Part V

Congressional Issues and Options

Chapter 11

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Genetic testing is an emerging technology. It has the long range potential to play a role in the prevention of occupational disease, but it also has the potential for misuse. Although only a handful of companies are using genetic testing now, many more are interested. Current law provides some incentive for its use and some safeguards against its misuse. Established ethical principles also provide some guidance for its use. However, many questions remain unanswered. Under these circumstances, it may be appropriate for Congress to balance the competing interests and to make the value judgments necessary in order to maximize the technology's potential benefits and minimize its risks.

This chapter provides an array of issues and options for congressional consideration. They may be grouped loosely around the following fundamental policy questions:

- Should the technology be stimulated and, if SO, how?
- Should there by any constraints on the use of the tests and, if so, what?
- To what degree should society protect workers who are at increased risk for developing disease, at what cost, and who should bear that cost?

The first issue is an overview of the options related to all of these questions. The issues and opt ions that follow focus on particular aspects.

ISSUE: What actions could Congress take with respect to genetic testing in the workplace?

OPTIONS:

A. *Maintain the status quo.*

Congress could choose not to take an-y action to stimulate, constrain, or regulate genetic testing. This would allow private parties to continue research into the merits of the technology. Constraints on its use would develop through court rulings in lawsuits between these parties or by negotiations between companies and unions. Interested congressional committees could continue their practice of holding oversight hearings to raise the issues for public discussion.

The primary argument supporting this option would be the view that congressional action would be premature. The technology is not being widely used, and it is primarily in the research phase of its development. In addition, there are existing constraints on its potential misuse. These include the possibility of lawsuits and adverse publicity. Finally, much of the important information necessary for legislation is unavailable because it is unknown. For genetic screening techniques, this information includes the number of workers who might be genetically predisposed to disease, the extent to which they might face adverse employment actions, the availability of other employment opportunities, and the cost of safeguarding these workers. For genetic monitoring techniques, this information includes their predictive value, the extent to which they might be used, and the costs associated with either using or not using them.

The arguments against this option relate to how society controls an emerging technology. Many policy decisions will need to be made with respect to genetic testing, and arguably Congress is a better forum for doing so than the courts or private parties. Congress can gather all information and viewpoints and then balance the conflicting interests. In addition, while the courts often play a major regulatory role for any technology, they are limited in their ability to encourage the development of a technology in a positive manner. However, Congress can do so by providing funds for research or other incentives.

B. Stimulate the technology's development and use.

Congress could stimulate the technology by providing additional money for research on the techniques, for epidemiological studies to determine associations between genetic indicators and disease, and for basic research on the cause of occupational disease in general. If genetic testing

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could be developed to the point where the tests are predictive of an individual's or group's increased risk for occupational illness, its use could result in a number of direct and indirect benefits. The principal direct benefit would be a lower incidence of occupational disease among workers. They and their families would be spared some of the pain, cost, and emotional trauma that accompany illness. In addition, employers would save some of their direct and indirect costs of occupational disease-employee time lost from work, insurance premiums, legal fees, and monetary damages assessed in lawsuits. Society would benefit through the greater health and productivity of its work force, A major indirect benefit of developing this technology might be a greater understanding of the causes of occupational disease and disease in general.

The principal argument against this option is the concern about the potential misuse of the technology and about potential adverse impacts. Some of these concerns relate to unfair employment discrimination and attention being directed away from other ways to address occupational diseases. These concerns might be dispelled by regulation to direct the technology's development in socially desirable ways, In fact, if the tests were highly predictive of future illness, the Occupational Safety and Health Administration (OSHA) could require their use and constrain how they were used, so long as those constraints were shown to enhance worker health and were not directed toward prohibiting fair employment practices.

Another drawback to this option is the fact that there is no information on the amount of occupational disease that could be prevented by genetic testing, even if the tests were reliable predictors of disease. Similarly, there is no information on what it would cost to get the tests to the point of clinical usefulness.

