

Scientific, ethical and legal challenges in work-related genetic testing in the United States

Esigenze scientifiche, etiche e legali nella conduzione di test genetici in ambito lavorativo negli Stati Uniti d'America

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Summary

Human monitoring in the workplace, sometimes referred to as medical screening, is a collation of practices that focuses on the workers as an indicator that: 1) disease may result on exposure to a toxic substance, radiation, or other traumas (medical surveillance); 2) a toxic substance has been absorbed into the body (biological monitoring); 3) a particular worker may be especially predisposed to disease (genetic screening or other probes of sensitivity); and 4) a pre-clinical disease state exists, indicating that potentially harmful exposure has occurred (genetic monitoring). These monitoring practices, especially when required or carried out by a government agency or the employer, raise serious and complex scientific, legal, and ethical concerns. This article focuses on the practice of “genetic testing” that involves mainly types 3 and 4, i.e., those involving both genetic screening for predisposition to disease, and genetic monitoring for indications of potential harm due to workplace exposure. However, the other two types of monitoring may also be relevant. The article also constructs a philosophical framework for: 1) examining the adequacy of law as an embodiment of ethical values, and sound science, concerning the genetic testing of workers; and 2) identifying possible solutions to the attendant legal and moral dilemmas. In the workplace, the analysis necessarily focuses on three sets of activities involving distinct participants: workers, employers, corporations, physicians – either in-house or under contract – and the government. The sets of activities deserving separate consideration are: 1) requiring the worker to submit to monitoring tests; 2) disseminating the results of the tests; and 3) using the test results. Because the different kinds of monitoring address different stages of the pathway from exposure to disease, and because what is monitored affects different groups of workers differently, specification of exemplar problems and a case-by-case analysis are essential, lest we face useless generalities at the end.

Key words: genetic monitoring, genetic screening, genetic testing, discrimination, privacy

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Riassunto

Il monitoraggio degli individui in ambito lavorativo, talvolta definito *screening* medico, è un insieme di procedure che si concentrano sui lavoratori, come indicazione che: 1) una malattia può insorgere a seguito dell'esposizione ad una sostanza tossica, a radiazioni, o ad altri traumi (sorveglianza medica); 2) una sostanza tossica è stata assorbita dal corpo (monitoraggio biologico); 3) un singolo lavoratore può essere particolarmente predisposto ad una malattia (*screening* genetico o altre prove di sensibilità); e 4) esiste uno stato preclinico di malattia che indica l'avvenuta esposizione potenzialmente dannosa (monitoraggio genetico). Queste pratiche di monitoraggio, specialmente quando richieste o eseguite da un'agenzia governativa o dal datore di lavoro, alimentano serie e complesse preoccupazioni scientifiche, legali ed etiche. Questo articolo si concentra sulla pratica del "test genetico" che coinvolge principalmente i suddetti punti 3 e 4, cioè sia lo *screening* genetico per indicare una predisposizione ad una malattia, che il monitoraggio genetico per indicare un potenziale danno dovuto ad una esposizione sul posto di lavoro. Però, anche gli altri due tipi di monitoraggio possono essere pertinenti. L'articolo costruisce anche una struttura filosofica per: 1) un esame dell'adeguatezza della legge come fusione di valori etici e valide basi scientifiche per quanto riguarda il monitoraggio genetico dei lavoratori e 2) l'identificazione di possibili soluzioni per gli annessi dilemmi legali e morali. Sul posto di lavoro, l'analisi necessariamente si concentra su tre tipi di attività che coinvolgono partecipanti distinti: lavoratori, datori di lavoro, sindacati, medici — sia interni che sotto contratto esterno — e governo. I tipi di attività che meritano considerazione separate sono: 1) la richiesta al lavoratore di sottoporsi a esami di monitoraggio; 2) la diffusione dei risultati delle prove; e 3) l'utilizzo di tali risultati. Poiché i diversi tipi di monitoraggio valutano diverse fasi del percorso dall'esposizione alla malattia, e poiché ciò che viene monitorato colpisce in modo diverso gruppi diversi di lavoratori, la descrizione dettagliata di situazioni modello ed un'analisi caso per caso sono essenziali per non trovarci di fronte alla fine ad inutili generalizzazioni.

Parole chiave: monitoraggio genetico, *screening* genetico, esame genetico, discriminazione, riservatezza

Introduction

Biomonitoring of workers raises important scientific, ethical and legal concerns and is usually done by, or at the instigation of, the employer who in law is responsible for their health and safety. Whenever workplace monitoring leads to the exclusion of workers from employment, removal of workers from certain jobs, or dismissal of workers, difficult issues emerge affecting labour-management relations, labour law and discrimination law. The resulting legal and ethical questions are usually framed within the context of the employment contract or relationship.

Human monitoring in the workplace, sometimes referred to as medical screening, is a collation of practices (Table 1) that focuses on the workers as an indicator that: 1) dis-

Table 1 - Types of human monitoring

- Medical surveillance
 - indicators of disease
 - Biological monitoring
 - indicators of the uptake or presence of toxic (or genotoxic) substances and/or their metabolites
 - Genetic screening
 - and other indicators of susceptibility
 - Genetic monitoring
 - pre-clinical manifestations of disease
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ease may result on exposure to a toxic substance, radiation, or other traumas (medical surveillance); 2) a toxic substance has been absorbed into the body (biological monitoring); 3) a particular worker may be especially predisposed to disease (genetic screening or other probes of sensitivity); and 4) a pre-clinical disease state exists, indicating that potentially harmful exposure has occurred (genetic monitoring). These monitoring practices, especially when required or carried out by a government agency or the employer, raise serious and complex scientific, legal, and ethical concerns^{1,2}. This article focuses on the practice of “genetic testing” that involves mainly types 3 and 4, i.e., those involving both genetic screening for predisposition to disease, and genetic monitoring for indications of potential harm due to workplace exposure. However, the other two types of monitoring may also be relevant.

The identification of DNA - or protein - carcinogen adducts, and other markers of exposure to chemicals and their effects on health, raise new and challenging questions for application of the emerging science of molecular epidemiology in the workplace. The new science may well have relevance for chemical regulation, workers’ compensation, and damage suits in the courts.

