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FULFILLING THE PROMISE OF GENETICS RESEARCH: ENSURING NONDISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON

S. 318

TO PROHIBIT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION WITH RESPECT TO HEALTH INSURANCE

JULY 25, 2001

Printed for the use of the Committee on Health, Education, Labor, and Pensions

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FULFILLING THE PROMISE OF GENETICS RESEARCH: ENSURING NONDISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT

WEDNESDAY, JULY 25, 2001

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 9:34 a.m., in room SD–430, Dirksen Senate Office Building, Senator Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Dodd, Clinton, Enzi, Hutchinson, and Warner.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

This morning we address the important issue of genetic discrimination in health insurance and employment.

We are honored that the committee will hear from our distinguished Majority Leader, Senator Tom Daschle, whose leadership and commitment to this issue is an example to us all.

Genetic discrimination is one of the most important issues facing our committee. I welcome further discussion of this essential issue and will provide the opportunity for additional discussion at another hearing on genetic discrimination that the committee will hold in early September.

Just over a year ago, scientists announced the completion of a task that once seemed impossible—deciphering the entire DNA sequencing of the human genetic code. Dr. Francis Collins, who led the NIH effort to sequence the human genetic code, is here today to talk about the remarkable opportunities that will increasingly be available to improve the health of all Americans.

I have in my hand a symbol of the promise of genetic research. This tiny DNA chip contains the sequencing of 60,000 human genes. It can be used to detect genetic traits in ways which will assist patients in receiving treatment or even taking steps which will prevent the onset of disease long before any symptoms of that disease are apparent.

But this same chip in the hands of an employer or a health insurance company could be used to deny a patient needed health care or to deny an employee a job or a promotion.

DNA chips like these will affect the 21st century as profoundly as the computer chip affected the 20th century. The challenge is to see that this technology is used to improve the health of Americans and not to discriminate against them.

As we will hear this morning, the danger of genetic discrimination is very real. Employers have already used genetic information to try to deny benefits to which workers are entitled. David Escher will testify that his employer, Burlington Northern Santa Fe Railroad, required any employee who suffered from carpal tunnel syndrome to undergo genetic testing. The company was not conducting these tests in the interest of science nor was it trying to assist its employees to determine the best treatment for their injuries; instead, it was collecting the information to try to avoid paying workers' compensation claims. It did not seek its employees' consent. In fact, employees who refused to agree to the test were threatened with loss of their jobs.

Clearly, we need to act now to stop these abuses of private medical information. President Bush has recognized the urgency of this problem and supports the enactment of legislation to ban genetic discrimination, and I am optimistic that such a ban will be signed into law this year.

Strong protections are contained in the legislation introduced by Senator Daschle. It prohibits health insurers from using genetic information to deny health coverage or to raise premiums for coverage. It bars employers from using genetic information to make decisions about hiring, promotion, salary, or other workplace rights and privileges. It bans insurers and employers from seeking genetic information and from requesting or requiring individuals to take genetic tests. It restricts disclosure of any genetic information that the insurer or employer possesses. It provides strong remedies, giving people who have suffered genetic discrimination the right to seek redress in court.

Prohibiting discrimination is not enough. We must also provide strong enforcement provisions and provide meaningful remedies to individuals whose rights are violated. Strong remedies are needed to ensure that employers and insurers will implement the necessary protections.

We owe it to all Americans to see that the extraordinary promise of this scientific revolution is fulfilled and that people are benefited—not harmed—by the wealth of new information.

The Daschle bill is urgently needed, and the time to pass it is now.

I will call on my friend and colleague, Senator Enzi, now.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you, Mr. Chairman.

I am here today to show my support for enacting Federal legislation which prohibits discrimination in both health insurance and employment on the basis of predictive genetic information.

On three occasions, the Senate has passed legislation introduced by Senator Snowe which would prohibit discrimination on the basis of genetic information with regard to health insurance.

This bill was the result of a great deal of time and attention. Unfortunately, I do not believe that the legislation extending genetic nondiscrimination to the employment context has yet been given the similar attention that is necessary.

As I said, I am committed to Federal legislation protecting against discrimination in employment based on predictive genetic information. Such legislation, however, must be consistent with existing Federal law relating to privacy and to employment nondiscrimination. To do otherwise is to upset the carefully designed balance of interests created by existing employment nondiscrimination statutes and to undermine the process for enforcing and redressing civil rights legislation.

For this reason, I cannot yet support S. 318 introduced by Senator Daschle, which deviates significantly from other employment nondiscrimination legislation. I hope that we can hold some additional hearings to clarify the privacy issue and the consistency with other employment nondiscrimination so that we can resolve these issues.

On a topic as important to the lives of so many people as genetic nondiscrimination in employment is, we have a responsibility to propose legislation that is effective and appropriate. To do so, we must ensure that the legislation is consistent with existing Federal employment, civil rights, and privacy laws.

I look forward to having the opportunity in further hearings to discuss these issues in depth and, from that, to passing legislation prohibiting discrimination on the basis of genetic information with respect to health insurance as well as employment.

I would ask that my full statement be included in the record.

The CHAIRMAN. It will be included in the record.

Senator ENZI. Thank you, Mr. Chairman.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Mr. Chairman. I am here today to show my support for enacting federal legislation which prohibits discrimination in both health insurance and employment on the basis of predictive genetic information. I believe that the promise that such information holds should be free of fears that it will be used to discriminate in health insurance and in the workplace.

On three occasions, the Senate has passed legislation introduced by Senator Snowe which would prohibit discrimination on the basis of genetic information with regard to health insurance. This bill was the result of a great deal of time and attention to ensure that the legislation would effectively address concerns relating to the use of predictive genetic information in health insurance decisions and to ensure that the legislation is consistent with existing federal laws. It specifically addresses the pending medical information privacy regulations, which were issued under the previous Administration and will be implemented by Secretary Thompson.

Equally important to ensuring the confidentiality and limited use of medical information is how we define these terms. The Snowe bill differs from the Daschle bill on several key definitions. The definitions for “genetic information” and “genetic test” must fairly and appropriately protect medical information, but must also balance and allow, again, for fair and appropriate, underwriting of health insurance products.

Unfortunately, I do not believe that legislation extending genetic nondiscrimination to the employment context has yet been given the similar attention that is necessary. This hearing today, called on short notice, does not afford the opportunity to address, in a truly substantive way, the issues that major new civil rights employment legislation deserves and requires.

As I said, I am committed to federal legislation protecting against discrimination in employment based on predictive genetic information. Such legislation must, however, be consistent with existing federal law relating to privacy and employment nondiscrimination. To do otherwise is to upset the carefully designed balance of interests created by existing employment nondiscrimination statutes and to undermine the process for enforcing and redressing civil rights legislation. Accordingly, I cannot support legislation that is inconsistent with current Federal employment nondiscrimination laws.

For this reason, I cannot support S. 318 in its current form introduced by Senator Daschle. S. 318 deviates significantly from other civil rights legislation, namely Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act, by circumventing the administrative process for the Equal Employment Opportunity Commission to investigate and enforce complaints of discrimination in the workplace and by disregarding the remedy structure established by the Civil Rights Act of 1991, which places a cap on consequential and punitive damages progressive with the size of the employer. I look forward to working with the majority leader.

It is difficult to see the justification for allowing claimants of genetic discrimination to file suit directly in court and, thereby, avoid the complaint process that claimants of other basis of employment discrimination must follow. It is also difficult to see the justification for allowing an individual claiming genetic discrimination, but who is unsymptomatic, to be able to recover more compensatory and punitive damages than a claimant of race discrimination or disability discrimination. Yet this is the inequitable result that S. 318 would create.

On a topic as important to the lives of so many people as genetic nondiscrimination in employment is, we have a responsibility to propose legislation that is effective and appropriate. To do so, we must:

1. Ensure that such legislation is consistent with existing Federal employment civil rights and privacy laws,
2. Examine state laws on this issue to learn from their successes and shortcomings, and
3. Explore the relationship between workers compensation laws and such legislation.

I look forward to having the opportunity in further hearings to discuss these issues in depth, and, from that to passing legislation prohibiting discrimination on the basis of genetic information with respect to health insurance as well as employment. Thank you, Mr. Chairman.

The CHAIRMAN. Welcome, Senator Hutchinson.

We are reverting to the policy of majority and minority opening statements, but I see that Senator Hutchinson is here on time, with some papers in his hand. If he will promise to be brief before my colleagues arrive on this side, we will be glad to hear from him on this occasion.

OPENING STATEMENT OF SENATOR HUTCHINSON

Senator HUTCHINSON. Thank you, Mr. Chairman, and I will try to be brief.

I want to thank you for holding the hearing today on the very important topic of genetic discrimination. Advances in genetics research and the recent decoding of the human genome have brought incredible promise and hope to disease detection, treatment, and prevention efforts.

The ability to find out whether an individual is genetically predisposed to a given disease and to take steps to possibly avert the actual onset of the disease is unprecedented, and there are legitimate worries about how this predictive genetic information may be used against an individual in some discriminatory action.

As you know, two genetic nondiscrimination bills have been introduced in the Senate in the 107th Congress, and I am pleased that one of the bills' sponsors, Senator Daschle, the majority leader, has been invited to testify today.

I am also pleased that Dr. Francis Collins, a pioneer of genetics research, will be before the committee to testify once again about the science of genetics research.

Twice during the 106th Congress, the Senate passed genetic nondiscrimination legislation with regard to health insurers. Unfortunately, this well-crafted legislation did not become law. I understand that the chairman would like to mark up legislation which also addresses the possibility of genetic discrimination by employers.

I am hopeful that this will be the first of several hearings so that the committee can hear from expert witnesses on such issues as how the bills pending before the committee interact with the medical records privacy regulations promulgated by the Clinton administration which are intended to prevent individually identifiable medical information from being disseminated without an individual's consent.

I also believe that the committee must examine to what extent the pending bills duplicate current discrimination protections under the Americans with Disabilities Act, and specifically with regard to the Daschle bill, how the private right of action allowed under the bill interacts with the current right to sue via the Americans with Disabilities Act.

Finally, I hope the committee will take time during a subsequent hearing to explore how the Daschle employer provisions affect the mandatory dispute resolution procedures under the Equal Employment Opportunity Commission.

There are a number of issues that need to be examined, and I hope this will be the first of a number of hearings to examine these issues. I appreciate our majority leader being here to testify today, and I thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

I indicated, Senator, that we will have another hearing in the fall, hopefully in early September, to address some of these issues. I think there are issues which ought to be considered.

As the principal author of the HIPAA with Senator Kassebaum, I think this is consistent, and I intend to work very closely with

Senator Harkin on the ADA; I think they are consistent. But I think there are issues and questions which have been raised, and we will work through those.

Just before asking the leader to speak, I want to thank my colleagues. Senator Harkin has been a leader in this committee on this issue as he has on so many other disabilities issues, and this has been a special interest of my colleague and friend, Senator Dodd, as well. Both of them have been very, very involved and active and have been enormously helpful in the development of legislation, so we are very, very grateful to them.

I also want to acknowledge Senator Snowe's efforts and those of Senator Jeffords. They have been real leaders in this area and in this effort, and we want to work closely with them as well. They are interested and involved.

Senator Ensign raised similar issues during the time of our patients' bill of rights, and obviously, we always welcome the involvement and leadership of our other colleagues, both on and off the committee.

I thank Senator Daschle for being here. I thank him not only for his leadership in our party, but this is a matter of very special interest that he has had for a very considerable period of time. He has spoken to the members of our committee and to me about the importance of holding these hearings and also to have some action by our committee. He has always been open to different ideas and suggestions about how to strengthen and clarify the language, and quite frankly, we would not be as far along in the whole public policy debate and, hopefully, resolution and solution to this if it had not been for his leadership. So we are delighted to welcome him to the committee.

Thank you, Senator Daschle.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. Mr. Chairman, thank you for your kind comments.

Senators Enzi and Hutchinson, thank you for your interest and for being here at this hearing this morning.

I want to thank the chairman especially for giving this matter the priority attention that it deserves by providing us the opportunity to discuss the bill and the issues today, and I am grateful for the chance to be here this morning.

This is the second time that I have had the privilege of testifying before this committee on this critically important issue. The first time I testified was 1 year ago last week. The purpose of that hearing was to try to determine whether the laws already on the books are sufficient to protect Americans from genetic discrimination—something that Senator Hutchinson raised a moment ago.

I said at the time I feared they were not.

The past 12 months have provided new and disturbing information to support that view. Experts such as Dr. Francis Collins have been warning Congress for some time now that we must pass comprehensive national standards to protect all Americans from genetic discrimination. If we fail to do so, the experts warn, we will almost certainly squander many of the enormous potential benefits of the genetic revolution.

It is time for us to heed the experts' warnings. It is time for us to pass real, enforceable, national protections against genetic discrimination.

It has been nearly 4 years since we first introduced a bill to do just that. In January, I reintroduced our bill as one of the top Democratic priorities in this Congress. Congresswoman Slaughter, one of the great champions of genetic protection, introduced the same bill in the House.

We now have more than 250 cosponsors in the House—Democrats and Republicans—and a growing number of Senate cosponsors, including Chairman Kennedy and Senators Harkin and Dodd.

Our bill does three things. First, it forbids health insurers from discriminating against individuals—denying them coverage, for instance—based on genetic test results.

Second, it forbids employers from discriminating in hiring, or in the terms and conditions of employment, based on genetic information.

Third, it prevents disclosure of genetic information to third parties, including insurance companies, employers, and anyone else who has no legitimate need for the information.

The growing support in Congress for our bill is one measure, we believe, of the growing concerns Americans have about the potential misuse of their genetic information.

Another indication of that concern is President Bush's recent announcement that he, too, favors national protection against genetic discrimination. I applaud him for his comments and welcome the leadership that he will bring to this important effort.

Americans' fear of genetic discrimination is very real. Unfortunately, actual cases of genetic discrimination are now real, too.

We are joined today by a man who knows this all too well. I met Dave Escher earlier this summer. He told us how his employer forced him to be tested—without his knowledge or consent—for possible genetic defects.

Mr. Escher has worked for the same company for 25 years, and by all accounts, he was and is a tremendously hard worker and an asset to his company. Yet last year, a few months after filing a personal injury report for carpal tunnel syndrome, Mr. Escher was told by his employer that he needed to attend a mandatory medical appointment. If he refused, he was told, he would lose his job.

That appointment, we know now, was for the purpose of gathering his genetic information. However, it was not until after the appointment, and only by accident, that Mr. Escher learned that the company's doctors had used his blood to conduct genetic tests for more than 20 medical conditions.

While stories like Mr. Escher's are still relatively rare, experts tell us that it is only because genetic testing itself is still relatively rare. As testing becomes more affordable and more common, the incidence of discrimination is likely to increase dramatically.

We must not wait until genetic discrimination becomes a widespread problem. We must specify, clearly and unambiguously, in the law how genetic information may be used and how it may not be used.

Some people argue that such protections should be limited to preventing misuse of genetic data by insurance companies only. As Mr. Escher's story shows, the problem of genetic discrimination is not limited to insurance. The solution should not be limited to insurance, either. It must safeguard against genetic discrimination in the workplace as well.

In this area, our bill sets three simple and I believe reasonable rules.

First, employers may not use predictive genetic information to make decisions about hiring, advancement, salary, or other workplace rights and privileges.

Second, they may not request, require, or disclose a person's genetic information without his or her informed consent.

Third, these provisions must be enforceable. If these rights are violated, victims of this discrimination must be able to seek relief in court.

It is time for our laws to catch up with our science. We cannot take one step forward in science but two steps backward in civil rights.

Discrimination based on genetic factors is just as arbitrary and unacceptable as discrimination based on race, national origin, sex, or disability. And like those other forms of discrimination, genetic discrimination hurts us all. It hurts our economy by keeping talented people out of the work force, and it diminishes us as people.

Once again this summer, the world is watching in awe as Lance Armstrong closes in on what may be another victory in the grueling Tour de France bicycle competition. His determination and skill leave us all speechless.

You may also have seen a TV commercial in which Mr. Armstrong talks about the potential of the genetic revolution. He talks about how grateful he is that his son Luke may grow up in a world in which scientists can identify and eliminate cancers like his years before the first symptoms appear.

That is the dream of every parent. Whether the genetic revolution helps fulfill that dream or becomes the stuff of nightmares for millions of Americans will be determined in no small measure by the extent to which we heed the experts' warnings.