C. *Prohibit the use of genetic testing in the workplace.*

The principal reason for prohibiting genetic testing in the workplace would be concern over its potential misuse, particularly at its current stage of development where its ability to predict future disease has not been demonstrated. This potential for misuse probably would be greater for genetic screening than for genetic monitoring because the former is targeted toward identifying individuals at increased risk while the latter focuses on groups at increased risk. However, concern exists that employers might use either screening or monitoring to exclude individuals from jobs. Existing law may offer protection in some circumstances, but there are many questions to be resolved. The collective bargaining process could be used by unions to negotiate protection for workers, but the primary focus of bargaining has been economic matters. While health matters have also been important, genetic engineering apparently has not been a bargaining issue. In addition, most of the work force is not unionized. Moreover, these remedies are not helpful if a susceptible person does not know why he or she was denied a job. Finally, while ethical principles provide guidance for the proper use of this technology, it is difficult to know if they are being followed.

The principal drawback to this option is that it is a drastic solution to the problem of potential misuse, Genetic testing does not appear to be widely used. Law, ethics, and public opinion provide incentives against its misuse. Moreover, banning its use would prevent research that might determine its usefulness in preventing occupational disease or provide basic knowledge about occupational disease.

Another argument in favor of this option would be the claim that an employee's risk of future illness is not an appropriate factor for job selection, even if screening or monitoring were highly predictive. Employees have no control over their genetic makeup and generally have no control over previous exposures to harmful agents. In addition, their increased risk would not affect their current ability to do the job.

There are at least two counterarguments to the assertion that risk of illness should not be a job selection factor. First, society accepts the proposition that immutable characteristics can be proper criteria for employment selection. Intelligence is at least an implicit selection criterion for many professional jobs and physical attributes are exceedingly important for jobs ranging from pro-

fessional basketball to neurosurgery. Second, this viewpoint places the autonomy interests of the individual above the interests of society in lowering the costs of occupational illness even when it may not be feasible to take other steps, such as lowering exposure.

D. Regulate the technology.

This option represents a judgment that any risks presented by the technology can be controlled and that the claimed benefits will be of value to society. The option would permit research to continue, yet constrain the manner in which genetic testing is used. One type of constraint would be limitations on what job actions employers could take on the basis of test results. Another type of constraint would be a requirement that the tests meet minimum standards of scientific validity before employment decisions were made on the basis of the results. Such a statute need not specify detailed standards; it could adopt a standard such as '(reasonably predictive of future illness" and allow the appropriate agency to provide details.

This option has the advantage of addressing the potential risks of genetic testing immediately and in a comprehensive manner rather than waiting for the law to develop on a case-by-case basis through the courts. Congress may be uniquely able to study the problem fully, balance competing interests, and provide comprehensive yet targeted solutions.

A possible drawback of this option is that the problem may not yet be "ripe" for congressional action. On the basis of available evidence, genetic testing in the workplace does not appear to be widespread. Moreover, there is no available evidence about: 1) the number of workers who potentially could be screened or monitored if the tests were sufficiently predictive, 2) the number who might be excluded from jobs, 3) the ease with which excluded workers could find comparable jobs, and 4) the costs of various regulatory alternatives. on the other hand, congressional action now could prevent potential misuse before the technology becomes widespread, and legislation could create a mechanism for gathering some of the presently unavailable data.

E. Encourage the development of voluntary guidelines on the acceptable use of genetic testing.

Congress could ask the National Academy of Sciences or a similar body to establish a special commission of representatives from industry, labor, academia, and other sectors of society to draft guidelines for the use of the tests. This would allow the parties most involved to make the difficult value judgments in balancing competing interests and would avoid direct governmental regulation.

ISSUE: How could Congress regulate genetic testing in the workplace?

OPTIONS:

A. constrain employment actions that may be taken on the basis of genetic testing.

Congress could address many of the concerns raised by genetic testing by regulating how employers may use the results of the tests, even if they were highly predictive. The following represents some possible elements of such an approach: 1) prohibit job exclusion on the basis of genetic makeup or genetic damage, 2) prohibit job transfers because of genetic makeup or genetic damage unless the transfer were to a comparable job at comparable pay and benefits, 3) require strict confidentiality of medical information, and 4) require that employees be told the results of testing and be given counseling.