The legal and ethical problems of disease detection and the communication of information in the context of the patient and personal physician relationship are thorny enough: workplace monitoring complicates the issue even further. The article constructs a philosophic framework for: 1) examining the adequacy of law as an embodiment of ethical values, and sound science, concerning the genetic testing of workers, and 2) identifying possible solutions to the attendant legal and moral dilemmas. In the workplace, the analysis necessarily focuses on three sets of activities involving distinct participants: workers, employers, corporations, physicians – either in-house or under contract – and the government. The sets of activities deserving separate consideration are: 1) requiring the worker to submit to monitoring tests; 2) disseminating the results of the tests; and 3) using the test results. Because the different kinds of monitoring address different stages of the pathway from exposure to disease, and because what is monitored affects different groups of workers differently, specification of exemplar problems and a case-by-case analysis are essential, lest we face useless generalities at the end.

Towards an ethical theory for human monitoring

The moral and legal enquiry in the area of human monitoring addresses the behaviour of particular actors engaged in the decision to undertake monitoring tests, and in their

design and conduct in the evaluation and dissemination of the test results, and in the use of the information. Ladd³ argues that it is important to distinguish ethics from law, custom, institutional practices, and positive morality (the body of accepted popular beliefs of a society about morality): ethics is concerned with what ought to be. Moral problems emanating from conflicts concerning human monitoring may be categorized as: 1) conflicts arising from differences in legitimate interests of different actors/institutions; 2) conflicts in moral and legal duties of each actor/institution; and 3) conflicts among actors/institutions arising from different perceptions of what is right or wrong, fair or unfair. In addition to conflicts, other problems arise during the various stages of monitoring activity, including the perennial problem of how much (information, safety, precaution, etc.) is enough to justify intervention, and the difficulty of responding responsibly to events and information when people are experiencing stress and misperception.

Certain rights are possessed by individuals, and those rights impose (moral) obligations on others. Rights and obligations must be viewed together in the context of particular relationships⁴. Ladd and others have argued that people have a general duty to support the fulfillment of the moral requirements of relationships, whether their own or those of others. Some of what is necessary to carry out this duty is embodied in rights and obligations, which may sometimes be given the force of law.

... the concept of rights, as a cluster of claims on society and its institutions on the part of the individual, derives its principal moral warrant from the concept of moral integrity. This concept, unlike the concept of simple self-determination, focuses on the integrity of personal relationships, concerns, and responsibilities. Everyone in society has a duty, individually and collectively, to defend, support, and nourish these moral relationships both personally and in others. The concept of rights provides an effective social and conceptual instrument for carrying out this general duty⁴.

The delineation of rights and duties gives rise to certain expectations or hopes on the part of society concerning human behaviour. In imposing rules or legal principles on individuals and institutions, the law often embodies societal attitudes, values, and expectations. Sometimes, but not always, this occurs when a significant societal consensus has been reached on a particular moral question derived from human conflicts. The law establishes legal rights, whose violation may be illegal, and the law provides remedies to correct their violation. But the law also recognizes that conflicts of legitimate interests, conflicts of legal duties, and differences in perception of what is right or wrong, fair or unfair, require a balancing in the fashioning of remedies. Indeed, there are both legal remedies (usually of statutory origin) and equitable remedies that give great discretionary power to the courts or adjudicating institutions, such as the Equal Employment Opportunity Commission in the United States. Rules are embodied in legislation and regulations; legal principles guide, but do not unequivocally settle, other conflicts. In examining of questions of conflict, the law does indeed view behaviour in the context of relationships. Justifiable expectations which one party has of another are translated into the legal concept of reliance. Thus, the law will sometimes find a physician-patient relationship between worker and company physician - when none was intended by the physician - because it was reasonable that the worker expected certain behaviour or transmission of information from the physician. Similarly, although the legal construct of the modern corporation in many countries bestows limited personal liability on corporate officers or employees⁵, the courts will “*pierce the corporate veil*”

when corporate behaviour violates the ethical norm. Discrimination law is replete with discretionary justice⁶.

The law, of course, does not always serve the ethical interests of the society so nobly. Legislation and legal institutions can be compromised by powerful special interests. In addition, if there is a lack of societal consensus or interest about a moral issue, the law may either not address that issue or fail to give helpful guidance concerning the boundaries of fair or equitable behaviour. This is currently the case concerning the problems encountered in both workplace and community monitoring. Thus, it is important to engage in both a legal and ethical enquiry concerning human and institutional behaviour.

In the context of the transfer of medical information resulting from workplace monitoring and discrimination resulting from its use, the legal and ethical norms are in a great state of flux. Conflicts of interest and conflicts of duty (for example, for the company physician or government official) abound. Moreover, given the arguable scientific validity of many screening tests and of resulting data, questions of what actions to take or not to take reflect differences in perceptions of fairness and risk-adverseness. The worker would rather be safe and keep his or her job; the employer wants to limit his or her legal and economic liability. In the face of great uncertainty, the actors prefer to take few chances, so that very divergent solutions are pursued concerning both the transmission of uncertain information and its use. On the other hand, some employers may be motivated to undertake medical screening solely out of a genuine concern for the health of their employees and may even feel a moral obligation to do so. In this case, there may be no conflict, if care is taken concerning the dissemination and use of the monitoring results.

Scientific and ethical issues

The sources of human intra-individual and inter-individual variability having relevance for the workplace environment range from the stochastic nature of differences among humans to genetic, environmental and disease factors related or unrelated to a particular place of employment (Table 2).

Table 2 - Sources of human variability

- Stochastic
 - epigenetic
 - Genetic “predisposition”
 - age/gender/race/specific genes
 - Environmental factors
 - Nutrition, diet and alcohol
 - Smoking
 - Other non-occupational exposures
 - Endocrine disrupters
 - Pre-existing disease
 - Non-occupationally induced
 - Prior occupationally induced
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The motivations behind using scientific information collected from genetic testing reflect the different purposes for which that information might be used:

- to discover increased harm or risk of harm in a population of workers;
- to notify populations at risk;
- to control or regulate toxic substances or other exposures in order to protect at-risk populations;
- to create or recognize a class eligible for compensation;
- to reduce
 - actual harm to workers (and to their offspring);
 - subsequent employer's liability;
- to remove or reassign
 - sensitive workers,
 - high-risk workers (and reduce risk to their offspring),
- to treat/provide therapy or establish a basis for future monitoring or surveillance;
- to compensate individual workers.