It would be a terrible travesty if, instead of unraveling the secrets that could save lives, genetic testing were used to unravel individuals' livelihoods.

Mr. Chairman, I want to thank the members of this committee for listening; my colleagues—you, Senator Kennedy, and my other colleagues on the committee, Senators Dodd and Harkin—for all of your help in this endeavor; and my partner in the House, Congresswoman Slaughter, for her tireless efforts to move our companion bill to the floor of that chamber.

I would like your consent to submit my complete statement for the record.

The CHAIRMAN. We will include your full statement in the record.

[The prepared statement of Senator Daschle follows:]

PREPARED STATEMENT OF SENATOR DASCHLE

Good morning. Chairman Kennedy, Senator Gregg, and members of the committee, I thank you for holding this hearing and for inviting me to testify. I particularly want to thank Chairman Kennedy for giving this matter the priority attention it deserves.

This is the second time I have had the privilege of testifying before this committee on this critically important issue.

The first time I testified was one year ago last week. The purpose of that hearing was to try to determine whether laws already on the books are sufficient to protect Americans from genetic discrimination.

I said at the time I feared they were not. The past 12 months have provided new and disturbing information to support that view.

Experts such as Dr. Francis Collins have been warning Congress for some time now that we must pass comprehensive national standards to protect all Americans from genetic discrimination. If we fail to do so, the experts warn, we will almost certainly squander many of the enormous potential benefits of the genetic revolution.

It is time for us to heed the experts' warnings. It is time for us to pass real, enforceable national protections against genetic discrimination. It's been nearly four years since we first introduced a bill to do just that.

In January, I reintroduced our bill as one of the Senate Democrats' top priorities in this Congress. Congresswoman Slaughter, one of the great champions of genetic protections, reintroduced the same bill in the House. We now have more than 250 cosponsors in the House -Democrats and Republicans—and a growing number of Senate cosponsors including Chairman Kennedy and Senators Harkin and Dodd.

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The growing support in Congress for our bill is one measure, we believe, of the growing concerns Americans have about the potential misuse of their genetic information. Another indication of that concern is President Bush's recent announcement that he, too, favors national protections against genetic discrimination. We welcome the leadership he can bring to this important effort.

Americans' fear of genetic discrimination is real. Unfortunately, actual cases of genetic discrimination are real, too. We are joined today by a man who knows this all too well. I met Dave Escher earlier this summer. He told me how his employer forced him to be tested without his knowledge or consent for possible genetic defects.

Mr. Escher has worked for the same company for 25 years. By all accounts, he was and is—a tremendously hard worker and an asset to his company. Yet, last year—a few months after filing a personal injury report for carpal tunnel syndrome, Mr. Escher was told by his employer that he needed to attend a mandatory medical appointment. If he refused, he was told, he could lose his job.

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While stories like Mr. Escher's are still relatively rare, experts tell us that is only because genetic testing itself is still relatively rare. As testing becomes more affordable and more common, the incidence of discrimination is likely to increase dramatically. We must not wait until genetic discrimination becomes a widespread problem. We must specify - clearly and unambiguously in the law—how genetic information may be used and how it may not be used.

Some people argue that such protections should be limited to preventing misuse of genetic data by insurance companies only. As Mr. Escher's story shows, the problem of genetic discrimination is not limited to insurance. The solution should not be limited to insurance, either. It must safeguard against genetic discrimination in the workplace as well.

In this area, our bill sets three simple, reasonable rules. First, employers may not use predictive genetic information to make decisions about hiring, advancement, salary or other workplace rights and privileges. Second, they may not request, require or disclose a person's genetic information without his or her informed consent. Third, these provisions must be enforceable. If these rights are violated, victims of this discrimination may seek relief in court.

Our bill ensures that victims of discrimination have a real remedy, because a nonenforceable right is no right at all. Strong remedies are the best way to ensure compliance, and are particularly important in this area because discrimination on the basis of genetic information affects not only the identified individual, but also their children and relatives.

Discrimination based on genetic factors is just as arbitrary and unacceptable as discrimination based on race, national origin, religion, sex or disability. And, like those other forms of discrimination, genetic discrimination hurts us all. It hurts our economy by keeping talented people out of the workforce, and it diminishes us as a people.

It is time for our laws to catch up with our science. We cannot take one step forward in science—but two steps backward in civil rights.

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It would be a terrible travesty if instead of unraveling the secrets that could save lives genetic testing was used to unravel individuals' livelihoods.

I thank the members of the committee for listening; my colleagues Senators Kennedy, Dodd, and Harkin for all of their help in this endeavor; and my partner in the House, Congresswoman Slaughter, for her tireless effort to move our companion bill to the floor in that chamber.

The CHAIRMAN. We know that you have many other responsibilities so, with the permission of the committee, we will excuse you, and we will work very closely with you as we are considering the legislation as it moves along.

We thank you very much for taking the time and for your excellent statement.

Just as an aside, I do not know if you saw the pictures of the bicycle race in France and of Armstrong. Evidently, a German cyclist was ahead and then went off the road, and Armstrong waited until he picked himself up, dusted himself off, straightened his bicycle out—whatever they do after a terrible spill like these fellows have—and got back on his bicycle; and Armstrong let him get started, and then the pictures showed Armstrong going right by him.

I think all of us are hoping for a good win for Lance Armstrong and a good win for this legislation. We are not going to have any slippage at all on this legislation.

Thank you very much for being here.

Senator DASCHLE. I like that metaphor, Mr. Chairman.

Thank you.

The CHAIRMAN. On our next panel, we welcome Dr. Collins, David Escher, and Kathy Zeitz.

Dr. Francis Collins, one of the world's leading experts in genetics, led the NIH team that completed the historic task of determining the complete sequence of the human DNA code. Dr. Collins' commitment to science is matched only by his commitment to ensuring that the new genetics knowledge is used in ways to benefit the patients, and he will share with us his expertise in genetics and the need to protect Americans from genetic discrimination.

Kathy Zeitz is an attorney, a cancer survivor, and a genetic testing participant. She works with the National Breast Cancer Coalition and is a leader in the fight to ensure that all women receive proper screening, preventive care and treatment for breast cancer. She has spoken extensively on ethical and legal questions relevant to health care, including genetic discrimination. She will share with us her personal and professional expertise in genetic testing and breast cancer.

David Escher has been employed by Burlington Northern Santa Fe Railroad and has been a member of the Brotherhood of Maintenance of Way Employees for 26 years. Mr. Escher will describe how his employer subjected him to genetic testing when he developed work-related carpal tunnel syndrome—testing done without his knowledge or consent.

Mr. Escher will describe the effects that this testing had on him and his family. The committee appreciates his willingness to share this information with us.

Dr. Collins, if you would be good enough to start.

STATEMENTS OF DR. FRANCIS COLLINS, DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD; KATHLEEN ZEITZ, NEBRASKA LEAD COORDINATOR, NATIONAL BREAST CANCER COALITION; AND DAVID ESCHER, EMPLOYEE, BURLINGTON NORTHERN SANTA FE RAILROAD, McCOOK, NE

Dr. COLLINS. Thank you, Mr. Chairman and members of the committee.

We at NIH appreciate the very strong support of the Congress in medical research and particularly the efforts of this committee to provide a protective framework so that the benefits of the Human Genome Project can be experienced by all without fear of misuse.

I believe that today is a very important hearing. In a recent Harris poll survey that was published earlier this year, 84 percent of the American public indicated they believed the overall impact of genomics research would be positive; but almost half listed "misuse of genetic information" as their most major concern.

So our discussion today is timely and touches at the heart of the American public's hopes and their fears.

For myself, it has been an exhilarating experience to stand at the helm of this Human Genome Project for the last 8 years. I am holding in my hand a CDROM that contains on it the sequence of the human genome—3.1 billion letters that we carry inside each cell of our body—a remarkable instruction book written in a simple alphabet with only four letters which we now have, immediately accessible to anybody with an Internet connection. And we are all now engaged in the decryption business of trying to understand how this information operates and why it goes wrong as it sometimes does in order to cause disease.

I thought it might be interesting as part of my opening statement to read you the sequence of the human genome, because it is a pretty significant moment in history that we now have this—but I calculate it would take about 32 years, and I suspect the committee would grow tired of that long before I got past the first few bases of chromosome 1.

Just the same, it is an historic moment to be able to contemplate doing such a thing.

The consequences of this for our ability to understand medical problems are truly stunning. I spent most of the 1980's—9 years, in fact—working with my research group at the University of

Michigan, trying to find the gene for cystic fibrosis. After those 9 years, we finally succeeded, after all sorts of blind alleys and frustrations.

Four years ago, a group working at NIH, using the tools of the Genome Project which had already been developed at that point, were able to pinpoint a gene for Parkinson's disease in just 9 days.

Two months ago, I read a paper in a medical journal where investigators trying to track down a gene for Crohn's disease, a relatively common intestinal disorder, were able to find that gene simply by going to the Internet and clicking on the appropriate sequence in something like 9 seconds.

So we have gone from 9 years to 9 days to 9 seconds as the timetable for finding a gene involved in disease. Surely, that is a revelation of the promise of this particular kind of research.

And we have many new and exciting opportunities in genomics. Just last week, we held a conference to talk about the possibility of uncovering the way in which human variation is organized and correlated in the genome, which will have profound abilities to speed up our efforts to find the hereditary factors in diabetes and heart disease and Alzheimer's disease. We have programs underway to understand how genes are turned on and off in health and disease and programs to understand how the protein products which do the work of the cell also carry out their functions, not just one protein at a time but in a more global way.

What can we expect the impact of this to be on medicine? Well, it is risky to make predictions in a field that moves so quickly, but I will try.

By 2010, I would predict there will be at least a dozen predictive genetic tests for common illnesses so that each of us will have the opportunity to potentially learn about our own risk. That will offer us—because many of those will be associated with interventions such as diet, lifestyle or medical surveillance so that the high-risk individuals can reduce that risk. Basically, this is a form of individualized preventive medicine instead of the current version, which is often one-size-fits-all. We are all different; this is a chance for our preventive medicine to adapt to that.

We will also in another 10 years have a number of drugs for which we are able to predict, based on genetic testing, whether that is the right drug for you or whether you ought to try an alternative, because the differences in drug response are in many ways also encoded by our genes.

By 2020, the full flowering of the therapeutic revolution based on genomics will be at hand. We will have gene-based designer drugs for diabetes, for Alzheimer's disease, for hypertension, that will be more effective and more individualized than the current opportunities that we have, because in fact most of the drug industry until now has focused on a very small number of targets—less than 500. Now, with the genome in front of us, we have tens of thousands of drug targets, and the pharmaceutical industry is pursuing those with great vigor.

By 2030, I believe that we will have a genomics-based form of health care which will focus on maintaining wellness and which will in fact have health economic benefits as well as benevolent benefits for maintaining human health. The prediction would be that this will allow a larger fraction of us to live out healthy lives without being cut down prematurely by chronic or potentially fatal illnesses.

But all of this can only come to pass if the American public feels safe acquiring genetic information about themselves. And as I mentioned at the beginning, in this survey, they currently do not. As Dave Escher will currently tell you, that is not the case in his circumstance; it is not the case that we have protections against the misuse of genetic information in the workplace, either.

In recent NIH studies looking at individuals who could be offered testing for colon cancer, breast cancer, or ovarian cancer, fully one-third of them opt out of the research because of their concern that the information might be used against them in health insurance or in the workplace.

I found particularly stunning a recently published report in the Journal of Clinical Oncology where they surveyed genetic counselors who are working in the field of cancer genetics—these are the experts—and they asked them: If you were in a circumstance where a BRCA-1 test was recommended as part of your medical care, would you in fact go through with it? They indicated that they probably would, but two-thirds of them said they would pay for it out-of-pocket rather than take the chance that the information would be available to their health insurance company; and over one-quarter of them said they would use an assumed name.

What kind of medical care situation are we proposing here where individuals contemplate taking on a false name in order to acquire medical information that would be beneficial for their own health care?

The Ethical, Legal, and Social Implications, or ELSI, program of the Human Genome Project has from the outset, since 1990, focused a significant fraction of our budget on researching these issues, and out of that has come a host of wonderful scholarship and policy recommendations. Papers published in Science Magazine in 1995 and 1996 brought together the best thinking of consumers, policy experts and scientists, and recommended the need for legislation to deal with genetic discrimination in both health insurance and in the workplace, and many States have acted upon that.

I am pleased to see the momentum building this summer to resolve this problem with effective, bipartisan Federal legislation. I was very pleased to hear the words of President Bush on June 23, who got it exactly right when he said, and I quote: “Genetic discrimination is unfair to workers and their families. It is unjustified to deny employment or insurance to a healthy person based only on a predisposition; it violates our country’s belief in equal treatment and individual merit.”

“In the past, other forms of discrimination have been used to withhold rights and opportunities that belong to all Americans. Just as we have addressed discrimination based on race, gender, and age, we must now prevent discrimination based on genetic information.”

Thomas Jefferson, writing some time ago, wrote about the inalienable rights of persons, but he also wrote the following: “Our laws and institutions must go hand-in-hand with the progress of the human mind.”

This issue is about fairness and justice. It is about all people with DNA—that happens to be all of us, of course. It is time to provide the American public with the reassurance they deserve that the revolution in genetic medicine which is coming quickly upon us will be used for their benefit and not to do harm.

Thank you, Mr. Chairman. I would be glad to answer your questions.

[The prepared statement of Dr. Collins follows:]

PREPARED STATEMENT OF FRANCIS S. COLLINS, M.D., PH.D.

Mr. Chairman, and members of the committee, it is a pleasure to be here today to discuss the recent scientific advances in genetics that will lead to improved health and the development of therapies to treat and prevent devastating diseases. First, I would like to thank the committee, and especially you Mr. Chairman, for your strong support of the Human Genome Project and your commitment to ensure that advances in our understanding are used to improve the health of our citizens and not for harm. Today I would like to focus my remarks on the great promise genetics research holds for all of us and the potential obstacle that genetic discrimination poses to the realization of this promise.

Human Genome Sequence

Last year, Human Genome Project scientists capped their achievements of the last decade with a historic milestone—the complete initial reading of the text of our genetic instruction book. This book is written in an elegant digital language, using a simple four letter alphabet where each letter is a chemical base, abbreviated A, C, G, or T. At present, more than 95 percent of the 3.1 billion bases of the human genome are freely available in public databases. This is an awesome step toward a comprehensive view of the essential elements of human life, a perspective that inaugurates a new era in medicine where we will have a more profound understanding of the biological basis of disease and develop more effective ways to diagnose, treat, and prevent illness.

Between March 1999 and June 2000 the international collaborators in the Human Genome Project sequenced DNA at a rate of 1000 bases per second, 7 days a week, 24 hours a day. After completing the working draft of the human genome sequence in June of 2000, Human Genome Project scientists and computational experts scoured the sequence for insights. They reported the first key discoveries in the February 15, 2001 issue of the journal Nature. Among the findings were the following:

- Humans are likely to have only 30,000 to 40,000 genes, just twice as many as a fruit fly, and far fewer than the 80,000 to 150,000 that had been widely predicted.
- Genes are unevenly distributed across the genomic landscape; they are crowded in some regions and spread out widely in others.
- Individual human genes are commonly able to produce several different proteins.
- The repetitive DNA sequences that make up much of our genome, and commonly regarded as "junk," have been important for evolutionary flexibility, allowing genes to be shuffled and new ones to be created. The repetitive DNA may also perform other important functions, and provides fascinating insights into history.

Finishing the human genome sequence

Because of the enormous value of DNA sequence information to researchers around the world, in academia and industry, the public Human Genome Project (HGP) has always been committed to the principle of free, rapid access to genomic information through well-organized, annotated databases. Databases housing the human genome sequence are being visited by tens of thousands of users a day. Over the coming two years, the HGP will increase the usefulness of the human genome sequence to the world's researchers by finishing the sequencing to match the project's long-standing goals for completeness and stringent accuracy. More than 40 percent of the draft sequence, including two of our 24 chromosomes, have already been finished into a highly accurate form containing no more than I error per 10,000 bases. Finished sequence for the entire genome is expected by 2003.

