloroethylene does the metabolite trichloroacetic acid peak in the urine. Ogata, *supra* note 161, at 390. In this case, urinary biological monitoring would not be useful if conducted on those exposed workers at the end of a shift.

224. Asbestos-related pulmonary diseases usually appear no sooner than 15 years after first exposure. OCCUPATIONAL HEALTH: RECOGNIZING AND PREVENTING WORK-RELATED DISEASE 164 (B. Levy & D. Wegman eds. 1983) [hereinafter cited as OCCUPATIONAL HEALTH]. Therefore, screening for asbestos disease in the first year of exposure would be highly unlikely to detect an asbestos-related pulmonary illness. Analyzing data gathered from populations for which the latency period (time between exposure and the development of disease) has not yet "ripened" may lead an observer to conclude, based on analysis of the data, that no occupationally related disease exists among the workers. This finding cannot be adopted with confidence, as the natural history of the disease relative to the exposure substance has not been considered. The workers may in fact have a dormant occupationally related disease that will be detected clinically or symptomatically after the latency period is reached or exceeded.

225. J. Ratcliffe, The Usefulness of Medical Screening Examinations in the Prevention of Occupational Diseases 2 (1982) (unpublished paper prepared for the National Institute for Occupational Safety and Health).

226. According to OSHA, "most companies have no mechanism (such as a unique identifying number) to permit easy linkage of medical and work history records, job de-

The data could be used for epidemiological (i.e., relating to morbidity, mortality) and biostatistical analyses as well as integrated with industrial hygiene data.[227]

The OSHA standards provide little guidance on what to do if an abnormal testing result is observed. Only the asbestos,[228] vinyl chloride,[229] cotton dust[230] and lead[231] standards mention any action to be taken based on abnormal human monitoring results. The remanded benzene standard provided guidance for further testing based on urinary phenol trigger levels,[232] and the recently proposed ethylene oxide standard recognizes the possibility of medical removal of the worker at a physician's discretion, as a means of placing "recommended limitations on the employee's exposure."[233] The asbestos, vinyl chloride, and cotton dust standards contain provisions for medical removal, and the lead standard contains provisions for medical removal protection.[234] The OSHA Final Rule, "Access to Employee Exposure and Medical Records," considers information gathered in the different testing schemes as part of the employee's medical record.[235] The components of the record include data obtained from any and all of the testing schemes.[236]

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scriptions, exposure data and medical test results." U.S. DEP'T OF LABOR, AN INTERIM REPORT FOR CONGRESS ON OCCUPATIONAL DISEASES 120 (1980).

227. According to the Occupational Medical Practice Committee of the American Occupational Medical Association,

> [w]hen appropriate, these data should be used to conduct epidemiological studies to assess the effects the workplace may have had or is having on the employees . . . . [T]he occupational health program must maintain occupational medical records on each employee, documenting the reasons for and the results of all physical examinations . . . . These data must be maintained confidentially . . . . [P]rocedures . . . allowing access to those with a bona fide need to know, must be developed.

Occupational Medical Practice Comm. of the Am. Occupational Medical Ass'n, *Scope of Occupational Health Programs and Occupational Medical Practice, Committee Report*, 21 J. OCCUPATIONAL MED. 497, 498–99 (1979) [hereinafter cited as *AOMA Comm. Report*].

228. 29 C.F.R. § 1910.1001(d)(2)(iv)(c) (1983).

229. *Id.* § 1910.1017(k)(5).

230. *Id.* § 1910.1043(f)(2)(v).

231. *Id.* § 1910.1025(k).

232. *See supra* note 166 and accompanying text.

233. 48 Fed. Reg. 17,312 (1983).

234. The distinction between medical removal and medical removal protection is important. *See supra* note 64.

235. 45 Fed. Reg. 35,278 (1980).

236. OSHA defines "employee medical record" as follows:

> (6)(i) 'Employee medical record' means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other health care personnel, or technician, including:
>
> (A) medical and employment questionnaires or histories (including job description and occupational exposure),
>
> (B) the results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including X-ray examinations and all biological monitoring),
>
> (C) medical opinions, diagnoses, progress notes, and recommendations,
>
> (D) descriptions of treatments and prescriptions, and
>
> (E) employee medical complaints.

*Id.*

A pre-employment exam is generally a routine procedure (like the familiar check-up exam given by a family doctor), frequently made a condition of employment. The purposes of conducting a pre-employment exam include: (1) to establish a baseline of medical testing results that can be used for comparison against future results; (2) to determine if the individual can physically perform the intended work; and (3) to determine whether there is any health condition that might require special precautionary care or job placement consideration.[237] A pre-employment exam commonly includes a medical history (including any pre-existing disease), selected medical information about the worker's parents, a smoking history, a physical exam, and routine medical surveillance tests like blood analysis, urinalysis and chest x-ray. If appropriate, baseline biological monitoring tests and pulmonary function tests may be conducted.

An occupational history is also a component of a thorough pre-employment exam. *The importance of a complete occupational history cannot be stressed enough.* Unfortunately, it often is overlooked, or the history consists of only the title of the employee's last job. Such incompleteness is not adequate to determine the work-relatedness of disease for either epidemiologic or legal purposes. While routine medical surveillance tests can raise suspicion or help confirm that a disease or injury is work-related, "ultimately it is information obtained from an occupational history that determines the likelihood that a given medical problem is work-related."[238] A complete *occupational history* should include: a description of all jobs held; work exposures; the timing of symptoms; the occurrence of symptoms or illness among other workers; and any non-work exposures and other factors (e.g., alcohol, smoking, location of residence).[239]

A pre-placement exam is conducted when an already employed worker is assigned to a particular job where certain exposures may be new or different from those associated with a current job. In some instances, a pre-placement exam can be the same as a pre-employment exam, depending on job assignment.

A pre-placement exam has basically the same purposes as those outlined above for a pre-employment exam.[240] According to the Occupational Medical Practice Committee of the American Occupational Medical Association, a pre-placement exam is considered to be an essential part of an occupational health program. It should include an assessment of health status and emotional status in order to ensure that the person can perform a job safely and efficiently without endangering the person's safety or health and that of others.[241] The recommendations made to

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237. *Genetic Screening and the Handling of High-Risk Groups in the Workplace, 1981: Hearings Before the Subcomm. on Investigation and Oversight of the House Comm. on Sci. and Technology*, 97th Cong., 1st Sess. 12 (1981) (statement of Everett Dixon, M.D.) [hereinafter cited as *Genetic Screening Hearings*].

238. OCCUPATIONAL HEALTH, *supra* note 224, at 29.

239. *Id.* at 30–34.

240. *Genetic Screening Hearings*, *supra* note 237, at 12.

241. *AOMA Comm. Report*, *supra* note 227, at 498.

management by a physician before job placement should be based on: (1) a medical history; (2) an occupational history (including a complete account of past work performed); (3) an assessment of organ systems likely to be affected by the assignment; and (4) an evaluation of the description and demands of the job under consideration.[242]

The components of a pre-placement exam must be valid and reliable[243] and any abnormal findings must have a relationship to an adverse health effect. In some instances, these two criteria are not met, and the tests are used improperly as a discriminatory tool. Discrimination in this context can be on an individual[244] or group basis.[245]

Periodic examinations are conducted most commonly on an annual or semi-annual basis for workers who are exposed to known health hazards via skin absorption, inhalation or ingestion.[246] These examinations should give special attention to target organs or bodily organ sys-

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242. *Id.*

243. *See supra* text accompanying note 78.

244. Low back pain is a common complaint among workers from many occupations, but it is most commonly associated with lifting and materials handling. For workers applying for physically demanding jobs, it has not been unusual for a low back x-ray to be included as part of a pre-placement exam. It was believed that abnormalities detected on x-ray served as predictors of future back injuries. The current opinion on this practice is that defects discovered on x-ray "are not etiologically related to the soft-tissue injuries of the back presented by workers." Felton, *The Industrial Medical Department*, in ENVIRONMENTAL AND OCCUPATIONAL MEDICINE 945 (W. Rom ed. 1983). Because developmental defects have no demonstrated predictability for future back injuries, the procedure served only to expose the job applicant to unnecessary doses of ionizing radiation. In addition, if employers incorrectly believed that any abnormal findings were linked to future back injuries, those workers having defects on their x-rays would probably not be hired for the job. To state it another way, those workers would be discriminated against for hiring or transfer purposes so as to protect the employer from liability in case of injury. This is discrimination on an individual basis.

245. Genetic screening as part of a pre-placement exam serves as an illustration of the possibility of discrimination on a group basis. For example, the DuPont Company, the thirteenth largest employer in the United States, routinely screens blacks for sickle-cell trait. Severo, *Screening of Blacks by Dupont Sharpens Debate on Gene Tests*, N.Y. Times, Feb. 4, 1980, at 1, col. 5. The company believes that sickle cell trait in combination with certain chemical exposures causes blood oxygen levels to decrease. At DuPont's largest plant, in Deepwater, New Jersey, Italian workers comprise the largest single ethnic group employed. *Id.* at 13, col. 1. Italians are a group ethnically linked to genetic traits for both beta thalassemia and G-6-PD deficiencies, and these genetic traits are believed to surpass the sickle-cell trait as health risks. In spite of this fact, the Mediterraneans received no genetic testing. Even though only 0.2 of 1% of American blacks develop sickle cell anemia, the blacks were the only ones tested for genetic traits. *Id.* at 13, col. 1. (Recall that OTA has determined that the state-of-the-art for genetic screening is not developed enough at this time to justify screening in the workplace.) In the future, however, the screening methods may become more scientifically valid and reliable. Even if the technology for genetic screening is improved to the point of workplace implementation, the very real and disturbing possibility of more group discrimination seems likely. *See generally infra* text accompanying notes 489–549.

246. The 23 OSHA standards all require periodic examinations, usually annually or semi-annually. The *NIOSH/OSHA Occupational Health Guidelines* (see *supra* note 19) recommends periodic testing, with the timing determined on a chemical-by-chemical basis.

tems that are most likely to be affected.[247] The testing intervals should be designated on a substance-by-substance basis so as to detect any adverse health effects early enough to permit remedial action and preclude lasting consequences.[248] Understanding the natural history of an occupationally related disease is of prime importance in determining the appropriate tests and testing intervals for workers exposed to specific substances. Both should be selected with reference to specific risks associated with certain exposures or occupations.[249]

The health status of a worker should be determined after an absence from work because of injury[250] or illness.[251] This determination will ensure

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247. *See AOMA Comm. Report, supra* note 227, at 498.

248. *Genetic Screening Hearings, supra* note 237, at 12.

249. For example, consider a non-smoking worker who will be exposed to chronic low levels of sulfur dioxide ($SO_2$). Studies show that $SO_2$ is very irritating to the mucous membranes of the upper respiratory tract, where 90% of the $SO_2$ is absorbed. OCCUPATIONAL DISEASES, *supra* note 173, at 437. There is only slight $SO_2$ penetration in the lower respiratory tract (i.e., lungs). 40 Fed. Reg. 54,520–21 (1975). To date OSHA has not promulgated a sulfur dioxide rule. Beliles, *OSHA Occupational Health Standards and the Sensitive Worker,* 3 ANNALS AM. CONFERENCE GOVTL. INDUS. HYGIENISTS 71, 75 (1982). Pulmonary response to low-level $SO_2$ includes broncho-constriction accompanied by increased pulmonary resistance. Therefore, workers exposed to low-level sulfur dioxide should have a pre-employment/pre-placement chest x-ray and pulmonary function tests in order to obtain baseline data measurements. Subsequent periodic exams should continue to include pulmonary function tests, comparing those results to the baseline measurements. Annual chest x-rays, however, for the purpose of detecting occupationally-related pulmonary disease related to low-level $SO_2$ exposure are not appropriate, as pulmonary function tests better determine the pulmonary pathology induced from sulfur dioxide. 40 Fed. Reg. 54,530 (1975). Consideration should also be given to smoking habits and exposures to other pulmonary irritants in both pre-placement and periodic exams. OCCUPATIONAL DISEASES, *supra* note 173, at 437.

In 1979, the Canadian Task Force on the Periodic Health Examination conducted a study on the usefulness of annual health examinations. Canadian Task Force on the Periodic Health Examination, *The Periodic Health Examination,* 121 CANADIAN MED. ASS'N J. 1193 (1979). The Task Force found insufficient justification to continue conducting annual exams and recommended that periodic exams be substituted in their place. Some of the conditions for which there was sufficient scientific evidence to warrant periodic examination include: (1) smoking — workers in asbestos, silica, uranium, coal and grain industries; (2) cancer of the bladder — smokers and workers exposed to bladder carcinogens; (3) cancer of the skin — outdoor workers and others in contact with polycyclic aromatic hydrocarbons; and (4) tuberculosis — those exposed to the disease through work.

250. The logging industry provides an example of testing after injury. NIOSH recommends that those workers employed in logging (from felling to first haul), who are absent for five or more days due to injury, receive a medical exam upon return in order to determine fitness. BioTechnology, Inc., OSHA Medical Surveillance Requirements and NIOSH Recommendations for Employees Exposed to Toxic Substances and Other Work Hazards (1980) (report prepared for the NASA Occupational Health Office).

251. The OSHA lead standard contains provisions for blood lead level testing before the return (to former job status) of workers who were removed because of high blood lead levels or other medical determinations. 29 C.F.R. §§ 1910.1025(k)(1)(iii)(A)(1)–(3) (1983). Depending on the blood lead level that caused the employee to be removed, the employee can be returned to former job status after two consecutive blood samples indicate that the employee's blood lead is at or below a specified level. An employee removed based on a medical determination can also be returned when it is medically determined that "the

that the worker has sufficiently recovered from the illness or injury to perform the job without undue risk to the individual or others, and that the worker is not taking any medication that increases the risk of illness or injury in the workplace.[252]

For the purposes of this discussion, episodic exams are those appropriate human monitoring tests that are administered after an emergency exposure, such as an accidental spill. Vinyl chloride[253] and 1,2-Dibromo-3-chloropropane (DBCP),[254] two OSHA standards, serve as examples for such testing following an emergency during employment.

An employee's health status should be evaluated upon termination or retirement. The employee should be informed concerning his or her health status and advised of any adverse health effects from his or her job.[255] Termination exams, also referred to as exit examinations, are required by several OSHA health standards.[256] Some NIOSH Criteria Documents provide recommendations, not requirements, for termination or retirement exams.[257]

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employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead." *Id.* § 1910.1025(k)(1)(iii)(A)(4).

252. *AOMA Comm. Report, supra* note 227, at 498.

253. Subpart 3 of the medical surveillance provisions of the vinyl chloride standard states that "each employee exposed to an emergency shall be afforded appropriate medical surveillance." 29 C.F.R. § 1910.1017(k)(3) (1983). An "emergency" in the vinyl chloride standard is defined as "any occurrence such as, but not limited to, equipment failure, or operation of a relief device which is likely to, or does, result in massive release of vinyl chloride." *Id.* § 1910.1017(a)(5).

254. Subpart 6 of the medical surveillance provisions of the DBCP standard states that "[i]f the employee is exposed to DBCP in an emergency situation, the employer shall provide the employee with a sperm test as soon as practicable . . . . The employer shall provide these same tests three months later." *Id.* § 1910.1044(m)(6). The "emergency situation" provision also contains specific requirements for those workers who have had a vasectomy or are unable to produce a sperm specimen. In this standard, an "emergency" is defined as "any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may, or does, result in an unexpected release of DBCP." *Id.* § 1910.1044(b).

255. *AOMA Comm. Report, supra* note 227, at 498.

256. Workers who are covered by the arsenic, 29 C.F.R. § 1910.1018(n)(3)(iii) (1983), coke oven, *id.* § 1910.1029(j)(3)(iv), or acrylonitrile, *id.* § 1910.1045(n)(3)(ii), standards and have not received medical exams within six months of terminating employment must have such examinations available to them before termination. Employees covered by the asbestos standard are to have exit exams within 30 calendar days before or after terminating employment. *Id.* § 1910.1001(j)(4).

257. For example, NIOSH recommends that workers engaged in the manufacture and formulation of pesticides have a comprehensive medical exam within one month after the end of employment. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, PUB. NO. 78-174, CRITERIA FOR A RECOMMENDED STANDARD . . . OCCUPATIONAL EXPOSURE DURING THE MANUFACTURE AND FORMULATION OF PESTICIDES 10 (1978). A termination exam is recommended for workers exposed to toxicants in coal gasification plants if no comprehensive medical exam was conducted within the preceding calendar year. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, PUB. NO. 78-191, CRITERIA FOR A RECOMMENDED STANDARD . . . OCCUPATIONAL EXPOSURES IN COAL GASIFICATION PLANTS 8 (1978).

The accuracy, reliability and predictive value of tests used in human monitoring vary greatly and may be especially sensitive to the timing of the exams. Because monitoring schedules must reflect both the need to track a variety of exposures and consequences and a concern for business or production constraints, a comprehensive industrial program for a workplace with multiple hazards and complex exposure patterns may be less-than-ideal on many counts.

## IV. Human Variability and High-Risk Groups

The rationale behind human monitoring is to identify those individuals or working populations that exhibit the early signs of occupational disease or the propensity to develop disease.[258] Individuals may differ in their responses to an increasing dose of a toxic substance. These individual responses contribute to a *population* dose-response curve, on which the percentage of the population affected is plotted against dose.[259] Those who react at low doses are the first to contribute to building up the incidence in the population.

Employer actions to change the work environment, provide alternative employment or suggest medical treatment ideally follow from the correct interpretation of monitoring results. The previous Part addressed the adequacy of tests and their interpretation. This Part discusses the application of monitoring results to the discovery of high-risk groups,[260]

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258. This monitoring can yield information important for standard setting to ensure that the permissible exposure limit protects all workers, or it can be used to encourage the removal of workers from a harmful environment. Section 20(a)(5) of the OSHAct authorizes the Secretary of Health, Education, and Welfare to "establish . . . programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the *susceptibility* of employees to such illnesses." 29 U.S.C. § 669(a)(5) (1982) (emphasis added). *See* R. Friedman, *supra* note 8.

259. *See infra* note 339.

260. Calabrese defines high-risk groups as "those individuals who experience toxic and/or carcinogenic effects significantly before the general population as a result of one or more biologic factors, including developmental influences [e.g., pregnancy, aging], genetic factors, nutritional inadequacies, disease conditions, and behavioral or life style characteristics." E. Calabrese, *supra* note 211, at 47. Levy and Wegman caution of the need to distinguish between hypersusceptibility and hypersensitivity. According to them, the term hypersusceptibility indicates

> an unusually high response to some dose of a substance. This term requires careful interpretation, however, because it is used in several different ways. It may refer to a genetic predisposition to a toxic effect; it may indicate a statistically defined deviation from the mean [average]; it may reflect an observer's subjective impression; or it may be used, incorrectly, as a synonym for hypersensitivity [which] is one form of hypersusceptibility, characterized by an acquired, immunologically mediated sensitization to a substance.

