DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The Assistant Secretary for Planning and Evaluation
Washington, D.C. 20201

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Chair, Secretary's Advisory Committee on Genetic Testing
National Institutes of Health
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MAR 1 5 2002

Dear Dr. McCabe:

Thank you for your letter to the Secretary advocating federal legislation to protect individuals from discrimination in health insurance and employment on the basis of their genetic information.

As you know, the fear that one's genetic information may be used by health insurance carriers to deny benefits or by employers to deny employment can prevent individuals from having genetic tests. Failure to have such tests can delay the identification of a potential medical disorder and thus the initiation of appropriate medical intervention which could save lives as well as reduce health care costs. Legislative protection against inappropriate or malevolent use of genetic information is essential if we are to ensure positive exploitation of new genetic technology.

As President Bush has said, genetic discrimination "should be an opportunity to prevent and treat disease, not an excuse for discrimination." Secretary Thompson has also been a strong advocate against genetic discrimination. In 1991, he signed a landmark law addressing genetic discrimination – the first comprehensive law that prevented unfair use of genetic information by health insurers and employers - and in 1998 he signed additional legislation strengthening the statutes that protect Wisconsin citizens from discrimination on the basis of genetic information.

However, the Administration recognizes that, in this area, state action alone is not adequate to assure necessary public protection. In testimony before the Senate on February 13, 2002, I stated that this Administration wants to work with Congress to enact sensible legislation that ensures Americans are protected from genetic discrimination. A copy of my full testimony is attached.

Your recommendations regarding this important issue will be helpful in ongoing efforts to develop federal legislation that will outlaw genetic discrimination. The Secretary and I appreciate your valuable contribution.

Sincerely

Bobby P. Jindal

TESTIMONY OF BOBBY P. JINDAL

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE

THE SENATE COMMITTEE ON

HEALTH, EDUCATION, LABOR AND PENSIONS

HEARING ON

PROTECTING AGAINST GENETIC DISCRIMINATION:

THE LIMITS OF EXISTING LAWS

Wednesday, February 13, 2002

Mr. Chairman, the Administration welcomes your focus on the important issue of discrimination in health insurance and employment based on genetic information. In his radio address on June 23, 2001, the President called for prohibiting the misuse of genetic information with Federal legislation that is fair, reasonable, and consistent with existing discrimination statutes. He noted that genetic discrimination violates our nation's belief in equal treatment and individual merit. The Administration wants to work with you and other Members of Congress to enact sensible legislation that ensures Americans are protected from genetic discrimination.

ADVANCES IN GENETIC MEDICINE

One year and one day ago, Human Genome Project scientists published the working draft DNA sequence of the human genome, the 3 billion-letter genetic instruction book for a human being. The hope of this ambitious project is to improve human health. With the sequence of the human genome in hand, scientists are moving rapidly to understand how all the genes work and to develop new diagnostic tests and therapeutics. Genetic information can be enormously valuable to patients and providers as it can lead to early detection, intervention, and prevention of many common diseases.

Today there are over 500 genetic tests available and this number is increasing rapidly. In some cases, these tests offer patients the opportunity to learn about their individual disease risk profile and, in time, we will have a host of new preventive interventions to help individuals decrease their disease risks. While most of us have not yet had genetic testing offered to us in the doctor's office, we soon will. How will we respond to this offer? The first and foremost consideration for each of us should be how genetic testing information will affect our health and how we, working with our doctors and other health care providers, will be able to use this information to make good health care decisions. Yet, just as we stand on the brink of a wonderful new era of genetic medicine, patients are fearful of taking advantage of these new genetic tests that could save lives. They are worried that information about their risk for future disease will be used by health insurers or employers to deny them insurance coverage or a job.

BARRIERS TO EFFECTIVE CARE

At the National Institutes of Health, study volunteers are hesitant to participate in critical biomedical research because they are concerned that their genetic information will not be kept confidential and will be used by health insurers or employers to discriminate against them. Individuals in a preliminary NIH colon cancer study were provided education and counseling before being offered the genetic test. In response to being asked what factors might lead them to take the test, the overwhelming majority stated that they wished to learn about their children's health risks and to gain information to help them plan their own cancer screening.