Human genetic variation

While the DNA sequence between any two individuals is 99.9 percent identical, that still leaves millions of differences. For understanding the basis of common diseases with complex origins, like heart disease, Alzheimer disease, and diabetes, it is important to catalog genetic variations and how they correlate with disease risk. Most of these are single letter differences referred to as Single Nucleotide Polymorphisms (SNPs). With a draft of the human genome sequence in hand, the pace of SNP discovery has increased dramatically. In FY 1999, NEGRI organized the DNA Polymorphism Discovery Resource consisting of 450 DNA samples collected from anonymous American donors with diverse ethnic backgrounds. NEGRI has funded studies looking for SNPs in these samples. The non-profit SNP Consortium came into being in April 1999, with the goal of developing a high-quality SNP map of the human genome and of releasing the information freely. Consortium members included the Wellcome Trust, a dozen companies (mostly pharmaceutical companies), three academic centers, and NIH. This has been remarkably successful, with 5 times more SNPs being contributed to the public domain than the consortium originally planned. As of June 22, the public database that serves as a central repository for SNPs has received 2,972,764 SNP submissions.

Just last week, we held a landmark workshop to discuss taking the study of human variation to the next step—deciphering patterns of variation across large regions of DNA (called haplotypes) which will greatly accelerate the ability to identify the hereditary factors in common disease.

With this increased knowledge about human variation, the genetic underpinnings of various diseases, including diabetes, are being discovered. The recent discovery of a gene, calpain-10, whose disruption contributes to diabetes, resulted from studies linking diabetes with genetic variations across the whole genome and then in a specific part of chromosome 2. The newly discovered gene variant suggests that a previously unknown biochemical process is involved in the regulation of blood sugar levels.

Gene expression

The new-found abundance of genomic information and technology is propelling scientists to go beyond the pattern of studying individual genes and into studying thousands at a time. Large-scale analyses of when genes are on or off (gene expression) can be used, for example, to study the molecular changes in tumor cells. This exciting new approach combines recombinant DNA and computer chip technologies to produce microarrays or DNA chips. Classifying cancer on a molecular level offers the possibility of more accurate and precise diagnosis and treatment. Intramural researchers at NEGRI have used large-scale expression studies to discover genetic signatures that can distinguish the dangers from different skin cancers, and that can distinguish between hereditary and sporadic forins of breast cancer.

Promise for new treatments and prevention

With the availability of a comprehensive view of our genes, genetic testing will become increasingly important for assessing individual risk of disease and prompting programs of prevention. An example of how this may work involves the disease hereditary hemochromatosis (HH), a disorder of iron metabolism affecting about one in 200 to 400 Americans. Those with the condition accumulate too much iron in their bodies, leading to problems like heart and liver disease and diabetes. The gene causing the condition has been identified, allowing early identification of those in whom HH may develop. Once people at risk are identified by genetic testing they can easily be treated by periodically removing some blood. The National Human Genome Research Institute (NGHRI) and National Heart, Lung and Blood Institute (NHLBI) are engaged in a largescale project to detennine the feasibility of screening the adult population for this very preventable disorder.

Genetic testing is also being us ed to tailor medicines to fit individual genetic profiles, since drugs that are effective in some people are less effective in others and, in some, cause severe side effects. These differences in drug response are genetically determined. Customizing medicine to a patient's likely response is a promising new field known as pharmacogenomics. For example, a recent publication in the journal Hypertension showed how pharmacogenomics applies to high blood pressure. Researchers found a variation in a particular gene that affects how patients respond to a commonly used high blood pressure drug, hydrochlorothiazide. Other recent studies reveal that doctors should avoid using high doses of a common chemotherapy treatment (6-mercaptopurine) in a small proportion of children with leukemia. Children with a particular forin of a gene (TPMT) suffer serious, sometimes fatal, side effects from the drug.

Genomics is also fueling the development of new medicines. Several drugs now showing promising results in clinical trials are "gene-based" therapies, where an exact appreciation of the molecular foundations of disease guides treatment design. One of the first examples is Gleevec (previously called STI571), produced by Novartis for treating chronic myelogenous leukemia (CML), a form of leukemia that mostly affects adults. CML is caused by a specific genetic flaw—an unusual joining of chromosomes 9 and 22 producing an abnormal fusion gene that codes for an abnormal protein. The abnormal fusion protein spurs uncontrolled growth of white blood cells. Novartis designed a small molecule that specifically inactivates that protein. In phase I clinical trials, this drug caused dramatically favorable responses in patients, while side effects were minimal. By targeting the fundamental biochemical abnormality associated with this form of cancer, rather than killing dividing cells indiscriminately as most chemotherapy does, the drug offers better treatment results and fewer toxic effects on normal cells. In May 2001, FDA approved Gleevec for the treatment of Chronic Myeloid Leukemia after a review time of less than three months. Meanwhile, Bayer and Millennium announced the development of another cancer drug born of genomics in January 2001. GlaxoSmithKline is testing a new genomics-derived heart disease drug that targets a protein involved in fat metabolism. Johnson&Johnson is testing a drug targeting a brain receptor identified through genomics, and involved with memory and attention. Human Genome Sciences has four clinical trials in progress to test gene-based drug candidates.

The Future of Genetic Medicine

As I recently wrote in the February 2001 issue of the Journal of the American Medical Association, by the year 2010, predictive genetic tests will exist for many common conditions where interventions can alleviate inherited risk; successful gene therapy will be available for a small set of conditions; and primary care providers will be practicing genetic medicine on a daily basis. By the year 2020, gene-based designer drugs are likely to be available for conditions like diabetes, Alzheimer's disease, hypertension, and many other disorders; cancer treatment will precisely target the molecular fingerprints of particular tumors; genetic information will be used routinely to give patients appropriate drug therapy; and the diagnosis and treatment of mental illness will be transformed. By the year 2030, I predict that comprehensive, genomics-based health care will become the norm, with individualized preventive medicine and early detection of illnesses by molecular surveillance; gene therapy and gene-based therapy will be available for many diseases.

Genetic Discrimination

Genetic information can be enormously valuable to patients and providers as it can guide early detection, intervention and prevention. But as President Bush recently noted, "this knowledge of the code of life has the potential to be abused. Employers could be tempted to deny a job based on a person's genetic profile. Insurance companies might use that information to deny an application for coverage, or charge excessive premiums."

Individuals in a preliminary NIH colon cancer study were provided education and counseling before being offered the genetic test. When asked what factors might lead them to take the test, the overwhelming majority stated they wished to learn about their children's health risks and to obtain information to help guide their own cancer screening. When asked what factors might lead them not to take the test, 10 percent indicated their greatest concern was handling the infonnation emotionally and 28 percent were concerned about the effect on family members. These are reasonable and very personal issues of concern. But, the number-one concern cited by 39 percent 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 opted not to participate said that they did so because of their concern about genetic discrimination.

In a survey of genetic counselors, published in the June 2001 edition of the Journal of Clinical Oncology, an overwhelming majority indicated that they would take a genetic test based on high-risk family history for colon or breast/ovarian cancer (91 peercent and 85 percent respectively). These professionals clearly know the value of the information. But, 68 percent said they would pay out of pocket for the testing rather than bill their insurer because of fear of discrimination. Twenty six percent said they would use an alias.

In conclusion, I would like to again quote President Bush, who got it exactly right when he said, "Genetic discrimination is unfair to workers and their families. It is unjustified. To deny employment or insurance to a healthy person based only on a predisposition violates our country's belief in equal treatment and individual merit. In the past, other forms of discrimination have been used to withhold rights and opportunities that belong to all Americans. Just as we have addressed discrimination based on race, gender and age, we must now prevent discrimination based on genetic information."

Thank you Mr. Chairman. I would be happy to answer any questions.

The CHAIRMAN. Dr. Collins, are you all right on time for a little bit?

Dr. COLLINS. Yes, I am fine.

The CHAIRMAN. Then, we will go ahead with Ms. Zeitz.

Ms. Zeitz, if you would, please.

Ms. ZEITZ. Good morning, Mr. Chairman, members of the committee.

My name is Kathleen Zeitz, and I am a breast cancer survivor, a genetic testing participant, and the Nebraska Field Coordinator for the National Breast Cancer Coalition. I am testifying today on behalf of the Coalition.

I am also an attorney and a member of the National Action Plan on Breast Cancer's Hereditary Susceptibility Working Group/Consumer Advisory Subcommittee.

The National Breast Cancer Coalition, a grassroots advocacy organization, has been working since 1991 to eradicate breast cancer. Addressing the complex privacy, insurance and employment discrimination questions raised by evolving genetic discoveries is one of NBCC's highest priorities.

The fear of genetic discrimination is very real, and the result is that the delivery of high-quality health care and advancements in research have been hindered. I have first-hand knowledge of that fear. My mother and I and my husband's mother and sister have all been diagnosed with breast cancer, and my mother-in-law did not survive the disease.

With this history, my daughter was the one who encouraged me to participate in genetic testing. After I had begun testing, she completely reversed her position based upon fear of genetic discrimination by health insurers and employers, and has decided not to be tested herself. Her fears about participating in genetic research are shared by many, to the detriment of research.

Since 1996, NBCC has been working with Members of Congress to enact comprehensive and enforceable genetic nondiscrimination legislation. NBCC has fought to ensure that the definition of protected genetic information is broad, including any information about genes or characteristics from family members, family history of the disease, and also genetic information derived from tests, regardless of whether the test was officially labeled a genetic test.

The Coalition has also worked to guarantee that individuals are protected from both health insurance and employment discrimination; that Federal protections include meaningful enforcement; and that the Federal law sets a minimum level of protection that will not preempt stronger State laws.

S. 318, The Genetic Nondiscrimination in Health Insurance and Employment Act, contains comprehensive and enforceable protections and establishes that floor. We especially thank the chairman and the members of the committee who cosponsored this legislation and urge Congress to enact S. 318 as soon as possible.

This morning, I want to focus on three main points and ask that my written statement be submitted for the record.

First, I want to emphasize why now is the time that Congress must enact Federal protections against genetic discrimination. Billions of dollars are being spent on biomedical research. The last decade of research led to the discovery of genes associated with the high risk of breast cancer. Since these genes have been identified, genetic tests for breast cancer risk have become widely available. And breast cancer is only one of many diseases that have genetic indicators.

Genetic discrimination and the fear of that discrimination is already deterring some individuals like my daughter from seeking genetic testing and from participating in clinical research. Fear of discrimination is also prohibiting some individuals from revealing their own medical histories or that of their families, and prevents them from getting the high-quality care that they deserve.

Enactment of S. 318 is necessary to protect individuals and their families so they can participate in biomedical research and reap the benefits of its breakthroughs without fearing repercussions from health insurers and employers.

Second, I want to explain why genetic discrimination legislation must be comprehensive, including both health insurance and employment protections.

Currently, there is no Federal law that adequately protects individuals from genetic discrimination. The Health Insurance Portability and Accountability Act provides some genetic protections but only extends those to group health plans and leaves those individuals in the individual market unprotected. HIPAA does not prohibit plans from requiring individuals to disclose their genetic information or from charging groups higher premiums based on the genetic information of an individual within the group.

It is currently being debated whether the Americans with Disabilities Act protects individuals with genetic predispositions from discrimination by their employers. But as committee members heard last year from the EEOC, there is not a clear answer to that question, and therefore, Federal legislation is needed to clarify this issue.

Finally, I want to highlight why it is critically important that genetic nondiscrimination legislation have strong enforcement mechanisms that include a private right of action.

If I am fired from my job or lose my health insurance because of the results of my genetic tests, what recourse will I have if a bill is passed without the right to sue? A right without strong enforcement that includes a private right of action is really a right to nothing at all.

While a number of genetic nondiscrimination bills have been introduced, S. 318 is the only comprehensive bill that contains strong enforcement mechanisms, and therefore it is the only bill that NBCC supports.

Thank you for the opportunity to testify before the committee. I would be happy to answer any questions.

The CHAIRMAN. Thank you very much.

[The prepared statement of Ms. Zeitz follows:]

PREPARED STATEMENT OF KATHLEEN ZEITZ

Thank you, Chairman Kennedy, Ranking Member Gregg and members of the Senate Health, Education, Labor and Pensions Committee for the opportunity to present the National Breast Cancer Coalition's position on federal genetic discrimination policy. In my testimony, I will make the followinor three points: (1) federal protections against genetic discrimination are needed now; (2) legislation must be comprehensive and Include both health Insurance and employment protections; and (3) legislation must be strong and enforceable in protecting individuals from misuse of their genetic information.

I am Kathleen Zeitz, a breast cancer survivor with a strong family history of the disease and a genetic testing participant. I am also a practicing attorney. I am here today as a proud member of the National Breast Cancer Coalition and as Nebraska's Lead Field Coordinator for the National Breast Cancer Coalition. I am also a member of the National Action Plan on Breast Cancer's Hereditary Susceptibility Working Group/Consumer Advisory Subcommittee.

On behalf of the National Breast Cancer Coalition (NBCC), the three million women living in this country with breast cancer, and all the women at risk of getting the disease—and that is all women, thank you for holding a hearing to address the need for legislation prohibiting genetic discrimination. NBCC wants to work with this Committee to pass effective and meaningful legislation that accomplishes our mutual goal of allowing the science to move forward while protecting individuals from the misuse of genetic information.

NBCC has endorsed S. 318, the Genetic Nondiscrimination in Health Insurance and Employment Act, because it contains the necessary scope and protections. The National Breast Cancer Coalition is a grassroots advocacy organization made up of over 600 organizations and tens of thousands of individuals, has been workina since 1991 to eradicate breast cancer thrOLIgh increased funding and new strategies for breast cancer research, access to quality health care for all women, and expanded influence of breast cancer activists at every table where decisions regarding breast cancer are made. Addressing the complex privacy, insurance and employment discrimination questions raised by evolving genetic discoveries is one of our top priorities.

(1) Federal protections against genetic discrimination are needed now

Genetic Information is Increasing Rapidly

Billions of dollars are being spent on biomedical research. This research has the potential to save lives, but only if people are not afraid to take advantage of it. The last decade of research led to the discovery of genes associated with a higher risk of developing breast cancer, such as BRCA1 and BRCA2. Since these genes have been identified, genetic tests for breast cancer risk have become widely available. While this is commonly recognized, breast cancer is only one of many diseases that have genetic indicators for susceptibility. Tests are currently available for close to 800 genes and that number keeps growing. It is very clear that the issues raised by the use of genetic information do not only apply to women with or predisposed to breast cancer, but rather to us all. Soon each one of us will be able to identify several diseases that we may be predisposed to develop in our lifetime. As President Bush recently announced, "Just as we have addressed discrimination based on race, gender, and age, we must now prevent discrimination based on genetic information." (President Bush's June 23, 2001 Radio Address).

The Definition of Protected Genetic Information Must be Broad in Order to Guarantee Necessary Protections

Individuals must be protected against the misuse of any of their genetic information. This information is not only found In an individual's genetic test results. The fact that an individual took a genetic test, regardless of the results, and family history could also be used as a source of discrimination. This information could lead to discrimination even in cases where individuals are healthy, may never develop disease, and the genetic condition has no effect on their ability to perform their job. It could also lead to discrimination against family members who have never taken a genetic test.

The definition of protected genetic information Must include any test that could reveal genetic information even if it was not administered with the purpose of obtaining genetic information. All genetic information must be protected, even if it is derived from a source that was not officially labeled as a genetic test. Otherwise, a loophole is created that would allow both health insurers and employers to dip into this information and use it for genetic purposes at a later date. This is not just speculation—Burlington Northern Railroad Company took blood samples from its employees that it used to test for genetic predisposition to carpal tunnel syndrome.

The Fear of Genetic Discrimination is Real: the Result is that Healthcare and Advancements in Research are Hindered

The potential for genetic discrimination makes women afraid to share necessary information with their health care providers and to take advantage of genetic technologies. I have first hand knowledge of the fear that surrounds genetic testing. Breast cancer has hit my family hard. My mother and I, my husband's mother and sister have all been diagnosed with breast cancer. My mother-in-law did not survive the disease. With this history, my daughter was the one who encouraged me to participate in genetic testing. After I had been tested, she completely reversed her position based upon fear of genetic discrimination by health insurers and employers. She has decided not to be tested or to participate in genetic research. Her fear is shared by many women who have avoided taking the test altogether to the detriment of research.

Fear has also motivated women to take extreme measures, such as using false names or paying for expensive tests out-of-pocket, to avoid identification and to blur any connection with information derived from their tests. Similarly, these women, concerned that their health and genetic status may affect their children in the future, have warned them not to disclose the existence of the disease when sharing their family history with doctors. This action could prevent them from getting proper care.