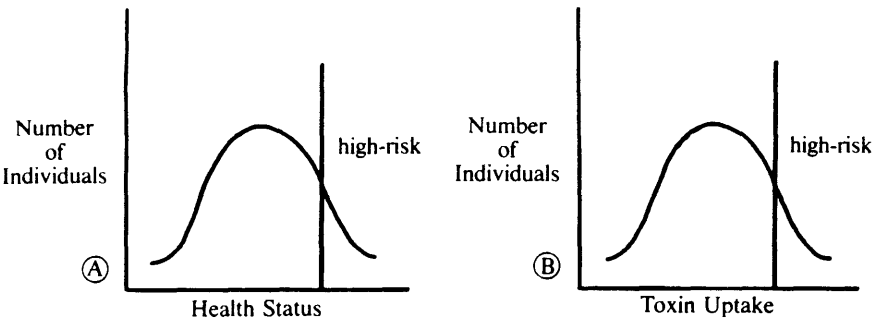
Occupational Health, *supra* note 224, at 134–35. Using this definition, workers at high risk may be considered to be hypersusceptible but not necessarily hypersensitive. To avoid confusion, this article refrains from using the term "hypersusceptible" in favor of using the term "high-risk."

the methodological limitations of the discovery process and the underlying causes of human variability. A monitoring activity is only a single snapshot that gives a measure of the specific chosen parameter at one time. Unless a sufficient number of successive snapshots are taken,[261] an incorrect interpretation and inappropriate remedial action may result.

### *A. Distribution of Monitoring Results and the Distinction between High-Risk and Hypersensitive Populations*

Monitoring activities yield one of two kinds of experimental data: a distribution of indicators of health status or a distribution of uptake

Figure 3: Distribution of Monitoring Results




indicators. Medical surveillance generally provides the first type of data and biological monitoring the second.[262] In the graph of each distribution, the vertical line represents a somewhat arbitrary fence separating the "high-risk" individuals from the remaining "normal" population. Remedial action concentrating on only the high-risk group is often misguided. More informative are the *changes* observed over time on an individual basis, because both "normal" and "high-risk" populations may shift over time as a result of continuing exposure. (See Figure 4.)

Often, remedial action taken for individuals not yet in the high-risk category may reverse or arrest a disease process that later may be difficult to affect significantly, if at all. Therefore, action directed exclusively toward the high-risk groups may result in the least effective preventive strategies.

The reasons that distributions of health status or toxin uptake occur lie in variations like current and past exposures, current health status,

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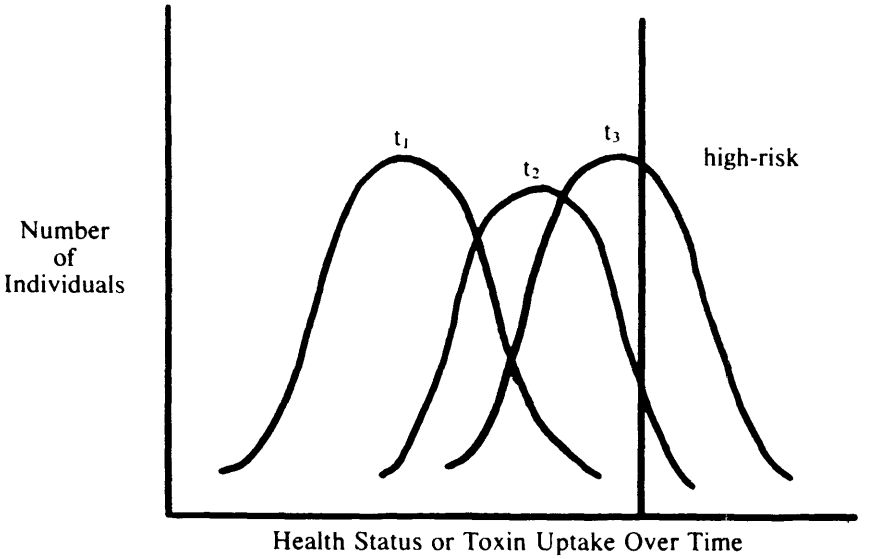
261. This stipulation relates to the timing of tests. *See supra* text accompanying note 223.

262. Examples are lung function results and lead uptake as reflected by blood lead levels, respectively.

Figure 4: Population Shifts over Time as a Result of Exposure



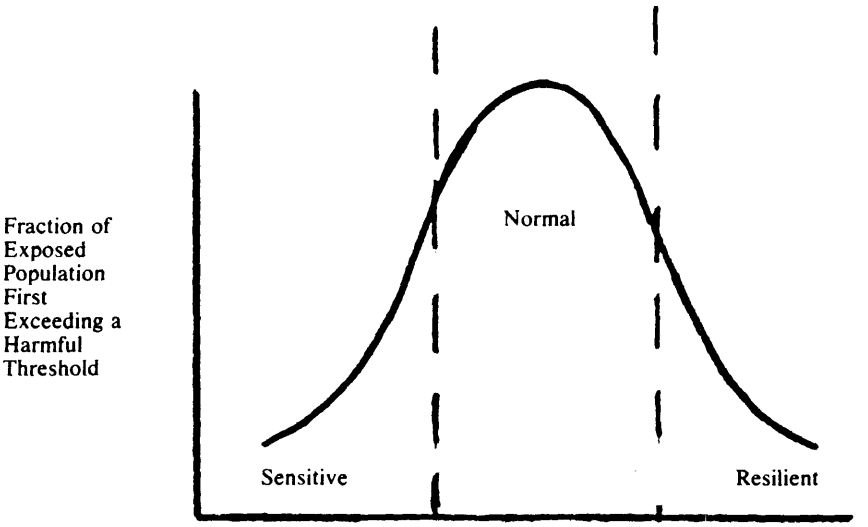

and "biological make-up." The distribution of "thresholds," the minimum dose necessary to exceed "normal" health status or "acceptable" toxin uptake, is shown in Figure 5. This graph represents the sensitivity distribution.

Those individuals who cross the normal fence for a health status indicator or toxin uptake indicator at low doses or exposure have been called sensitive or "hypersensitive"[263] individuals. They may or may not be in a high-risk group. The high-risk group may include those with greater exposure, prior disease, or a variety of other characteristics, as well as some who are hypersensitive.

The underlying causes of variability in sensitivity and variability of high-risk status are complex. Both sensitivity and an individual's position on a monitoring results distribution are dynamic. Hence, distributions are dynamic. An individual can be in the sensitive area one month and in the resilient area the next. Furthermore, sensitive populations may or may not comprise a significant portion of the high-risk group. This outcome is due in part to the fact that acute responses (revealed in monitoring results of health status or toxic uptake) may not be strongly correlated with human disease.

263. For a discussion of hypersensitivity, see OCCUPATIONAL HEALTH, *supra* note 224, at 134–35. *See also supra* note 260.

Figure 5: Sensitivity Distribution




### *B. Underlying Causes of Human Variability*

Different workers exposed equally to the same substance may exhibit differences in the results of both medical surveillance and biological monitoring. There are a number of factors that cause a wide distribution of testing results in a homogeneously exposed population, including factors that are determined by nature, factors somewhat in the control of the employee, and factors in the control of the employer. The following discussion of variability follows these three controlling factors and includes stochastic variability, genetic predisposition, age, sex, environmental factors (including behavioral/life style components), and pre-existing disease.

#### *1. Stochastic, Genetic, Age and Sex Variability*

Stochastic variability, which relies on the premise that population subjects are the same, includes differences in response or uptake occurring "by chance." In the simplest sense, it addresses variability based on biological differences.[264] Even though the amount, route, and duration of

264. The authors acknowledge the term "ecogenetics," which refers to studies of "genetically determined differences among individuals in their susceptibility to the action of physical, chemical, and biologic agents in the environment. The underlying biochemical mechanisms for such individuality may include differences in rates of metabolic activation and inactivation and variation in susceptibility of tissue enzymes or receptors." Omenn &

exposure can be controlled, "there is still likely to be a great deal of variation in the response of individual members of a population to a specific toxic agent. Some of this variation can be attributed to factors that influence the absorption, distribution, metabolism or excretion of the toxic agent . . . ."[265]

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Motulsky, *'Eco-genetics': Genetic Variation in Susceptibility to Environmental Agents*, in GENETIC ISSUES IN PUBLIC HEALTH AND MEDICINE 83 (B. Cohen, A. Lilienfield & P. Huang eds. 1978). Further,

> the field of human ecogenetics deals with the question of why only a certain proportion of exposed human beings will be injured by harmful environmental agents . . . . [T]he working hypothesis of ecogenetics is the concept that an individual's internal make-up will often determine the response to an environmental agent, particularly if not all human beings react equally to that particular agent.

Motulsky, *Ecogenetics: Genetic Variation in Susceptibility to Environmental Agents*, in HUMAN GENETICS, PROCEEDINGS OF THE FIFTH INTERNATIONAL CONGRESS OF HUMAN GENETICS, MEXICO CITY, OCTOBER 10–15, 1976 376 (S. Armendares & R. Lisker eds. 1977). The term by definition encompasses the concept of stochastic variability, but for purposes of this brief discussion, the authors have separated out the genetically determined biochemical mechanisms that affect rates of metabolism and excretion from those genetic traits that might be used for worker screening purposes (e.g., G-6-PD).

Recently, Hattis and Ballew have begun efforts to quantify observed stochastic variability in physiological parameters that determine susceptibility to the action of ordinary toxic agents. D. Hattis & M. Ballew, Human Variability in Susceptibility to Toxic Chemicals — I. A Preliminary Analysis of Pharmacokinetic Data from Normal Volunteers (Dec. 15, 1983) (manuscript submitted to the U.S. Envtl. Protection Agency, Envtl. Criteria and Assessment Office). They divide these physiological parameters into three broad groups:

> (1) Exposure-determining parameters that alter the dose taken into the body for a given concentration of chemical present in air, water or food. These include, for example:
> — Differences among people in breathing rates for a given amount of activity.
> — Behavioral differences such as dietary habits (people who eat a great deal of swordfish will tend to get a larger dose of swordfish mercury than people who do not).
> (2) Pharmacokinetic parameters that determine the relationship between the external dose and the concentration and length of time of the chemical in the blood or at its site of action in the body. Such parameters include internal body half-lives of chemicals.
> (3) Response parameters that determine differences in toxic responses, *after controlling for differences in the first two kinds of parameters*, that is, controlling for differences in concentration of chemicals in the blood for each unit of chemicals in the environment.

Hattis and Ballew reviewed data on the second group of parameters listed above for 32 chemicals from studies conducted in normal healthy adults. For the typical chemical, the variability in this restricted set of parameters was such that the most sensitive two percent of the normal healthy population would be expected to be about 1.8 times as sensitive as the median normal healthy person. For the four chemicals with the greatest inter-individual variation in the parameters studied, the most sensitive two percent of the normal healthy population would be expected to be over three times as sensitive as the median normal healthy person. It should be stressed that these data represent a minimal estimate of stochastic inter-individual variability because they exclude variability that would be produced by "exposure" and "response" type parameters.

265. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 70. In the review of studies related to solvent exposure, Gompertz accounts for variability in uptake by noting that "[e]xperimental studies have shown that uptake of any solvent depends on pulmonary ventilation . . . [the solvent's] solubility in blood and tissues and the relative size of adipose tissue [deposits]." *Solvents*, *supra* note 30, at 407.

The concept of biochemical individuality may also account for variability in testing results. According to Calabrese, "[o]verwhelming biochemical evidence has shown that each person has his/her own characteristic metabolic pattern, identifiable and recognizable by the activities of the enzymes involved . . . . Each . . . responds in an individualistic fashion to various toxic agents."[266]

Certain easily recognized genetic traits may cause a variation in response to toxic agents.[267] Genetic factors may also play a role in infectious resistance as well as adaptation to climate and high altitude in certain populations.[268] The mechanism accounting for the biologic variation may be the inherited structure of protein receptors, which causes abnormal reactivity to toxic agents or drugs.[269]

It is often difficult to distinguish genetic from environmental contributions to variability. According to one researcher, "a major problem in man is that most populations are markedly heterogeneous with respect both to environmental and genetic factors . . ." and "many environmental factors that alter rates of drug disposition do so by affecting genetic mechanisms . . . ."[270] Pharmacokinetic factors that control the results of clearance and metabolism of solvents are probably both genetically and environmentally determined.[271]

Approximately 150 genetic diseases have been identified in humans, and 26 of those were identified as having a "theoretical basis for causing enhanced susceptibility to toxicants."[272] Stokinger reported that only five genetically determined specific enzymes should be used to predict increased susceptibility to toxicants in industrial settings.[273] The OTA has reviewed genetic traits for screening,[274] but the extent to which these traits are responsible for occupational disease is unknown. It is believed,

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266. E. CALABRESE, *supra* note 211, at 243.

267. *See generally* Omenn, *Predictive Identification of Hypersusceptible Individuals*, 24 J. OCCUPATIONAL MED. 369 (1982). For example, individuals with G-6-PD deficiency are considered more susceptible (i.e., sensitive) to chemicals like aniline, methylene blue and naphthalene and to certain drugs like aspirin. OCCUPATIONAL HEALTH, *supra* note 224, at 359. When exposed to these agents, their red blood cells have a decreased capacity to carry oxygen. Also, serum alpha$_1$-antitrypsin deficiency has been linked to emphysema.' Omenn & Motulsky, *supra* note 264, at 89. *See also* E. CALABRESE, POLLUTANTS AND HIGH RISK GROUPS: THE BIOLOGICAL BASIS OF INCREASED HUMAN SUSCEPTIBILITY TO ENVIRONMENTAL AND OCCUPATIONAL POLLUTANTS 55 (1978).

268. Motulsky, *supra* note 264, at 383.

269. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 76. One researcher found that genetic factors are predominantly responsible for large inter-individual variations in drug disposition in twin (fraternal and identical) studies. Vesell, *Genetic and Environmental Factors Affecting Drug Disposition in Man*, 22 CLINICAL PHARMACOLOGY & THERAPEUTICS 659, 659 (1977).

270. Vesell, *supra* note 269, at 659.

271. *Solvents*, *supra* note 30, at 409.

272. E. CALABRESE, *supra* note 211, at 54.

273. Stokinger & Scheel, *supra* note 143, at 572–73.

274. *See supra* note 132.

however, that enhanced susceptibility to stressor agents due to genetic deficiency usually affects only minor subsegments of the population.[275]

Persons are more susceptible to adverse effects from environmental agents at certain ages.[276] Studies using laboratory animals of different ages have shown that "differences in the rate of drug metabolism have been shown in senescent animals and thus metabolic and excretion patterns may be contributing to toxicity variation at both extremes of the life-span rather than simply in the newborn."[277] Although at least one researcher has found that "age plays a small role in controlling the rate of elimination of certain drugs,"[278] others believe that the blood level and excretion following a given dose of a medicine changes with age. Because the metabolism and excretion of industrial chemicals use the same enzymes and excretion mechanisms, similar changes could be expected for industrial chemicals.[279]

Other changes occur with age. Blood pressure increases,[280] and individuals above the age of fifty may retain pollutants such as fluoride.[281] After adolescence, the immune system progressively degenerates, possibly increasing sensitivity to carcinogens and respiratory irritants.[282]

In humans, sex is a factor that might affect chemical concentration in expired air analysis.[283] Differences result from variations in total blood volume and extra-cellular fluid, affecting the rate of saturation of the chemical.[284] Another source of sex-related differences is that sex hormones influence the enzymatic biotransformation of an agent.[285]

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275. E. CALABRESE, *supra* note 211, at 54.

276. Section 20(a)(7) of the OSHAct directs the Secretary of Health and Human Services to "conduct and publish industry-wide studies of the effect of chronic or low level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in *aging adults*." 29 U.S.C. § 669(a)(7) (1982). The very young and the very old have enhanced susceptibility to respiratory infections. E. CALABRESE, *supra* note 211, at 47. Infants and children show differential absorption of pollutants such as barium, lead and radium as a function of age. E. CALABRESE, *supra* note 267, at 187; *see also* Redolfi, Borgogelli & Lodola, *Blood Level of Cimetidine in Relation to Age*, 15 EUR. J. CLINICAL PHARMACOLOGY 257, 257–61 (1979).

277. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 78.

278. Vesell, *supra* note 269, at 644.

279. Waritz, *supra* note 158, at 280, 282.

280. Tuthill & Calabrese, *Age as a Function in the Development of Sodium-Related Hypertension*, 29 ENVTL. HEALTH PERSPECTIVES 35, 35 (1979).

281. E. CALABRESE, *supra* note 267, at 187.

282. *Id.*; Doll, *An Epidemiological Perspective of the Biology of Cancer*, 38 CANCER RESEARCH 3573 (1978). To date, according to Bennett, "one can state that susceptibility to chemical carcinogenesis is associated with relative dysfunctions of the immune system and that age is important because it affects immune function." Bennett, *Effect of Age on Immune Function in Terms of Chemically Induced Cancers*, 29 ENVTL. HEALTH PERSPECTIVES 17, 20 (1979).

283. *See supra* note 187.

284. Waritz, *supra* note 158, at 298.

285. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 77. Animal studies show differences in toxicity based on sex. For example, aspirin and nicotine have been

*2. Environmental Factors*

This subsection treats behavioral and lifestyle factors as environmental factors. This discussion moves out of the area in which variables are controlled by "nature" and into an area in which the worker may be able to exert more control over exposures. Exposures to environmental factors are numerous and complex, making it "exceedingly difficult to attribute quantitatively different portions of the total interindividual variation to specific single environmental factors."[286] Environmental factors can cause variability in biological response, toxin uptake, or both.

Nutritional deficiencies may exacerbate the toxic effects of certain pollutants.[287] Dietary factors can influence toxicity by producing changes in body composition, physiologic and biochemical functions, and nutritional status.[288] Diet, particularly an unbalanced one, could alter enzymatic activity, leading to changes both in metabolism and in excretion of workplace chemicals.[289] Diets low in vitamin E can enhance toxicity to environmental agents, especially ozone, nitrous oxide,[290] and lead.[291] A vitamin E deficiency coupled with a G-6-PD deficiency may markedly enhance the toxicity of ozone to red blood cells.[292] Vitamin C deficiencies may enhance the toxicity of agents like carbon monoxide, arsenic, lead and mercury.[293] Persons deficient in riboflavin (30% of women and 10% of men aged 30–60 ingest less than two thirds of the recommended daily allowance) may exhibit enhanced toxicity to lead, ozone and hydrocarbon carcinogens.[294]

Alcohol is the most widely used and abused liver-damaging agent in the United States across all age ranges.[295] Persons who ingest large quantities of alcohol frequently have otherwise inadequate diets, particularly in B vitamins, which are necessary for normal liver maintenance.[296] Alcohol intake may also affect the absorption, metabolism or excretion of some nutrients.[297] Alcohol, metabolized in the liver, may damage that organ and thereby reduce the ability of the liver to deactivate toxins. For employees who drink alcohol and work with various chemicals like lead

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found more toxic to female than male rats, and epinephrine and digoxin have been found more toxic to male rats and dogs, respectively. There is also inconclusive evidence that benzene is more toxic to women than to men. Goldstein, Benzene Haematotoxicity 2 (paper presented at Luxembourg Seminar, *supra* note 29).