Scientific and science policy considerations

Whether or not information is good enough (i.e., reliable enough) to be used for any of these purposes depends, among other things, on whether the tests used have sufficient sensitivity, specificity, and predictive value (positive or negative), and reproducibility^{1, 2}. The reader is reminded that, from a scientific perspective, unless the underlying frequency of a condition or marker in a population is known in advance, no estimate can be made as to the predictive value of the test on an individual worker or subject. Also important to recognize is that biomarkers often lack validation for field use^{1, 2, 7}. Vineis, Schulte and McMichael observe that:

Although rare and highly-penetrant mutations in cancer genes [with strong correlation between the gene and the phenotype of interest] could act with no interaction with external factors (for example by direct interference with basic mechanisms of cell replications and differentiation), gene-environment interactions are intrinsic to the mode of action of low-penetrant genes⁸.

For low-penetrant genes, a large number of workers would have to be screened in order to prevent one cancer. Further,

...the proportion of diseases attributable to low-penetrant genetic traits is clearly difficult to establish and is probably much lower than the burden of disease to environmental agents. ... In general we can expect little from genetic screening of the population, apart from limited groups (usually families) with a concentration of high-risk mutations⁸.

...[Genetic monitoring] [t]ests for genetic damage in somatic cells have also been misunderstood. ...without assessment of predictive value, the marker will not be useful in screening populations⁸.

In addition to these scientific issues, questions of *science policy*, reflecting the need to achieve scientific consensus, arise regarding central technical considerations in the adoption of testing protocols. They mirror the preferences of scientists and other involved health professionals, but their determination is by no means 'objective'.

- In investigatory or screening studies, what are appropriate threshold values for biomarker specificity, sensitivity, and predictive value?
- How are the normal reference ranges for biomarkers to be determined and how are sensitive subgroups dealt with appropriately?
- How can it be ensured that reference groups are sufficiently well-characterized for known confounders?
- Can agreement be reached on the cut-offs for categorization of the acceptability of conducting future studies as unacceptable, justified and recommended?
- Can this be done independent of the purpose to which the information is to be put?
- Does it matter whether the biomarker is a marker of exposure, susceptibility, or disease?
- What are similarly acceptable *a priori* values for investigations that research the *suitability* of biomarkers for future applications?
- Are we ready to specify standards and quality assurance criteria for accuracy and reproducibility of tests?
- What are acceptable participation rates in worker-based investigations? Can statistical sampling of subjects be used in lieu of high participation rates for population-based studies?

In addition to these considerations, there is an obvious preference for non-invasive and non – dangerous (low-risk/high-benefit) methods. The study design should address population- as well as individual-relevant information, inter- and intra-individual variability (all tests are only a snapshot in time) and, of course, accuracy and reliability.

Ethical and public policy considerations

From an ethical or public policy perspective, what constitutes sufficient reliability in fact depends on the specific uses to which the information is put. Publishing biomonitoring results in a scientific journal generally requires more stringent limitations than notifying populations at risk. Taking political or legal action may embody a precautionary approach that relaxes the evidentiary basis for action⁹.

The extent to which workers are required by their employer to submit to monitoring or tests, and the permissible dissemination and use of both individual and population-based monitoring data by employers and government, are governed to some extent by statutory and common law in the United States (see later discussion). The strictures placed on independent researchers or investigators may not be so governed, and thus significant ethical issues arise. They are enumerated below. Beyond compliance with law, additional ethical issues arise when the employer or his/her contracted researchers/investigators conduct monitoring studies.

A. Monitoring by independent researchers and investigators

Making ethical considerations an integral part of a biomonitoring study/research design

Ethical issues should be considered before planning, conducting, and using information from a biomarker investigation. They include 1) recruitment methods, and 2) possible impacts on individuals and groups from the dissemination, and the use of, or failure to make use of, the results obtained. These impacts could include implications for:

- reducing exposure;
- preventing, arresting, or treating disease;

- improving health status; and
- follow-up actions.

In addition, failure to think through the implications of a particular study could:

- inflict mental distress and adversely affect the psychological health of the subject-participants and similarly-situated groups (of workers) as a result of publication of the study;
- compromise the moral integrity of the subject-participants resulting from uncertain and equivocal results.

If there is some significant risk of particular tests, what goes into the risk/benefit calculus?

- The benefits of the proposed study should not be overstated, nor the risks understated (reflecting possible investigator bias).
- The proposed study might be classified as unacceptable, justified, or recommended.
- Distinction should be drawn between expected individual and population-based validity (and hence benefit).
- Risks should include risk to employment status, in addition to impacts on physical and mental health.

Recruiting the subject-participants

The recruitment of subjects should be undertaken:

- without an implied/false sense of benefit when none/little is expected;
- without under-representation of the risks (both safety and economic/social) of tests;
- without coercion stemming from
 - displeasure of physicians/employers/fellow workers,
 - concern with job security,
 - fear of/actual withholding of benefits (treatment, compensation, etc.);
- without creating adverse psychological effects and compromise of moral integrity;
- by having a clear agreement on the restricted uses of samples taken;
- with appropriate consideration of remuneration.

Concerns related to informed consent

- What are the essential elements of informed consent in the biomonitoring context?
- Is informed consent meaningful when there are great uncertainties attending risks and/benefits?
- The positive and negative consequences (health and non-health) of both participating and not participating need to be divulged.
- The anticipated uses of individual and group data should be explained.
- Is ‘decisional autonomy’ possible for trans-generational effects?

Notifying (disseminating the results to) the subject-participants

Results of the investigations need to be communicated in an understandable and compassionate manner:

- in a timely fashion;

- after anticipating and planning an appropriate response to the possible impacts of notification on subject-participants and on others who might be affected by the information;
- along with awareness of/provision for more communication, information and advice to affected persons;
- along with options for prevention, control, treatment of disease, and future monitoring.

