



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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March 29, 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) would like to thank you for your letter of October 10, 2003 reaffirming the Administration's support for S. 1053, the Genetic Information Nondiscrimination Act of 2003, and your commitment to work for its advancement in the Senate and House. With the Senate's unanimous passage of the bill last fall, focus has now shifted to the House of Representatives. Yet, as we learned from public testimony at our meeting earlier this month, movement on this issue in the House is flagging despite strong bipartisan support for genetic nondiscrimination legislation among Members. A synopsis of the information we received during our meeting on this issue is attached for your information.

SACGHS respectfully requests that you use the substantial authority of your office to energize the House of Representatives on this issue. We believe that Members of the House can be motivated to act by a strong reiteration of the Administration's support for this legislation and a statement about its priority as a domestic policy issue. As you know, House genetic nondiscrimination legislation has been referred to three different committees. Given the shortened legislative calendar, the prospects for completing bill consideration and mark-up in all three committees are dim. Moreover, since existing House bills are very different from S. 1053, a prolonged conference is likely. It appears, then, that the course of action with the best chance of success in this Congress is introduction of the Senate version of the bill as a House companion. Thus, we urge you to request that the House leadership introduce a House version that mirrors S. 1053 and to expedite committee and full House consideration of the bill. Doing this would build on and take advantage of existing momentum around this issue and would represent an important bipartisan achievement in an election year. It would also send a clear message that the Administration is actively taking steps to ensure that genetic discrimination is prevented and the American people are adequately protected.

Page 2 – The Honorable Tommy G. Thompson

SACGHS regards passage of Federal genetic nondiscrimination legislation as the most important issue at the intersection of genetics, health, and society today, and we greatly appreciate all that you have done already to champion the passage of this important legislation. Enactment of Federal genetic nondiscrimination legislation would be a commendable civil rights achievement for you and the President, and SACGHS would welcome any opportunity to help the Administration bring this important accomplishment to fruition.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward R.B. McCabe". The signature is written in a cursive, flowing style.

Edward R.B. McCabe, M.D., Ph.D.
SACGHS Chair

Attachment

Key Points Regarding the
Status of Genetic Nondiscrimination Legislation
From Public Testimony at the 3rd Meeting of the
Secretary's Advisory Committee on Genetics, Health, and Society

PART I – SYNOPSIS OF PUBLIC TESTIMONY

On March 2, 2004, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) addressed the issue of genetic discrimination¹ during its deliberation on the status of genetic nondiscrimination legislation. In October 2003, the Senate unanimously passed Senate Bill 1053, the Genetic Information Nondiscrimination Act.² Advocates of legislation are endeavoring to press for action in the House of Representatives. Specifically, advocates have been urging the House leadership to introduce S. 1053 as a House companion. Most believe that House consideration of S. 1053, rather than any of the several House bills that have been introduced, is essential for enactment of genetic nondiscrimination legislation this year.

Thus far, there has been no movement in the House on genetic nondiscrimination legislation, due in part to the legislative calendar and crowded hearing schedule. In addition, a coalition of business and trade associations has expressed concerns with the employment title of S. 1053. In particular, they have raised the following points: there is no evidence that genetic discrimination in the workplace is occurring; existing laws and regulations, specifically the Americans with Disabilities Act, Health Insurance Portability and Accountability Act, and the Federal Privacy Rule, already provide significant protections; and S. 1053's definition of protected genetic information is too broad and should only include genetic test results, not family history information.

SACGHS members suggested that it may be useful to discuss the concerns that have been raised by the opposition in more detail and explore how those arguments might be countered. SACGHS members engaged the public commenter in a deeper dialogue about the points of concern and how they might be addressed in order to speed House consideration of this important legislation. The discussion concluded with an affirmation on the part of SACGHS of the importance of Federal legislation in this area and a commitment to continue advocacy efforts within the Department of Health and Human Services. The salient counterpoints to the three main points of concern, which were developed subsequent to the SACGHS meeting, are discussed in a separate section below.