Biomedical Research Would Benefit From Clear Protections **Against the Misuse of Genetic Information**

Protection against genetic discrimination in health insurance and employment is vital to the advancement of biomedical research. Knowledge about how to prevent and cure breast cancer will only come if women participate in research through clinical trials. However, participation in genetic testing and clinical trials is currently hampered by the lack of clear protections.

NBCC is committed to ensuring that neither genetic technology nor genetic information is used or abused to the detriment of individuals and their families. Only at a time when the proper protections are in place will the true benefit of advancements in genomic sciences become a reality. We need protection now so that there are no barriers to what we can achieve.

(2) Genetic Nondiscrimination legislation must be comprehensive and include both health insurance and employment protections

Since its inception, NBCC has played a central role in the development of policy recommendations addressing genetic discrimination. As Co-Chairs of the National Action Plan on Breast Cancer (NAPBC) with the U.S. Public Health Service Office on Women's Health, NBCC helped lead a joint working group of the NAPBC and the National Institutes of Health Department of Energy Working Group on Ethical, Legal and Social Implications of Human Genome Research (NAPBC-ELSI Working Group) to address the issue of genetic discrimination in health insurance and employment.

Genetic Discrimination Must be Addressed in Both Health Insurance and Employment

Congress must pass legislation that clearly prohibits discrimination in health insurance and employment on the basis of genetic information. Information learned from one's aerietic blueprint should only be used to treat, Cure and prevent various genetic diseases and cancer. Advances and beneficial applications of genomics technology greatly depend on the availability of comprehensive protections against genetic discrimination.

Health insurance and employment genetic discrimination are inextricably linked. Since most Americans receive health insurance through their employers, they risk losing their health insurance if they lose theirjob as a result of discrimination based on their genetic information. No federal law specifically prevents employers from using medical records when making decisions about promotions, hiring and firing. All employers have access to employee medical records, regardless of whether they self-insure or not. This medical information is considered by many of the largest employers in the United States in making employment decisions.

Policy Recommendations for Health Insurance

NBCC's policy recommendations are that insurance providers should be prohibited from: (1) requesting or requiring collection or disclosure of genetic information; (2) using genetic information, or an individual's request for genetic services, to deny or limit any coverage for established eligibility, continuation, enrollment or contribution requirements: (3) establishing differential rates or premium payments based on genetic information, or an individual's request for genetic services; and (4) disclosing genetic information to other health plans, members of the same controlled group, employers or entities that collect or disseminate insurance information.

Policy Recommendations for Employment

NBCC recommends that employment organizations should be prohibited from: (1) using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits or termination of employment, unless the employment organization can provide this information is job related and consistent with business necessity; (2) requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment; or under all other circumstances, from requesting or requiring, collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity; (3) accessing genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement for health care costs, and other services; and (4) releasing genetic information without specific prior written authorization of the individual.

Health plans or employers who violate these provisions must be held accountable. NBCC supports a private right of action in state or federal court for individuals. Only comprehensive legislation can meet the challenges presented by this issue. NBCC believes that the Genetic Nondiscrimination In Health Insurance and Employment Act, S. 318 appropriately addresses the issue.

Currently there are no comprehensive protections in federal law

The reality is that there are no federal laws that provide sufficient protection. For example, the Health Insurance Portability and Accountability Act (HIPAA) only extends protection against genetic discrimination to those in group health plans, not to those with individual coverage. Nor does HIPAA prohibit plans from requiring people to disclose genetic information, or from charging groups higher premiums based on genetic information of individuals within the group.

The recently implemented HIPAA Medical Privacy Regulations are also insufficient to guard individuals against the misuse of genetic information. While the regulations take an important step forward in protecting individuals against disclosures of their health information, they do not provide individuals with a private right of action to enforce their rights. Moreover, the Regulations do nothing to protect individuals against the actual misuse of their health information once it is disclosed. And the Medical Privacy Regulations do not directly cover employers.

There must be clear, direct law stating that genetic discrimination in employment is prohibited. The Americans with Disabilities Act's (ADA) protection is debatable. The ADA's protection on this issue was a question before this Committee last year. The testimony at that hearing made it clear to all that protections against genetic discrimination in employment needed to be clasrified. The EEOC's witness, Commissioner Paul Miller, suggested that additional specific federal legislation may provide more appropriate protection than that offered under the ADA. For example, the ADA does not protect workers from requirements or requests to provide genetic information to the employers.

(3) Legislation must be strong and enforceable in protecting individuals from misuse of their genetic information

Meaningful Enforcement is Necessary

It is most important to NBCC that effective legislation is passed. Legislation designed to protect individuals against discrimination based on aerietic information must be enforceable to be meaningful. Therefore, legislation must include strong enforcement mechanisms. including, the right to hold violators legally accountable in a state and federal cause of action. A right without a remedy is no right at all. NBCC wants to ensure that Congress enacts a bill that individuals can rely on to protect them.

Federal Law Should Set a Minimum Level of Protection

A federal genetic nondiscrimination law should set a minimum level of protection. It should act as a floor and not a ceiling, State laws that offer more complete protection should not be preempted.

The current patchwork of state legislation addressing genetic discrimination does not provide adequate protection. Some states offer extensive protections, some offer little or none. Many states have laws that purport to protect against discrimination, but they are not enforceable. The impractical result is that individuals similarly situated can only rely upon protections avaiiable to them according to their zip code.

Conclusion

NBCC believes that the significant gaps in federal protection against genetic discrimination could be addressed by passage of S. 318, the Genetic Information Nondiscrimination in Health Insurance and Employment Act, because it is comprehensive and enforceable and would help protect all individuals from discrimination in the employment and in health insurance.

NBCC looks forward to working with this Committee, Members of Congress, and the Administration in passing this legislation to ensure that all Americans are guaranteed enforceable and comprehensive protections against discrimination on the basis of their genetic information.

Thank you for inviting me to testify and for your leadership on this issue that is critical not only to women predisposed to breast cancer—but to all individuals.

The CHAIRMAN. Mr. Escher.

Senator WARNER. Mr. Chairman, if I could just ask the chair—a group of us here in the Senate is going down to meet with the President and get a report on his trip to Europe; I am among them—could I ask unanimous consent to put questions in for the record?

The CHAIRMAN. Yes, certainly. If the Senator wants to ask a question or two now, we are happy to permit that, but we would welcome your questions.

Senator WARNER. Mr. Chairman, I join all others in doing our best to stop this genetic discrimination; it should not occur. I am inclined to look at the ADA as the means by which we can amend it to achieve that, rather than with separate legislation, but this is a very important hearing, and I look forward to the hearing in the fall.

I thank the chairman.

The CHAIRMAN. Fine. We thank the Senator. We will have a chance to get back into the ADA. We certainly know, with the various court hearings, that there is a real question about how far that legislation really goes in terms of protecting people from this problem, but I think it is a legitimate issue. We ought to have an understanding so that we all agree as to what the legislation is meant to do and does do.

So we appreciate the Senator's comments. We have that; we have the more recent publications of the privacy legislation in terms of the HIPAA that have come up, and most of that has come in since other legislation has been introduced, so that has to be adjusted. But I think those are legitimate questions, and I think we will probably hear from Dr. Collins and others that it will still be necessary to have this form of legislation to meet the particular challenges of genetic discrimination.

But we thank the Senator for his interest.

Senator WARNER. I thank the chair.

[The questions of Senator Warner with responses were not available at press time, when received, they will be retained in the files of the committee.]I21The CHAIRMAN. We look forward to hearing from you now, Mr. Escher.

Mr. ESCHER. Thank you, Mr. Chairman and members of the committee.

My name is Dave Escher. I am 47 years old, and I have been employed by Burlington Northern Santa Fe and a member of the Brotherhood of Maintenance of Way Employees for the past 26 years. I was born and raised in Herndon, KS, a small northwestern town with a population of about 200 people. I graduated from high school there in 1972, and I began working with Burlington Northern in 1976. I married my wife Deb in 1986 and have three daughters—Kelsey, Kara, and Kristen. We have made our home in McCook, NE for the past 11 years.

My jobs within the company have included such positions as laborer, truck driver, assistant foreman, machine operator, and foreman. I was appointed to the division safety committee 12 years ago and held such positions as vice chairman and safety facilitator. I was also selected as the McCook Division Safety Employee of the Year in 1994 by management and am currently involved with the safety committee.

A couple of years ago, I began experiencing numbness, pain and tingling sensations in my right hand. When the numbness began to move through my hand and up my arm into my upper bicep, I want to see a doctor who referred me to a specialist. It was determined that I had developed work-related carpal syndrome for which surgery was necessary.

After meeting with the operating surgeon, I received a letter from corporate headquarters stating that they were not satisfied with the initial test results and that they required further testing.

In a subsequent visit to a neurologist, I once again had my hands x-rayed and another nerve conductor study performed. The results again confirmed that I had carpal tunnel syndrome, that surgery was required, and that the condition was work-related.

Within 3 weeks of the surgery, I received another letter from management demanding that I undergo more extensive testing and that an appointment was already set for me. Included in this letter were the requirements of Safety Rule 26.3, which gives the medical department the authority to require an employee to meet all requirements set forth by the medical department and that everyone "must" comply with these instructions or face the consequences of disciplinary action for being an "insubordinate" employee.

After receiving this letter, I immediately contacted the company medical case manager with whom I had been dealing and reminded her that I had already seen four medical professionals, undergone two nerve conductor studies, had received six separate x-rays of each hand, and now the company was demanding that I see yet a fifth doctor and undergo yet another nerve conductor study with more x-rays. When I pressed for an explanation, I was told that as far as she understood, more information concerning my medical condition was needed.

I went to the appointment as I had been ordered. During the procedures, seven vials of my blood were extracted, and the doctor once again confirmed that I did suffer the effects of carpal tunnel syndrome and that the condition was work-related.

In a matter of a few days, I would learn from a coworker who had refused to submit to the same order and who also had been diagnosed with carpal tunnel syndrome that I had been subjected to a genetic test through the blood which was taken from me. This was done without my knowledge or my consent.

I found myself in a State of disbelief and humiliation. I could not believe or accept what had just occurred. I experienced stages of denial, disbelief, and depression. I felt totally violated and devalued as a person. I had just been used as a laboratory rat in a carefully devised scheme where my employer would benefit greatly. By trying to prove that carpal tunnel syndrome was a genetic disorder rather than a work environment-related condition, they could relieve themselves of the financial obligations to their employees who suffer work-related injuries within the workplace.

This was a very difficult concept for me to accept. My attitude toward the company became very negative. My moods of anger and depression resulting from the constant stress and uncertainty of my job situation affected my family as well. I became despondent to the needs and concerns of my wife and daughters as I tried to work through this seemingly unconquerable and endless situation.

I was also fearful of the fact that no one could tell me where all the vials of my blood had been dispersed, what information was being learned about me, who was going to receive this information and how it could be used to discriminate against not only myself but my family when they go out into the workplace.

The constant worries of where would I go to find another job at this point in my life and to be able to obtain insurance for my family seemed to me insurmountable. This was a very trying time in my life.

One of the most heart-wrenching moments occurred when my little 7-year-old daughter Kristen began crying one night because she was scared that Daddy was going to lose his job, and her little world would be turned upside-down. How do you explain to a young child that you could lose your job not because of what you have done to your employer but because of what your employer has done to you?

I feel that this new science of genetic information is a great asset when left in responsible hands; but it can also be very devastating when put into the hands of the wrong people.

I am fearful of the power that corporations, including insurance companies, would have if they were allowed to subject their employees and policyholders to genetic testing and then make decisions based on what is learned from those tests.

We have laws to protect us from people wire-tapping our phones, stealing our mail, and defrauding our bank accounts. How can we allow employers to steal the blood of their employees and use it to discriminate through the predispositions discovered through the information learned from the genetic studies?

S. 318 guarantees that that would not happen. On behalf of myself and all those other individuals who have experienced a similar situation, I want to express our appreciation to Majority Leader Daschle for introducing this bill and making it a priority.

Equal appreciation goes to you, Mr. Chairman, not only for bringing attention to this important issue with this hearing today, but also for your cosponsorship of the bill and your co-leadership on this issue.

Mr. Chairman, through the tactics of deception, intimidation, lying and stealing, the company to which I have given 25 years of my life took from me something they can never give back, and that is the very essence of my being—my genetic makeup.

I want to thank the committee for the opportunity to testify, and I urge enactment of S. 318.

Thank you.

The CHAIRMAN. Thank you for very powerful and moving testimony, and to Ms. Zeitz as well, and the enormously challenging testimony from Dr. Collins.

We are joined by Senator Dodd who, as I mentioned earlier, is one of the important leaders in this area on this committee and has been very active in the development of legislation. We look forward to hearing from him.

Senator DODD. Why don't you go ahead with your questions first, Mr. Chairman, and I will follow.

The CHAIRMAN. Thank you.

Senator Clinton has joined us as well, and we thank her so much.

We will go to some questions. Dr. Collins, one question that is constantly raised is that if we enact the legislation along the lines that Senator Daschle and others have proposed, this will result in harming medical research. As one of the premier researchers in the country in this area, could you help us understand whether passage of this legislation will harm research or whether in some way it might benefit research? What is your assessment of the impact of this legislation in the enormously important and significant and promising area of genetic research?

Dr. COLLINS. Senator, I appreciate the question, and I think it is a very important issue. Clearly, legislation that aims to offer protections against genetic discrimination, if not carefully worded, could potentially inadvertently do damage to medical research by putting up barriers for important studies that we all need in order to understand the connections between genes and disease.

I believe, however, that it is entirely possible to craft legislation that avoids that kind of outcome. I am not a policy expert, but I will tell you that my reading of the bill that Senator Daschle has introduced does not in fact in any way restrict the use of genetic information as part of research. It remains fairly silent on that topic.

In fact, I would say the regulations on the way in which genetic information is going to be used in research would be much more a subject of the current privacy regulations that are being promulgated by the Department as a consequence of HIPAA and, very importantly, would be overseen by institutional review boards as part of the human subject protections in 45 CFR 46.

So I believe that this kind of protection as exemplified by the Daschle bill will actually benefit research for the following reason. As I mentioned in my opening statement, the number one reason why people currently shy away from participating in genetic medical research that involves testing is their fear of discrimination. Providing them with the confidence that that outcome would no longer occur would be a great boon, I believe, to those of us who are trying to carry out these studies and who cannot confidently at the present time tell people who are considering participating that they are completely safe in doing so.

The CHAIRMAN. I think it would be helpful for the committee, since this is at the heart of much of the concern about this legislation, if you could perhaps submit a brief written response and analysis, too, that we will make a part of the record, if you would.

Dr. COLLINS. I would be happy to do so.

[Written response of Dr. Collins follows:]

NATIONAL INSTITUTES OF HEALTH,
NATIONAL HUMAN GENOME RESEARCH INSTITUTE,
31 Center Drive MSC 2152, Building 31, Room 41309
Bethesda, MD, February 4, 2002.

The Honorable EDWARD M. KENNEDY,
United States Senate,
SR-315 Senate Office Building,
Washington, DC.

DEAR SENATOR KENNEDY: It was a pleasure to testify before your committee on July 25, 2001. During that hearing you asked me to follow up in writing with an analysis and assessment of how S. 318 and S. 382 would affect the conduct of biomedical research.

In our evaluation of the Genetic Nondiscrimination in Health Insurance and Employment Act (S. 318), we find that it would not restrict researcher access to or use of genetic information. Title I, "Prohibition Of Health Insurance Discrimination On The Basis Of Protected Genetic Information", lays out certain restrictions on the collection, use, and disclosure of genetic information by health insurers. The provisions governing the disclosure of genetic information by health insurers specifically identify four entities to whom health insurers may not, without consent, disclose protected genetic information. Researchers are not included on this list. The collection, use, and disclosure of genetic information in biomedical research are not mentioned in this title and therefore, we believe that unless there is a conflict with state law, the title would not apply to the conduct of biomedical research.

Section 207 of Title II, "Prohibition Of Employment Discrimination On The Basis Of Protected Genetic Information", of the bill provides for the disclosure "of protected genetic information . . . to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations." This is the only direct reference to research in the legislation and it allows disclosure of information to researchers.

The Genetic Information Nondiscrimination in Health Insurance Act of 2001 (S. 382) would also not appear to restrict access or use of genetic information by researchers. The bill does not mention research and therefore would not affect a researcher's use of genetic information. A researcher's collection of genetic information from an insurer covered by the bill would be subject to the insurer's confidentiality practices. The bill requires that covered entities develop confidentiality safeguards and that compliance with the HIPAA health information privacy regulations would be sufficient.