Again, distinctions between individual risks and population-based risks have to be clarified.

Disseminating the results to others

- How is the balance to be maintained for concerns with confidentiality and informing the subjects' physician, family, employer, and fellow workers?
- Even population-based information can be damaging to privacy interests of individual workers.
- Are different answers forthcoming for biomarkers of exposure *versus* susceptibility *versus* disease?
- Distinction might be drawn between *ex post* and *ex ante* consent required for publication of the study results. *Ex ante* consent may not be truly informed consent. Subject relate differently to the results of an actual study, than to some hypothetical description of expected results.

Commitments to follow-up activities

- Those undertaking the investigations have to be prepared to take follow-up action or to assist in securing commitments from others.
- How far do these commitments go?
- Are they to be restricted to expected results of the investigations or do they extend to unanticipated results?

Securing the participation of the subjects in all aspects of monitoring

- Ethical principles would seem to dictate the participation of subjects (individually or through their representatives or nominees) in decisions preceding, during and following the actual study, i.e., in the choice of what is to be monitored, the design of the protocol, the choice of the investigator, the actual conduct of the study, the evaluation of the results, the dissemination of the results, the decisions to act upon those results and the actions themselves.
- Vehicles to enable and empower subject-participants include:
 - The subject choices of professionals as investigators, evaluators, or technical observers
 - The use of management-labour health and safety committees
- The earlier key actors are involved in the process, the more effectively can adverse effects and loss of trust be avoided or minimized

An in-depth exploration of these value-laden questions and issues is beyond the scope of this paper. The reader is referred to other thoughtful commentaries for further discussion^{8, 10-14}.

B. Monitoring by the employer or his researchers and investigators

In addition to the ethical issues that should be considered by independent researchers and investigators, it is argued that employer-sponsored studies have an ethical obligation to ensure that:

- actions taken as a result of monitoring reduce both individual and total harm;
- environmental monitoring is also used;
- resources are not diverted from redesigning cleaner and inherently safer technology;
- medical removal protection is provided for earnings and job security, even if not required by law.

Legal challenges in work-related genetic testing in the United States

Legal problems and challenges related to genetic testing arise in the context of 1) requiring workers to submit to monitoring, 2) dissemination of monitoring results/data, 3) the employer's use of monitoring results, and 4) the use of monitoring data in tort and workers' compensation cases. These are explored below.

Requiring workers to submit to human monitoring

Personal privacy is an important issue. In the abstract sense, an employee may always refuse to be the subject of human monitoring. Thus the US Occupational Safety and Health Administration (OSHA), the US National Institute of Occupational Safety and Health (NIOSH), and the employer have no authority to compel employees to cooperate. Refusal to participate, however, may mean loss of a job, so that the relevant enquiry is the extent to which the employer may predicate employment on such cooperation. For example, may an employer require a prospective employee to submit to genetic or biologic screening as a precondition to employment? May he or she require a current employee to submit to periodic biologic monitoring or medical surveillance? These questions raise important issues of confidentiality and discrimination. Apart from these issues, however, the question of the employer's general authority to require human monitoring of employees needs to be considered.

Monitoring in response to agency directive

At the outset, a distinction must be made between the human monitoring that OSHA, NIOSH, or the US Environmental Protection Agency (EPA) may require and the monitoring that the employer implements on his or her own initiative. When a federal agency requires that monitoring be done, the worker has a valid objection only if he or she asserts a statutory or constitutional violation. The US Congress was mindful of constitutional considerations in developing human monitoring programmes. For example, it specifically acknowledged the need for a balancing of interests when an employee asserted a religious objection to a monitoring procedure. Human monitoring can also impinge on the worker's constitutional right to privacy. In the case of human monitoring, the right to privacy 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. Depending on the nature of the procedure, it may infringe the right to be free from unwelcome physical intrusions and the right to make decisions regarding one's own body. Although these rights are obviously related, the former is grounded in the fourth amendment's proscription against unreasonable search and seizure, whereas the latter is closely associated with the rights of personal privacy commonly identified with the ninth and tenth amendments. Although protected by the US Constitution, these rights of privacy are not inviolate.

US 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 judicial 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 workers' health, or for the enforcement or evaluation of existing standards, serves an important public health purpose. Furthermore, although the US Constitution protects against government paternalism, 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 (indeed, Bayer¹⁵ raises the question of whether workers may actually have a moral obligation to cooperate in such monitoring for the collective good. He argues that without safeguards, coercive monitoring is unfair). 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 predictive value of a particular intrusion, however, the weaker the case for violating physical privacy.

At some point, the degree of risk or intrusiveness of monitoring 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 have a right to insist on an alternative, 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 that goal.

An additional and critical question is whether the employee may refuse to participate in a programme of agency-directed monitoring when he or she believes that the employer may use the resulting information as a basis for termination of employment. For example, the worker who suffers chromosomal damage as a result of workplace exposure may fear that medical screening will reveal this condition to the employer and thus induce job loss or reassignment (i.e. removal). Thus, participation in a monitoring programme can be tantamount to self-incrimination.

This form of self-incrimination conflicts with the right to personal privacy. 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 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 substantial if health data are 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.

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 Medical Removal Protection (MRP) programmes as part of their human monitoring requirements. MRP provides earnings protection and employment security during medical removal. Properly used, an MRP programme would help to ensure employee cooperation with monitoring.

Monitoring in the absence of agency directive

Under common law, employers can require their employees to comply with reasonable programmes of human monitoring. The US Congress did not intend the Occupational and Safety and Health Act (OSHAct) to "*preempt the field*" by authorizing the implementation of human monitoring requirements. One of the Act's express purposes is to "*stimulate employers ... to institute new and to perfect existing programs for providing safe and healthful working conditions*". Congress intended that employers take the initiative on a number of fronts, including human monitoring, in developing health and safety programmes. As long as it promotes "*safe and healthful working conditions*", employer-initiated human monitoring would appear to be allowed. However, the Genetic Information Nondiscrimination Act of 2003, passed by the Senate and awaiting action by the House, or its successors, would appear to significantly limit these efforts in the case of genetic testing (see the discussion below). Nothing in the OSHAct precludes employers who are subject to OSHA monitoring requirements from implementing additional programmes. Further, it could be argued that employers have a moral obligation to initiate monitoring if they suspect their employees are at risk. To date, however, this moral obligation has not been translated into a legally enforceable duty to undertake medical screening.