This option would clearly protect the interests of workers, preventing potentially serious consequences to individuals who have no control over the reason for discrimination against them, In addition, no difficult judgment would have to be made as to how predictive the tests should be before they are permitted.

There are at least two major disadvantages to this option. First, it may be too broad. If not carefully drafted, a statute could reach genetic diseases (not traits) that do affect *an* employee's current ability to perform the job safely and effectively. It is generally accepted that inability to perform a job, even for medical reasons, is a valid criterion for job selection. Second, if workers with

certain traits were in fact predisposed to occupational illnesses and chose to ignore that information, the additional direct and indirect costs of their illnesses eventually would be borne by society. This would be the case even if employers were required to install additional engineering controls, since the costs of those controls would be passed on to society. On the other hand, if excluded workers were unable to find comparable jobs, society would bear the costs of lost productivity and possibly additional unemployment payments. The answer to the question of who should bear the costs associated with genetically predisposed or damaged individuals will depend not only on economic analyses but on prevailing political views of distributive justice.

B. Prohibit employment decisions on the basis of genetic testing unless the employer can demonstrate that the results are reasonably (or substantially) predictive of future illnesses.

This option places the burden on an employer to justify the claimed correlation between test results and risk of illness. The specific criteria for meeting a necessarily general statutory standard could be provided by agency regulation and case law.

There are several advantages to this option, especially when compared to option A. First, it focuses on the immediate concern of job denial on the basis of poorly predictive tests, thus protecting employees' interests. Second, it protects employers' interests in lowering their costs from occupational diseases, by excluding workers when there is a rational, scientific basis for doing so. Third, it would allow research on the techniques to continue.

The principal drawback of this option is that it could be a de facto determination without a full public debate that future risk of illness is a proper job selection criterion. On the other hand, there is a substantial lack of the type of information desirable for deciding this fundamental issue at this time.

C. *Amend the Rehabilitation Act of 1973 to state that genetic makeup is a handicap and clarify whether individuals who are genetically predisposed to illness are considered to be "otherwise qualified" within the meaning of that act.*

A major advantage of this option would be working with an existing statute rather than devising an entirely new one, Sections 503 and 504 of the Rehabilitation Act deal with problems that conceptually are very similar to those posed by genetic screening. If applied to genetic screening, the act would require at a minimum that the tests be reasonably predictive of future illness.

On the other hand, this option would force legislative activity into an existing statutory framework that may not be completely suited to genetic screening. The Rehabilitation Act was designed to bring millions of handicapped people into the mainstream of American life. Genetic screening has not created a problem anywhere close to the magnitude of that addressed by the Rehabilitation Act. Moreover, section 503 requires employers to take affirmative action to employ the handicapped. Congress may not wish to require affirmative action to employ people who are geneticall y predisposed to occupational illness, if that predisposition can, in fact, be demonstrated.

D. Require that research on employees be done according to existing Federal regulations designed to *protect* human subjects *of* research.

The Department of Health and Human Services has promulgated regulations governing federally funded biomedical and behavioral research on humans. The regulations contain provisions designed to protect the interests of the research subjects. Requiring private companies to follow these regulations in research involving genetic testing or any other kind of research done in the workplace would mitigate the potential for abuse.

E. Require full disclosure to employees and their representatives of the nature and purpose of all medical procedures performed on employees.

Under current law, employees and unions have access to employee medical records, but employers are not required to disclose the nature and purpose of medical procedures and how the results are used. Required disclosure of this information to the employee at the time the procedure was being performed would be a strong incentive to employers for self- regulation. If workers and their medical advisors had full knowledge of a company's medical procedures, they could take

steps to prevent abuses, through negotiation or legal action. Publicity alone could prevent the worst abuses. This would also protect the autonomy interests of workers by allowing them to be part of a decisionmaking process that affects their health and economic interests. Some of the arguments against this option would be that it might be burdensome and costly for employers and that it would intrude too much on the professional judgment of the occupational medical specialist.

ISSUE: How could Congress foster the development and use of this technology?