286. Vesell, *supra* note 269, at 659.

287. E. CALABRESE, *supra* note 211, at 55.

288. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 76.

289. Waritz, *supra* note 158, at 267.

290. Menzel, *Nutritional Needs in Environmental Intoxication: Vitamin E and Air Pollution, An Example*, 29 ENVTL. HEALTH PERSPECTIVES 105, 111 (1979).

291. E. CALABRESE, *supra* note 140, at 575.

292. *Id.* at 574.

293. E. CALABRESE, *supra* note 211, at 51.

294. *Id.* at 52.

295. E. CALABRESE, *supra* note 140, at 221.

296. *Id.* at 215.

297. *Id.*

or pesticides, toxicity may be enhanced.[298] Thus, alcohol may not only contribute to nutritional deficiencies, but also potentially cause damage to the liver, decreasing the ability of the body to detoxify workplace chemicals.

Adverse health conditions related to cigarette smoking, such as lung cancer, cardiovascular disease, chronic bronchitis and emphysema are well known. Cigarette smoking coupled with certain occupational exposures places workers at an even greater risk of developing disease. For example, significant exposure to cigarette smoke is associated with a risk of death from lung cancer that is eleven times greater than that to the general population.[299] Smokers working in occupations with asbestos exposures, however, have a risk fifty-five times as great.[300]

Workers may develop airway obstruction as a result of occupation alone (e.g., coal miners, firefighters and cotton textile workers). Those who smoke develop an even greater degree of airway obstruction than nonsmokers.[301] In addition, cigarettes may facilitate oral entry of some substances, such as lead, simply by contamination. Some substances that enter the body by cigarette contamination are chemically transformed by the heat of the cigarette, and workers may become ill after inhaling the combination of the transformed substance and cigarette smoke.[302]

A multitude of non-occupational agents may account for variability in observed responses and testing results. Those more or less under the direct control of the worker have already been mentioned. Environmental chemicals may alter the receptor for the toxic agent in the biologic test system or the absorption, distribution and excretion of the toxic agent.[303] Some of these environmental factors include outdoor and indoor air pollutants, drinking water contaminants and consumer products like household cleaning agents[304] and cosmetics. Exposures to these agents may cause allergic sensitization,[305] possibly resulting in exacerbated responses to workplace chemicals among some workers.[306]

Aside from causing allergic sensitization, environmental exposures may also burden the body with the same substance that the worker is being exposed to at work. For example, a particular blood lead level

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298. E. CALABRESE, *supra* note 267, at 193.

299. OCCUPATIONAL HEALTH, *supra* note 224, at 157.

300. *Id.*

301. Holbrook, *Cigarette Smoking*, in ENVIRONMENTAL AND OCCUPATIONAL MEDICINE 793 (W. Rom ed. 1983). The cilia, which are instrumental in clearing the lungs, may become paralyzed by cigarette smoke. *Id.* at 787–88.

302. *Id.* at 792–93.

303. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 82.

304. Swartz, *Litigating Household Caustics Injuries*, 88 CASE & COMMENT 3 (1983).

305. Sensitization is an immunologically mediated response that requires prior exposure or preconditioning. For example, the use of certain soaps or cosmetics may sensitize an employee to workplace agents that contact the skin, causing or exascerbating a dermatitis.

306. Steinberg, *ACGIH TLV's and the Sensitive Worker*, 3 ANNALS AM. CONFERENCE GOVERNMENTAL INDUS. HYGIENE 77 (1982).

measurement will generally reflect lead exposure from work, ambient air exposure to lead in gasoline, and dietary lead exposure. The most recent documented decrease in blood lead levels among workers in lead exposed industries resulted as much from decreases in ambient air lead concentrations due to the lowered lead content of gasoline as from decreases in occupational exposure.[307]

The influence of other less studied environmental factors on human responses to toxins is beginning to receive more attention. For example, emotional factors may "influence the susceptibility of man to toxic agents in his environment . . . [and] epidemiologists increasingly include consideration of such effects as urbanization, noise, adaptive response to change, and other social and economic pressure in the etiology of disease states associated with air and water pollution."[308] Growing experimental data indicate that environmental factors such as vibration, acceleration, and magnetism may influence biologic responses both in experimental animals and in man.[309] Increasing exercise can cause a considerable increase in solvent uptake simply by increasing the respiratory rate and volume of contaminated air inhaled.[310]

Some environmental exposures may lead not only to allergic sensitization but also to increased risk of disease or exacerbation of existing disease. For example, living near a hazardous waste site could increase the risk of certain diseases for local residents.[311] In atmospheres where there is a significant concentration of cigarette smoke coupled with poor ventilation, enough carbon monoxide may build up to exacerbate symptoms of angina pectoris (cardiac-related chest pain) and chronic obstructive pulmonary disease.[312] Peak levels of nitrous oxide have been observed in homes using gas stoves for cooking purposes.[313] This exposure could trigger an asthmatic attack in sensitive persons.[314]

### *3. Pre-Existing Disease*

Pre-existing disease can result from non-occupational origins as well as from past or current occupational exposures. Regardless of the origin, poor health, varying degrees of organ pathology and various disease conditions are likely to influence the toxic response in the exposed in-

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307. R. Goble, D. Hattis, M. Ballew & D. Thurston, Implementation of the Occupational Lead Exposure Standard (1983) (CPA-83-11) (Center for Policy Alternatives, Massachusetts Institute of Technology).

308. CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 78.

309. *Id.* at 79.

310. *Solvents*, *supra* note 30, at 407.

311. S. Lagakos, B. Wessen & M. Zelen, Synopsis: The Woburn Health Study, An Analysis of Reproductive and Childhood Disorders and Their Relation to Environmental Contamination (Jan. 1984) (Harvard School of Public Health study).

312. Holbrook, *supra* note 301, at 794.

313. Spengler & Colome, *The In's and Out's of Air Pollution*, 85 TECH. REV. 32, 41 (1982).

314. For example, "[n]itrogen dioxide within homes increases respiratory infections and decreases lung function in children." *Id.* at 37.

dividual.[315] Disease states may also significantly alter and conceal genetically controlled drug (and perhaps toxin) elimination.[316]

Persons with certain pre-existing diseases of non-occupational origin may increase the severity or frequency of their symptoms when exposed to certain workplace agents. For example, those with chronic respiratory disease or asthma may have their symptoms aggravated by respiratory irritants like ozone or sulfates.[317] Persons with coronary artery disease may find the condition exacerbated by stress or exposure to carbon monoxide, fluoride or respiratory irritants.[318]

Medical surveillance measures not only the effects of current occupational exposure, but also the deterioration of health status from occupational disease induced by prior employment. For example, a worker currently exposed to cotton dust may exhibit reduced lung function due to both current exposures and prior impairment caused by exposure to asbestos associated with work in construction.

## V. Consequences to the Worker from Medical Removal

The decision to remove a worker from a job is closely linked to the results of biological monitoring tests, medical surveillance tests, or a combination of the two. Realizing that the decision to remove a worker depends strongly on these results, one must assess again the appropriateness and validity of the test for the substance of concern.[319] For example, in a situation in which testing may give false positive results, workers incorrectly diagnosed as sick may be inappropriately removed. Conversely, asymptomatic workers who have false negative results may remain on the job when, in fact, they should be removed.

### *A. Medical Removal in OSHA Standards*

Of the twenty-four OSHA standards, only the vinyl chloride and lead standards discuss removal action based on medical surveillance or biological monitoring results. The asbestos and cotton dust standards contain medical removal provisions that apply only when a physician determines that a worker is unable to wear a respirator. This determination is based on the results of non-specified medical surveillance testing.

#### *1. Standards Requiring Removal Based on Medical Surveillance and Biological Monitoring Triggers*

The OSHA vinyl chloride standard, promulgated in October 1974, provides for medical removal. In the *medical surveillance requirements,*

315. Casarett and Doull's Toxicology, *supra* note 95, at 79.
316. Vesell, *supra* note 269, at 660.
317. E. Calabrese, *supra* note 367, at 192.
318. *Id.* at 193.
319. *See supra* notes 78 & 249 and accompanying text.

the standard states "[i]f any employee's health would be materially impaired by continuous exposure, such employee shall be withdrawn from possible contact with vinyl chloride."[320] The rule does not provide the employee with either job or economic security after removal. Employees might choose, therefore, not to consent to medical exams for fear of abnormal findings that would lead to loss of their jobs, temporary lay-offs, or transfers to a lower paying position. This non-specific removal policy differs very little, if at all, from the policy of a typical lead smelter. This policy states that an employee showing a blood lead level of eighty or above will be given a written warning notice and advised that his blood lead level must be returned to a level below eighty within the next ninety days. The employee's blood lead level will be checked each thirty days and he will be advised of the results. If at the end of the ninety day period the employee's blood level has not returned to less than eighty, excepting extraordinary mitigating circumstances, he shall be discharged.

The OSHA lead standard, promulgated in 1978, contains the most specific and stringent medical removal protection (MRP) provisions of any OSHA standard to date.[321] These MRP requirements are contained in a separate MRP section of the standard. They are the first provisions to be triggered by results of biological monitoring, not of medical surveillance alone.

The lead standard does not specify where a removed worker must be placed and states "practically any action is permissible provided the worker is not exposed to lead at or above the action level [30 $\mu g/m^3$]."[322] Removal options include reduction of hours worked, transfer to a job with reduced or no lead exposure, or temporary lay-off. No matter which option is selected, the standard requires that a removed worker receive MRP benefits. "[T]he employer shall maintain the earnings, seniority, and other employment rights and benefits of an employee as though the employee had not been removed from normal exposure to lead or otherwise limited."[323] The employer must provide these MRP benefits for up to eighteen months *each time* the employee is removed from lead exposure.[324]

Maintaining economic and employment benefits during removal is an attractive feature for workers. The employee does not risk continued exposure, and the guarantee of benefits encourages workers to participate in medical exams and biological monitoring. This incentive is one reason OSHA included MRP in the lead standard.[325]

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320. 29 C.F.R. § 1910.1017(k)(5) (1983).

321. *Id.* § 1910.1025(k).

322. 43 Fed. Reg. at 52,975 (1978).

323. 29 C.F.R. § 1910.1025(k)(2)(ii).

324. *Id.*

325. The agency stated that "[c]onvincing evidence presented during the lead proceedings established that many workers will either refuse or resist meaningful participation in medical surveillance unless economic protection is provided . . . . MRP was included in the final standard as a means of maximizing meaningful participation in medical surveillance provided to lead-exposed workers." 43 Fed. Reg. at 52,973.

An interesting distinction between the MRP provision of the lead standard and that of the asbestos standard[326] involves the availability of a comparable transfer job. While the MRP benefits for workers exposed to asbestos are contingent on the availability of a comparable position,[327] OSHA promulgated more stringent criteria in the final lead standard. The agency stated that "the standard by implication rejects industry suggestions that the provision of MRP benefits should be contingent upon the employer's ability to locate an available transfer position. Such an available position precondition would end MRP's role as a means of effectuating meaningful participation in medical surveillance."[328]

The removal provisions of the lead standard take individual variability into account and thereby recognize individual risk. The standard (as of March 2, 1983) provides a blood lead trigger level for removal of 50 μg/100 g, but not all workers will necessarily be safe with blood lead at that level. The standard provides for removing a worker whose lead levels remain *below* the threshold if a physician determines that, for medical reasons, the worker should have reduced or no lead exposure.[329] In such instances, removal would be triggered not necessarily or exclusively by biological monitoring results, but also by results of medical surveillance testing. Workers so removed are still entitled to full MRP benefits.[330]

*2. Standards Requiring Removal Based on Respirator Usage*

The OSHA asbestos standard, promulgated in 1972, contains an MRP provision in the personal protective equipment section for employees who cannot wear respirators, provided that a different job is available.[331] The regulation does not clarify what happens to a worker who is unable to wear a respirator when no alternative position exists. In that case, the worker may be limited to medical removal only, with no opportunity to retain wages or employment benefits. The asbestos standard does not specify what types of medical surveillance results trigger removal, where the removed worker is to go, what are the allowable exposure limits in the different job, when the worker can return, or whether he or she can return at all.

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326. *See infra* note 331 and accompanying text.
327. *Id.*
328. 43 Fed. Reg. at 52,976.
329. 29 C.F.R. § 1910.1025.
330. *Id.*
331. The provision states:

> No employee shall be assigned to tasks requiring the use of respirators if, based upon his most recent examination, an examining physician determines that the employee will be unable to function normally wearing a respirator, or that the safety or health of the employee or other employees will be impaired by his use of a respirator. Such an employee shall be *rotated* to another job or given the opportunity to transfer to a different position whose duties he is able to perform with the same employer, in the same geographical area and with the same seniority, status, and rate of pay he had just prior to such transfer, *if such a different position is available*.

*Id.* § 1910.1001(d)(2)(iv)(c) (emphasis added).

The respirator section of the OSHA cotton dust standard, promulgated in 1976, includes MRP provisions as well.[332] As with asbestos, these MRP provisions depend solely on the worker's inability to wear a respirator, as determined by an examining physician. Again, there is no link between the section in which the MRP provisions appear and the section describing the medical surveillance tests. In addition, the standard gives no criteria for removal. The MRP in this standard protects employment benefits more than the simple medical removal clause in the vinyl chloride standard, but not as much as the MRP provision in the lead standard.

On June 17, 1981, the Supreme Court upheld most of the cotton dust standard. The court remanded the MRP provisions,[333] however, stating that "the Agency has failed to make the necessary determination or statement of reasons that its wage guarantee requirement is related to the achievement of a safe and healthful work environment."[334] Since the remand, the agency has not reintroduced the MRP provisions for the cotton dust standard. Therefore, as of this writing, MRP is not legally required under the cotton dust standard.

*3. NIOSH/OSHA Guidelines on Removal*

The *NIOSH/OSHA Occupational Health Guidelines* provides substance-by-substance recommendations, not requirements, for the type and timing of medical surveillance and biological monitoring tests.[335] In following these guidelines, employers may, on their own initiative, choose to remove workers from exposure on the basis of test results. The guidelines provide no recommendations for medical removal protection.

### *B. Limitations of Medical Removal*

It is important to recognize that removing certain workers[336] only removes the "sensitive canaries."[337] Certain sensitive workers may sim-

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332. The provision states:

> Whenever a physician determines that an employee is unable to wear any form of respirator, including a power air purifying respirator, the employee shall be given the opportunity to transfer to another position *which is available* or which later becomes available having a dust level at or below the PEL [Permissible Exposure Limit]. The employer shall assure tha [sic] an employee who is tranferred due to an inability to wear a respirator suffers no loss of earnings or other employment rights or benefits as a result of the transfer.

*Id.* § 1910.1043(f)(2)(v) (emphasis added).

333. *Supreme Court Rejects Cost-Benefits, Upholds OSHA's Cotton Dust Standard*, 11 O.S.H. REP. (BNA) 54 (June 18, 1981).

334. American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 537–38 (1981).

335. *See supra* notes 45–46 and accompanying text.

336. The Threshold Limit Values Committee of the American Conference of Governmental Industrial Hygienists advocates removing the sensitive worker, rather than attempting to set a safe level for exposure. *See* Steinberg, *supra* note 306. For a discussion of OSHA's position on protecting sensitive workers, see generally Beliles, *supra* note 249.

337. Coal miners used to take caged canaries into the mines with them. When methane

ply exhibit symptoms or suspicious monitoring results earlier than the rest of the working population. "Like the proverbial canary in a coal mine, the most sensitive worker may herald dangers that will ultimately affect all workers."[338] Removing particular employees may therefore give a false sense of security to remaining and replacement workers. In addition, a false sense of security may develop from the unwarranted conclusion that because the risk to the removed individual is reduced, the risk to the work group as a whole is lessened.

Before considering a medical removal strategy, it is important to identify both the toxic substance of concern and the effects of exposure to given levels. Determining dose-response relationships[339] (especially at low doses), however, is an area of much debate. Frequently, human data are unavailable, and scientific studies on the substances involve only animals. Even the best available data do not allow an accurate determination of a threshold or no-response level.

Dose-response relationships are usually available for the response of a given population to an exposure to a *single* agent. In the workplace, workers are frequently exposed to multiple agents simultaneously. It is therefore difficult to ascertain which substance is responsible for the observed effect or to determine whether the response is due to the interaction of the multiple agents. Only when the dose-response curve has been approximated from the best available scientific evidence can one assess the usefulness of rotating workers.

The rotation of workers can, in some instances, cause more total disease. This result depends on both the substance and the shape of the curve. The rationale behind removing workers is that their exposure and risk of harm decreases. If the dose per worker were reduced from a high dose to a dose below the threshold, no worker would be at risk. If, however, the dose per worker were reduced to a level that is *above* the threshold, then each worker would still incur a finite, though lower risk. If replacement workers fill the job assignments of the removed workers, more workers are exposed to the toxin as a result of the rotation. For those substances for which a threshold exists, rotating workers would assure a reduction in total damage only if the dose for *each* worker were below the threshold.[340]

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concentrations reached a certain level, the canaries would die, signaling the workers that methane was climbing to unhealthy levels.

338. *Banning Workers to Protect Them*, N.Y. Times, Mar. 22, 1980, at 20, col. 2.

339. A dose-response relationship reflects the fraction of an exposed *population* adversely affected as a function of dosage. It is, of course, dependent on what is defined as an "effect" or "response." In contrast, a dose-effect relationship is expressed as the fractionary loss of a vital function or organ either for a population average or for an individual, e.g., fraction of liver destroyed as a function of alcohol intake. For a complete discussion of dose-response relationships, see CASARETT AND DOULL'S TOXICOLOGY, *supra* note 95, at 17–22.

340. The basic pathological mechanisms underlying adverse responses to chemical exposure have implications for the design of medical removal programs that redistribute dosage among an exposed population. For classical reversible toxicity, which overwhelms the body's homeostatic defense systems, one should expect that the dose response rela-

Carcinogens and mutagens are presumed to exhibit a threshold at or near zero. For a linear dose-response curve, rotating exposed workers will not change the total amount of health damage. For those substances that have a convex-upward shaped dose-response curve, one will observe *more* adverse responses after rotation.[341] The opposite occurs for those substances with a concave-upward shaped curve. Unfortunately, except in the case of radiation,[342] no clear evidence reveals the shape of dose-response curves at levels likely to be appropriate for rotation.[343]

Rotation might be advantageous only if the biological effects or toxin uptake were more reversible for rotated workers than for workers continuously exposed to higher doses. Available data rarely allow determination of a no-response threshold for a *population*, or of a no-effect level or the dose at which the effects become irreversible on an *individual* basis.[344] If identification of hypersensitive individuals could in fact ensure

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tionship will have a threshold. There should be some level of dose/perturbation that will not produce an effect in a given individual (assuming that the individual is not already at the borderline or beyond the ability to cope with the insult). Therefore, the effect usually may be avoided entirely in an exposed population, if the dose is distributed among a group large enough that no individual receives greater than an individual threshold dose of the toxic agent. Further, if the agent, such as lead, induces a chronic rather than acute response, biological monitoring will likely detect individuals who are approaching dangerous levels of internal accumulation. Hattis, *From Presence to Health Impact: Models for Relating Presence to Exposure to Damage*, in ANALYZING THE BENEFITS OF HEALTH, SAFETY, AND ENVIRONMENTAL REGULATIONS Ch. 5 (Sept. 1982) (CPA-82-16) (submitted to the U.S. Envtl. Protection Agency by the Center for Policy Alternatives, Massachusetts Institute of Technology).