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

Informed consent is also an important issue in the context of workplace monitoring. Assuming that a human monitoring programme is permissible, there are limitations on the manner in which an employer may implement the programme. In general, one who undertakes the performance of monitoring procedures has a duty to perform those procedures properly and will face liability for damages caused by the negligent administration of a monitoring procedure.

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 stems from a belief that persons have a right to make decisions governing their bodies and health. 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. Commonly, they are 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 as to whether and to what extent the traditional doctrine of informed consent has meaning in the occupational setting.

Initially, one may enquire 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 workers' 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 examination requested by the prospective employer. 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.

Similarly, the doctrine of informed consent is tied closely 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 of these assumptions into question. Monitoring may not be "treatment" in the conventional sense of the word. In many cases, monitoring benefits the employer more than the employee. 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 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.

Regardless of the applicability of informed consent in the traditional sense, a complete and accurate disclosure of risks seems an advisable adjunct to a programme 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 regarded as a physical 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 programme of human monitoring, employee and union scrutiny will act as an incentive for the employer to develop programmes 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. 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.

An important question concerns the scope of the required disclosure of procedural risks. 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 programme of human monitoring may be the loss of jobs? The Code of Ethical Conduct¹⁶ adopted in 1976 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.

Under this formulation, although the physician may not disclose to the employer the specific results of human monitoring, the employee's job security may be endangered nonetheless. Employers are "entitled to counsel about the medical fitness of individuals in relation to work". A preferable alternative practice¹⁷ would involve the worker in such discussions between the physician and the employer.

Title II (Employment) of the Genetic Information Nondiscrimination Act of 2003, applying to private-sector employers with 15 or more employees, was passed by the Senate and

*...would prohibit employers, labor organizations, employment agencies and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, or other employment decisions. **Employers are also prohibited from requesting, requiring, or purchasing genetic information of employees.** The genetic information protected extends to the employee, his or her spouse and all of their blood relatives, as well as adopted children. Employers who obtain genetic information about their employees inadvertently, through compliance with other laws (such as the Family and Medical Leave Act) or through certain efforts to preserve employee health (such as employee wellness programs or monitoring of biological effects of toxic substances in the workplace) would not be penalized unless they used such information to discriminate against the employee...¹⁸ (emphasis added).*

In addition to prohibiting the requiring or accessing of genetic information of employees, dissemination and discriminatory use of genetic information is also prohibited (see the discussion below).

Dissemination of monitoring results

Employee's right of access

An employer may not limit or deny an employee access to his or her medical or exposure records. The OSHA regulation 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 reserve and maintain these records for an extended period of time (in the absence of OSHA regulation, employees would arguably still have a right of access under common law or state statute in many jurisdictions¹⁹). There appears to be some overlap in the definition of "medical" and "exposure" records, because both may include the results of biologic monitoring. The former, however, is generally defined as those records pertaining to "the health status of an employee", while the latter is defined as those pertaining to "employee exposure to toxic substances or harmful physical agents".

The employer's duty to make these records available is a broad one. The regulations

provide that upon any employee's 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". In addition to the right of access, there are duties to inform workers of exposure to occupational hazards²⁰.

Employees' right to confidentiality

Of all of the issues raised by human monitoring, employee confidentiality may have received the most attention²¹. An employee's right to maintain the confidentiality of information regarding his body and health places a significant limitation on the ways in which others can use that information. As programmes 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 technologic 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 US Bill of Rights and is one component of the right of personal privacy discussed previously. With regard to private intrusions, the right is grounded in state law. 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 and may be limited or waived. US 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. The key is the development of information-based technology that will make that approach more readily available.

Title II (Employment) of the Genetic Information Nondiscrimination Act of 2003 prohibits disclosure of genetic information except to the employee, health researchers, or in compliance with federal and state law¹⁸.

Notification of workers at high risk

Caldart²² and Ashford and Caldart²³ have addressed the worker's right to information and the employer's duty to provide information concerning occupational risks without request. Recently, there has been increasing attention to the government's responsibility to notify workers if they have been identified as being part of a high-risk group based on epidemiologic studies. The reader is referred to the excellent works of Schulte *et al*²⁴⁻²⁶, which deal with the multitude of legal and ethical problems arising out of the right-to-know.

Employer's use of human monitoring results

Even if an employer obtains human monitoring data through a legitimate exercise of his right of access, the right to use such data is not absolute. In the United States,

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 an employer use health or exposure information to limit or terminate the employment status of an individual employee or to deny employment to a prospective employee? Further, to what extent and under what conditions does the employer have an obligation to remove the worker? If removing a worker and rotating another employee to take his or her place reduces each worker's individual risk but increases the total number of diseased workers, what is the employer to do?

Common law limitations

In early common law (court-developed law through successive cases), 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. 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". Although federal labour law, workers compensation, and recent common law limitation on the doctrine of "employment at will" have profoundly 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. 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 from performing his or her job. Workers compensation legislation, of course, facilitates termination of the jobs of permanently disabled workers.

Human monitoring, however, places the issue in a somewhat different light. Monitoring designed to reveal whether an employee has been, or in the future may be, harmed by workplace hazards raises the question of 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 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 or 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, in the absence of 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, then the employer is violating the public policy embodied in the OSHAct. Workers are only infrequently able to obtain compensation for disability due to occupational disease. In this case, to permit the employer to discharge the employee is to permit a further violation of public policy. 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 by common law to find safe assignments for the workers at comparable pay or bear the costs of their removal.

Limitations 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. When monitoring information reveals that an employee risks serious health damage from continued exposure to a workplace toxicant, 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. In the case of a toxic substance, this would appear to require reduction of the exposure, not mere removal of presumptively sensitive employees from the site of exposure.

The issue is amenable to regulatory solution. The implementation of mandatory MRP for toxic substances exposure in general, as OSHA has done with its lead standard²⁷ might be accomplished by a generic MRP standard. An employer's compliance with a mandatory MRP provision for a particular exposure would remove the threat of a general duty clause citation.