I hope this information is useful as you continue your consideration of pending genetic antidiscrimination legislation. Please let me know if you have any further questions.

Sincerely,

FRANCIS S. COLLINS, M.D., PH.D.
Director

The CHAIRMAN. Now, I do not assume that you are a specialist in the HIPAA legislation or the Americans with Disabilities Act, but those are issues that have been raised as well as whether Federal legislation is really necessary because of what is happening out there in the States.

To the extent that you might be able to give us some insight into your own view about whether Federal legislation is needed or whether the actions in the States provide adequate protections in terms of your concern, we would like to hear from you on that.

Dr. COLLINS. I appreciate the question, Senator.

In terms of State legislation, more than two dozen States have passed legislation dealing either with health insurance or employment discrimination or in some instances, both of those. But it is quite a patchwork of protections that are provided. Some of those bills are better crafted than others; in some instances, perhaps the definitions have not been as carefully put together as one might hope to see. This has been a learning process, I think, for many of the States that have been wrestling with these issues going back 10 years.

Furthermore, there are some States that have not passed such protections, and it would seem unfortunate to end up with an uneven set of protections that depend on which State you happen to be living in at the moment. If this is a matter that is rising to the importance that it seems to be in the minds of the American public, I think it would make a lot more sense to have uniform protections across the board for all Americans.

With regard to the question of whether the Americans with Disabilities Act applies in this circumstance, that has been the subject of considerable discussion, and I think it is fair to say that there has been no effective resolution of that in the courts. But certainly no less an expert on the ADA than Paul Miller, a commissioner of the Equal Employment Opportunity Commission, has certainly raised both the hope that ADA might cover this circumstance but also considerable concerns about whether in fact that would hold up to legal scrutiny. In a recent piece that he published titled, "Is there a Pink Slip in Your Genes?" he outlines the arguments that have been raised in this circumstance, pointing particularly to the Bragden versus Abbott decision of the U.S. Supreme Court where Chief Justice Rehnquist specifically refers to this and in many people's view seems to have cast some doubt about whether the ADA would apply to predictive genetic information.

So among the experts who have gathered about this—and again, this has been going on for some 5 or 6 years, this analysis about the need for employment discrimination protections and whether we need additional things beyond ADA—I think the majority view is that one should not be confident that ADA is going to cover this, and if one is really concerned about incidents such as what Dave

Escher has gone through being prevented in the future, that we ought to take action.

The CHAIRMAN. Have you had a chance to review the recent privacy rules that have been promulgated?

Dr. COLLINS. Senator, I tried, and when I got to page 412——

The CHAIRMAN. It makes that little chip, with the 32 pages, seem like lively reading, I am sure. [Laughter.] Well, I think there is the general concern as well, as you have mentioned, with regard to the ADA; but if you would like to add anything in a written comment on that, we would be happy to have your views. I think we are going to have to address this, as you can see from the earlier comments.

So having your very important comments about the impact of this legislation on the basic research is enormously important and very significant.

I will just take another moment. Ms. Zeitz spoke powerfully when she was talking about her daughter not wanting to go ahead with genetic testing because of fear of discrimination. Ms. Zeitz, I know that you were active in the NIH several years ago and were involved in the hearings that took place there about women like yourself who were in similar situations with regard to genetic testing. Is this a real problem? Do you find that women who have a disposition in terms of the cancer gene not being willing to be involved in the kind of detection to find out whether they have the gene and therefore being excluded from insurance? Do you find that this is a real problem?

Ms. ZEITZ. It is a very real problem because women are afraid that by testing, they are revealing information not only about themselves but about other family members—their siblings who will now have information they may not want. All of that can get into medical records. They are trying to keep it out of medical records, yet by doing that, you are not getting good quality care because it may be important to your treatment. So the barriers are huge.

If you do not mind, I would also like to comment on some of your other questions.

The CHAIRMAN. Yes, please.

Ms. ZEITZ. In terms of HIPAA, I am an in-house attorney for a health system, so I am in the midst of the 1,500 pages of HIPAA in terms of compliance. And I can tell you that there are some definite eases of things that you can do in terms of disclosure.

Even though it is a privacy regulation that we are convinced will help us in the long run in many ways of protecting information, ultimately, we can develop a privacy disclosure statement—and if you have seen some of the things I am talking about, they can range from 8 to 10 pages in length—and we can in fact include in that a genetic information release. We can release information for treatment purposes related to genetics.

So there are some areas of disclosure that are still able to happen under the HIPAA privacy regulations. It is not necessarily the perfect magic bullet in reference to genetic information, especially when that is such a unique and, as Mr. Escher said, intimate key to our very persona.

I think that HIPAA is not necessarily sufficient in and of itself.

As to the ADA, you might have noticed in my bio that I wrote a paper in 1991, convinced that the ADA was going to be effective in protecting against genetic discrimination. But I think that the courts have changed that opinion and have weakened the law to the extent that, not only for genetic discrimination, but in many other ways, the ADA is not the protection that many people thought it would be.

The CHAIRMAN. You heard the comments from colleagues here earlier about the ADA as well as HIPAA and how they intersect. I might ask you if you would take the opportunity to give us a written analysis about what you think are the areas that we ought to try to make sure are not duplicative or conflicting in order to achieve the outcome which everyone has commented on and on which there is pretty broad agreement. I think that as a professional, you could be enormously helpful to us.

Ms. ZEITZ. I will do that.

The CHAIRMAN. I appreciate it.

[Written response of Ms. Zeitz follows:]

WRITTEN RESPONSES TO QUESTIONS ASKED BY COMMITTEE

What gaps would the Genetic Nondiscrimination in Health Insurance and Employment Act (S. 318) close that are currently in the Final Health Insurance Portability and Accountability Act Medical Privacy Regulation?

The Health Insurance Portability and Accountability Act (HIPAA) (1996) (Pub. L. 104–191) does not prohibit all genetic discrimination in the health insurance arena. HIPAA was an important first step. While it bans some health insurance entities from using genetic information to discriminate against individuals, it does not address workplace genetic discrimination, nor does it cover all entities or types of discrimination in the health insurance arena. For example, it only applies to group health plans. In addition, it does not prevent group health plans from charging higher premiums based on genetic information of an individual within a group plan. HIPAA did mandate that the Department of Health and Human Services (HHS) create privacy standards to prevent unwarranted disclosures of medical information if Congress failed to enact privacy legislation by August 1999. After this deadline passed, HHS established the standards for privacy of individually identifiable health information ("privacy regulation").

The privacy regulation does not address genetic discrimination, nor does it require all healthcare entities to maintain medical privacy. The essence of genetic discrimination is the hann that occurs when an individual's genetic information is used against them. Nothing in the privacy regulation specifically addresses this problem. The privacy regulation simply regulates the methods of disclosure and access to medical information by health plans (group and individual), clearinghouses and providers. While some argue that limiting disclosures will prevent genetic discrimination from occurring in the first place, various entities can legitimately obtain genetic information that could later be misused. Even within the healthcare arena, the privacy regulation does not extend to all group health plans. For example, it does not pertain to self-administered plans with fewer than fifty participants.

S. 318 addresses the gaps mentioned above in both HIPAA and the privacy regulations by limiting disclosures by all health plans and preventing genetic discrimination by all health insurers.

The privacy regulation allows a broad range of disclosures for purposes of treatment, payment, or health care operations. Disclosures can legitimately occur in a number of ways within the privacy regulation's limits. Health plans or providers can obtain permission to disclose genetic information within a multi-page privacy notice/consent form. Very few people will read and fully understand that they have given permission to release the information to a variety of entities. If a women diagnosed with breast cancer elects to have genetic testing to make a more informed decision about her treatment options, that information will flow into the medical records and billing system of her physician and hospital. External reviewers for the insurer will have access to the information for coverage decisions. Group health plans or health insurance issuers can disclose genetic information to employers or plan sponsors in order to pay for claims or to perform other plan administration functions.

In contrast, under S. 318, plans and insurance issuers cannot disclose genetic information to the individual's employer or plan sponsor.

There is no private right of action against a covered health entity who improperly discloses information or uses the information to discriminate against an individual. The HFIS Office of Civil Rights (OCR) has the responsibility of enforcing the privacy regulation. OCR's enforcement powers include working with covered entities to secure voluntary compliance through the provision of technical assistance and other means; responding to questions regarding the regulation and providing interpretations and guidance; responding to state requests for exception determinations; investigating complaints and conducting compliance reviews; and, where voluntary compliance cannot be achieved, seeking civil monetary penalties and making referrals for criminal prosecution. OCR can also impose civil monetary penalties, and criminal penalties for intentional disclosure of protected health information for commercial use.

Alternatively, S. 318, the Genetic Nondiscrimination in Health Insurance and Employment Act would provide individuals with the ability to enforce their rights in court and receive economic, non-economic and punitive damages. NBCC strongly believes that in order for any protections against genetic discrimination to be meaningful, they must include a private right of action in state court.

The privacy regulation does not extend to discrimination or medical disclosures in the workplace. The privacy regulation only tangentially relates to the workplace by addressing disclosures by employer-sponsored group health plans.

In contrast, the employment title of S. 318 reaches employers directly by prohibiting employers from refusing to hire, firing or otherwise discriminating against an individual on the basis of protected genetic information. It also prevents employers from requesting, collecting, purchasing or requiring genetic information from an individual.[1]

As shown above, the existence of the privacy regulation does not negate the need for specific legislation to address genetic discrimination. If we are ever to reap the rewards that genetic research has to offer in finding better treatment and potential cures for many diseases, Congress must enact meaningful and comprehensive legislation.

Do you believe it is important that legislation include family medical history in a definition of protected genetic information?

It is critical that family medical history be included in the definition of protected genetic information. Genetic information is uniquely private information about inherited characteristics. Inherited characteristics may be found through genetic tests, medical exams, and family histories. These sources provide insight into our genetic makeup, but none of them are 100 percent accurate in predicting what diseases we will develop in our lifetime.

A family medical history can be used as a surrogate for a genetic test. One does not have to take a genetic test to know his or her family medical history. A family medical history provides information about one's health, but also about the health of parents, siblings, and children. A certain amount of information about genes and inherited characteristics can be inferred from this history and can be used as a basis of discrimination.

An individual's family medical history contains third party information that can extend genetic discrimination to family members. For example, a health insurer or an employer could discriminate against a daughter based solely on the fact that her mother had breast cancer, regardless of whether her mother had a genetic marker for the disease. This information in her family history may lead one to believe that she is genetically predisposed to developing breast cancer, even though not all daughters of women with breast cancer will develop the disease, nor will all women with a genetic marker for breast cancer. The possibility of this discrimination has led patients to fear being honest about their medical history, which may impact the care that they receive.

"Genetic information" must refer to information about genes, gene products or inherited characteristics that may derive from the individual or family member. As a member of the National Action Plan on Breast Cancer, NBCC helped shape the definition of genetic information. This definition is a significant part of legislation that NBCC supports because it ensures that there is no loop-

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[1] The only exception is for genetic monitoring of biological effects of toxic substances where the employee would give prior voluntary consent and the employer would only receive the results in aggregate terms that would not disclose the identity ofspecifiic employees.

hole that would allow discrimination against an individual on the basis of a family member's medical history.

Do you think that workplace protections against genetic discrimination in the Americans with Disabilities Act are sufficient?

Clarification is needed on whether the ADA protects individuals against workplace genetic discrimination. This issue has been the subject of active debate for over a year in the Senate and has been examined recently in the House of Representatives. Title I of the ADA does not directly address genetic discrimination, nor do the EEOC interpretations of its scope set out a workable policy to adequately protect individuals with genetic predispositions from workplace discrimination.

While the Equal Employment Opportunity Commission interprets the ADA as protecting individuals with genetic markers from discrimination in employment, the EEOC's position has not been tested in the courts. The EEOC's policy guidance does not have the same force of law as a federal statute or regulation. This is reflected by the Supreme Court's treatment of EEOC interpretations. For example, in two 1999 cases: Sutton v. United Airlines (527 U. S. 471 (1999)) and Murphy v. United Parcel Service, Inc. (527 U. S. 516 (1999)), the Court called into question the validity of EEOC interpretations of the definition of disability and the authority of the agency to make such determinations. The Supreme Court's reasoning in these recent cases makes it likely that an ADA claim based on genetic discrimination would not be successful.

The ADA has not provided its intended protection. When Congress passed the ADA in 1990, it intended that the law would cover an individual who has a genetically-related illness, disease or disability once it becomes manifest and substantially limits a major life activity. For example, as the ADA is written, if a woman received a diagnosis of breast cancer or some other disease, she should not be subject to unwarranted discrimination in the workplace. Since the ADA went into effect in 1992, the ADA's scope of coverage has been significantly restricted. See, e.g., Toyota Motor Manufacturing, Kentucky, Inc. v. Williams (No. 001089, Decided January 8, 2002), where the Supreme Court further narrowed what would be regarded as an impairment that substantially limited an individual in a major life activity. Moreover, in many cases, individuals who have alleged discrimination based on cancer, epilepsy, diabetes, heart and respiratory conditions, mental illness, and a range of other health conditions have been turned away on the grounds that they are not sufficiently "disabled" to receive legal protection under the ADA. The courts have essentially required that to be covered under the ADA, an individual must be so debilitated by his or her impainnent that it is difficult for the person to function at all. The same reasoning that has eliminated legal protection under the ADA for individuals with a range of health conditions may be used to deny coverage under the ADA for individuals with genetic predictive information or family histories regarding such conditions.

Specific federal legislation would provide the needed protection. Even if some courts did determine that the ADA protects individuals from workplace genetic discrimination, the ADA does not prohibit employers from requiring or requesting their employees to provide genetic information to them. This is an invasion into an individual's most uniquely private information.

The CHAIRMAN. Mr. Escher, I want to thank you very much for your comments. No one could listen to you talk about your family and not feel the kind of intrusiveness and violation of your whole being that these tests had.

This committee has for a long time been strongly committed to freeing workers from all forms of discrimination in the workplace. That has been an ongoing and continuing commitment. We have overturned U.S. Supreme Court decisions. We have supported the various protections for workers' rights on the basis of race and gender and sexual orientation in a wide range of areas. So we are strongly committed to protecting American workers and having them considered in terms of what their abilities are in being able to do the job and not being discriminated against. I think your testimony is about as clear an indication of the need for this kind of legislation in terms of employment as we can possibly hear. I know that you have stated it on other occasions, but I will tell you that today it is as powerful as ever, and I want to thank you very much for all of your good work and your help.

Senator Dodd.

Senator DODD. Thank you very much, Mr. Chairman, and I thank you immensely for holding the hearing.

I am sorry I was not here at the outset to listen to Majority Leader Daschle talk about the bill, on which he is our lead sponsor. I have been very pleased over the year to cosponsor this legislation and to be a lead sponsor with you and Senator Daschle and others. I know that our colleague from New York, Senator Clinton, feels strongly about this issue as well.

Listening to your questions this morning and the debate going on on stem cell research issues, I think we are being confronted with some very complex issues, more and more every day. I have had the privilege of being with Dr. Collins on several occasions. As I think you know, Mr. Chairman, Senator Hutchinson of Arkansas and I co-chair a caucus or task force on biotechnology, and the hearings we have had have been very exciting. Dr. Collins was gracious enough to spend time with our task force a number of weeks ago talking about related subject matter. Certainly, those of us in New York, Connecticut, and Massachusetts take some pride as well in what is going on in our respective States in this area. So the things that are occurring are tremendously exciting.

Just your testimony alone this morning, Dr. Collins—we are living science fiction. For those of us who grew up in a generation where science fiction became a genre for television and movies, listening to what we can do with the study of the human genome, it is just phenomenal. Being able to see or scan unique genetic blueprints and predict the likelihood or at least the possibility of contracting certain illnesses is a wonderful thing for a generation of Americans coming along to have the ability to do.

It is so exciting to know what new areas we are going to be able to enter into and provide some wonderful help for people who, weeks and months ago, could not have hoped for much in the way of scientific breakthroughs.

So on that side of the equation is wonderful news, and obviously, with that comes exactly what we are hearing about on the other side of the equation, which we have to balance and deal with all the time, much as we do with the embryonic stem cell research issues, where there is some wonderful news and there are also some very complex ethical and moral questions.