341. For carcinogens, mutagens or those substances that cause irreversible, incremental damage, the potential benefits of medical surveillance and dose redistribution measures are much more limited. If dose-response curves tend to be linear and without thresholds at low doses, redistribution of dosage without changing the aggregate exposure of the population as a whole will in general tend to leave the total number of individuals harmed unchanged. To the extent that individuals in the population at risk have been exposed to very high levels, redistributing new exposure to previously unexposed people may actually increase the total number of people who get cancer, because those who already carry latent mutations that will lead to fatal cancers may not be capable of suffering further injury. The irreversible nature of previous damage means that if removals are to be used as a social policy tool, the removals must essentially be permanent, in contrast to removals associated with reversible disease. Society may still wish to avail itself of dosage redistribution measures to limit the amount of damage that any individual is required to suffer, but the permanent nature of the removal and the sometimes convex shape of the dose-response curve mean that substantial net economic and health costs for society may accompany such individual protection programs. *Id.*

342. *See generally* National Research Council, National Academy of Sciences, The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980 (1980) (report of the Committee on the Biological Effects of Ionizing Radiation prepared for the EPA).

343. The dose-response curve for formaldehyde has been posited by Hattis as a concave-upward shaped curve. *See generally* D. Hattis, C. Mitchell, J. McCleary-Jones, N. Gorelick & N. Ashford, Control of Occupational Exposures to Formaldehyde: A Case Study of Methodology for Assessing the Health and Economic Impacts of OSHA Health Standards (Apr. 1981) (CPA-81-17) (submitted to the U.S. Dep't of Labor by the Center for Policy Alternatives, Massachusetts Institue of Technology).

344. OSHA acknowledged that one of the major problems in setting a no-effect level

the identification and removal of only the high-risk workers *and* if no remaining or replacement workers were adversely affected (at high risk) at a later time, then and only then would the total number of adverse effects be certain to diminish (provided that the dose to which each worker was exposed was below the level causing irreversible effects). Indeed, partly because such special conditions are rarely ascertainable, OSHA standards are to be established to protect the most sensitive workers as much as possible.[345]

An employer may rotate workers for several reasons. The first is to protect the individual worker by reducing his or her risk of an adverse effect. A second motivation may be that of avoiding liability. As the probability of disease per worker decreases, those workers who actually contract disease have a harder time claiming compensation. Although the process of rotating workers — spreading the same exposure over a large number of workers — might lead to an increased number of claims, each individual will have much more difficulty showing causation.

Rotating workers may also divert attention from cleaning up the workplace. Instead, attention is placed on the affected worker. Such action reinforces a "blame the worker" attitude, as though the worker were responsible for his condition. By removing (with no MRP) those workers who exhibit illness or toxin uptake, an employer may have less economic motivation for more stringent engineering controls. The incentives to remain lax persist. If the conditions of the workplace remain unaltered, it seems likely that a removed worker will again be affected when returned to the same environment, or that remaining or replacement workers will also be affected. If workers are frequently removed, then environmental exposures should be decreased to ensure that preventive actions yield real results.

## VI. Limitations on the Authority to Require Human Monitoring

The employer who intends to implement a program of human monitoring should be conscious of two related sets of constraints. First, the imposition of human monitoring will be subject to limitations on the employer's authority to *compel* the employee to submit to the monitoring procedures. Second, the employer's authority to *use* the information obtained through monitoring will be limited. This Part of the article addresses the issues raised by the first set of constraints: the limits on compulsion, the kinds of monitoring procedures that may be used and the conditions of administration. The following Part discusses access to and limitations on the use of monitoring information.

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for a carcinogen is the large variation in individual susceptibilities. 45 Fed. Reg. 5137 (1980). *See also supra* note 336.

345. R. Friedman, *supra* note 8, at 29–30.

### *A. Personal Privacy*

In the abstract sense, an employee may always refuse to be the subject of human monitoring. OSHA, NIOSH and the employer have no authority to compel employees to cooperate.[346] Refusal to participate, however, may well mean loss of a job. Thus, the relevant inquiry is the extent to which the employer may condition employment on such cooperation. For example, may an employer require a prospective employee to submit to genetic or biological screening as a precondition to employment? May he or she require a current employee to submit to periodic biological monitoring or medical surveillance? These questions raise important issues of confidentiality and discrimination. Apart from these issues, however, there remains a question as to the employer's general authority to require human monitoring of his or her employees.

#### *1. Monitoring in Response to Agency Directive*

At the outset, a distinction must be made between human monitoring that OSHA, NIOSH or the EPA requires[347] and monitoring that the employer implements on his or her own initiative. In the first case, in which a federal agency requires monitoring, the worker will have a valid objection only if he or she asserts a constitutional violation. Congress was mindful of constitutional considerations in developing human monitoring programs. For example, it specifically acknowledged the need for a balancing of interests where an employee asserted a religious objection to a monitoring procedure.[348] Human monitoring can also impinge on the worker's constitutional right to privacy.[349] In the case of human monitoring, the privacy right may be articulated in two ways: the right to physical privacy and the right to withhold information likely to prove detrimental to one's self-interest.

If an employee does not wish to comply with a monitoring procedure required by agency regulation, imposing that procedure as a condition of employment may invade that employee's constitutional right to physical privacy. It may, depending on the nature of the procedure, infringe upon the right to be free from unwelcome physical intrusions and on the right to make decisions regarding one's own body. While these rights are obviously related, the former is grounded in the fourth amendment's

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346. Although the OSHAct grants explicit authority to OSHA and NIOSH to require the employer to perform certain actions, it grants OSHA and NIOSH no similar authority with regard to employees.

347. *See infra* notes 413–436 and accompanying text.

348. Section 20(a)(5) of the OSHAct provides that "[n]othing in this or any other provision of this Act shall be deemed to authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others." 29 U.S.C. § 669(a)(5) (1982). The balance struck here — protection of the rights of the individual except if they are outweighed by the health needs of others — may well be appropriate in attempts to reconcile the purpose of the Act with rights of individual privacy.

349. *See infra* notes 350–354 and accompanying text.

proscription against unreasonable search and seizure,[350] while the latter is closely associated with the rights of personal privacy commonly identified with the ninth and tenth amendments.[351] Although protected by the Constitution, these rights of privacy are not inviolate.

Courts have recognized a general need to balance the privacy interests of the individual with the public health interests of society. In certain situations, the former will be deemed to outweigh the latter, but in others intrusion will be permitted in the name of public health. To date, no reported decision has mentioned an asserted constitutional right to refuse participation in human monitoring as a condition of employment. Nevertheless, one can identify the factors that would bear upon an evaluation of that right.

The public health significance of human monitoring, when properly used, is difficult to deny. Gathering information through human monitoring to develop standards for the protection of worker health, or for the enforcement or evaluation of existing standards, serves an important public health purpose. Furthermore, although the Constitution protects against government paternalism,[352] the fact that this public health interest parallels the affected worker's own interest in a healthy workplace may make monitoring a less onerous invasion of privacy than it would be otherwise. To the extent that monitoring serves a legitimate public health purpose, a limited intrusion of physical privacy appears constitutionally permissible. The less the accuracy, reliability, or predictability of a particular intrusion, however, the weaker the case for violating physical privacy.

The scope of permissible intrusion depends on the nature of the monitoring. The insertion of a urethral tube, for example, involves a greater invasion of personal privacy than the taking of a blood sample. Some monitoring procedures also involve greater risk than others. A program of periodic lung x-rays, for instance, poses a greater risk than a program of periodic lung function tests. At some point, the degree of risk or intrusiveness may be sufficiently compelling to outweigh the public health interests. Some forms of human monitoring may simply be too risky or too intrusive to be constitutionally permissible. Furthermore, even if a monitoring procedure is not constitutionally impermissible *per se,* the worker may well have a right to insist on an alternate, less intrusive procedure that adequately fulfills public health purposes. To survive constitutional challenge, a regulation requiring human monitoring should be reasonably related to a legitimate public health goal and should impose the least intrusive method necessary to achieve its goal.

An additional and critical question is whether the employee may refuse to participate in a program of agency-directed monitoring when

350. *See, e.g.*, Mapp v. Ohio, 367 U.S. 643 (1961).
351. *See, e.g.*, Roe v. Wade, 410 U.S. 113 (1973).
352. *See, e.g.*, Griswold v. Connecticut, 381 U.S. 479 (1965).

he or she believes that his or her employer may use the resulting information as a basis for termination. For example, the worker who suffers reduced lung capacity as a result of workplace particulate exposure may fear that a program of medical surveillance will reveal this condition to the employer and thus induce removal. Participation in a monitoring program can be tantamount to self-incrimination.

This form of "self-incrimination" conflicts with the right to personal privacy.[353] If there is a constitutional right to preserve the confidentiality of information pertaining to one's health, there may also be a right to retain that information within one's body. Stated differently, there may well be a limited constitutional right to refuse to comply with physical procedures that result in the initial disclosure of confidential information. Although this right is not absolute, damage to the employee can be quite substantial if health data is likely to affect employment status adversely. A worker's interest in preserving his employment status may rise to the level of "property" protected by the fifth amendment.[354]

In developing monitoring requirements, an agency should seriously consider the constitutional dimensions of human monitoring. To avoid a challenge on a "self-incrimination" basis, OSHA and NIOSH might consider including mandatory MRP programs as part of their human monitoring requirements.[355] Properly used, an MRP program would safeguard the employment rights of employees whose health was damaged or threatened by workplace exposure and would help ensure employee cooperation.[356]

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353. In the criminal law context, the Court recognized the connection between the fourth amendment right of privacy and the fifth amendment prohibition against compulsory self-incrimination as early as Boyd v. United States, 116 U.S. 616, 630 (1885):

> The principles laid down [in the British common law prescriptions against unreasonable searches and seizures] affect the very essence of constitutional liberty and security . . . . [T]hey apply to all invasions on the part of the government and its employees of the sanctity of a man's home and the privacies of life . . . . [A]ny forcible and compulsory extortion of a man's own testimony or of his private papers to be used as evidence to convict him of crime or to forfeit his goods, is within [those principles]. In this regard, the Fourth and Fifth Amendments run almost into each other.

354. A contractual right to continued employment may, under certain circumstances, be "property" within the meaning of the due process clause. This has been held to be the case with tenured teachers. *See* Perry v. Sindermann, 408 U.S. 593 (1972); Connell v. Higginbotham, 403 U.S. 207 (1971); Slochower v. Board of Educ., 350 U.S. 551 (1956); Wieman v. Updegraff, 344 U.S 183 (1952).

355. CPA Medical Surveillance Report, *supra* note 22, at 26–27.

356. The Court of Appeals for the District of Columbia Circuit has upheld OSHA's authority to require a mandatory MRP program as part of the lead standard. United Steelworkers of Am. v. Marshall, 647 F.2d 1189, 1228–38 (D.C. Cir.), *cert. denied*, 453 U.S. 913 (1980). The court specifically noted that the MRP program would facilitate worker cooperation with biological monitoring. *See also supra* note 325.

*2. Monitoring in the Absence of Agency Directive*

Under common law, employers can require their employees to comply with reasonable programs of human monitoring.[357] Congress did not intend the OSHAct to "preempt the field" by authorizing the implementation of human monitoring requirements. One of the OSHAct's express purposes is to "stimulate employers . . . to institute new and to perfect existing programs for providing safe and healthful working conditions."[358] Congress intended that employers take the initiative on a number of fronts, including human monitoring, in developing health and safety programs. As long as it promotes "safe and healthful working conditions," employer initiated human monitoring would appear to be welcome. Similarly, nothing in the Act precludes employers who are subject to OSHA monitoring requirements from implementing additional programs.

If an employer institutes a human monitoring program in the absence of agency directive, he or she is still subject to applicable restrictions under state common law, state statute and federal labor law. Common law requires that human monitoring be implemented in a "reasonable" fashion.[359] Determining reasonableness involves balancing the benefits gained by monitoring against the risk, discomfort and intrusiveness of the monitoring procedure. The National Labor Relations Act may also require such balancing.[360] In a given jurisdiction, the balance might be affected by a state statute defining a right of personal privacy.

### *B. Informed Consent*

Assuming that a human monitoring program is permissible, there will be limitations on the manner in which an employer implements the program. In general, one who undertakes the performance of monitoring procedures will have a duty to perform those procedures properly and will face liability for damages caused by the negligent administration of a monitoring procedure.[361]

A troublesome question arises, however, with regard to the applicability of the doctrine of informed consent. Strictly speaking, "informed consent" is a medico-legal concept, and grows out of a belief that persons

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357. *See supra* note 76 and accompanying text.

358. 29 U.S.C. § 651(b)(1) (1982).

359. *See supra* note 76 and accompanying text.

360. 29 U.S.C. §§ 151–169 (1982). This balancing is apparently required with regard to employee *confidentiality*. *See infra* text accompanying notes 446–474.

361. Even if the procedure is not performed by a medical professional, ordinary rules of negligence should mandate such a result. An employer might argue, however, that he would not have undertaken to perform human monitoring in the absence of agency regulation, and that he is thus relieved of liability for any damages that flow from that monitoring. Unless he is ordered to perform an unreasonably dangerous procedure, this argument should prove unpersuasive.

have a right to make decisions governing their own bodies and health.[362] Thus, a medical professional is said to have a duty to inform the patient honestly and accurately of the potential risks and benefits of a proposed medical procedure so that the patient can make an informed choice whether to consent to that procedure. All human monitoring procedures are medical or quasi-medical in nature. Most commonly, they will be performed by medical professionals: physicians, physician assistants, nurses or nurse practitioners. Thus, the concept of informed consent appears at first glance to be applicable. The differences between human monitoring and medical treatment, however, are not insignificant, and they raise serious questions whether and to what extent the traditional doctrine of informed consent has meaning in the occupational setting.

Initially, one may inquire to what extent the relationship between the worker and the medical professional who administers the monitoring procedure can be characterized as a "physician-patient" relationship. Quite often, neither the employee nor the union selects the occupational physician. Rather, the employer selects and often directly employs the physician. Accordingly, some courts have held that the performance of a physical examination, which would clearly establish a physician-patient relationship in a purely medical context, does not create that relationship if it is a pre-employment exam requested by the prospective employer.[363] To the extent that the physician-patient relationship does not exist in the occupational setting, traditional notions of informed consent may not be applicable to human monitoring.[364]

Similarly, the doctrine of informed consent is closely tied to the concept of medical *treatment*. It assumes that not only is the patient being requested to submit to a procedure designed for his or her own benefit, but also that the patient is in a position to make a voluntary choice to participate. Human monitoring calls both these assumptions into question. In many cases, monitoring benefits the employer more than the employee. Monitoring may not be "treatment" in the conven-

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362. An excellent statement of the theoretical basis of the doctrine is found in Cobbs v. Grant, 8 Cal. 3d 229, 242, 502 P.2d 1, 9 (1972), in which the court identified four touchstones upon which informed consent can be said to rest:

> The first is that patients are generally persons unlearned in the medical sciences and therefore, except in rare cases, courts may safely assume the knowledge of patient and physician are not in parity. The second is that a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment. The third is that the patient's consent to treatment, to be effective, must be an informed consent. And the fourth is that the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the physician that transcends arms-length transactions.

363. *See, e.g.*, Wilcox v. Salt Lake City Corp., 26 Utah 2d 78, 484 P.2d 1200 (1971); Lotspeich v. Chance Vought Aircraft, 369 S.W.2d 705 (Tex. Civ. App. 1963); New York Cent. R.R. v. Wilner, 124 Ohio St. 118, 177 N.E. 205 (1931).

364. *See* Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1.

tional sense of the word. Furthermore, monitoring is usually compulsory in that it is a condition of continued employment. It may be meaningless to speak of "informed consent" if the worker/patient is not free to reject the proffered procedure without jeopardizing his or her job. In this light, the applicability of informed consent appears particularly dubious in the case of agency-directed monitoring. Neither the employee nor the employer has the discretion to discontinue monitoring.[365]

Regardless of the applicability of informed consent in the traditional sense, a complete and accurate disclosure of risks seems an advisable adjunct to a program of human monitoring. Whether or not a physician-patient relationship exists, imposing a medical procedure on a person not fully informed of the risks of that procedure may still be a battery and may give rise to liability in tort. In addition, prudent social policy requires full disclosure of risks. If the employer is required to disclose all risks inherent in a program of human monitoring, employee and union scrutiny will act as an incentive to the employer to develop programs that use the safest and least intrusive techniques possible. Indeed, unions may have a right to demand such information as a part of the collective bargaining process.[366] Recognition of a duty to disclose material risks seems as appropriate in the area of human monitoring as it is in the area of medical treatment.

A final question concerns the scope of the required disclosure. The employer should, of course, disclose all material physical risks. The most significant risk of all, however, may be dismissal from employment. Should employers or occupational physicians be required to warn employees that one of the risks of submitting to a program of human monitoring may be a loss of a job? The "Code of Ethical Conduct" adopted by the American Occupational Medical Association and the American Academy of Occupational Medicine, states that physicians should

> treat as confidential whatever is learned about individuals served, releasing information only when required by law or by over-riding public health considerations, or to other physicians at the request of the individual according to traditional medical ethical practice; and should recognize that employers are entitled to counsel about the medical fitness of individuals in relation to work, but are not entitled to diagnoses or details of a specific nature.[367]

Under this formulation, even though the physician may not disclose to the employer the specific results of human monitoring, the employee's

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365. As the OSHAct expresses no congressional desire to infringe on the physician-patient relationship, and as OSHA itself has been careful to limit its intrusions into this relationship, OSHA monitoring regulations do not appear to preempt state laws regarding informed consent without a specific statement to this effect.

366. *See infra* text accompanying notes 440–445.