Limitations under the 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 antidiscrimination laws. Although not all workplace discrimination is prohibited, US state and federal laws 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 follows.

Section 11(c) 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"*. If an employee insists on retaining his job in the face of medical data indicating that continued exposure to a workplace toxicant will be likely to 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. Inferentially, then, the Act vests employees with a concomitant right to insist that their workplace be free of such hazards. By insisting on retaining employment, the employee is asserting his right to a workplace that comports with the requirements of the general duty clause. Accordingly, an employer who discharges or otherwise discriminates against a worker because of perceived susceptibility to a toxic exposure arguably violates the prohibition of section 11(c). When an employer asserts that an employee cannot work without injury to health, the employer tacitly admits that the workplace is unsafe. That admission triggers the remedial provisions of the OSHAct.

An OSHA regulation, issued under section 11(c) and upheld in an unanimous US Supreme Court decision²⁸, gives individual workers a limited right to refuse hazardous work when there is a situation likely to cause "serious injury or death"²⁹. 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. According to the district

court to which the issue was remanded for consideration, withholding the employee's pay during the period in which the employee exercises the right is also prohibited.

As a worker may be absent 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 from employment.

While these legal safeguards would seem to go some way in offering protection to workers, in the case where monitoring or screening involves genetic information, Title II of the Genetic Information Nondiscrimination Act of 2003 explicitly provided that the bill:

...would prohibit employers, labor organizations, employment agencies and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, or other employment decisions...

Penalties for violation of the law are those available under Title VII of the Civil Rights Act which prohibits employment discrimination based on race, color, religion, sex, or national origin [see below]. The procedures and remedies under the bill are the same as under current law. Employees who believe they have a claim must make a complaint to the Equal Employment Opportunity Commission (EEOC) or the appropriate state agency. The EEOC will investigate the claim and bring suit on behalf of the employee if evidence of a violation is found. The EEOC also may pursue mediation if the employer and employee agree to that option. In cases in which the EEOC chooses not to bring suit, the employee may bring suit independently. Penalties for Title VII violations include reinstatement, back pay, injunctive relief, equitable relief and attorney's and expert witness fees.

No charges may be filed for "disparate impact" discrimination, which is not an intentional diverse employment action but a discriminatory effect on a protected class caused by an employment practice or policy that appears to be nondiscriminatory. The bill would direct a commission to be formed six years after the bill's enactment to report on the possibility of allowing disparate impact claims¹⁸.

The only outright federal prohibition against employee discrimination based on genetic information is Executive Order 13145 issued in 2000 which prohibits such discrimination in federal employment.

Handicap discrimination

Employees may be able to assert further rights against discriminatory use of human monitoring data under laws protecting the handicapped/disabled. US Congress and most states have passed laws barring discrimination against handicapped/disabled 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 adopted a case-by-case approach, the worker who is denied employment opportunities on the basis of monitoring results often falls within the literal terms of many hand-

icap discrimination statutes. In general, two issues will be determinative regarding disability: whether the workplace in question is covered by a state or federal handicap act; and if so, whether the worker in question is handicapped/disabled under the act.

Until recently, the general applicability of handicap/disability discrimination statutes to the use of human monitoring information in general remained unclear. However, a recent case brought before the Equal Employment Opportunity Commission (EEOC)³⁰ and the Genetic Information Nondiscrimination Act of 2003 would seem to have settled the matter in the federal courts with regard to genetic information^{31, 32}. In a genetic testing discrimination suit against an employer secretly testing its employees for a rare genetic condition associated with carpal tunnel syndrome, the EEOC sent a clear message that the Americans with Disabilities Act (ADA) was intended to cover genetic testing of existing employees, and other medical tests³³, and that employers “*shall not require a medical examination... unless such examination or inquiry is shown to be job-related and consistent with job necessity*”.

In 2002, in a case involving an individual with occupationally-caused musculoskeletal impairments who claimed she was substantially limited in performing manual tasks, housework etc, the Supreme Court restricted the reach of the ADA, holding that the definitional terms in the ADA “*need to be interpreted strictly to create a demanding standard for qualifying as disabled*”^{34, 35}. Putting these two cases together gives mixed results. While genetic and other medical tests are covered by the ADA, what characteristics qualify as an impairment – or might be regarded as an impairment – under the ADA has been greatly narrowed in the federal context. However, state courts in several states have rejected the federal narrowing of the ADA and interpret state disability laws more favourably for disabled workers³⁴.

Examining the definitional criteria in the federal act, on which many – perhaps most – of the state statutes are based, will illustrate the issues facing courts, and the potential range of logical interpretations. The US National Rehabilitation Act of 1973 as well as the ADA of 1990 define a handicapped/disabled 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*”.

In the great majority of cases, persons facing reduced employment opportunities 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. The Act seems designed primarily to protect the seriously handicapped, but its wording is broad enough to cover discriminatory practices based on data obtained through human monitoring.

Even in cases in which handicap/disability discrimination is established, an employer may escape liability if the discriminatory practice is reasonably necessary for efficient operation of the business. The US National Rehabilitation Act provides employers with no affirmative defense, but does require the handicapped/disabled individual to prove that he is “qualified” for the job. Thus, if a handicap/disability prevents a worker from safely or effectively performing the job, an exclusionary practice may be permissible under the Act. Most state handicap statutes include some form of affirmative defense. Although these vary among jurisdictions, many appear analogous to the familiar defenses that have developed under Title VII of the US Civil Rights Act of 1964.

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 of the Civil Rights Act prohibits employment discrimination on the basis of race, colour, religion, sex, or national origin. The scope of the Act is substantially broader than that of the federal handicap discrimination act, and it affords protection for the great majority of American employees. In addition, many states extend similar protection to employees not covered by the federal act. The Age Discrimination in Employment Act of 1967 and some state acts provide protection of comparable breadth against discrimination on the basis of age.