Talking informally with my colleague from New York the other day, she so eloquently talked about the complexity of these issues and how we have to think carefully—in fact, she made a suggestion which I have now quoted her on—the idea of continuing to revisit these issues as we learn more and as our capabilities advance. We still have many questions unanswered about the information we hope to receive from a map of the human genome and as we increase our understanding, we should check and recheck our policies.

But certainly in the area of insurance and employment, it seems to me this is about as common sense as anything I can think of here, and certainly your testimony, Mr. Escher, is—I wish I could tell you that what happened in your case is unique, that this was an aberration, but unfortunately, it is not. As I am sure others may have already pointed out, a new study of 1,500 companies conducted by the American Management Association shows that one-fifth of companies, 20.1 percent, are requiring genetic or medical family history data from employees or job applicants. Twenty percent of 1,500 firms—that is an indication of where this trend is going.

According to the same survey, more than one-quarter, 27.3 percent, of the companies that require genetic or family medical history tests use the results of those tests in hiring or other employment decisions.

If there is any doubt about the need for this legislation, that data alone should speak loudly and clearly. This is not a hypothetical problem; it is one that is already very much in the workplace.

As Senator Kennedy and others have pointed out, I wish I could tell you that we do not need to do anything here because our States are acting on this issue. My State Connecticut has adopted legislation to protect people from job discrimination and insurance discrimination—but 41 percent of the people whom I represent are not covered by it because of ERISA and the preemption. So almost one out of two of my constituents is not affected by Connecticut law despite the intentions of my State legislators and the Governor to act in this area. So it is important that there be Federal legislation, in my view.

I am very grateful to all of you for your presence today and your strong testimony on the value and the need for us to move forward.

If I can, let me raise a couple of questions—I think I have become chairman of this committee; I do not know if Senator Kennedy is coming back, so we might have some fun in here. I guess I do not have a quorum to write legislation, but if I did, believe me, we would pass this law immediately.

And let me tell you something—and I am not engaging in hyperbole here—this will become law. This will become law. We are going to stop the discrimination in employment.

Mr. Escher, your presence here means so much. I want you to go home and tell your daughter not to worry. She should be very, very proud of her father that you came here this morning and were able to talk about this. You go home and tell her that Congress is going to do something about it so that people like you across the country are not going to have to worry about losing their jobs because of this.

This is wonderful news about a wonderful area that we are breaking into and if, with all of that good news, we find that people are going to lose insurance or lose employment, people will question the value of this, and we are going to have a hard time getting people to participate.

This is the question I want to raise with you, Dr. Collins. We are talking about what we think ought to happen here. As you are so deeply involved in the Human Genome Project, how have you addressed these ethical questions? In your own work, you have obviously had to address some questions, or you would not have had people able to participate. What have you done?

Dr. COLLINS. I appreciate the question. Jim Watson, who was the original director of the Human Genome Project, decided at the outset more than 10 years ago that the ethical, legal, and social implications of this accelerated pace of genetic research were going to be so significant that we would put a significant fraction of the budget into studying those issues, and the so-called ELSI Program was born, the Ethical, Legal, and Social Implications Program. It has become since that time the largest research effort in bioethics since the Planet began spinning. It has recruited into this endeavor a cohort of superb scholars and has produced a remarkable record of published scholarship and recommendations about the major issues that are raised by this accelerated pace of our own genetic self-discovery.

Early on out of that process, discrimination and health insurance in the workplace were identified as among the highest priorities. A task force chaired by Tom Murray who is now head of the Hastings Center produced a report about the need to take action in the health insurance arena way back in 1993.

Subsequent to that, in a variety of partnerships, particularly with the National Breast Cancer Coalition, which has been a wonderful partner in debating these issues, but also with a wide variety of other consumer organizations and policy experts, various authoritative documents have been published in the peer-reviewed literature, especially in Science Magazine, making recommendations about the need for action in genetic discrimination and specifically in health insurance and in the workplace. And in fact, those publications back in 1995 and 1996 served as the blueprint for many of the State laws that were subsequently passed.

So we have been very involved in this issue. When I came to the NIH in 1993, I expected, because of my personal interest in this, to spend a considerable amount of time on those issues, but I was unprepared for how consuming it would be. And to be honest, it is very difficult. We can do research. We can identify the issues. We can carry out samplings of the public to find out what is on people's minds. We can convene workshops of folks who really know what is going on and produce recommendations. But ultimately, there is a hand-off to the policymaking process, which is why we are here today, to talk about that hand-off. And then it really does get into the arena of the public debate as exemplified by Congress and the administration.

I must say that I am very encouraged this year by the attention now coming to this issue, the leadership that has been shown by yourself and other members of this committee and other Members of the Congress, and very encouraged by the President's statement just a month ago which comes out very strongly stating the need for legislation to deal with this issue.

So this is not a partisan event; this seems to be a circumstance that everybody who has studied it is coming to the same conclusion, and now, the hope would be to get it across the finish line, and I appreciate your very strong statements that you believe that that is achievable.

Senator DODD. And I apologize—I should have mentioned President Bush as well, because you are absolutely correct, he did make a very good, strong statement on this. I think sometimes the public sees us up here as Democrats and Republicans, always arguing with each other, but in the vast majority of cases, we find common ground, and this is one area where clearly, at least rhetorically, we have, and that is a major step forward.

At this point, we think he could do a tremendous amount if he would endorse the specific legislation here. That would really be an impetus for some people who raise legitimate questions. None of us is questioning the honesty or the integrity of the questions being raised. But as you point out and others have as well, there is obviously a greater need here that is ongoing. When you look at the numbers in these surveys, if I thought this problem were just beginning to be one, we could say maybe we could wait 6 months or a year. But when you see the numbers where almost 30 percent of these firms are using this information in hiring decisions, that is no longer a hypothetical issue—and that is just based on one survey. We are not going to every firm or business in the country.

So I think the need to act is long overdue. There is a real need here for immediate action.

Mr. Escher, I am always intrigued, because I suspect that as a result of your own personal experience, you become familiar with others who have gone through similar things. Do you have indications from people you have talked with who have been through situations similar to yours?

Mr. ESCHER. I have been encouraged by a lot of people who have come up since this all started and really encourage us to keep going forward with this. They tell us about similar experiences that they have had. But a lot of people, because they are so intimidated by their employers, will not say anything publicly or in any way be held accountable for what they might say. So they are really giving us kind of a pat on the back for continuing to step forward and bringing this issue forward to as many people as we can. Any chance we have to get this out in a newspaper or a magazine, radio or television—we feel, especially since we have experienced this ourselves, how important an issue this is.

I really do commend you people for the work that you are doing, and I am going to hold you to that, that I can go home and tell Kristen that she does not have to worry about this anymore.

Senator DODD. That is a nice name, "Kristen." Please tell her that.

Let me also point out, Ms. Zeitz, that I spend a lot of time at the medical school at Yale and others on a variety of issues. I was deeply impressed on a tour I went on a year or two ago on the work being done there and the high degree of probability on the result of work on the predisposition for breast cancer. They were working on—and I am sure Yale will call me and correct me if I get this wrong—but I think it was a study on twin girls at birth and watching them over a number of years; it is incredibly high, the degree of probability—or possibility, predisposition—which is obviously great news. Imagine being able to know early on lifestyle decisions you should be making about diet and so forth in order to minimize the possibility of this occurring. But imagine also that information in the hands of people who want to make employment or insurance decisions and want to discriminate against someone who has been afforded the benefits of having that kind of information available.

I wonder if you might briefly—and this is my last question—as an attorney who has studied existing discrimination protections describe why there is such a need for Federal legislation. I mentioned the problem with 41 percent of my constituents, but beyond that, why do you think there is a need for Federal legislation?

Ms. ZEITZ. Right now, I can tell you that Nebraska is a perfect example as far as State laws and how they work. Up until this year, I have sought to find sponsors for genetic discrimination bills, and except for Mr. Escher, we would not have one today. It was passed this year with unanimous support, but it has no enforcement. So when I look at it, I am happy that it is there, but I cannot hang my hat on it, and it will not protect the women whom I work with in Nebraska. And that is at least a law; there are many States that do not have laws.

If we do not have Federal legislation, we are not going to have protection. Maybe 10 years from now, we will have it in all States, but it will still be a patchwork quilt. We need strong floors. I do not object to keeping the stronger bills that might be out there that might have even more teeth than you are talking about, but it is absolutely essential that we have a national bill.

Senator DODD [presiding]. Thank you very much.

Let me turn to my colleague from New York and thank her for being here today.

Senator CLINTON. Thank you so much, Senator Dodd.

Let me start by thanking the witnesses. Nebraska is very well-represented here today. I love the fact that Nebraska is leading the way, Mr. Escher and Ms. Zeitz, and I hope you will tell your friends and colleagues that you were here on a very important mission to bring this message to the entire country.

Dr. Collins, it is always a great pleasure to be with you. You know that I am one of your great admirers and am very grateful for the work that you have done on behalf of all of us.

I have long been worried about this issue. As some of you might recall, I have been worried about health insurance for a long time. I am looking for a policy that covers worry because that seems to be my genetic predisposition.

But as we have been marveling at the advances in our knowledge of the human genome, my worry has only increased, because with this information comes, I believe, the inevitability that every one of us will be determined to have some genetic vulnerability or susceptibility to something, which will render all of us under current insurance practices uninsurable. And that time is not very far off.

So the bill that we are discussing today, which I am proud to have been an original cosponsor of along with Senator Daschle and the chairman and Senator Dodd is a very important step which must be taken as soon as possible. But it is part of a much larger problem which Dr. Collins referred to in speaking about the ethical and legal and social implications of this scientific revolution that we are in the midst of.

If we are to harvest the benefits in terms of the extension of life and the awareness of conditions that can be ameliorated or prevented, we have to take a strong stand against any and all discrimination in the use of this information.

I am particularly grateful for the work of the National Breast Cancer Coalition. I believe that breast cancer advocates around our country, and I must say particularly from the State of New York, who have been on the front lines of this issue have pushed forward these questions to the benefit not only of breast cancer survivors or potential victims of this disease, but really every one of us.

With Ms. Zeitz here representing the breast cancer survivor community and the Coalition, I want to thank you and all of your colleagues for doing such a great public service. You have pushed the frontiers of science, and you have forced policymakers to ask hard questions and to put people like yourself at the table to make the decisions that we are all grappling with.

I want to ask a series of questions, and Mr. Escher's experience really highlights this. Senator Dodd referred to the research that we are now compiling about how employers, perhaps understandably—not fairly and not appropriately, but understandably—would want to protect themselves against inevitable or at least foreseeable risks, so they want this information so that they can negotiate new insurance policies that write people out if there is any kind of genetic predisposition. That is the way our system currently operates. I think it is a very shortsighted system; it creates more costs than we should have to pay, and it puts people like Mr. Escher not only at risk of being uninsurable but of the kind of emotional trauma that he so eloquently testified to.

In the last several months, I have been doing a lot of work on environmental health and recently gave a speech at the National Press Club based on not only the work that I have done but two field hearings—one that I attended in Fallon, NV, where there is a cancer cluster of children with leukemia, and one that I held on Long Island, where the rate of breast cancer is higher than the national average. In both of those hearings, we did not come to any answers, but we made very clear that there is an interaction between our genetics, our behavior, and our environment that determines our health status.

If we do not take advantage of learning everything we possibly can without fear that we are going to be discriminated against, we will never come to the point where each of us will be able to make the best possible choices. As I said, I think each one of us has some susceptibility to something; we need to know that. We should not have to assume an alias to have a test to determine whether we carry the BRCA-1 or 2 gene. We should know everything about our behavior that can possibly trigger our genetic susceptibility so that, once and for all, we stop smoking because we are no longer going to be able to kid ourselves about the implications of that—or we take other actions to do everything within our power to control our health risks.

But then, there are many hidden risks in our environment. Mr. Escher testified to what we are learning about carpal tunnel syndrome. This is basically a modern disease because it uses muscles in a repetitive way and affects our nervous system in such a manner that it is a disease of the modern workplace. One hundred years ago, that was not something we had to cope with; today, it is, because we have changed the work environment. We have invented more than 80,000 new chemicals since World War II, and we are only now understanding the implications of those to environmental change and our health.

So this bill that we are talking about today has such far-reaching implications. Yes, we have to end discrimination in the workplace and in the insurance industry. By doing that, we not only give much-needed security to every American, which is why it has to be a Federal bill—it cannot depend on State-by-State enactment in different standards. That is not the way our country works. Mr. Escher could live in Nebraska today and then get an opportunity in Illinois, or hopefully New York or someplace like that, and he needs to know that he has the same protection as an American citizen to be free from discrimination.

So my hope is that this hearing will lead to fast action on this bill. But I want to reiterate that it is only a first step. It is not the end of the ethical, legal, and social implications that we here in the Congress have to wrestle with in order to take advantage of the extraordinary progress that Dr. Collins and his colleagues have unlocked for us.

So I guess I would ask each of the witnesses if you would to sum up from your own specific perspective and experience the best arguments for this bill and the reasons why this bill is an important first step for this Congress to take, because when we go to markup in this committee and when we go to the floor, I want to be sure that I am making your arguments, because you are the people who are really helping us deal with a very important and exciting opportunity to unlock better health for every American.

Dr. Collins, would you respond?

Dr. COLLINS. Thank you, Senator, for your very articulate remarks. I think you have hit the nail on the head in many instances here in terms of the interactions between genetics and the environment—and I am glad you added "behavior," because our own free-will decisions are often pretty important as well in terms of our health.

But we can benefit that greatly if we have information; yet if information about our genes is something that strikes terror in our hearts because of how it might be misused, then that wonderful opportunity will go away. And we do not have a lot of time, I think, to deal with this issue. The public in many surveys is indicating their high level of concern, and in research studies right and left, it is clear that many people are opting out of participation if it involves a genetic test because of this fear. And we could potentially see this wonderful genetic revolution that we are on the brink of slowed down or even stopped in its tracks if we are not able to give assurances to the public that these things have been taken care of.

With specific regard to your question, I think it is clear from all the analyses that have gone on over the last decade that there is a need for this kind of protection, that it needs to apply to both health insurance and employment settings, that it ought to be available to all Americans and not in an uneven fashion. And the way in which that has now been endorsed by the Congress in the introduction of the various bills under discussion, and by the President in his recent remarks a month ago, tells me that we are on the right track to get this taken care of.

And I must say that every month that goes by where action is not taken, it is going to get harder to take that action because it will be more and more becoming the standard by which health insurers and employers begin to operate. If there is no prevention of that outcome, it will be more difficult to change those things in the future than it is right now.

I think you are absolutely right, though, that this is part of a much larger equation, and the ELSI Program has in fact identified quite a long list of high-priority issues that need attention. This one is, I think, at the top of the list in the public's mind and in the minds of most of our policy experts.

But certainly related to that are questions about the environment. I hope that people who draw the conclusion that either you are in favor of studying genetics or you are in favor of studying the environment are beginning to figure out that that is not the right conclusion; that the way we really understand genetics is to include as much information as we can about the environment and vice versa. It may be that some environmental influence that is perfectly safe for you is toxic for me, or vice versa, and we will only begin to understand that if we have the ability to collect large amounts of information, large studies, good epidemiology, good genetics, and making that kind of research study of the sort that the public feels safe participating in is a very high priority, and that is another reason why we need these protections.

Senator CLINTON. Thank you, Dr. Collins.

Ms. Zeitz.

Ms. ZEITZ. Certainly in my case, because of the breast cancer involvement, I am most concerned about finding a cure for breast cancer, which I am convinced is tied to genetics and the research that can come from it; and yet my daughter is living testimony to the fact that she will not be tested and will not participate in that research. And there are so many women like her. Well, what does my grand-daughter have to look forward to?

If we do not make this change, that scenario is not going to change. This is so critically important in terms of accruing participants to research that I do not think there is anything more important in my life right now than this particular bill.

I think that insurance discrimination, as you mentioned, we are all going to have—one of Dr. Collins' colleagues told me that eventually, they expect every one of us to have seven predispositions to disease. So for the short term, they will exclude people based upon the few that we have identified, but eventually they will just surcharge us higher premiums based upon all of that, so that we will basically all be surcharged.

Each one of us is covered by insurance right now. We are all genetically predisposed to disease. They have been able to make good profits without any problem whatsoever without the need for that knowledge. I think that both in terms of the insurance and the employment aspects, we have to provide those protections. Everyone across this country is focused on this and looking for that protection when it comes to breast cancer or colon cancer or any of the other identifiable genes and any other diseases besides cancer. It is the key to our future research to open that great door in terms of genetic knowledge.