367. *Code of Ethical Conduct for Physicians Providing Occupational Medical Services*, 18 J. OCCUPATIONAL MED. 703, 703 (1976) (section 7).

job security may be endangered nonetheless. Employers are "entitled to counsel about the medical fitness of individuals in relation to work." A preferable alternative practice would involve the worker in such discussions between the physician and the employer.[368]

## VII. Use of Monitoring Results

### *A. Employees' Right of Access*

#### *1. OSHA Regulations*

An employer may not limit or deny an employee access to his or her own medical or exposure records. The current OSHA regulation,[369] promulgated on May 23, 1980, grants employees a general right of access to medical and exposure records kept by their employer. Furthermore, it requires the employer to preserve and maintain these records for an extended period of time.[370] There appears to be some overlap in the definitions of "medical" and "exposure" records, because both may include the results of biological monitoring. The former, however, are generally defined as those pertaining to "the health status of an employee," while the latter are defined as those pertaining to "employee exposure to toxic substances or harmful physical agents."[371]

The employer's duty to make these records available is a broad one. The regulations provide that upon any employee request for access to a medical or exposure record, "the employer *shall* assure that access is provided in a reasonable time, place, and manner, but in no event later than fifteen (15) days after the request for access is made."[372]

Because the regulations define "access" as including the right to make copies of records,[373] the employer appears to have an affirmative

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368. At the New York Conference on Ethical Issues in Occupational Medicine, Donald Whorton and Morris Davis offered an alternative formulation to section 7 of the AOMA Code, *id.*: "The occupational physician shall fully inform the employee in writing of consequences of job changes or continuation that may affect his or her health status and shall not make nor participate in restrictive decisions regarding the employee's ability to work without the participation and concurrence of the employee." Whorton & Davis, *Ethical Conduct and the Occupational Physician*, 54 BULL. N.Y. ACADEMY MED. 733, 740 (1978).

369. 29 C.F.R. § 1910.20 (1983). *See also* 45 Fed. Reg. 35,277 (1980). The regulation has survived constitutional challenge in federal district court, Louisiana Chemical Ass'n v. Bingham, 550 F. Supp. 1136 (W.D. La. 1982), *appeal docketed*, Nos. 80-1178, 80-1201, 80-1199 (5th Cir. Jan. 3, 1983).

370. In the absence of OSHA regulation, employees would arguably still have a right of access under common law or state statute in many jurisdictions. *See generally* Annas, *Legal Aspects of Medical Confidentiality in the Occupational Setting*, 18 J. OCCUPATIONAL MED. 537 (1976).

371. 29 C.F.R. §§ 1910.20(c)(5)-(6) (1983).

372. *Id.* § 1910.20(e)(1)(i) (emphasis added).

373. *Id.* § 1910.20(c)(1).

duty to maintain such procedures as necessary to ensure that the employee has a copy of the records in his or her possession within fifteen days after the request. The employer cannot escape this duty by contracting with others to maintain the records. Although the regulations do not specifically require a physician, health maintenance organization, or other health care provider to permit employee access to records, they do require the employer to "assure that the preservation and access requirements of this section are complied with *regardless of the manner in which records are made or maintained.*"[374] Thus, any employer contract with a third party must provide for the disclosure of those records.[375]

An employee's right of access to *medical records* is limited to records pertaining specifically to that employee.[376] The regulations allow physicians some discretion as well in limiting employee access. The physician is permitted to "recommend" to the employee requesting access that the employee: (1) review and discuss the records with the physician; (2) accept a summary rather than the records themselves; or (3) allow the records to be released instead to another physician.[377] Further, where information in a record pertains to a "specific diagnosis of a terminal illness or a psychiatric condition," the physician is authorized to direct that such information be provided only to the employee's designated representative.[378] Although these provisions were apparently intended to respect the physician-patient relationship[379] and do not limit the employee's ultimate right of access, they could be abused. In situations in which the physician feels loyalty to the employer rather than the employee, the physician could use these provisions to discourage the employee from seeking access to his or her records.

Similar constraints do not apply to employee access to *exposure* records. Not only is the employee assured access to records of his or her own exposure to toxic substances, but the employee is also assured access to the exposure records of other employees "with past or present job duties or working conditions related to or similar to those of the employee."[380] In addition, the employee enjoys access to all general exposure information pertaining to the employee's workplace or working conditions and to any workplace or working condition to which he or she is to be transferred. All information in exposure records that cannot be correlated with a particular employee's exposure is accessible.[381]

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374. *Id.* § 1910.20(b)(3) (emphasis added).

375. Section 1910.20(b)(3) of Title 29 of the Code of Federal Regulations specifically acknowledges that employers may maintain their records on "an in-house or contractual (e.g., fee-for-service) basis." *Id.* The preparatory agency comments contain a discussion of the various kinds of third-party arrangements that employers can make. *See* 45 Fed. Reg. at 35,223.

376. 29 C.F.R. § 1910.20(e)(2)(ii) (1983).

377. *Id.* § 1910.20(e)(2)(ii)(C).

378. *Id.* § 1910.20(e)(2)(ii)(D).

379. 45 Fed. Reg. at 35,273.

380. 29 C.F.R. § 1910.20(e)(2)(i)(B).

381. *Id.* § 1910.20(e)(2)(i)(C)-(D). In the explanatory comments, OSHA noted that

One criticism of the OSHA regulation is that it does not require the employer to compile medical or exposure information but merely requires employee access to such information if it is compiled. The scope of the regulation, however, should not be underestimated. The term "record" is meant to be "all-encompassing," and the access requirement appears to extend to all information gathered on employee health or exposure, no matter how it is measured or recorded.[382] Thus, if an employer embarks upon any program of human monitoring, no matter how conducted, he or she must provide the subjects access to the results. This access requirement may serve as a disincentive for employers to monitor employee exposure or health if it is not clearly in the employer's interest to do so.

Despite the fact that the access requirement has no effect on the monitoring of exposures regulated under section 6(b) of the OSHAct,[383] it may affect the monitoring of other exposures. The *NIOSH/OSHA Occupational Health Guidelines* offers medical surveillance and some biological monitoring guidelines, but OSHA has not promulgated monitoring requirements for exposures to the 450 substances regulated under section 6(a).[384] Nor has OSHA imposed general monitoring requirements for unregulated exposures. At present, the OSHA regulations do not prevent employers from denying employees the benefit of having health or exposure data for a number of substances merely by failing to record such data. Any recordkeeping required under TSCA, however, will presumably be available to workers under the OSHA regulation.[385]

The trade secret interest of employers places a further limitation on employee access. Section 15 of the OSHAct mandates that OSHA be cognizant of the trade secret interest of employers in its collection and use of occupational safety and health information.[386] In promulgating the

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this would include "area, grab, or wipe samples which would not specifically characterize the exact exposure of any one employee" and "material safety data sheets and other records which simply reveal the identity of a toxic substance or harmful physical agent." 45 Fed. Reg. at 35,273.

382. The definition includes "any item." 29 C.F.R. § 1910.20(c)(9). As noted in the preparatory comments, "the definition . . . is meant to be all-encompassing." 45 Fed. Reg. at 35,265. Further, even without such a broad definition, physicians and other health care professionals who perform the monitoring would likely be induced by fear of malpractice liability to keep accurate records.

383. Specific monitoring requirements have been included in the section 6(b) standards. *See supra* text accompanying notes 53–61.

384. *See supra* text accompanying notes 51 & 57. *See also* NIOSH/OSHA OCCUPATIONAL HEALTH GUIDELINES, *supra* note 19.

385. *See infra* text accompanying notes 413–439.

386. 29 U.S.C. § 664 (1982) provides as follows:

> All information reported to or otherwise obtained by the Secretary or his representative in connection with any inspection or proceeding under this chapter which contains or which might reveal a trade secret referred to in section 1905 of title 18 shall be considered confidential for the purpose of that section, except that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter. In any such proceeding the Secretary, the Commission, or the court shall issue such orders as may be appropriate to protect the confidentiality of trade secrets.

present regulations, OSHA noted that section 15 "reflects an apparent Congressional interest in balancing competing interests based on providing protection to trade secrets to the extent consistent with carrying out the overall statutory purposes [of the OSHAct]."[387]

In an attempt to achieve this balance, the regulations permit the employer to deny access to "trade secret data which discloses manufacturing processes . . . or . . . the percentage of a chemical substance in a mixture," provided that the employer:

(1) notifies the party requesting access of the denial;
(2) if relevant, provides alternative information sufficient to permit identification of when and where exposure occurred; and
(3) provides access to all "chemical or physical agent identities including chemical names, levels of exposure, and employee health status data contained in the requested records."[388]

The key feature of this provision is that it ensures employee access to the precise identities of chemicals and physical agents. This access is especially critical for chemical exposures. Within each "generic" class of chemicals there are a variety of specific chemical compounds, each of which may have its own particular effect on human health. The health effects can vary widely within a given family of chemicals.[389] Accordingly, the medical and scientific literature on chemical properties and toxicity is indexed by specific chemical name, not by generic chemical class.[390] To discern any meaningful correlation between a chemical exposure and a known or potential health effect, an employee must know the precise chemical identity of that exposure.[391] Furthermore, in the case of biological monitoring, the identity of the toxic substance or its metabolite is itself the information monitored.

Particularly in light of the public health emphasis inherent in the OSHAct, disclosure of such information does not constitute an unreasonable infringement on the trade secret interests of the employer. In general, chemical health and safety data are the least valuable to an employer of all the "proprietary" information relevant to a particular manufacturing process.[392]

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387. 45 Fed. Reg. at 35,249–50.

388. 29 C.F.R. § 1910.20(f) (1983).

389. *In vitro* tests for metaphase arrest, an abnormality in nonreproductive cell division, produced by a number of chemicals in the hydantoin (2, 4-imidazoladinedione) family, for example, produced widely different results. *See* MacKinney, *A Comparison of Potency of Hydantoins in Metaphase Arrest and Inhibition of Microtubular Polymerization*, 17 MOLECULAR PHARMACOLOGY 275 (1980).

390. Chemicals are commonly indexed by their individual Chemical Abstracts Service (CAS) number.

391. This is particularly the case where the route of entry (e.g., inhalation vs. dermal exposure), particle size, synergism with other chemicals or metabolic conversion is a critical factor in correlating exposure with health effects.

392. *See* M. King, Balancing Trade Secret Protection Against Regulatory Disclosure in the Implementation of the Toxic Substances Control Act and the Occupational Safety and Health Act 22–35 (May 11, 1979) (available from the Dep't of Political Science at the Massachusetts Institute of Technology).

*2. Proposed OSHA Regulation*

On July 13, 1982, OSHA proposed a modification of the employee access regulations.[393] The proposed regulation maintains much of the form and spirit of the present access rule but contains certain provisions that could significantly impair employee access to exposure information. The proposed regulation would continue to require employers to maintain and preserve medical and exposure records and would continue to place the primary burden for ensuring employee access to these records on the employer. The employer, however, would be permitted to delegate this responsibility to third-party physicians or health care providers if the employer advised them of the preservation and access requirements and made "a good faith effort to assure, by modification of the contract [with the third-party provider] if necessary, that such persons comply with [them]."[394]

This language, on its face, appears less likely to ensure employee access than the corresponding provision in the current regulations.[395] The explanatory comments, however, indicate that OSHA's intention is to require employers to do "everything reasonably possible to assure compliance."[396] The proposed regulation should be modified to reflect this intention clearly.[397]

The more critical proposed modifications are those that affect the nature of the information to which employees will have access. In general, the proposed regulations seem to favor reducing employer compliance costs over promoting employee health and safety. Although a thorough critique of these proposed changes is beyond the scope of this article, the potential restrictions on employee access to exposure information are worth noting. Under both the present and proposed regulations, employers are only required to preserve records, if any, of exposure to substances defined as "toxic." The *current* regulations define "toxic substance" with appropriate breadth, and include as "toxic" all chemicals identified as potential human toxins in the "Registry of Toxic Effects of Chemical Substances" compiled by NIOSH.[398] The *proposed* regulation, however, includes as "toxic substances" only those chemicals that have *already* been shown to be toxic in humans or toxic at specified

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393. *Occupational Safety and Health Administration Proposal to Modify the Access to Medical Records Rule*, 12 O.S.H. REP. (BNA) 164 (1982) [hereinafter cited as *OSHA Proposal*]; 47 Fed. Reg. 30,420 (1982).

394. Proposed language of 29 C.F.R. § 1910.20(b)(3); *see also OSHA Proposal, supra* note 393, at 178 n.7.

395. The current regulations require the employer to "assure" compliance with the access requirements, regardless of "good faith." Arguably, the proposed regulations provide somewhat less incentive for employer compliance.

396. *OSHA Proposal, supra* note 393, at 167.

397. Medical providers will most probably feel constrained to preserve and maintain accurate records out of fear of malpractice liability. Unless the employer takes pains to ensure employee access to those records, however, that access might be limited in some jurisdictions.

398. 29 C.F.R. § 1910.20(c)(11) (1983).

significant levels in animals.[399] Not only would the proposed definition potentially exclude certain human and animal mutagens and certain chemicals that display mutagenic potential in short-term, *in vitro* tests, but it would also discourage epidemiological research on chemicals not already known to be toxic.

One major purpose of occupational epidemiology is to determine the toxic effects of substances not presently known to be toxic to humans, so that employers can take the steps necessary to reduce workplace exposure. The OSHAct was intended to facilitate that process. The value of epidemiological research in this area, however, will depend in large part on the availability of reliable data regarding employee exposure to substances not already proven toxic. The proposed regulation, as OSHA has acknowledged, would greatly reduce the availability of such data.[400] The agency noted that the proposed redefinition of "toxic substance" would bring about "a greater than 90 percent decrease in the number of chemicals specified,"[401] and commented that this modification

> may cause some reduction in the benefits of the proposal because some substances that do not currently meet the proposed criteria may be found to be hazardous long after exposure has already occurred and the results have been discarded. Asbestos, for example, was long believed to be biologically inert, but has proven to be a potent carcinogen.[402]

The proposed regulation would narrowly constrain employee access to exposure information when the employer claims that access would infringe upon a trade secret. As under the present regulations, the employer would be permitted to withhold trade secret information pertaining to manufacturing processes or mixture content.[403] The employer, however, would be permitted to withhold the "precise chemical name of a chemical" if:

(1) it can "substantiate" that such information is a trade secret;
(2) the chemical "is not a carcinogen, mutagen, teratogen, or a cause of significant irreversible damage to human organs or body systems for which there is a need to know the precise chemical name;"
(3) it provides a "generic chemical classification" as an alternative; and
(4) it provides "all other information on the properties and effects of the chemical."[404]

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399. Proposed language of 29 C.F.R. § 1910.20(c)(10); *see also OSHA Proposal, supra* note 393, at 170.

400. In the recently promulgated "Hazard Communication Standard," however, OSHA has required the employer to notify employees of exposures to carcinogens for which a single animal study is the only evidence available. 48 Fed. Reg. 53,208 (1983) (to be codified at 29 C.F.R. 1910.1200(d)(2)).

401. *OSHA Proposal, supra* note 393, at 170.

402. *Id.* at 176.

403. *Id.* at 173–74 (to be codified at 29 C.F.R. § 1910.20(f)(1)).

404. *Id.* at 174 (to be codified at 29 C.F.R. § 1910.20(g)(2)).

The employer, however, would have to disclose trade secret information to a treating or consulting physician who submitted a written request indicating that a worker had health problems that "may be the result of occupational exposure."[405] Such information would be provided "on a confidential basis."[406]

This access provision is unduly restrictive and defeats much of the public health purpose of protecting employée access to exposure information. Limiting access to precise chemical identities to only those substances already determined to be highly toxic could have a chilling effect on efforts to determine what other substances may cause significant human toxicity. Without ready access to adequate exposure data, it will be difficult to establish the necessary baseline information on the relationship of various substances to various health outcomes. Piecemeal dissemination of exposure data to physicians on a confidential basis will not suffice, and may occur too late to prevent occupational disease.

A second disturbing feature of the proposed trade secret restrictions is the inclusion of a provision that would permit the employer to condition release of any "names of trade secret chemicals" upon "acceptance of a reasonable confidentiality agreement."[407] The current regulations contain a similar provision,[408] but the explanatory comments to those regulations make it clear that the confidentiality agreement "may not be used as a pretext for more onerous requirements such as the posting of penalty bonds, liquidated or punitive damages clauses, or other preconditions."[409] The proposed regulations, however, appear to welcome contractual restrictions of this nature. They specifically authorize the confidentiality agreements to include clauses that "provide for compensation or other legally appropriate relief for competitive harm." As the agency noted in its explanatory comments, "OSHA intends to be neutral on the kinds of damages provisions that may be included."[410] If put into effect, this proposed regulation would permit employers to condition access to trade secret data on whatever restrictions or penalties appeared "reasonable" under state law. Liquidated damages clauses, at the very least, might be routinely imposed.

In sum, the proposed regulation appears to be based on an implicit determination that the protection of "trade secrets," however broadly defined, is of greater social value than the preservation of employee health. In light of the tenuous relationship between health and safety data and legitimate trade secret protection, and especially in light of the

405. *Id.* (to be codified at 29 C.F.R. § 1910.20(g)(3)).
406. *Id.* (to be codified at 29 C.F.R. § 1910.20(g)(3)).
407. *Id.* (to be codified at 29 C.F.R. § 1910.20(f)(4)).
408. 29 C.F.R. § 1910.20(f)(3) (1983).
409. 45 Fed. Reg. at 35,275.
410. *OSHA Proposal*, *supra* note 393, at 174.

language and purpose of the OSHAct,[411] this seems both dangerous and unwarranted.[412]

*3. Requirements of TSCA*

TSCA[413] imposes substantial requirements on chemical manufacturers and processors to develop health effects data.[414] TSCA requires testing under section 4,[415] pre-market manufacturing notification under section 5,[416] and reporting and retention of information under section 8.[417] TSCA imposes no specific medical surveillance or biological monitoring requirements. However, to the extent that human monitoring is used to meet more general requirements of assessing occupational health or exposure to toxic substances, the data resulting from such monitoring are subject to an employer's recording and retention obligations.

Under section 8(a), the EPA has promulgated regulations[418] requiring general reporting on some 300 chemicals, including information related to occupational exposure.[419] Section 8(a)(2) allows the EPA Administrator to require the reporting and maintenance of those data "insofar as known" or "insofar as reasonably ascertainable."[420] Thus, if monitoring is undertaken, it must be reported. The EPA appears to be authorized to require monitoring as a way of securing information that is "reasonably ascertainable."

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411. The Act contains a strong and broad mandate to protect worker health. Section 2, for example, affirms that it is the "purpose and policy" of the OSHAct "to assure so far as possible every working man and woman in the nation safe and healthful working conditions." 29 U.S.C. § 651(b) (1982).

412. Although it does not pertain to *monitoring* information, OSHA's proposed "hazard communication" regulation will be of interest to workers seeking information regarding workplace exposures. This rule, which has a phased-in compliance period culminating on May 25, 1986, requires employers in the manufacturing industry to provide data to their employees regarding certain chemical hazards in the workplace. The rule also, however, contains broad trade secret protections and purports to preempt many state "right to know" laws.48 Fed. Reg. 53,208 (1983) (to be codified at 29 C.F.R. § 1910.1200).

413. 15 U.S.C. §§ 2601–2629 (1982).

414. Section 2601(b)(1) states that:

> It is the policy of the United States that — (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.

*Id.* § 2601(b)(1)

415. *Id.* § 2603.

416. *Id.* § 2604.

417. *Id.* § 2607.

418. 40 C.F.R. § 712 (1983).

419. *Id.* §§ 712.1, 712.28(d).

420. *Id.* § 2607(a)(2).