As with handicap discrimination, until recently the applicability of these laws to the use of human monitoring information was unclear. In a 1998 case involving genetic testing in the workplace, administrative employees were secretly tested for their propensity to develop sickle cell anaemia during a pre-employment examination³⁶. The US Court of Appeals for the Ninth Circuit ruled that employees' claims based on invasion of privacy grounds might go to trial, but not those barred on the ADA³².

Even if not intended as discrimination, the practical impact of an exclusionary practice may fall disproportionately on a particular race, sex, ethnic or age group. The US Supreme Court has long held that a claim of disparate impact states a viable cause of action under the Civil Rights Act. A similar rationale has been applied in the area of age discrimination. In a 1975 decision, the Court held that job applicants denied employment on the basis of a pre-employment screen can establish a *prima facie* case of racial discrimination if 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*”. 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.

The potential for disparate impact is inherent in many uses of human monitoring data. A genetic screen for sickle-cell anaemia, for example, will disproportionately exclude blacks and certain ethnic groups 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. The permissibility of foetus protection policies, which exclude women of child bearing capacity 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 this issue, see Ashford and Caldart²⁰.

Finally, a wide variety of exclusionary practices based on monitoring data may have a disparate impact on older workers. Older workers are likely to 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 preexisting illness as a result of previous workplace exposures or on account of age alone.

Interestingly, the Genetic Information Nondiscrimination Act of 2003 provides that “*no charges may be brought for disparate impact discrimination*” based on genetic information, reserving that issue for the deliberations of a Commission to be established 6 years after the act goes into effect¹⁸.

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*”. If such a showing is made, the practice will withstand a charge of disparate impact discrimination. The US Supreme Court has characterized the defence of business necessity as requiring “*a manifest relation to the employment in question*”. 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*”. Further, if the plaintiff can establish that another, less discriminatory practice will accomplish the same purpose, the defence of business necessity will not stand.

The defence of business necessity is available only in cases of disparate impact. If a practice is discriminatory on face value 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 defence is available under the Civil Rights Act for discrimination based on sex, national origin, or religion (but not for discrimination based on race or colour) and under the Age Discrimination in Employment Act. The BFOQ defence requires the employer to establish that the discriminatory practice is “*reasonably necessary to the normal operation of business*”. The US Supreme Court has characterized the defence as an “*extremely narrow*” one.

There are two principal reasons why business necessity may be difficult to establish for exclusionary practices based on human monitoring data. The first is that most 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 worker³⁷. That position may well encounter a chilly judicial reception. As noted in one 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*”³⁸. Another, and potentially more serious, obstacle to the successful assertion of a defence of business necessity is the unreliability of the screening procedures themselves. If the exclusion of susceptible, 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 screening tests are currently far from reliable, the availability of the business necessity defence is questionable.

The foregoing discussion of discrimination has presupposed that the screened worker will be excluded from the workplace. Employers, however, may 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 were filed, courts might find that an adequate MRP programme obviated the charge of discrimination. This could be one area in which good law and good social policy coincide.

The use of monitoring data in tort and workers' compensation cases

From a legal perspective, the most important impact of human monitoring information may be its use as evidence in tort and workers' compensation cases. Although its potential in this area is still to be realized, the science of biological markers may eventually serve to answer the evidentiary question that has plagued most compensation cases involving human exposure to toxic substances: how do we know whether a *particular* exposure caused a *particular person's* medical condition? At present, the problem remains a major one, except for exposure to a few substances, such as vinyl chloride and asbestos.

Obviously, to the extent that increased use of human monitoring adds to the existing database on the observed correlations between particular diseases and particular chemicals, it will provide increased evidence for use in compensation proceedings generally. More than this, though, human monitoring has the potential to bring about a change in the nature of the evidence used in these cases.

Typically, the evidence offered to prove causation in chemical exposure cases is premised on a statistical correlation between disease and exposure. Whether the underlying data are from epidemiologic studies, from toxicological experiments, or from the results of a complicated risk assessment model, they are usually population-based. This places the plaintiff at the mercy of the attributable risk (expressed as the percentage of cases of the disease attributable to the exposure) for the study population. Unless the attributable risk is greater than 50% – that is, unless the incidence rate among those exposed to the chemical is more than double the background rate – the plaintiff cannot prove on the basis of the available statistical evidence, that it is more likely than not that his or her particular case of the disease was caused by the chemical exposure.

The developing science of human monitoring may offer a way to distinguish individual claimants from the population at risk. Conceivably, the data generated by various human monitoring procedures will:

- increase our knowledge of the “sub-clinical” effects of toxic substances, thus permitting us to track the effect of a chemical exposure over time, and also expanding the universe of “medical conditions” for which compensation may be provided;
- eventually enable us to establish that a particular person has been exposed to a particular chemical (or class of chemicals); and
- eventually enable us to establish that a particular person's medical condition (or subclinical effect) was caused by exposure to a particular chemical (or class of chemicals).

Already, human monitoring data are being used in some situations to identify sub-clinical changes thought to be associated with particular chemical exposures. This can have many applications in toxic substance compensation cases. In the long term, evidence of subclinical changes occurring between the time of exposure and the time of disease may be a way of distinguishing those whose disease was caused by the exposure from those who contracted the disease because of other factors. Such evidence may also give rise to more immediate legal relief. There is a growing trend toward allowing those who can establish that they have been exposed to a toxic substance – and thus that they have been placed at increased risk of future harm – to recover the costs of medical surveillance from the responsible party. Proof of certain subclinical effects, such as DNA damage, would tend to support an allegation of increased risk, and would make the claim for medical surveillance all the more compelling. Further, such evidence may support a

separate claim for damages for having been put at increased risk of future harm, although it is not clear that such a claim would be viable in most states.

Finally, some evidence of “subclinical” effects may give rise to a right to recover compensation for those effects themselves. For example, human monitoring can detect certain changes in the immune system. There is a body of literature suggesting that chemical exposures can harm the immune system³⁹, and evidence of immune system damage has been offered in cases involving toxic substance exposure⁴⁰. Thus far, allegations of immune system damage have met with mixed success in the courts, both because the relationship between chemical exposure and immune system damage is not yet clear, and because the evidence of immune system damage was not always considered persuasive. Although human monitoring may not be able to tie particular immune system deficiencies to particular exposures, it should be able to establish with greater certainty whether immune system damage has, in fact, occurred.