SACGHS also heard public testimony at its March meeting.³ The public testimony included a discussion on the prospects for legislation in the House. Currently in the House, genetic nondiscrimination legislation has been referred to three different committees. Given the shortened legislative calendar, the prospects of consideration and mark-up in all three committees

¹ Joann Boughman, Ph.D., Executive Vice President, American Society for Human Genetics, representing the Coalition for Genetic Fairness.

² At its first meeting in June 2003, SACGHS was briefed by the Senate HELP Committee staff on the status of Federal genetic nondiscrimination legislation. SACGHS unanimously recommended that a letter be sent to the Secretary supporting the need for Federal genetic nondiscrimination legislation and specifically endorsing S. 1053.

³ Joann Boughman, Ph.D., Executive Vice President, American Society for Human Genetics, representing the Coalition for Genetic Fairness.

are dim. Moreover, since existing House bills are very different from S. 1053, a prolonged conference is likely. Public testimony indicated that, therefore, the course of action that has the best chance of success in this Congress is introduction of a House companion bill to S. 1053 and expedited Committee and full House consideration of the bill. It was brought to SACGHS' attention that the House is unlikely to bypass its Committee process on this bill since it values this issue highly and wants to deliberate on it thoroughly. Furthermore, identifying a key leader in the House willing to introduce the Senate version of the bill as a House companion and champion the bill is clearly critical to achieving the bill's ultimate passage. Based upon this public testimony, SACGHS unanimously reaffirmed the importance of this critical issue and voted to send a letter to the Secretary to convey the urgency of encouraging the House to move this bill forward at this juncture.⁴

PART II – COUNTERPOINTS TO MAIN CONCERNS ABOUT FEDERAL GENETIC NONDISCRIMINATION LEGISLATION

Evidence for Federal Legislation

Point. Opponents assert that legislation is not necessary because there is no appreciable evidence or clear trend that employers are engaging in genetic discrimination.

Counterpoint. While the number of publicly documented cases of genetic discrimination may be small, those that have been profiled in the press demonstrate that misuse of genetic information in the workplace has occurred in the past and could happen again. For example, in 2001, the Equal Employment Opportunity Commission sued the Burlington Northern Santa Fe Railroad Company for conducting genetic testing on employees without their knowledge or consent to assess claims for work-related injuries based on carpal tunnel syndrome. A 1998 case involving Lawrence Berkeley Laboratory revealed that employees were being tested for sickle cell disease, as well as other medical conditions such as syphilis, without their consent. Moreover, misuse of genetic information occurred on an even wider scale in the 1970s when many African Americans were screened for sickle cell disease, found to be carriers and subsequently denied employment as well as educational opportunities.

Some suggest that these cases are aberrations and do not represent a problem significant enough to warrant Federal action, and they question why more cases have not been documented. Possible reasons that more cases have not surfaced include the following:

- Genetic discrimination can be extremely difficult to prove because an employer is unlikely to disclose the underlying cause of a job termination or demotion and a health insurer may not be forthcoming with an honest reason for a policy termination or change.
- An individual who has experienced genetic discrimination may worry about further negative repercussions due to the insufficient protection that allowed the initial discrimination to occur in the first place.
- Health information is intensely personal and people may be reluctant to reveal that they have a genetic mutation. Traditional civil rights claims based on age, sex or race do not reveal anything about an individual. Since genetic information also has implications for family members, people may not pursue complaints out of concern for the privacy of their family members.

⁴ SACGHS first wrote to the Secretary on this issue in June 2003 urging support for the enactment of Federal genetic nondiscrimination legislation and commending the Administration's endorsement of S. 1053.

- Genetic testing is still in its infancy. Although there are more than 600 genetic tests in clinical use and hundreds more in development, their integration into clinical medicine is far from complete. Once genetic technologies and services are more fully incorporated into the healthcare system, rates of genetic discrimination are likely to grow.

Furthermore, according to the public commentary, the House is currently receiving messages from concerned constituents across the country stating that genetic discrimination is a real problem based on their own personal or professional experience.

Regardless of the documented evidence of genetic discrimination, however, public testimony gathered by the Committee's predecessor, the Secretary's Advisory Committee on Genetic Testing, clearly shows that individuals are reluctant to use genetic tests and services due to concerns about genetic discrimination. Federal legal protections may lessen the public's fear of genetic discrimination in health insurance and employment and enable Americans to reap the health benefits of the genetics revolution.