When asked what factors might lead them not to take the test, the primary concern cited by 39% was losing insurance. In a similar study involving genetic testing for increased risk of breast and ovarian cancer, fully one third of the individuals who chose not to participate did so because of their concern about genetic discrimination. As the applications of genetics move out of the research lab and into broad clinical practice, this problem will only become more acute.

Thus, genetic discrimination, and the fear of potential discrimination, threatens both society's ability to use new genetic technologies to improve human health and the ability to conduct the very research we need to understand, treat, and prevent genetic-based diseases. The challenge, and it is a formidable one, is to nurture scientific exploration, encourage the translation of these new discoveries into life-saving medicines, and to put in place public policies reflective of our core American values that prevent the unjust, unfair, and discriminatory use of genetic information. Genetic research and genetic medicine hold great hope for improving the health of our Nation, but we must act now to make sure that this hope is not extinguished by fear. We understand the need to examine this issue closely, and to find workable solutions to address genetic discrimination in health insurance and employment.

EXISTING LAWS

Today, many states prohibit insurance companies from using genetic information for enrollment purposes, including determining eligibility for a plan, imposing pre-existing condition exclusions, or determining benefits or exclusions under the plan. In addition, many regulate the use of genetic information for rating purposes, either upon initial enrollment or renewal.

Congress has also addressed several key discrimination issues in Title I of the Health Insurance Portability and Accountability Act (HIPAA) in 1996. The law prohibits discrimination in enrollment in group plans based on health status (including genetic information), prohibits increasing the contribution rates of an individual in a group plan based on his or her genetic information, and prohibits using genetic information in the absence of a diagnosis as a pre-existing condition.

THE NEED FOR LEGISLATION

Further measures are needed to address the following discrimination issues that were left unresolved by HIPAA. First, the Administration believes that insurers in the individual market as well as the group market should not be permitted to deny enrollment based solely on a healthy individual's genetic predisposition to a future disease. No one should be blocked from this coverage because their genetic information indicates that they might one day develop a particular disease or condition.

Second, the Administration believes that insurers in the individual and group markets should be prohibited from adjusting health insurance premiums based solely on the genetic predisposition for future illness or disease of an individual or group of individuals. Patients should know that they may be tested and receive important information without the threat of skyrocketing premiums. They should feel confident and comfortable in seeking genetic testing and other appropriate medical treatments. Insurers in the individual market must continue to have access to and be able to use information about an individual's current health status in making underwriting decisions, but predictive genetic information—in absence of a diagnosis related to such information—should be protected.

The Administration believes these changes will greatly reduce the potential for genetic discrimination in health insurance.

PRIVACY

In Title II of HIPAA, the Congress gave the Administration the authority to promulgate a Privacy Rule that protects the uses and disclosures of individually identifiable health information--including genetic information. The resulting Rule is very broad and comprehensive. Compliance with the Privacy Rule is required by April 14, 2003 for most plans, providers, and clearinghouses, and by April 14, 2004 for small health plans.

One of the goals of the HIPAA Privacy Rule is that **all** health information should be afforded the same high standard of privacy protection. The Administration believes that the Privacy Rule affords the appropriate level of protection for all individually identifiable health information, including genetic information. Having separate rules for genetic information could actually be harmful. If providers have different rules for different types of information, the potential for confusion or unintended misuses might actually increase. Consistent rules for privacy should be the goal.

CONCLUSION

Looking ahead, all Americans should benefit from the advances in genetics made possible by the Human Genome Project, but if the public does not feel protected from genetic discrimination they may be denied that chance. We can foresee in the next ten years, predictive genetic tests will exist for many common conditions where interventions can alleviate inherited risk. But achieving health benefits from these research advances may not be possible without protections from genetic discrimination.

The President and the Administration support enactment of legislation to protect all of us from being discriminated against based on our genetic make-up. As the President stated earlier this week at the Medical College of Wisconsin, "Genetic information should be an opportunity to prevent and treat disease, not an excuse for discrimination."

As we begin a new age of genetic medicine, now is the time to enact genetic non-discrimination legislation in order to provide the necessary safeguards to enable all of our citizens to benefit from the genomic revolution. The Administration welcomes your focus on genetic discrimination and looks forward to working with this Committee on this important issue.