OPTIONS:

A. *Fund research for the development of tests with high reliability and validity.*

Genetic variability and differential susceptibility' to toxic chemicals are well-established concepts in the scientific literature. Currently, there are many genetic screening tests that could be done in a workplace setting to detect potentially susceptible individuals. For the most part, these tests are reliable and valid for identifying the genetic traits in question; a notable exception is the test for aryl hydrocarbon hydroxylase (AHH) inducibility, Research on developing tests for those traits that are more prevalent in the population should receive higher priority because they are more likely to hate a high predictive value. The only test covered in this report that falls into this category is AHH inducibility.

With respect to genetic monitoring, it is less well established scientifically that exposure to toxic chemicals and ionizing radiation can cause genetic damage in humans, although there is an over - whelming amount of evidence that this is true in experimental mammals. Not known at all is the impact of genetic damage on one's risk for disease, especially cancer, or on future generations, yet the current thinking of the scientific community is that increased amounts of genetic damage is generally deleterious,

Alternatives are needed to the time-consuming cytogenetic tests currently in use. If genetic monitoring is to be done on a large scale, the availability of automated tests becomes important. The development of various noncytogenetic methods could be useful in this respect. Those that show promise currently include tests for detection of: mutagens in urine, alkylated hemoglobin, HGPRT mutation in lymphocytes, hemoglobin mutations, chemically damaged deoxyribonucleic acid bases, and LDH-X variants in sperm. For both cytogenetic and noncytogenetic tests, a better understanding of the factors that contribute to genetic damage in the absence of occupational exposure is needed (that is, a "normal" or baseline response) in order for the tests on exposed populations to be meaningful.

The government agencies which could be involved in these studies include the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the National Institute for Environmental Health and Safety (NIEHS).

B. Fund epidemiologic studies in occupational settings directed by NIOSH or NIEHS.

Data are most lacking concerning the correlation of genetic traits or genetic damage to an increased risk for disease. Epidemiologic studies in an occupational setting can address this problem. If these studies were to be undertaken, they must use good epidemiological practices and document exposures. Studies should only be undertaken if they are likely to yield statistically reliable data. For instance, genetic monitoring studies would require exposure levels high enough to yield a clear-cut statistical response between exposed and nonexposed groups without having to use excessively large numbers of people. Especially important would be to establish a dose-response relationship. Genetic screening studies would have to focus on genetic traits that have a significant prevalence in the population (greater than 1 percent).

Epidemiologic studies are very costly and difficult to control, especially if they run over long time periods. Some genetic screening studies could be done in a short time (1 to 3 years) once a population with the trait was selected because, presumably, the symptoms of disease resulting from exposure would manifest themselves soon after exposure. These traits include the red blood cell traits. Most of the other traits reviewed here

are potentially correlated with diseases which have a long latent period, such as emphysema and cancer. To assess correctly the exposure information with the disease endpoint, much longer epidemiologic studies (10 **to** 30 years) are necessary.

For genetic screening, higher priority should be given to studies on traits with a high prevalence in the population. These include SAT deficiency, AHH inducibility, carbon oxidation ability, and the association of particular human leukocyte antigens with risk for disease.

Epidemiologic studies using genetic monitoring techniques would have to be long term in order to determine the association between genetic damage and cancer. The chemicals chosen for study would have to be selected carefully. Many of the agents discussed in this report are known already to cause cancer in humans (for example, ionizing radiation, benzene, vinyl chloride), and occupational exposure to these is very low and possibly not detectable by the genetic techniques now in use.

C. Establish a federally funded data bank, directed by NIOHS, EPA, or NIEHS, to be used in the study of the causes *of differential susceptibility to occupational disease.*

Because the study of the effects of harmful agents includes many scientific disciplines, it would be useful **to** have the relevant data collected in an accessible location. This computerized data bank could include not only genetic factors affecting toxicity, but developmental, aging, nutritional, and lifestyle factors as well. The data bank would include epidemiologic studies that have been or are being done in occupational settings, either governmentally or privately funded (somewhat in the same manner as EPA's Gene- Tox Program). Those working in the field of genetic toxicology could draw on the information in the bank in order to design studies and to prevent duplication of effort. The toxicology data would be of considerable value to various regulatory agencies in their standard setting.