Looking farther to the future, it is quite possible that further developments in the science of biomarkers will permit the identification of “chemical fingerprints” – a distinctive change in the DNA that can be linked with exposure to a particular chemical or class of chemicals. At the very least, this should make it much easier to distinguish those who have been exposed to a particular chemical in the workplace from those who have not, and to identify which of the many potential defendants was responsible. More importantly, it should eventually permit the correlation of particular cases of diseases such as cancer with exposure to particular chemicals (or classes of chemicals). To the extent that this happens, it will narrow the scope of the evidence from the population to the individual, and will place the deliberations in these cases on firmer scientific footing.

Positive uses of human monitoring in the workplace

The strategies used for human monitoring must be fashioned on a toxicant-specific basis because the state-of-the-art techniques differ from substance to substance. In general, medical surveillance and biologic or genetic monitoring for populations should be used only in combination with environmental monitoring. In the 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 serve as an early indicator that exposure to a certain chemical has occurred in a worker population. However, the use of that kind of screening for this purpose is in its infancy. Genetic screening focuses on removal of the worker before exposure and is preventive for that worker only.

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 test is accurate and reliable and the predictive value is high; 4) monitoring is not used to divert resources from reducing the presence of the toxic substance in the workplace or from modifying the hazardous technology; and 5) medical removal protection for earnings and job security is provided. New solutions involving both technologic innovation and job redesign may obviate the necessity of human monitoring. Conflicts now arise only because, with existing technology, workers continue to be exposed to toxic substances.

If conditions one through five are met, the question remains whether the employer is obligated to remove the worker from the workplace. It would seem so, since the employ-

er owes that duty of care to his or her employees. But what if the monitoring test is unreliable? The extent of the obligation would appear to be less, although the dissemination of the test results to the worker arguably would still be required. Is the employer under a greater or lesser obligation to remove the worker if he or she provides no earnings and job security protection; greater, because it costs him or her nothing to protect the worker; or lesser because the worker is economically disadvantaged?

Finally, if a particular workplace cannot be made safer and the removal (and rotation-replacement) of workers results in lower individual risk but greater total disease, is this morally defensible? Exposure to radiation or some carcinogens can represent such a situation. These are difficult questions that deserve careful consideration.

Solutions to the legal and ethical conflicts in the workplace

The extensive discussion in the previous section reveals the complexity and difficulty with which the law balances competing interests and equities. In some cases, the law embodies the belief that *de facto* discrimination against certain protected classes of people (e.g. a minority race) is to be affirmatively avoided and cannot be justified by resulting health benefits. In other cases, such as those involving workers who are perceived as handicapped, the burdens to industry of providing protection may be relevant in deciding how much employment security to require. Discrimination law necessarily involves the exercise of discretion by courts and adjudicating institutions – with its attendant inconsistency and unpredictability.

Discriminatory practices and consequential tort suits, anti-discrimination suits, deterioration of labour-management relations, and agency sanctions may follow poorly conceived and poorly executed human monitoring programmes. The weaker the scientific foundation for the monitoring test, the less secure are the legal grounds and defences available to the employer. In light of the sometimes preliminary, unreliable and non-specific nature of many techniques used in human monitoring, the practice is a problematic activity itself in most instances.

With legal and ethical norms in flux, it is important to examine the policy options for dealing with future and continuing ethical dilemmas. The possible strategies that deserve consideration include:

- 1) encouragement of ethical enquiry in the conduct and use of medical screening and testing, i.e., educating workers, management, and health professionals to think more seriously about the problems – indeed, ethicists should be consulted in designing the screening and testing programmes;
- 2) use of legislative and regulatory means to clarify rights and duties, such as encouraging OSHA in the United States to promulgate a generic earnings and job security protection requirement for all cases of medical removal, or enacting legislation that requires workers to be notified of occupational risks and prohibits discrimination outright;
- 3) encouragement of the use of self-help techniques by workers, such as union bargaining, the filing of discrimination complaints, and the right to refuse hazardous work;
- 4) encouragement of better disposition of conflicts by improving procedural fairness in attempts at resolution, such as full and complete disclosure of information to workers, the better maintenance of confidentiality of worker records, or the use of corporate ombudspersons;

5) encouragement of shared decision-making through joint health and safety committees.

These options differ in the extent to which the rights and freedoms of some are diminished to protect those of others. Regulatory or legislative fiats define acceptable behaviour and in the process, decrease freedom of choice. On the other hand, freedom from harm and discrimination is preserved. Sharpening self-help mechanisms preserves choice, but fosters an adversarial solution. Education can persuade and enlighten; it can also sensitize the discriminated to assert their rights. Procedural fairness tends to right the imbalance of access to legal and political institutions.

The choice of options at any one time reflects the seriousness with which society wishes to address the moral and legal dilemmas. Thinking about these problems is a first and necessary step⁴¹⁻⁴⁴.

Finally, there is an obvious additional rôle for government in addressing the following unresolved issues:

- what additional legislative/regulatory protections need to be in place to ensure the right to privacy?
- how are competing requests by potential subjects (workers) for study to be decided?
- if there is a significant risk to the subject, how can an independent risk-benefit evaluation be done?
- is there a need for a national panel/regulatory body to comment on acceptable biomarkers/tests?
- how can appropriate worker participation be ensured in governmental deliberations?
- in some state jurisdictions, information derived from biological monitoring investigations may be used to impose liability on employers and others in order to compensate exposed individuals, thus creating a disincentive to undertake monitoring; to the extent that there may be a need to encourage more study and application of biomarkers, how should this conflict of social goals be addressed?

The Genetic Information Nondiscrimination Act of 2003 only begins to answer some of these concerns.

In 1998 during the Clinton Administration, the Department of Health and Human Services created the Secretary's Advisory Committee on Genetic Testing. Their preliminary report issued on April 1, 2000 echoed the cautions of previous commentators concerning limitations of the evolving science and inadequacy of protective standards⁴⁵. The committee's charter was allowed to expire and a new committee, the Secretary's Advisory Committee on Genetics, Health, and Society was formed in the George W. Bush Administration.

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