Applicability of Existing Laws and Regulations

Point. Opponents assert that existing laws and regulations, specifically, the Health Insurance Portability and Accountability Act (HIPAA), Federal Privacy Rule, and Americans with Disabilities Act (ADA), already provide significant protections against genetic discrimination.

Counterpoint. There are a number of reasons why these laws may not protect or be applicable to individuals with a genetic predisposition to disease.

HIPAA. HIPAA prohibits raising rates for or denying coverage to an individual based on genetic information within the group coverage setting. However, it does not prohibit raising rates for the group as a whole. HIPAA protections are also limited to the group market.

Federal Privacy Rule. The Federal Privacy Rule, which was authorized by HIPAA, protects the use and disclosure of individually identifiable health information, including genetic information. The regulation does not, however, prohibit the use of genetic information in underwriting. Genetic nondiscrimination legislation is needed to close this loophole. S. 1053 bans the collection, use or disclosure of genetic information for underwriting purposes.

ADA. The ADA was designed to protect those individuals who are living with a disability. The ADA defines disability as 1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual; 2) a record of such impairment; or 3) being regarded as having such an impairment. While the ADA provides protections for people who have current disabling genetic illnesses, it is not clear whether the law covers individuals who have a genetic mutation that predisposes them to disease. Although no court has ruled specifically on this issue, recent court cases have established a general trend of narrowing ADA's scope.

The first part of ADA's definition of disability probably does not cover individuals with pre-symptomatic genetic predisposition to disease because a predisposition is not (yet) an impairment that substantially limits a life activity. Many thought *Bragdon v. Abbott* (1998) might prove to be a relevant case. The court in this case determined that asymptomatic HIV infection is a physical impairment because it has underlying physiological effects and that it qualifies as a "disability" under the ADA because it substantially limits a major life activity (reproduction). However, with a genetic predisposition to disease, there may be no comparable effects at a physiological level.

It also is unclear whether the third part of the definition covers individuals with pre-symptomatic genetic predisposition to disease. The Equal Employment Opportunity Commission announced in 1995 that individuals who are subject to discrimination in employment because of a genetic predisposition will be regarded as having a disability, thereby meeting the third prong of the definition. However, several subsequent cases have suggested otherwise. In *Laws v. Pact* (2000), the plaintiff, who had been diagnosed with Huntington disease but was still essentially asymptomatic, argued that her employer knew of her diagnosis, regarded her as disabled, and discriminated against her on that basis. However, the court held that the plaintiff had not provided evidence that her employer regarded her as being substantially limited in a major life activity. Moreover, courts have generally interpreted "substantially limited" very restrictively, making the prospects for success unlikely in any event. *Sutton v. United Airlines, Inc.* (1999) and *Murphy v. United Parcel Service, Inc.* (1999) both held that a job requirement that excludes certain individuals based on an impairment does not establish that those individuals are regarded by the employer as substantially limited. Under these cases, a person is protected only if the employer believes that the person is substantially limited in a major life activity at the time the employment decision is made. A court could find that an employer's belief that a person might become substantially limited in the future because of a genetic predisposition does not mean that the employer presently considers the person to be disabled.

These cases suggest how difficult it will be for an individual with a pre-symptomatic genetic predisposition to disease to be defined as "disabled" under the ADA. Finally, even if a court did find that a genetic predisposition is covered by the definition of disability under the ADA, the ADA does not effectively prohibit an employer's access to genetic information if it is job-related and/or consistent with business necessity.

Definition of Genetic Information

Point. Concerns have been raised that the definition of protected genetic information in S. 1053 is too broad and that it should include only genetic test results and not family history.

Counterpoint. Genetic testing and family history are inextricably medically linked and family history often serves as a proxy for genetic test results. Distinguishing genetic test results from family history is impractical. If family history is not included in the definition section of S. 1053, not only would it be incomplete and scientifically and medically questionable, it would provide a loophole that would effectively negate any protections offered by the bill in the first place.