Senator CLINTON. Thank you.

Mr. Escher.

Mr. ESCHER. Senator Clinton, this is probably the single best reason I have, right here—this is a picture of my three daughters.

But the other thing that really bothers me is the fact that I am 47 years old and 13 years away from retirement. If I were to lose my job because of predispositions found through genetic testing, where would I go to find another job at this point in my life and be able to have the money available at the end of that time to retire, as we hope to someday?

The other thing is the way that information is bought, sold and traded today among corporations, big businesses, and so on, where would I go to find another job?

The other aspect of it is where would you go to find insurance. You would not only be unemployable, you would be uninsurable. What kind of life would that be for our children?

So this is a very serious matter, and I really do hope that we can get a law passed this year, as you people so enthusiastically hope that we can. To be able to use the science of genetics for the purpose of evaluating and then discriminating against employees is absurd.

Senator CLINTON. Thank you all very much.

Senator DODD. Thank you, Senator. I was thinking about one other question as you were going through this. One aspect of the bill that we have talked about is obviously genetic testing, but we also include the language of family medical history.

Something that Senator Clinton said I think is very important. To one extent, you have to understand why businesses and insurance companies are anxious to have this information. Again, once information is produced which can help calculate risk, there is going to be an appetite to have it.

The predisposition because of genetic testing seems to be rather clear-cut in my view, because we are not talking about actually acquiring some disease but rather a predisposition to it; whereas opposed to if you have had an illness of some kind and you have applied for a job, in my view, an employer has a right to know on the hiring practice whether you have an illness of some kind. That is a different matter.

So you get into the family history, and this gets into a bit of a grayer area. I wonder if any of you, particularly Ms. Zeitz and Dr. Collins, have thought about this, where you go back and ask about the parents and whether there were any particular illnesses in the family. I wonder if you might comment on this family medical history issue? I am interested in knowing if you make a distinction between genetic predisposition and family medical history in terms of a business' right to have that information.

Ms. ZEITZ. When you are talking about the medical history, if you are asking about whether a family member has taken a genetic test and had genetic test results——

Senator DODD. No, I did not mean that. Questions about your parents—I have filled out those kinds of questions any number of times; I am thinking back about whether it was insurance applications or not—whether you have had a family history. Obviously, when you go to see a doctor, you fill out this stuff about who has had heart problems or coronary issues and other questions.

Ms. ZEITZ. I have no problem with that. The medical history that we were referring to was anything related to the genetics.

Senator DODD. OK.

Ms. ZEITZ. Everyone has a right to know, if they are going to be insuring me, whether I have a history of cancer—but they do not have a right to ask my daughter if I have a genetic predisposition.

Senator DODD. OK.

Dr. Collins.

Dr. COLLINS. Senator, I think it is important that we not contemplate a circumstance where a health care professional—your personal physician, for example—is in some way uneasy about asking about information that is going to be part of your medical care. And I know that is not where you are going with this—the question is should family history information be usable by insurers in setting premiums or deciding whom to exclude.

This is an issue that has been much discussed, and you will look at some of the State bills and see that some include family history and some do not.

I guess I would put forward a possible scenario and let you draw your own conclusion. If, for instance, I find out that people in my family have developed colon cancer, and a number of them have gotten it at an early age, and I decide that I need to go and find out my own situation, so I get some genetic counseling, it is indicated that there is a fairly high risk that in my family there is a gene that is responsible for this, and a test is available. I think about this and decide that, yes, this is information that I want to have. Colon cancer is a preventable disease. If I am at high risk, there are things that I should be doing, like colonoscopy every year. So in this hypothetical, I go through the test, and it turns out to be positive.

That information, the majority would agree and I think you just stated, ought not be used to exclude me from insurance, especially at this point where I may be at most benefit from it, practicing good preventive medicine that will save money down the road.

But if the protections are only for the genetic test and not for the family history, well, the reason I got the test in the first place was because of my strong family history of cancer. If that could still be used to exclude me—even though the test result is off the table, if the family history is still on the table—many would question whether that is really the kind of protection that is going to help out somebody like that in the circumstance where one would like not to see this kind of discriminatory practice carried out.

And because in fact at the present time, and probably in many instances in the future, the genetic test is really only carried out in the context of a positive family history, the separating of the test from the family history makes it sort of difficult for many people to see how this would be as robust a protection as is desired.

Ms. ZEITZ. And that really is a vague piece of information to have. It is not something that is very helpful to an underwriter in reference to the individual whom they may be asking the question of. Their family history is out there, there is some disease, but that does not tell you what that individual's potential for disease will be in the future, so that when you use it, you use it inaccurately.

Senator DODD. Mr. Escher, do you want to comment on this?

Mr. ESCHER. No.

Senator DODD. Thank you. I appreciate that very much.

We are going to leave the record open for 14 days; other members may have questions they would like to address to you in writing, and we would ask you to respond to those as quickly as you can.

I am very, very grateful to all of you. You will not be surprised when I express a particular sense of gratitude to you, Mr. Escher. You are not a professional, in a sense, and obviously, you put a human face on this. We talk about numbers and data and so forth, but I think it is very helpful for us to hear from people who have been through these situations in a very direct way. So we are especially grateful to you for telling a public story, which takes a lot of courage, and that does not go without notice here, so I express deep appreciation on behalf of every member of this committee. Regardless of how we might end up voting on a bill here, we admire people who come up here and are willing to tell family stories that can help us develop some clarity on the issues.

I thank you again, Ms. Zeitz.

Dr. Collins, once again, you are always welcome—we may make you an honorary Member of the Senate if you keep appearing here—provided, of course, you would be a good Democrat. [Laughter.]

We will include for the record statements of Senators, organizations, and additional material submitted for the record.

[The prepared statements of Senators, organizations, and additional material submitted for the record follow:]

PREPARED STATEMENT OF SENATOR MIKULSKI

Mr. Chairman, I want to thank you for calling this hearing on genetic discrimination. As a Senator from Maryland, the home of the National Institutes of Health and such cutting edge companies as Celera Genomics, genetic testing and its implications for Marylanders and all Americans is especially important to me.

I'm a proud cosponsor of the Genetic Nondiscrimination in Health Insurance and Employment Act (S. 318) introduced by Senator Daschle. This bill would prohibit genetic discrimination in health insurance and employment. It would provide important protections so that people will take advantage of the potential that genetic testing can offer, without losing their job or their health insurance. I commend Senator Daschle and Senator Snowe, as well as my other colleagues on this committee, who have been real leaders on this issue.

Twenty-five years ago, the idea of mapping the entire human genome seemed like science fiction. But we have a rough draft of it. Ten years ago, the thought of testing individuals for a genetic predisposition to an illness seemed decades away, but here we are in 2001 with the technology and knowledge to do that. Someone with a genetic predisposition for a disease could begin preventive measures in diet and lifestyle, years before symptoms even appear.

But with this new technology comes responsibility—the responsibility to protect the people that these new technologies seek to help. What good is knowing that you have a genetic predisposition for diabetes, if you lose your health insurance because of it? How does knowing that you may be more likely to develop breast cancer help, if you can't get a job because of this information? Individuals should also have the information they need to make an informed decision about whether or not to get a genetic test.

In February of last year, President Clinton signed an Executive Order that gave Federal employees protection against genetic discrimination in the Federal workplace. Now Congress should act to help ensure that individuals can choose to get genetic tests that could help save or prolong their lives, without fear of discrimination in the workplace or by health insurance providers. Until a woman can be screened for a genetic predisposition to ovarian cancer without fear of her health insurance premiums rising or losing her job, the plethora of information made available by genetic testing has not reached its true potential.

PREPARED STATEMENT OF SENATOR HARKIN

1 thank the Chairman for holding today's hearing. I also want to welcome our Majority Leader, Senator Daschle, to the HELP Committee. Both Senator Kennedy and Senator Daschle have provided critical leadership on this issue and brought it to the top of this session's legislative agenda.

I want to talk first about genetic research because that's how I first came to understand the issue of genetic discrimination. I have been involved in the effort to fund the Human Genome Project since the late 1980s. Just two weeks ago I chaired a hearing on human genome research in the Labor-HHS Appropriations subcommittee. Scientists—and even a movie star—testified to the critical importance of NIH research in this area.

Francis Collins made it quite clear that the mapping of the human genome marks the beginning of the genomics era, not the end. Genomics will revolutionize the way we prevent and treat disease and illness. All of the witnesses pointed to a time in the not too distant future when genetic testing and therapies will be the non-n in American health care. We'll be able to find out in advance which conditions we're susceptible to, so we can take steps to reduce the risks. Phannaceutical researchers are already making progress in treatments for Alzheimer's, schizophrenia, and cancer based on the NIH's map of the human genome.

Unfortunately, as I've come to understand, genetic research also could also result in a darker future, where people could get fired or lose their health insurance because of a genetic predisposition to disease.

One witness at the hearing, a doctor from my home state of Iowa, talked about the impact of genetic research on real people. Right now, as part of his practice in Iowa City, he treats children and adults with genetic diseases. In the future, his patients would be the biggest beneficiaries of genetic testing and therapies. However, the doctor made it very clear that the benefits of genetic research won't mean a thing to the average American without nondiscrimination protections. People are afraid that by taking a genetic test they will be at risk of discrimination in their job or health insurance.

All of us should be concerned about this issue, because all of us have genetic information that could be used against us. Without genetic nondiscrimination protections in place, our doctors, our nurses, our genetic counselors, cannot in good conscience counsel us—their patients—that genetic testing is a safe bet.

In Congress, we invest Federal tax dollars in scientific research to produce results that will make Americans' lives healthier and more productive. We can't let discrimination and the fear of discrimination threaten our ability to conduct the very research we need to understand, treat, and prevent genetic disease. Nor can we let such discrimination prevent our constituents from enjoying the health benefits of our scientific research and progress.

That is why I am an original co-sponsor of the Genetic Nondiscrimination in Health Insurance and Employment Act with Senators Daschle, Kennedy, and Dodd. This legislation includes meaningful protections against genetic discrimination in both employment and insurance and prohibits inappropriate disclosure of the information.

But, you don't need to listen to me on this topic. Today we will hear from several witnesses who will bring it all home and talk about their own real life experience with genetic discrimination and explain how nondiscrimination protections would make a difference in their lives.

PREPARED STATEMENT OF SENATOR FRIST, M.D.

Mr. Chairman, thank you for calling today's hearing to further examine the issue of genetic discrimination. This continues a series of bipartisan hearings on this important topic that began under former Committee Chairman Jeffords.

I believe that the threat of genetic discrimination—both in the workplace and with respect to health insurance coverage—is one of the most troublesome issues before us. Genetic discrimination clearly is a growing concern to the American people. As a physician, as a medical researcher, as former Chairman of the Subcommittee on Disability Policy, and as former chairman and now ranking member of the Subcommittee on Public Health, I have a long and deep interest in this issue.

I have spent my life working to improve and save the lives of patients through direct treatment and medical research. My father was a physician as well; and I have been privileged, through my experiences, to directly compare the advances in medicine between the time my father practiced medicine and the cutting edge treatments of today. He always carried his black physician's bag with him and often visited patient's homes. The miracles of modern medicine have enabled me to literally save lives by transplanting individual organs, for instance, into babies only a few days old. Indeed, the transformation of medicine has been dramatic.

However tremendous the medical advances of the past several decades, they will likely pale in comparison to the changes we will witness through advances made possible by research involving the human genome. Having access to the secrets of human genes may open doors to critical new methods of medical diagnoses and treatment—potentially evolving into an entirely new practice of medicine over the coming decades. We may witness drugs designed for specific genes or genetically engineered organs for use in organ transplants, as well as the ability to improve preventive care based in large part on genetic testing.

Genetic testing may help physicians to recognize patients who may have an increased likelihood of developing cancer or another genetic disease and to work with patients to change certain behaviors that are known to contribute to disease and help lower the probability of disease.

However, there is also the threat that the powerful tool's made possible through human genome research may be used against patients in ways that will not improve quality health care. Therefore, I strongly believe that if we are to achieve the true scientific promise and medical potential that this research holds, we must pass Federal legislation that protects people from the threat that their genetic information can be used to deny them access to health insurance coverage or to the full benefits of employment.

For example, I am deeply troubled by reports of patients declining genetic testing out of fear that they may lose their health insurance even though a genetic test may aid in the early detection of a disease or illness that can be treated. When I first joined Senators Snowe, Jeffords, Collins, and others to introduce legislation banning genetic discrimination in health insurance, almost one-third of women offered a test for breast cancer risk at the National Institutes of Health declined, citing concerns about health insurance discrimination. If unchecked and unregulated, this fear of discrimination clearly has the potential to prevent individuals from participating in research studies or taking advantage of new genetic technologies to improve their medical care.

Scientific advances hold the promise of higher quality medical care, yet there is a pressing need for Federal legislation to reassure the public that learning this information is safe. I am committed to a bipartisan legislative solution, and I am pleased to have worked with Senators Snowe, Jeffords, Collins, and a number of the members of this committee over the past several years to investigate this issue as it relates to health insurance. I believe that, together, we have made an important step in addressing this through the Genetic Information Nondiscrimination in Health Insurance Act, which has been passed by the Senate on three separate occasions.

The task before us now is to act in a fair and thoughtful manner to build upon our progress in the health insurance area and expand the Snowe legislation to address the threat of employment discrimination based on predictive genetic information.

In the past, Congress has acted to protect individuals from the threat of discrimination, most notably through the landmark Civil Rights Act and Americans with Disabilities Act. As former chairman of the Subcommittee on Disability Policy, I am well aware of the positive impact that this law has had on the lives of individuals with disabilities.

I believe we face the same need here—to protect individuals with genetic predisposition toward certain diseases from the threat of employment discrimination. To accomplish this task, we must build upon existing anti-discrimination laws to make sure that people are fully protected from the threat of genetic discrimination.

I am troubled by some legislative approaches before this committee that would place these new rights outside of the established framework of our time-tested civil rights laws. And I hope my colleagues will join me in building on the good work of Senator Snowe and others in the health insurance area, as well as our strong bipartisan history of protecting against discrimination through civil rights laws and other antidiscrimination statutes—such as the Americans with Disabilities Act—to protect individuals from the threat of genetic discrimination.

I look forward to working with the committee to examine this issue in further detail and to pass strong bipartisan legislation that protects individuals from both employment discrimination and health insurance discrimination based upon their genetic makeup. Today's hearing represents the start of this important process.

PREPARED STATEMENT OF SENATOR HUTCHINSON

Thank you, Mr. Chairman, for holding this hearing today on the very important topic of genetic discrimination. Advances in genetics research and the recent decoding of the human genome have brought incredible promise and hope to disease detection, treatment, and prevention efforts.

The ability to find out whether an individual is genetically predisposed to a given disease and to take steps to possibly avert the actual onset of the disease is unprecedented, and there are legitimate worries about how this predictive genetic information may be used against an individual, in some discriminatory action.

Two genetic non-discrimination bills have been introduced in the Senate in the 107th Congress, and I am pleased that one of the bill sponsors, Senator Daschle, has been invited to testify today. I am also pleased that Dr. Frances Collins, a pioneer of genetics research, is before the committee to testify once again about the science of genetics research.

Twice during the 106th Congress, the Senate passed genetic non-discrimination legislation with regard to health insurers. Unfortunately, this well-crafted legislation did not become law. I understand that the Chairman would like to markup legislation which also addresses the possibility of genetic discrimination by employers.

I am hopeful that this will be the first of several hearings, so that the committee can hear from expert witnesses on such issues as how the bills pending before the committee interact with the medical records privacy regulations promulgated by the Clinton administration, which are intended to prevent individually identifiable medical information from being disseminated without an individual's consent.

I also believe that the committee must examine to what extent the pending bills duplicate current discrimination protections under the Americans with Disabilities Act, and specifically with regard to the Daschle bill, how the private right of action allowed under the bill interacts with the current right to sue via the Americans with Disabilities Act.

Finally, I hope that the committee will take time during a subsequent hearing to explore how the Daschle employer provisions affect the mandatory dispute resolution procedures under the Equal Employment Opportunity Commission.

PREPARED STATEMENT OF SENATOR COLLINS

Mr. Chairman, just a few months ago, scientists—under the leadership of Dr. Francis Collins, who will be testifying this morning—completed the mapping of the human genome which many consider to be among the greatest scientific achievements of all time. Through a better understanding of our genetic codes, we may one day have the tools to prevent and cure countless diseases.