In addition to the general reports required for specific chemicals listed in the section 8(a) regulations, the EPA has promulgated rules[421] for the submission of health and safety studies required for 169 substances under section 8(d).[422] A health and safety study includes "[a]ny data that bear on the effects of a chemical substance on health."[423] Examples are "[m]onitoring data, when they have been aggregated and analyzed to measure the exposure of humans . . . to a chemical substance or mixture."[424] As under section 8(a), only data that are "known" or "reasonably ascertainable" need be reported.[425]

Records of "significant adverse reactions to [employee] health" must be retained for thirty years under section 8(c).[426] A recently promulgated rule implementing this section[427] defines significant adverse reactions as those "that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment."[428] Under the rule, human monitoring data, especially if derived from a succession of tests, would seem especially reportable.[429] Genetic monitoring of employees, if some basis links the results with increased risk of cancer, also seems to fall within the rule.

Section 8(e) imposes a statutory duty to report "immediately . . . information which supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health."[430] In a policy statement issued on March 16, 1978, the EPA interpreted "immediately" in this context to require receipt by the agency within fifteen working days after the reporter obtains the information.[431] Substantial risk is defined exclusive of economic considerations.[432] Evidence can be provided by either designed, controlled studies or undesigned, uncontrolled studies, including "medical and health surveys" or evidence of effects in workers.[433] In the EPA's rule for section 8(c),[434] section 8(e) is distinguished from section 8(c) in that "[a] report of substantial risk of injury, unlike an allegation of a significant adverse reaction, is accompanied by information which reasonably supports the seriousness of the effect or the probability

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421. 40 C.F.R. § 716 (1983).
422. 15 U.S.C. § 2607(d).
423. 40 C.F.R. § 716.3(e)(1).
424. *Id.* § 716.3(e)(2).
425. 15 U.S.C. §§ 2607(d)(1)(B)–(C).
426. *Id.* § 2607(c).
427. 48 Fed. Reg. 38,178 (1983) (to be codified at 40 C.F.R. Part 717).
428. *Id.* at 38,188 (to be codified at 40 C.F.R. § 717.3(i)).
429. The proposed rule seems to envision that the employee, a union or others outside of management will make the necessary report, although reports "[b]y any source" are included. *Id.* at 38,189 (to be codified at 40 C.F.R. § 717.10(c)). The plain language of the Act does not support a restriction on who reports.
430. 15 U.S.C. § 2607(e) (1982).
431. 43 Fed. Reg. 11,110 (1978).
432. *Id.* at 11,111.
433. *Id.* at 11,112.
434. *See supra* text accompanying notes 426–429.

of its occurrence."[435] Human monitoring results indicating a substantial risk of injury would thus seem reportable to the EPA. Either medical surveillance or biological monitoring data would seem to qualify.[436]

Section 14(b) of TSCA gives the EPA authority to disclose from health and safety studies the data pertaining to chemical identities, except for the proportion of chemicals in a mixture.[437] In addition, the EPA may disclose information, otherwise classified as a trade secret, "if the Administration determines it necessary to protect . . . against an unreasonable risk of injury to health."[438] Monitoring data thus seem subject to full disclosure.[439]

*4. Under Federal Labor Statutes*

In addition to the access provided by OSHA regulations, individual employees may have a limited right of access to medical and exposure records under federal labor law. Logically, the right to refuse hazardous work, inherent in section 7 of the NLRA and section 502 of the Labor Management Relations Act,[440] carries with it the right of access to the information necessary to determine whether or not a particular condition is hazardous. In the case of toxic substance exposure, this may mean a right of access to all information relevant to the health effects of the exposure and may include access to both medical and exposure records. This is clearly not an adequate substitute for OSHA access regulations, however, as there is presently no systematic mechanism for enforcing this right.

*Collective* employee access, however, is available to unionized employees through the collective bargaining process. In four recent cases, the National Labor Relations Board (NLRB) has held that unions have a right of access to exposure and medical records so that they may bargain effectively with the employer regarding conditions of employment.[441] Citing the general proposition that employers are required to bargain on health and safety conditions when requested to do so,[442] the NLRB adopted a broad policy favoring union access. "Few matters can be of

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435. 48 Fed. Reg. 38,178 (1983) (to be codified at 40 C.F.R. Part 717); 45 Fed. Reg. 47,008 (1980).

436. EPA has published three volumes of preliminary evaluations of initial section 8(e) notices. 4 TSCA CHEMICALS-IN-PROGRESS BULL. 12 (1983).

437. 15 U.S.C. § 2613(b) (1982).

438. *Id.* § 2613(a)(3).

439. *See generally supra* text accompanying note 392.

440. *See generally* Ashford & Katz, *Unsafe Working Conditions: Employee Rights Under the Labor Management Relations Act and the Occupational Safety and Health Act*, 52 NOTRE DAME LAW. 802 (1977).

441. The first three were companion cases: Minnesota Mining & Mfg. Co., 261 N.L.R.B. 27 (1982); Borden Chemical 261 N.L.R.B. 64 (1982); and Colgate-Palmolive Co. 261 N.L.R.B. 90 (1982). *Minnesota Mining* is the lead case. Citing *Minnesota Mining*, the Board then decided Plough, Inc., 262 N.L.R.B. 1095 (1982).

442. *See, e.g.*, Gulf Power Co., 156 N.L.R.B. 622 (1966), *enforced*, 384 F.2d 822 (5th Cir. 1967).

greater legitimate concern to individuals in the workplace, and thus to the bargaining agent representing them, than exposure to conditions potentially threatening their health, well-being, or their very lives."[443]

The NLRB, however, did not grant an unlimited right of access. The union's right of access is constrained by the individual employee's right of personal privacy. Furthermore, the NLRB acknowledged an employer's interest in protecting trade secrets. While ordering the employer in each of the four cases to disclose the chemical identities of substances to which the employer did not assert a trade secret defense, the NLRB indicated that employers are entitled to take reasonable steps to safeguard "legitimate" trade secret information.[444] The NLRB did not delineate a specific mechanism for achieving the balance between union access and trade secret disclosure. Instead, it ordered the parties to attempt to resolve the issue through collective bargaining. Given the complexity of this issue and the potential for abuse in the name of "trade secret protection," the NLRB may find it necessary to provide further specificity before a workable industry-wide mechanism can be achieved.[445]

### *B. Employees' Right to Confidentiality: Access to Employee Records by Agencies, Unions and Employers*

Of all of the issues raised by human monitoring, employee confidentiality may have received the most attention.[446] An employee's right to maintain the confidentiality of information regarding his or her body and health places a significant limitation on the ways in which others can use that information. As programs of human monitoring are developed, mechanisms must be found that maximize both the employee's interest in privacy and society's interest in promoting general workplace health and safety. In the final analysis, this may be more a technological challenge than a legal or ethical one.

In a broad sense, private citizens do have a right to protect the confidentiality of their personal health information. With regard to *governmental* invasions of privacy, this right is created by the Bill of Rights

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443. *Minnesota Mining*, 261 N.L.R.B. at 29.

444. *Id.* at 32. Only three members out of five signed the majority opinion. One concurring member would have granted broader access, while the other would have provided more protection for the employer.

445. The union has filed a petition for judicial review of the Board's order. For a discussion of certain procedural issues in the case, see Oil, Chemical, & Atomic Workers Union v. N.L.R.B., 694 F.2d 1289 (D.C. Cir. 1982). For an excellent treatment of the *Minnesota Mining* cases, and the union access issues yet to be resolved, see Mentzer, *Union's Right to Information About Occupational Health Hazards Under the National Labor Relations Act*, 5 INDUS. REL. L.J. 247 (1983).

446. *See, e.g.*, Schechter, *Medical Records Access: Who Shall See What, and When?*, OCCUPATIONAL HEALTH AND SAFETY, July 1982, at 23; Collings, *Medical Confidentiality in the Work Environment*, 20 J. OCCUPATIONAL MED. 461 (1978); McLean, *Management of Occupational Health Records*, 18 J. OCCUPATIONAL MED. 530 (1976); Warshaw, *Confidentiality Versus the Need to Know*, 18 J. OCCUPATIONAL MED. 534 (1976).

and is one component of the right of personal privacy discussed above.[447] With regard to *private* intrusions, the right is grounded in state law.[448] In the medical setting, it grows out of the confidential nature of the physician-patient relationship, although rights of confidentiality exist outside this relationship as well. In essence, the recognition of a right of privacy reflects an ongoing societal belief in the need to protect the integrity of the individual.

This right to privacy, however, is not absolute[449] and may be limited or waived. Courts nonetheless remain vigilant in their attempts to protect individual privacy. They generally look for a reasonable middle ground when faced with legitimate interests on both sides of the confidentiality question. They prefer an approach that permits both the use of health information for a socially useful purpose and the protection of the privacy of the individual.[450] The key is the development of technology that will make that approach more readily available.

Developing such technology will be especially important in protecting the confidentiality of information generated by human monitoring. Both medical and exposure records contain health information of a confidential nature, and the employee has a legitimate interest in limiting its disclosure. At the same time, public agencies, unions and employers have a legitimate interest in using this information. From a technical point of view, the solution will lie in mechanisms that allow third parties to use meaningfully health information that is not tied by name or other common identifier (such as a social security number) to any one individual, and that allow data relevant to toxic substances exposure to be separated from other health information. When disclosure is limited to relevant medical and exposure information[451] that cannot be traced to any worker by name, the detrimental effect of disclosure will be held to a minimum.

Proper development of the necessary technology, however, will not follow from piecemeal solutions devised by reviewing courts. Rather, what is needed is a concerted, comprehensive, multidisciplinary approach. OSHA, NIOSH and the EPA could pursue such technology

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447. *See, e.g.*, Whalen v. Roe, 429 U.S. 589 (1977) (discussed *infra* in text accompanying notes 452–455).

448. Depending on the state, this right may be part of the common law, may be created by statute, or both. *See generally* Annas, *supra* note 370. At present, there is no *federal* common law right of privacy beyond that embodied in the Constitution. Many states have recognized the common law tort of invasion of privacy. *See, e.g.*, Biederman's of Springfield, Inc. v. Wright, 322 S.W.2d 892 (Mo. 1959); Hull v. Curtis Publishing Co., 182 Pa. Super. 86, 125 A.2d 644 (1956).

449. *See generally supra* notes 348–354. *See also* Whalen v. Roe, 429 U.S. 589, 598–604 (1977) (state system of monitoring sales of prescription drugs did not pose a threat to patients' reputation or independence sufficient to invade any right to privacy).

450. *See, e.g.*, Whalen v. Roe, 429 U.S. 589.

451. Much of the information found in medical records — such as details of the patient's sexual activities, marital relations, emotional difficulties — may often have little relevance to the workplace.

either as an agency research and development project or through cooperation with private industry. This technology, once developed, could then be made available to employers at the cost of installation and equipment. No system will resolve completely the conflict between confidentiality and disclosure, and the potential for abuse will always be present. A method of recordkeeping, however, that permits the effective use of relevant health information without requiring the disclosure of other personal data would eliminate much of that conflict. Presently, the conflict remains substantial, especially regarding medical records prepared under methods that are ill-adapted to protective disclosure.

*1. Agency Access*

The Constitution imposes limitations on federal agency access to monitoring information.[452] The Supreme Court has outlined a number of important issues in this general area in *Whalen v. Roe*,[453] a case involving a New York law that required physicians to provide the state with the names of persons receiving prescriptions for certain controlled drugs. The court upheld the statute against privacy claims raised by both patients and physicians because the law was narrowly drawn to apply only to a limited class of arguably dangerous drugs and New York had a legitimate public health interest in controlling the dissemination and use of those drugs.[454] In doing so, the Court indicated the broad framework within which questions of constitutional privacy rights must be decided. On the one hand, the right to confidentiality clearly can be limited when such limitation is necessary to meet a legitimate public health purpose:

> [D]isclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to *public health agencies* are often an essential part of modern medical practice even where the disclosure may reflect unfavorably on the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community does not automatically amount to an impermissible invasion of privacy.[455]

On the other hand, the Court also indicated the confidential information disclosed should be confined to that necessary to meet the desired public health purpose. "The right to collect and use such data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid *unwarranted* disclosures."[456] As with the protection of physical privacy, the Constitution demands a careful balancing of the individual's right to confidentiality and the legitimate interests of society.

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452. Any *state* law of confidentiality would probably be preempted by the federal statute creating agency access. *See, e.g.*, General Motors Corp. v. Director of Nat'l Inst. for Occupational Safety and Health, 636 F.2d 163, 165 (6th Cir. 1980).

453. 429 U.S. 589 (1977).

454. *Id.* at 598–604.

455. *Id.* at 602 (emphasis added).

456. *Id.* at 605 (emphasis added).

Both OSHA and NIOSH have sought to achieve this balance. The agencies, however, have taken markedly different paths toward this end. OSHA access to medical records is secured by a regulation[457] designed to protect employee confidentiality. In general, records obtained under this regulation must be secured through a specific, written access order,[458] must be used only for the purposes indicated on the order,[459] and must be destroyed or returned after OSHA has completed such use.[460] A significant flaw in this regulation is the fact that it applies only to "personally identifiable employee *medical* information."[461] By its terms, it is inapplicable to "*exposure* records, including biological monitoring records."[462] Instead, OSHA access to exposure records is governed by a separate regulation that grants OSHA "immediate" entry to such records without privacy protection provisions.[463] To the extent that these records contain constitutionally protected health information, this lack of privacy protection appears to violate the doctrine enunciated in *Whalen v. Roe*.

NIOSH, on the other hand, has not promulgated access regulations. Instead, it has sought access on a case-by-case basis by using its subpoena power. In each case, the employer has resisted the subpoena on the basis of the employees' constitutional rights to privacy. As a result, decisions of various federal courts have developed limitations on NIOSH access.[464]

In general, the courts have applied the *Whalen* doctrine and have conditioned access by NIOSH upon the development of procedures designed to limit the intrusion on individual worker privacy. The Court of Appeals for the Sixth Circuit, for example, noted that there should be "no public disclosure of the medical information" beyond the agency itself.[465] Significantly, the court also recognized that the conflict between confidentiality and public health grows more out of practical than philosophical considerations. It "[did] not believe that the parties' interests . . . were mutually exclusive. With proper security administration, [NIOSH] should be able to complete [its health studies] without jeopardizing the constitutional rights of the individuals involved."[466] This recognition of practical constraints underscores the need for a creative approach to medical and exposure information storage and transfer.

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457. 29 C.F.R. § 1913.10 (1983).
458. *Id.* § 1913.10(d).
459. *Id.* § 1913.10(h)(4).
460. *Id.* § 1913.10(j).
461. *Id.* § 1913.10(b)(1) (emphasis added).
462. *Id.* § 1913.10(b)(3) (emphasis added).
463. *Id.* § 1910.20(e)(3).
464. *See generally* Walderman, *Investigative Authority of the National Institute for Occupational Safety and Health*, in LEGAL AND ETHICAL DILEMMAS IN OCCUPATIONAL HEALTH 131 (J. Lee & W. Rom eds. 1982).
465. General Motors Corp. v. Director of Nat'l Inst. for Occupational Safety and Health, 636 F.2d at 166.
466. *Id.*

*2. Union Access*

Although a union is usually presumed to be acting on behalf of its members, at times the union's assertion of access to medical or exposure records will conflict with an employee's interest in keeping those results confidential. All employees have an interest in ensuring that the union's right of access is not unchecked, but rather is limited to legitimate purposes.

Employee interests are protected under federal labor law[467] and will be balanced against the union's interest in securing disclosure. The nature of this balance is not yet clear. The NLRB has acknowledged the importance of protecting employee confidentiality, but has not specified the extent to which such confidentiality will bar disclosure. In two recent cases before the NLRB, an employer asserted the physician-patient privilege as a defense to a union's claim of access to medical records.[468] In both cases, the NLRB ordered the employer to provide access "to the extent that such data does not include medical records from which identifying data have not been removed."[469] Although the removal of personal identifying data may not serve as a solution in all cases of this nature, the NLRB did indicate in both of these decisions that the union's interest in securing health and safety information could be satisfied without disclosure of personal identifiers. It thus did not foreclose the possibility that a broader right of access might be appropriate if the union establishes a legitimate need for such data.

It is not clear, however, whether more exacting employee protection might be required when the employee, rather than the employer, asserts the right to confidentiality. The additional protection, if any, available to dissenting union employees has not yet been delineated. As a matter of policy, it seems that the rationale for protecting personal privacy is as compelling in the case of union access as it is in the case of agency access and that the union's interest in collective bargaining could be accommodated in a manner that respects the confidentiality of the individual employee.

*3. Employer Access*

Perhaps the most obvious threat to employee confidentiality is that posed by employer access. Of all parties seeking access to employee health information, the employer has a direct economic incentive to use

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467. *See generally* O'REILLY, UNIONS' RIGHT TO COMPANY INFORMATION (1980).

468. Minnesota Mining & Mfg., Inc., 261 N.L.R.B. 27; Plough, Inc., 262 N.L.R.B. 1095.

469. Plough, Inc., 262 N.L.R.B. at 1095. In *Minnesota Mining*, the union asked *only* for access to medical records from which all personal identifying data had been removed. 261 N.L.R.B. at 30. In *Plough*, the union requested access to "the results of all physicals taken by employees" for a particular time period. 262 N.L.R.B. at 1095. Noting that it did not agree with the administrative law judge's conclusion that this information would lose its value if all identifying data were removed, the Board conditioned disclosure on the removal of such data. *Id.* at 1096.

that information in ways detrimental to the employee. On the one hand, the employer may choose to use human monitoring data to screen "susceptible" prospective employees from the workplace or to discharge employees once it becomes clear that an unsafe workplace is proving hazardous to their health. On the other hand, human monitoring data is essential for those employers who strive in good faith to eliminate workplace hazards. The proper balance between confidentiality and disclosure thus may be difficult to achieve.

By accepting or seeking employment, the employee implicitly consents to certain limitations on his right of confidentiality. To the extent that health information is relevant to a legitimate employer interest,[470] disclosure of human monitoring data to the employer is permissible. In general, employers should have access to information that bears upon the employee's ability to perform his or her job and to information that indicates the levels of toxic substance exposure in the workplace. Other health and personal information is arguably protected either by the physician-patient relationship[471] or by tort concepts of personal privacy,[472] and therefore should be unavailable to the employer.

In practice, however, this may not be the case. Testimony taken before the promulgation of the present OSHA employee access regulation indicates that many employers routinely gain access to an employee's complete medical file. According to OSHA, the following statement by a member of the United Auto Workers is representative of the testimony received:

> I have been in medical . . . trying to talk to the company doctor. A member of [management] would come down and just, you know, hi, doc, and then go through the records, the medical records, and pull a particular individual's medical record and without even consulting the doctor first or a nurse or anybody as far as that goes, just directly [go] to the cabinet and pull an individual's record . . . . They will just go directly down and pull the file themselves. So there is no confidentiality.[473]

It appears that many employees do not presently enjoy the level of confidentiality that the law presumes.

OSHA has acknowledged that this is a "serious problem"[474] but has thus far declined to take any specific remedial action. It does not discuss the issue in the proposed revisions to the employee access rule. As a

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470. The "legitimacy" of an employer's interest, of course, will be shaped in part by federal and state statutes forbidding certain kinds of discrimination.

471. If the company doctor takes in personal information unrelated to employer needs, he or she is arguably acting on behalf of the employee, not the employer.

472. The employee may have a cause of action against the doctor for invasion of privacy. *See generally* Annas, *supra* note 370.

473. 45 Fed. Reg. 35,243 (1980). The quote is attributed to Mattillion of the United Auto Workers.

474. *Id.*

practical matter, much of the problem might be alleviated if human monitoring and the maintenance of medical and exposure records were undertaken by a third-party health care provider, such as a health maintenance organization.[475] Much of the abuse inherent in employer access to employee health information arises from simple proximity. The employer is often the keeper of the information to which claims of confidentiality attach. If this information were held by a third party, such as a health maintenance organization, that party would be in a better *practical* position to ensure that all those with legitimate rights of access — the employee, the agency, the union and the employer — exercise those rights in full compliance with the law.

### *C. Limitations on Employer Use*

Even if an employer obtains human monitoring data through a legitimate exercise of his or her right of access, the right to use such data is not absolute. Employers may not use health information to discriminate against employees on a basis deemed impermissible by federal or state law. Beyond discrimination, however, a more essential — and perhaps more difficult — question arises: to what extent may employers use health information to limit or terminate the employment status of individual employees or to deny employment to a prospective employee?

#### *1. Under Common Law*

At early common law, an employer had the right to take an employee's health into account in determining whether to continue to employ that person. If the employment contract was "open," with no definite term, the employee could be discharged for any reason, including health status, at the will of the employer.[476] If the contract of employment was for a definite term, the employee could be discharged for "just cause." Typically, significant illness or disability constituted "just cause."[477] Although federal labor law, workers compensation and recent common law limitations on the doctrine of "employment at will"[478] have profoundly

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475. *See* N. Ashford & S. Owen, Draft Report: Expanded HMOs for Providing Comprehensive Health and Safety Services to Small- and Medium-Sized Firms (1977) (manuscript from Center for Policy Alternatives, Massachusetts Institute of Technology).

476. *See generally* 53 AM. JUR. 2D, *Master and Servant* §§ 49, 123 (1970).

477. *Id.* §§ 50, 123.

478. A number of courts have held that an employer may be liable in tort if the discharge of an employee violates a clear mandate of public policy. *See, e.g.*, Parnar v. Americana Hotels, Inc., 65 Hawaii 370, 652 P.2d 625 (1982) (tort of retaliatory discharge recognized when plaintiff discharged as inducement to leave jurisdiction in order to prevent her from testifying against employer); Palmateer v. International Harvester Co., 85 Ill. 2d 124, 421 N.E.2d 876 (1981) (tort of retaliatory discharge recognized when employee discharged for informing police of fellow employee's suspected criminal behavior); Lally v. Copygraphics, 85 N.J. 668, 428 A.2d 1317 (1981) (cause of action upheld for wrongful discharge of employee who had filed workers' compensation claim). *See also* 81 AM. JUR. 2D, *Workmen's Compensation* § 55 (Supp. 1983) (citing recent cases on this topic). *But see*

affected the nature of employee-employer relations in this century, courts continue to recognize an employer's interest in discharging employees who cannot perform their work safely.[479] Thus, if the worker has no statutory or contractual protection, an employer may retain a general common law right to discharge the worker whose health status makes continued employment dangerous or whose health status prevents him or her from performing his or her job.[480]

Human monitoring, however, places the issue in a somewhat different light. Monitoring is designed to reveal whether an employee has been, or in the future may be, harmed by the workplace itself. It raises the question whether the employer may discharge an employee merely because the employee was, or may be, harmed by a situation *created by the employer*. The rights of the employer to discharge the employee might not be as broad then as in the general case.

Suppose that an employer is complying with an existing OSHA standard for a particular toxic exposure and monitoring reveals that one of the firm's employees is likely to suffer serious and irreparable health damage unless he or she is removed from the workplace. In this situation, the employer is complying with public policy as enunciated by OSHA and, absent a mandatory MRP provision, is arguably free to discharge the employee. If an employer fails to comply with applicable OSHA standards, however, or if no standard exists, and the employer permits workplace exposure levels that violate state and federal requirements to maintain a safe place of employment,[481] the employer is violating the public policy embodied in the OSHAct. To permit him or her to take advantage of that violation by discharging the employee is to permit a further violation of public policy. The courts would be loath to allow the

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Green v. Amerada-Hess Corp., 612 F.2d 212 (5th Cir.), *cert. denied*, 449 U.S. 952 (1980) (no cause of action under Mississippi statutes or common law for retaliatory employment practices).

479. *See, e.g.*, Cussimanio v. Kansas City S. R.R., 5 Kan. App. 2d 379, 617 P.2d 107 (1980).

480. *See* Dairy Equip. Co. v. Department of Indus., Labor & Human Relations, 95 Wis. 2d 319, 290 N.W.2d 330 (1980). Pension plans, obviously, may affect the *terms* of the discharge.

481. Section 5(a)(i) of the OSHAct imposes a general duty on an employer to "furnish to each of his employees employment and a place of employment which are free of recognized hazards that are causing or likely to cause death or serious physical harm to his employees." 29 U.S.C. § 654(a)(1) (1982). In addition, many states have statutes creating a similar duty, and there is a generally recognized common law duty as well. *See, e.g.*, Shimp v. New Jersey Bell Tel. Co., 145 N.J. Super. 156, 368 A.2d 408 (1976).

The courts have placed OSHA in a peculiar position. OSHA may not issue a citation for a violation of the general duty clause cited above if an applicable OSHA standard exists, governing the route of exposure for a particular substance. National Realty & Constr. Co. v. OSHRC, 489 F.2d 1257 (D.C. Cir. 1973). Thus, if an existing standard is acknowledged to be imperfect in its protection of all workers because of feasibility limitations, the employer need not protect all workers. If no standard exists, however, the employer is obligated to protect *all* workers from recognized serious hazards under his general duty obligation.

employer who wrongfully breaks the arm of an employee subsequently to fire that employee because of a resultant inability to do heavy lifting. Although the analogy is not perfect, one who subjects employees to toxic substances commits substantially the same act.[482] An employer's use of human monitoring data for this purpose may well be impermissible as a matter of public policy and employers may be obliged *at common law* to find safe assignments for the workers at comparable pay or bear the cost of their removal as part of doing business.[483]

*2. Under the OSHAct General Duty Clause*

The use of monitoring data to limit or deny employment opportunities raises other issues under the general duty clause of the OSHAct.[484] When monitoring information reveals that an employee risks serious health damage from continued exposure to a workplace toxin, it may also indicate that the employer is in violation of the general duty clause. When a workplace exposure constitutes a "recognized hazard" likely to cause death or serious physical harm, an employer violates the general duty clause if he or she does not take appropriate steps to eliminate the hazard.[485] In the case of toxic substances, this would appear to require reduction of the exposure itself, not mere removal of presumptively sensitive employees from the site of exposure.[486]

The issue is amenable to regulatory solution. The implementation of mandatory MRP for toxic substances exposure in general, as OSHA has

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482. A key to judicial treatment of this issue at common law may be the extent to which the employee can be otherwise compensated for his loss of employment. A federal district court in Georgia took this approach some years ago in Jones v. Central of Georgia Ry. Co., 220 F. Supp. 909 (N.D. Ga. 1963). Although that case did not involve exposure to toxic substances, it did involve a worker who was discharged as the result of a job-related injury. After receiving a permanent disability award through the workers' compensation system, the worker brought suit to regain his former job. The court reasoned that he had been compensated for lost future earnings through the award of disability and was thus not entitled to receive those earnings a second time through subsequent employment. Accordingly, it dismissed his suit. The applicability of the *Jones* rationale to the use of human monitoring data is unclear. If a worker has been incapacitated by toxic substance exposure and a right of compensation clearly exists, this doctrine may apply. But in cases in which the worker is discharged merely because he or she displays an increased *susceptibility* to disease from toxic substance exposure, either because of past exposure levels or because of a perceived genetic or biological predisposition, there is likely to be no compensation for lost future earnings.

483. If the courts apply the rationale of the "retaliatory discharge" cases, *supra* note 478, it is not clear that reinstatement or job reassignment would be available remedies. The employer would still bear the cost of removal, however, in the form of damages to the discharged employee.

484. 29 U.S.C. § 654(a)(1) (1982).

485. *Id.*

486. Under the OSHAct, the primary burden of ensuring workplace health and safety rests with the employer. As noted in a Senate Committee report to Congress on the general duty clause, "[e]*mployers* have primary control of the work environment and should insure that it is safe and healthful." S. REP. NO. 1282, 91st Cong., 2d Sess. 9, *reprinted in* 1970 U.S. CODE CONG. AND AD. NEWS 5177, 5186 (emphasis added).

done with its lead standard,[487] might be accomplished by a generic MRP standard.[488] An employer's compliance with a mandatory MRP provision for a particular exposure would remove the threat of a general duty clause citation.

*3. Under Anti-Discrimination Laws*

In addition to potential liability under the common law and the OSHAct general duty clause, an employer who uses monitoring information to limit employment opportunities may also face liability under anti-discrimination laws. Although not all workplace discrimination is prohibited,[489] state and federal law forbid certain *bases* for discrimination. Many of these may apply to an employer's use of human monitoring information. A detailed discussion of the relevant discrimination laws is beyond the scope of this article, but an outline of their potential impact on human monitoring is set forth below.[490]

*a. Section 11(c) of the OSHAct*

Section 11(c)(1) of the OSHAct prohibits employers from discharging or otherwise discriminating against any employee "because of the exercise by such employee on behalf of himself or others of any right afforded by this chapter."[491] If an employee insists on retaining his or her job in the face of medical data indicating that continued exposure to a workplace toxin will likely pose a danger to health, the employee may well be asserting a "right" afforded by the OSHAct. The Act's general duty clause imposes on employers a duty to maintain a workplace that is free of "recognized hazards" likely to cause death or serious physical harm.[492] Inferentially, then, the Act vests employees with a concomitant right to insist that their workplace be free of such hazards. In insisting on retaining employment, the employee is asserting his or her right to a workplace that comports with the requirements of the general duty clause.[493] Accordingly, an employer who discharges or otherwise discriminates against

487. *See supra* note 67.

488. *See supra* note 22.

489. As used here, the term "discrimination" means nothing more than treating a particular worker, or class of workers, differently from the majority of workers. This discussion assumes that the discrimination in question is based on *human monitoring data* and not some other reason. It assumes that the excluded workers would be qualified to perform the work in question if the monitoring data were ignored.

490. For more extensive treatments of this issue, see Rothstein, *supra* note 9, and McGarity & Schroeder, *supra* note 9.

491. 29 U.S.C. § 660(c)(1) (1982).

492. *See supra* notes 484–485 and accompanying text.

493. Although an employee has no right to prosecute a violation of the general duty clause because OSHA is the "exclusive prosecutor" of OSHAct violations, Oil, Chemical & Atomic Workers Union v. Occupational Safety & Health Review Comm'n, 671 F.2d 643, 649 (D.C. Cir.), *cert. denied*, 456 U.S. 969 (1982), this is mainly a *procedural* limitation on the employee's exercise of his right to a workplace free of serious hazards, not an eradication of the right itself.

a worker because of perceived susceptibility to a toxic exposure arguably violates the section 11(c) prohibition. When an employer asserts that an employee cannot work without injury to health, the employer admits that the workplace is unsafe. That admission triggers the remedial provisions of the OSHAct.[494]

An OSHA regulation, issued under section 11(c) and upheld in an unanimous Supreme Court decision,[495] gives individual workers a limited right to refuse hazardous work when there is a situation likely to cause "serious injury or death."[496] The employer may not take discriminatory action against the employee by discharging the employee or by issuing a reprimand to be included in the employment file.[497] According to the district court to which the issue was remanded for consideration,[498] withholding the employee's pay during the period in which the employee exercises the right is also prohibited.

As a worker may absent him or herself from a hazardous work assignment under certain conditions without loss of pay or job security, it seems anomalous to allow an employer to discharge or remove the employee without pay because of the same hazardous condition. This would make the employee's status depend on whether he or she asserted a right to refuse hazardous work before the employer took action to discharge him or her from employment.

*b. Handicap Discrimination*

Employees may be able to assert further rights against discriminatory use of human monitoring data under laws protecting the handicapped. Congress[499] and most states[500] have passed laws barring discrimination against handicapped individuals in certain employment situations. The laws, which vary widely among the jurisdictions, all place potential limitations on the use of human monitoring data. Although the courts have

494. Section 11(c) provides a procedure for redress against the employer. 29 U.S.C. § 660(c)(2)(3) (1982). The aggrieved worker must file a complaint with OSHA within 30 days, and OSHA must then conduct an investigation. If OSHA "determines that the provisions of [section 11(c)] have been violated," it must then institute legal action to obtain "all appropriate relief." *Id.* Although the extent to which the worker may be able to *compel* OSHA to take action under this section is not yet clear, at least one court has held that OSHA is liable in tort for *negligently* representing a worker's interest under section 11(c). Chadsay v. United States, 11 O.S.H. REP. (BNA) [Cases] 1198 (D. Ore. 1983).

495. Whirlpool Corp. v. Marshall, 445 U.S. 1, 21 (1980).

496. 29 C.F.R. § 1977.12(b)(2) (1983). *See also* Ashford & Katz, *supra* note 440.

497. Whirlpool Corp. v. Marshall, 445 U.S. at 21.

498. Marshall v. Whirlpool Corp., 9 O.S.H. Cas. (BNA) 1038 (N.D. Ohio 1980).

499. 29 U.S.C. §§ 701–794 (1982). For a general discussion of the federal act, see Comment, *Potluck Protection for Handicapped Discriminatees: The Need to Amend Title VII to Prohibit Discrimination on the Basis of Disability*, 8 LOY. U. CHI. L.J. 814 (1977).

500. As of 1983, 41 states and the District of Columbia reportedly had laws prohibiting employer discrimination against the handicapped. For a listing of the state statutes, see Rothstein, *supra* note 9, at 1436–37.

adopted a case-by-case approach,[501] the worker who is denied employment opportunities on the basis of monitoring results often falls within the literal terms of many handicap discrimination statutes. In general, two issues will be determinative: whether the workplace in question is covered by a state or federal handicap act and, if so, whether the worker in question is "handicapped" under that act.

The Federal Rehabilitation Act of 1973[502] provides handicapped persons with two potential avenues of protection against job discrimination. Section 503 prohibits private employers with federal contracts of $2500 or more from discriminating against a present or prospective employee on the basis of handicap.[503] Courts have generally held, however, that section 503 does not create a private right of action on the part of the aggrieved individual.[504] A private right of action *is* available under a companion provision, section 504,[505] but many courts have held that this section applies only to employers who have received federal funds for the specific purpose of creating employment.[506] Consequently, the scope of the federal act is far from all-inclusive and at least half of the nation's employers probably lie beyond its purview.[507]

The various state acts offer a potential for more extensive coverage. Most extend beyond public contractors and apply to most of the major employers within the state.[508] The state acts may have the most telling impact on human monitoring.

A worker excluded from a workplace or job assignment because of the results of human monitoring has been removed because he or she is ostensibly at higher risk of injury or illness than the majority of workers. The worker is perceived as having a physical condition that sets him or her apart from others. Although this is clearly discrimination on the basis of physical status, an applicable handicap discrimination statute will not prohibit the action unless it meets the relevant definitional criteria. The stated criteria do not differ widely among most jurisdictions,[509] but judicial interpretations of these criteria have varied substantially. Some state

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501. *See, e.g.*, E.E. Black, Ltd. v. Marshall, 497 F. Supp. 1088, 1100 (D. Hawaii 1980).

502. 29 U.S.C. §§ 701–796 (1982).

503. *Id.* § 793(a).

504. *See, e.g.*, Davis v. United Air Lines, 662 F.2d 120 (2d Cir. 1981), *cert. denied*, 102 S. Ct. 2045 (1982); Rogers v. Frito-Lay, Inc., 611 F.2d 1074 (5th Cir. 1980), *cert. denied*, 449 U.S. 889 (1980). *But see* Clarke v. Felec Serv., Inc., 489 F. Supp. 165 (D. Alaska 1980).

505. 29 U.S.C. § 794 (1982); *see, e.g.*, Pushkin v. Regents of Univ. of Colo., 658 F.2d 1372, 1380 (10th Cir. 1981).

506. *See, e.g.*, Trageser v. Libbie Rehabilitation Center, Inc., 590 F.2d 87 (4th Cir. 1978), *cert. denied*, 442 U.S. 947 (1979). *But see* Jones v. Metropolitan Atlanta Rapid Transit Auth., 681 F.2d 1376 (11th Cir. 1982), *petition for cert. filed*, 51 U.S.L.W. 3535 (U.S. Jan. 11, 1983).

507. Rothstein estimates that "[t]hree million firms — about half the businesses in the country — may be covered by the Act." Rothstein, *supra* note 9, at 1439.

508. According to Rothstein, state handicap discrimination laws "usually only exempt small employers." *Id.* at 1437 n.392.

509. Most of the state laws are modeled after the federal law. Some, however, are more restrictive. *See, e.g.*, HAWAII REV. STAT. § 378-1(7) (1976).

courts have interpreted handicap discrimination laws broadly, taking positions that appear to limit significantly the use of monitoring data for employee exclusion.[510] Others have taken much more restrictive positions.[511] At least one federal court has adopted a middle-ground approach.[512]

At present, the general applicability of handicap discrimination statutes to the use of human monitoring information remains unclear. Examining the definitional criteria in the federal act, on which many of the state statutes are based, will illustrate the issues facing courts — and the potential range of logical interpretations. The Rehabilitation Act of 1973 defines a "handicapped" individual as "any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment."[513]

In the great majority of cases, the persons facing reduced employment opportunity as a result of human monitoring data do not *presently* have a substantially debilitating medical condition and thus do not satisfy either the first or second clauses of the federal definition. Rather, they are *perceived* as having an increased risk of developing such a condition in the future. Are they, then, "regarded" as having a substantial impairment under the third clause? A narrow reading of the statute might lead to a negative conclusion. In a literal sense, such persons are regarded only as being *at risk* of an impairment, and cannot be said to be regarded as having the impairment itself.[514] They are arguably being treated, however, *as if* they had a substantial impairment by being denied employment opportunities normally extended to those without such a disability. In this sense, they are regarded as substantially impaired. This latter interpretation finds support in the Senate Committee Report presented before

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510. *See, e.g.*, Dairy Equip. Co. v. Department of Indus., Labor and Human Relations, 95 Wis. 2d 319, 290 N.W.2d 330 (1980); Chicago, Milwaukee, & St. Paul R.R. v. Washington State Human Rights Comm'n., 87 Wash. 2d 802, 557 P.2d 307 (1976).

511. *See, e.g.*, Advocates for the Handicapped v. Sears, Roebuck & Co., 67 Ill. App. 3d 512, 385 N.E.2d 39 (1978), *cert. denied*, 444 U.S. 981 (1979); Burgess v. Joseph Schlitz Brewing Co., 298 N.C. 520, 259 S.E.2d 248 (1979).

512. *See infra* text accompanying notes 517–521.

513. 29 U.S.C. § 706(7)(B). The Department of Labor has promulgated a set of implementing regulations that contain further interpretive definitions at 41 C.F.R. § 60-741.2 (1983). To prove discrimination under the Act, the handicapped individual must prove that he or she was "qualified" for the job. *See* SENATE COMM. ON LABOR AND PUBLIC WELFARE, REHABILITATION ACT AMENDMENTS OF 1974, S. REP. NO. 1297, 93d Cong., 2d Sess. 5, 24, *reprinted in* 1974 U.S. CODE CONG. & AD. NEWS 6373, 6390. The Supreme Court has held that the handicapped person must be so qualified even though he or she is handicapped; it is not sufficient that he or she would be qualified if there were no handicap. Southeastern Community College v. Davis, 442 U.S. 397 (1979).

514. Rothstein, in fact, cautions that "because a handicapped individual must have an impairment that substantially limits one or more major life activities, the Rehabilitation Act may not prohibit the most arbitrary, illogical, and baseless form of discrimination — that based on an individual's slight medical or genetic imperfection." Rothstein, *supra* note 9, at 1451.

the insertion of this language into the Act.[515] The Senate Report explained that the third clause of the definition applies both to "persons who do not in fact have the condition which they are perceived as having" *and* to "persons whose mental or physical condition does not substantially limit their life activities."[516] This second provision appears broad enough to cover persons excluded on the basis of monitoring information.

The one federal district court that directly examined the issue has affirmed the applicability of the 1973 Rehabilitation Act to pre-employment screening of perceived high-risk individuals. In *E.E. Black, Ltd. v. Marshall*,[517] the federal district court for Hawaii held that a twenty-nine-year-old who had been denied employment as a carpenter's apprentice as a result of positive findings in lower back x-rays was protected by section 503. The court rejected the suggestion that employers may avoid the Act's proscriptions merely by establishing that they have discriminated against a worker on the basis of an *insubstantial* physical disability. In this regard, the opinion noted that the purpose of the Act is not to permit an employer to "be rewarded if his reason for rejecting the applicant were ridiculous enough."[518]

Nonetheless, the court in *E.E. Black* also emphasized that not all high risk individuals would be treated as "handicapped" under the Act. Addressing the requirement that the actual or perceived disability must "substantially limit" a major life activity, the court read into the Act a requirement that the actual or perceived impairment be "a substantial handicap *to employment*."[519] In determining whether a particular condition meets this criterion, the court indicated that one must first assume that all similar employers within the relevant geographic area use the disputed pre-employment screen (or other discriminatory practice) and then weigh that against the physical and mental capabilities of the particular applicant. If the resultant employment limitations appear "substantial," the person will be deemed "handicapped."[520]

Although perhaps not wholly consistent with the literal terms of the Act, this construction of the statute appears to be an attempt to fashion a viable framework for evaluating the treatment of perceived high-risk individuals within the context of "handicap" discrimination. The Act seems designed primarily to protect the seriously handicapped,[521] but its language is broad enough to cover discriminatory practices based on data

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515. The definition of "handicap" was revised in 1974. *See supra* note 513.

516. SENATE COMM. ON LABOR AND PUBLIC WELFARE, REHABILITATION ACT AMENDMENTS OF 1974, S. REP. NO. 1297, 93d Cong., 2d Sess. 39, *reprinted in* 1974 U.S. CODE CONG. & AD. NEWS 6373, 6389–90.

517. 497 F. Supp. 1088, 1100 (D. Hawaii 1980). For further proceedings, see E.E. Black, Ltd. v. Donovan, 26 Fair Empl. Prac. Cas. (BNA) 1183 (D. Hawaii 1981).

518. 497 F. Supp. at 1100.

519. *Id.* (emphasis added).

520. *Id.* at 1100–02.

521. *See, e.g.*, S. REP. NO. 318, 93d Cong., 1st Sess. 18–19, *reprinted in* 1973 U.S. CODE CONG. & AD. NEWS 2076, 2092.

obtained through human monitoring. The middle-ground adopted in *E.E. Black* imposes a reasonable limitation on an employer's use of monitoring data.

Even in cases in which handicap discrimination is established, an employer may escape liability if the discriminatory practice is reasonably necessary for efficient operation of the business. The Rehabilitation Act provides employers with no affirmative defense, but does require the handicapped individual to prove that he or she is "qualified" for the job.[522] Thus, if a handicap prevents a worker from safely or effectively performing the job, an exclusionary practice may be permissible under the Act.[523] Most state handicap statutes include some form of affirmative defense.[524] Although these vary among jurisdictions, many appear analogous to the familiar defenses that have developed under Title VII of the Civil Rights Act.[525]

*c. Civil Rights and Age Discrimination*

Employers who exclude workers on the basis of monitoring information may also run afoul of the more general laws against discrimination. Title VII[526] prohibits employment discrimination on the basis of race, color, religion, sex or national origin. The scope of the Civil Rights Act is substantially broader than that of the federal handicap discrimination act, and it affords protection for the great majority of the nation's employees. In addition, many states extend similar protection to employees not covered by the federal act.[527] The Age Discrimination in

522. *See supra* note 513. Although this appears to place the burden on the worker to prove that the worker could properly perform the job if given the opportunity — rather than requiring the employer to prove that the worker could not do so — it also appears to remove from consideration the various *economic* arguments that may be available to employers asserting a "business necessity" defense under Title VII or the Age Discrimination in Employment Act. *See infra* text accompanying notes 539–545. Indeed, the court in *E.E. Black* declined to consider employer cost in determining whether or not the applicant was "qualified." Nonetheless, many of the factors relevant to a consideration of the "business necessity" defense may still be relevant here.

523. *See, e.g.*, Strathie v. Dep't of Transp., 547 F. Supp. 1367 (E.D. Pa. 1982).

524. McGarity and Schroeder note that "almost all state handicap laws contain some reference to employer defense." McGarity & Schroeder, *supra* note 9, at 1035.

525. See *id.* for a short discussion of the types of defenses available. Although the wording of each statute's defense should be examined with care, three general classes of defense may be identified: (1) those that require the employer to establish a "bona fide occupational qualification," *see infra* note 542; (2) those that require the employer to establish "business necessity" (indeed, Rothstein assumes that a "business necessity" defense is available under the federal act, Rothstein, *supra* note 9, at 1445); and (3) those that require the employer to prove that the handicapped individual cannot perform the job (similar to the federal act, but a shifting of the burden, *see, e.g.*, N.J. REV. STAT. § 10:5-4.1 (1978)).

For a discussion of the applicability of the "business necessity" test to discrimination based on human monitoring, see *infra* text accompanying notes 542–549.

526. 42 U.S.C. § 2000e (1976 & Supp. II 1978).

527. *See, e.g.*, MASS. GEN. LAWS ANN. ch. 151b (West 1979).

Employment Act[528] and some state acts[529] provide protection of comparable breadth against discrimination on the basis of age.

As with handicap discrimination, the applicability of these laws to the use of human monitoring information is not yet clear. In the ordinary case, exclusionary practices based on monitoring data will not be *per se* discriminatory on the basis of race, sex, national origin or age.[530] Nor are they likely to involve *disparate treatment* of one of these protected classes. They will not be part of a policy that, while neutral on its face, masks a specific employer intent to discriminate on one or more of these impermissible bases.[531] The practical impact of an exclusionary practice, however, may fall disproportionately on a particular race, sex, ethnic or age group.

The Supreme Court has long held that a claim of disparate impact states a viable cause of action under the Civil Rights Act.[532] A similar rationale has been applied in the area of age discrimination.[533] In a 1975 decision,[534] the Court held that job applicants denied employment on the basis of a pre-employment screen establish a *prima facie* case of racial discrimination when they demonstrate that "the tests in question select applicants for hire or promotion in a racial pattern significantly different from that of the pool of applicants."[535] Proof of disparate impact thus requires statistical analysis demonstrating a "significantly" disproportionate effect on a protected class. The cases provide no clear guidance, however, as to the level of disproportion that is required before an effect is deemed "significant."[536]

The potential for disparate impact inheres in many uses of human monitoring data. A genetic screen for sickle-cell anemia, for example,

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528. 29 U.S.C. §§ 621–678 (1982).

529. *See, e.g.*, MASS. GEN. LAWS ANN. ch. 149, § 24A (West 1979).

530. The policies will not be discriminatory *on their face*. For example, they will not by their express terms exclude blacks, but may exclude persons who have the sickle-cell trait. *See infra* notes 537–538 and accompanying text. An employer would be engaging in *per se* discrimination if it required genetic screening for male but not for female employees. Such discrimination, however, would be based on sex, rather than on human monitoring data.

531. For example, an employer might have a neutrally worded policy requiring genetic screening for *all* workers, but might *use* only men. Here again, the discrimination would be on the basis of sex.

532. The court recognized disparate impact in Griggs v. Duke Power Co., 401 U.S. 424 (1971).

533. *See generally* Note, *The Cost of Growing Old: Business Necessity and the Age Discrimination in Employment Act*, 88 YALE L.J. 565 (1979).

534. Albermarle Paper Co. v. Moody, 422 U.S. 405 (1975).

535. *Id.* at 425.

536. "Significantly" refers to more than mere *statistical* significance. Guidelines established by the Equal Employment Opportunity Commission suggest that a difference of more than 20% (that is, where the selection rate for the racial, sexual or ethnic class in question is less than 80% of the rate for the group with the *highest* selection rate) should be sufficient. 29 C.F.R. § 1607.4 (1983).

will disproportionally exclude blacks[537] and certain ethnic groups[538] because they have a much higher incidence of this trait than does the general population. Similarly, tests that consistently yield a higher percentage of positive results in one gender than the other may give rise to exclusionary practices that discriminate on the basis of sex.[539] Finally, a wide variety of exclusionary practices based on monitoring data may have a disparate impact on older workers. Older workers have been in the workforce longer and usually have been exposed to hazardous work environments much more often than their younger colleagues. Their prior exposure may have impaired their health or left them more vulnerable to current workplace hazards. They may, for example, have a pre-existing illness as a result of previous workplace exposures.[540] Their age alone may account for a certain degree of body deterioration.[541]

When the plaintiff establishes a *prima facie* case of disparate impact, the employer will have an opportunity to justify the alleged exclusionary practice by showing that its use constitutes a "business necessity."[542] If such a showing is made, the practice will withstand a charge of disparate impact discrimination.[543] The Supreme Court has characterized the business necessity defense as requiring "a manifest relation to the employment in question."[544] In the words of an often cited opinion, this means that the practice must be "necessary to the safe and efficient operation of the business."[545] Further, if the plaintiff can establish that another,

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537. *See, e.g.*, OTA REPORT, *supra* note 2, at 91; E. CALABRESE, *supra* note 267, at 153.

538. OTA REPORT, *supra* note 2, at 91. The sickle cell trait is reported to be more prevalent in equatorial Africa, parts of India, the Middle East, and the countries along the Mediterranean.

539. The permissibility of "fetus protection policies," which exclude fertile women from the workplace to avoid exposure to reproductive hazards, is beyond the scope of this article, as it does not involve discrimination on the basis of monitoring data. For a brief discussion of that issue, see Ashford & Caldart, *The Control of Reproductive Hazards in the Workplace: A Prescription for Prevention*, 5 INDUS. REL. L.J. 523, 533–35, 541–47 (1983).

540. *See supra* text accompanying notes 317–318.

541. *See supra* text accompanying notes 276–282.

542. The "business necessity" defense is available only in cases of disparate *impact*. If a practice is discriminatory on its face or involves disparate treatment, the employer may avoid liability only by demonstrating that the basis of the discrimination constitutes a "bona fide occupational qualification" (BFOQ). This defense is available under the Civil Rights Act for discrimination based on sex, national origin or religion (but not for discrimination based on race or color), 42 U.S.C. § 2000e-2(e) (1976), and under the Age Discrimination in Employment Act, 29 U.S.C. § 623(f)(1) (1982). The BFOQ defense requires the employer to establish that the discriminatory practice is "reasonably necessary to the normal operation of . . . business." 42 U.S.C. § 2000e-2(e) (1976). The Supreme Court has characterized the defense as an "extremely narrow" one. Dothard v. Rawlinson, 433 U.S. 321, 334 (1977).

543. *See* Griggs v. Duke Power Co., 401 U.S. at 431 (as to Title VII); *supra* note 528 (as to the Age Discrimination in Employment Act).

544. Griggs v. Duke Power Co., 401 U.S. at 431.

545. Robinson v. Lorillard Corp., 444 F.2d 791, 798 (4th Cir.), *cert. denied*, 404 U.S. 1006 (1971).

less discriminatory practice will accomplish the same purpose, the business necessity defense will not stand.[546]

There are two principal reasons why a "business necessity" may be difficult to establish for exclusionary practices based on human monitoring data. The first is that the great majority of these practices are not designed to protect the health and safety of the public or of other workers. Instead, their "business purpose" is the protection of the excluded worker and, not incidentally, the protection of the employer from the anticipated costs associated with the potential illness of that worker.[547] That position may well encounter a chilly judicial reception. As noted in one recent analysis, "the courts are usually skeptical of an employer's argument that it refuses to hire qualified applicants for their own good, and they often require a higher level of justification in these cases than in cases in which public safety is at stake."[548]

Another, and potentially more serious, obstacle to the successful assertion of a business necessity defense is the unreliability of the screening procedures themselves. If the exclusion of susceptible (i.e., high-risk) individuals truly *is* a "business necessity," its rationale disappears if the test used as the basis for such exclusion cannot provide reasonable assurance that those excluded are actually susceptible (i.e., at high risk). Indeed, without such assurance, the test becomes little more than an instrument for arbitrariness and only adds to the discriminatory nature of the exclusionary practice. As many of the tests are currently far from reliable,[549] the availability of the business necessity defense is questionable.

The foregoing discussion of discrimination has presupposed that the "screened" worker will be excluded from the workplace. Employers may, however, have another option. In many cases, they may be in a position to provide these workers with other jobs in workplaces that do not involve exposures to the substances from which they may suffer adverse health effects. If such alternative positions were supplied, at benefit levels comparable to those of the positions from which exclusion was sought, employers might avoid the proscriptions of the various discrimination laws. Providing an alternative position would certainly remove much of the incentive for filing a discrimination claim. Further, even if such a claim was filed, courts might find that an adequate MRP program obviated the charge of discrimination.[550] This could be one area where good law and good social policy coincide.

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546. Albermarle Paper Co. v. Moody, 422 U.S. at 425.

547. These anticipated "costs" might include: an employer's future liability to pay workers' compensation or, in some cases, a tort judgment; adverse publicity from having a high incidence of occupational illness at its workplace; decreased productivity associated with occupational illness; and the expense of training replacement employees.

548. McGarrity & Schroeder, *supra* note 9, at 1049.

549. *See supra* text accompanying notes 82–221.

550. In *E.E. Black*, the court indicated that employees who were offered reasonable alternative positions would not be considered "substantially" limited — and thus would not be considered "handicapped" — under the federal handicap law. 497 F. Supp. at 1099.

## VIII. Policy Considerations

### *A. Goals of Human Monitoring*

As discussed in the Introduction, human monitoring activities have a number of sometimes conflicting goals: (1) to discover an increased harm or risk of harm in a population of workers; (2) to encourage the removal of especially sensitive workers or workers who are in a high-risk group; (3) to reduce actual harm to workers and subsequent employer liability; and (4) to relieve the employer of costs that would otherwise be expended for cleaning up the workplace.

Both workers and employers tend to be risk-averse, i.e., to err on the side of caution to avoid human and economic costs each might otherwise have to bear. The worker, however, would prefer to have the workplace as hazard-free as possible, while the employer would prefer to minimize legal and financial liability by removing "problems" (workers) before they arise. The resolution of conflicts between these goals fundamentally depends on one's sense of fairness about where the costs of preventing harm should lie.

### *B. Recommendations for Proper Use of Human Monitoring*

Each type of monitoring has certain advantages and limitations. Strategies for coordinating the several activities that constitute human monitoring with environmental monitoring must be designed to optimize the reduction of risk from workplace hazards. Considering the various advantages and limitations for each type of monitoring, an optimal combination could include environmental monitoring (ambient and personal), medical surveillance and, where appropriate, biological monitoring.

Environmental monitoring can, in theory, detect the presence of a toxic substance prior to significant exposure. Thus, the most preventive strategy is the early elimination of a potential hazard from the workplace. If medical surveillance is used as the sole monitoring mechanism, many physiological effects may not be detected until late in the progression of a disease. This limitation has significant negative impact for those diseases that are serious, or reversible only in early stages.

Biological monitoring falls between environmental monitoring and medical surveillance in preventive potential. Biological monitoring hopefully occurs before any significant health impact. Genetic monitoring may detect an early, pre-clinical disease state resulting from exposure. Further development of this type of monitoring may at some point lead to confirmation of exposure and suggest possible health consequences.

The strategies used for human monitoring must be fashioned on a toxin-specific basis because the state-of-the-art techniques differ from substance to substance. In general, medical surveillance and biological monitoring for populations should be used only in combination with environmental monitoring. In a case in which a specific harmful substance

cannot be identified, however, and the workplace is suspected of being unsafe, medical surveillance may indicate whether a problem exists. In the future, genetic monitoring may also serve as an early indicator that exposure to certain chemicals has occurred in a worker *population*. Genetic screening focuses on removal of the worker before exposure and is preventive *for that worker only*.

In sum, human monitoring should be used only if: (1) given the specific workplace problem, monitoring serves as an appropriate preventive tool; (2) it is used in conjunction with environmental monitoring; (3) the tests are accurate and reliable and the predictive values are high; (4) it is not used to divert resources from reducing the presence of toxic substances in the workplace or from redesigning technology; and (5) medical removal protection for earnings and job security is provided.

New solutions involving both technological innovation and job redesign may obviate the necessity of human monitoring. Conflicts now arise only because, under existing technology, workers continue to be exposed to toxic substances.

### *C. Conclusion*

Discriminatory practices and consequential tort suits, anti-discrimination suits, deterioration of labor-management relations and agency sanctions may follow poorly conceived and poorly executed human monitoring programs. The weaker the scientific foundation for the tests, the less secure are the legal grounds and defenses available to the employer. In light of the sometimes preliminary, unreliable and nonspecific nature of the techniques used in human monitoring, the practice is a problematic activity itself in most instances.

If the courts do extend protection from responsibility for discriminatory practices to employers who remove workers "for their own good," then expansion of the worker's right to refuse hazardous work should follow. It seems likely that the employer will either pay for medical removal protection or the worker will be inclined to "remove himself," with the consequence that he or she will demand pay to exercise fully the right to refuse hazardous work. The economic burden of removal will then have to be weighed against the cost of hazard reduction by the employer. The authors believe that when costs of removal are fully internalized in the costs of production, human monitoring as a primary control strategy will not be as economically attractive as early proponents have argued.