Scientists are now finding genetic links to a host of diseases and disorders ranging from cystic fibrosis to Alzheimer's disease. Today, there are widely a vailable blood tests that can reveal whether or not a person carries genes that increase the risk of getting over 400 diseases and disorders, including breast and colon cancer, glaucoma, Parkinson's and Huntington's disease.

Knowledge is power, and, in the best of all worlds, this information would be widely used by individuals to encourage them to get more frequent check-ups or to take preventive precautions. This power, however, has tremendous potential for abuse, and there is understandable concern that this information could be inappropriately released or used by health insurers or employers to unfairly discriminate against these individuals and their families. This is particularly unfair since a genetic predisposition toward a particular disease or condition does not mean that it will actually develop. To deny health insurance or employment to a healthy person on the basis of a genetic test is nothing more than medical speculation, and I believe that this kind of discrimination should be, prohibited.

That is why I am an original cosponsor of legislation, the Genetic Information Nondiscrimination in Health Insurance Act, introduced by my colleague from Maine, Senator Snowe, which provides strong protection to all Americans against the unfair and improper use of genetic information for health insurance purposes. This bill ensures that individuals cannot be denied insurance coverage on the basis of genetic information. They also cannot be dropped from coverage or charged exorbitant premiums on the basis of genetic information, nor can they be discriminated against for requesting or receiving genetic services.

In addition, I believe that we should work toward similar legislation that is fair, reasonable, and consistent with existing discrimination statutes to protect against genetic discrimination in employment, and I look forward to participating in more substantive hearings and meaningful discussions on this issue in the future.

PREPARED STATEMENT OF SENATOR SNOWE

Mr. Chairman, Mr. Ranking Member and Members of the Committee, I thank you for the opportunity to offer my comments on the issue of genetic nondiscrimination. As the author of legislation to address this complex issue, I welcome having the opportunity to address the Committee today.

The issues surrounding the use of genetic information are numerous and complex. It is vital that we have this opportunity to learn from the experts—both those who are here to testify on how we should construct policy and those who are unwilling experts here to share stories of their experiences with this type of discrimination.

Mr. Chairman, the threat of discrimination based on a person's genetic information has been a concern of mine for many years. That's why in April of 1996, I introduced the Genetic Information Nondiscrimination in Health Insurance Act. This legislation was designed to protect people's genetic infonnation and results of genetic testing, or requests for genetic testing, from being used against them by their health insurers.

Almost 4 years later, in June of 2000, the announcement was made that the first working draft of the Human Genome was completed—that the Project had been a success. This is a fantastic accomplishment and one that holds great promise. Like Orville and Wilbur Wright, the scientists who worked on the Genome project have opened the door to a whole new world. In 1996, when I introduced my legislation, time was on our side as the completion of the genome was many years off. That is no longer the case.

Science has continued to hurtle forward, further opening the door to early detection and medical intervention through the discovery and identification of specific genes linked to diseases like breast cancer, Huntington's Disease, glaucoma, colon cancer and cystic fibrosis. However, not only has the completion of the Genome opened the door to possibilities for detection and intervention, but, like all progress, it has brought with it the potential for harm.

The need for protections against genetic discrimination by both health insurers and employers is becoming more urgent every day. If, because of concerns about the way the information could be used, people are unwilling to use the potential unlocked by the Genome project to take proactive steps to protect their health, and that of their loved ones, then we will never reap the true benefits of this discovery.

While we cannot yet prevent diseases such as breast cancer, genetic testing makes it possible for carriers of these diseases to take extra precautions. In fact, early detection is the best weapon we have to combat many of these diseases we can now identify, and for breast cancer it is a critical component when one considers that almost 180,000 women will be struck by the disease this year. Technological advances in screenings coupled with the ability to identify who carries the gene linked to breast cancer can help us in our efforts to reduce this number. The possibilities for this discovery are limited only by the willingness or unwillingness—of people to use this knowledge.

In 1997, a woman from Maine brought the reality of this dilemma home for me when she wrote of her very real fear of the repercussions associated with genetic testing. Bonnie Lee Tucker has nine women in her immediate family who were diagnosed with breast cancer, and she herself is a survivor. She wrote to me about her fear of having the BRCA test for breast cancer, because she worries it will ruin her daughter's ability to obtain insurance in the future.

Bonnie Lee isn't the only one who has this fear. When the National Institutes of Health offered women genetic testing, nearly 32 percent of those who were offered a test for breast cancer risk declined to take it citing concerns about health insurance discrimination. What good is scientific progress if it cannot be applied to those who would most benefit?

Dr. Francis Collins, the Director of the National Human Genome Research Institute, who is here today, testified before this Committee last summer about the next step for those involved in the Genome project. He explained that the project's scientists were engaged in a major endeavor to "uncover the connections between particular genes and particular diseases,"—to apply the knowledge they just unlocked. In order to do this, Dr. Collins said, "we need a vigorous research enterprise with the involvement of large numbers of individuals, so that we can draw more precise connections between a particular spelling of a gene and a particular outcome." However, this effort cannot be successful if people are afraid of possible repercussions of their participation in genetic testing.

There are two separate issues before the Committee, the first is to restrict discrimination by health insurers and the second to prevent employment discrimination, based upon genetic information. First we must focus on crafting legislation to protect from discrimination based on genetic information by health insurance. This is a subject on which many of us have spent considerable time. In fact several members of this Committee were instrumental in working with me on the legislation I have authored, and I thank Dr. Frist and Senator Jeffords for their continuing efforts in this area and Senators Enzi and Collins for cosponsoring this legislation. In addition to our efforts, I know the Chairman shares my interest as does the Majority Leader, Senator Daschle.

With regard to health insurance, the issues are fairly clear. We must ensure that we protect genetic information, genetic tests, as well as information regarding a request for genetic testing, from being used by the insurer against the patient. Genetic information only detects the potential for a genetically linked disease or disorder, and potential does not equal a diagnosis of disease. However, it is critical that this information be available to doctors and other health care professionals when necessary to diagnose, or treat, an illness. It is this difference that we must recognize when we draft legislation to protect patients from potential discriminatory practices by insurers.

When it comes to the issue of protecting people from employment discrimination, I believe that the issues aren't quite as clear. When Congress first addressed the issue of discrimination by health insurers, it was in the context of the consideration of larger privacy issues. As Congress debated what is now the Health Insurance Portability and Accountability Act of 1996, we also addressed the issues of privacy of medical information. While I agree with the Majority Leader that the potential for misuse of genetic information by employers is great, I believe that we have not yet delved into the issue as fully as we have on the health side. Although last July's hearing on "Genetic Information in the Workplace" was a sound beginning for our attention to this matter, I believe we have only begun to touch on the issues related to employment discrimination. That is why this hearing is so important as we continue to lay the foundation for our efforts.

As we work to address the threat of employment discrimination, we face a number of challenges. Before we move forward, I believe that there are several questions which need to be addressed. For instance; how do we address the efforts of the 28 States that have already enacted varying degrees of protection against genetic discrimination? How would a new law regarding genetic information interact with the new HHS privacy regulation mandated by passage of HIPAA? What sort of remedies would people have to ensure against employer discrimination? Would these remedies be different than those available to people under current law, for instance under the ADA or the EEOC?

These questions are not new, however they do, I believe, hold the key as to how we move forward. The protections in the 28 States that have enacted their own laws against employer discrimination vary widely. We would need to address these differences. Remedies in the states also vary, and the remedy offered by the Majority Leader would allow for court remedies. Under current statutes, those who feel they are victims of discrimination by their employer can only file a claim with the Equal Employment Opportunities Commission - the Leader's bill would allow those who were discriminated against because of a potential disease to take stronger immediate action than those with a diagnosis of a disease.

I believe that after thoughtful review of these questions we will find the answers necessary to craft efficient, effective and comprehensive protections which will ensure that a person is hired or fired from a job based upon their qualifications and not on a potential disease they may, or may not, develop in the years to come.

It has been over a year since the completion of the working draft of the Human Genome. Just as we've mapped out the genetics of the human budy we must map out a legislation solution to genetic discrimination. Like a book which is never opened, the wonders of the Human Genome are useless unless people are willing to take advantage of it.

Last year, Paul Miller, the Commissioner of the Equal Employment Opportunity Commission, said before this Committee that, "there is an increased risk that employers will discriminate based on (genetic) information." it is time that Congress act while this remains a threat and is not yet a common practice.

I look forward to working with my colleagues on the Committee, the Majority Leader, and others, to address the issues we have raised here today. Again, I thank you Mr. Chairman and the Ranking Member for allowing me to share my comments today.

PREPARED STATEMENT OF THE NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES

Thank you for the opportunity to provide written testimony on the need for genetic discrimination legislation.

The National Partnership for Women & Families is a nonprofit, nonpartisan organization, dedicated to improving the lives of women and families. Through public education and advocacy, the National Partnership promotes fairness in the workplace, quality health care, and policies that help women and men meet the dual demands of work and family. The National Partnership works with government, business, advocates, unions, and the media to make the concerns of women and families our nation's priorities.

Every moment of every day, individuals reveal their most personal medical information—including genetic information—in doctors' offices, clinics, and hospitals across the country. Just talking to a health care provider about family history can reveal genetic information and predisposition to disease—information that becomes part of one's permanent medical record. And requesting or receiving genetic counseling can be treated as an indication of having a genetically based condition.

In the future, more advanced and precise genetic tests will be used widely to predict the likelihood of developing certain diseases, and how we can control or avoid disease development or progression by altering our behavior. Genetic testing will dramatically improve how we care for ourselves and our families by providing information on how we can prevent future health problems, and cope more effectively with unavoidable conditions.

Genetic discrimination, in the broadest sense, occurs when genetic information is used to treat people differently. In the insurance context, this information may be used to charge higher premiums or refuse people insurance coverage altogether. In the employment setting, genetic information may be used to make decisions about who gets hired, fired, or promoted based on the belief that a genetic marker indicates that an employee will become too sick to work or too costly to insure.

The National Partnership has been a leader on the issue of genetic discrimination for years, because women have been at the center of advances in genetic research. From the earliest pre-natal testing, to more recent and sophisticated breast and ovarian cancer screening, women have had and will continue to have a great deal at stake in the genetics revolution. Although many of science's most remarkable advances in genetic medicine are yet to come, women already struggle to weigh the benefits of genetic testing against the potential economic and emotional harm that knowledge of a potential birth defect or predisposition to illness can bring.

No individual should have to choose between the benefits of genetic testing and keeping a job or health insurance. And we know that unless Congress acts quickly and decisively, people's fears about genetic discrimination may prevent them from getting the health care they need. In addition, we are concerned that the more individuals fear discrimination, the less willing they will be to participate in clinical trials and studies that may require genetic testing—the very kind of research that could help all of us live longer, healthier lives in the future.

Recently, some lawmakers have stated that current law, specifically the Health Insurance Portability and Accountability Act (HIPAA) and the Americans with Disabilities Act (ADA), may provide sufficient protection from genetic discrimination. We strongly disagree.

HIPAA

The National Partnership played a key role in helping to pass the Health Insurance Portability and Accountability Act of 1996, and in particular, the inclusion of a provision that prohibits genetic discrimination in group health insurance. HIPAA solved one important, but small piece of the puzzle. HIPAA guarantees that individuals who are in a group health plan cannot be denied insurance or have their individual rates raised because of their genetic information. But HIPAA does not protect people in the individual market from being denied coverage or being charged unaffordable premiums because of their genetic information. In addition, HIPAA does not prevent plans from charging more to all members of a group plan because of the genetic makeup of specific members of the group. Indeed, HIPAA would not prevent a health plan from making a group's health insurance premiums so high that coverage became unaffordable, effectively denying health coverage to the entire group. We are committed to expanding the protections in HIPAA.

ADA

When the Americans with Disabilities Act was passed, many hoped that it would provide protection from genetic discrimination. Indeed, the EEOC issued guidelines to employers stating that the ADA protects employees from genetic information. However, this interpretation of the ADA has never been fully tested. In addition, because of recent federal court decisions, proving employer bias under the ADA has become increasingly difficult. We believe Congress must enact specific legislation addressing the issue of genetic discrimination.

STATE LAWS

Although many states have begun to address the issue of genetic discrimination in state laws, they vary greatly and many do not go far enough. Many do not cover both insurance and employment discrimination. Some have narrow definitions of what genetic information is protected; for example, some laws leave out family history. Some laws address genetic information related to only specific diseases, such as cancer. Others appear to have good protections but have no enforcement mechanisms, rendering them ineffective. Even if the patchwork of protections in the state were more complete, we believe a federal law is necessary to provide uniformity. An individual's civil rights should not depend on where he or she lives.

Clearly the protections in current law are not sufficient. Comprehensive federal legislation is needed. The National Partnership has founded and leads a new multi-organizational coalition called the Coalition for Genetic Fairness, made up of patient groups, civil rights and civil liberties groups, women's groups, people with disabilities or potential disabilities, and health care providers. The coalition is urging Congress to pass comprehensive, clear federal protections against genetic discrimination in employment and insurance.

The Coalition for Genetic Fairness has developed the following core principles that we believe legislation banning genetic discrimination must follow.

Coverage/Definitions: Legislation must cover all genetic information—including family history—that predicts future health risks in healthy individuals.

Scope: Legislation must prohibit both health insurers and employers from collecting predictive genetic information and from using it to discriminate in the health care system and the workplace.

Strong Enforcement: Legislation must provide individuals who experience genetic discrimination the right to seek redress through legal action, with access to meaningful remedies.

Privacy/Disclosure: Legislation must ensure that those entities holding genetic information about individuals will not disclose it to third parties without the permission of the individual.

Based on these principles, the National Partnership for Women & Families strongly endorses S. 318, the Genetic Nondiscrimination in Health Insurance and Employment Act sponsored by Senators Tom Daschle (D-SD), Christopher Dodd (D-CT), Ted Kennedy, (D-MA), and Tom Harkin (D-IA). An identical House bill is sponsored by Representatives Louise Slaughter (D-NY) and Connie Morella (R-MD). The bill would provide the protections Americans need from genetic discrimination in health insurance and in the workplace.

S. 318 is much stronger than other legislative proposals in several ways. Unlike other proposals, it includes protections from discrimination in employment. Without such protections, individuals could lose their job, and their employment-based health insurance, on the basis of genetic information. People will continue to fear genetic discrimination unless such comprehensive protections are in place.

S. 318 also more comprehensively defines what genetic information is protected from misuse. It protects all predictive genetic information, while other legislative proposals have significant loopholes. For example, other proposals would exempt from protection any information that was discovered through a test not intended to reveal genetic information—for example, a routine cholesterol test that reveals information linked to a genetic predisposition to disease. We believe that all predictive genetic information should be protected, and not subject to arbitrary exceptions based on the purpose of the test that revealed it.

Finally, S. 318 provides meaningful remedies and penalties for those who are victims of genetic information. We believe that all plaintiffs must have the opportunity to be fully compensated for the wrong done to them. Artificial caps on damages in effect protect the worst offenders by protecting them from full liability. In addition, we believe that the employee's ability to seek strong penalties acts as an important deterrent against illegal behavior by employers and insurers.

We commend Chairman Kennedy for his years of hard work on this issue and look forward to working with this Committee in the future.

PREPARED STATEMENT OF HADASSAH, BONNIE LIPTON, NATIONAL PRESIDENT

My name is Bonnie Lipton and I am the National President of Hadassah, the Women's Zionist Organization of America. With 300,000 members and 1,100 chapters nationwide, Hadassah is the largest women's and largest Jewish membership organization in the country.

On behalf of Hadassah, I thank you for the opportunity to submit testimony to this Committee and urge your swift passage of legislation that would prohibit discrimination based on genetic information.

Hadassah was founded in 1912 to bring public health infrastructure to the Middle East. Today, the Hadassah Medical Organization in Israel is the most advanced health care system in the region, providing the highest quality treatment—regardless of religion or nationality. In the United States, Hadassah members are also very active in promoting women's health through education and advocacy.

Hadassah has been involved in the issues surrounding genetic testing and research for some time. Our medical center in Israel has conducted a great deal of research and screening of recessive genetic disorders in the Jewish community, like Tay-Sachs disease. In 1995, Hadassah Medical Organization proudly joined with researchers at N.I.H. to publish the groundbreaking dominant genetic research on BRCA1 mutations in the Ashkenazi, or Eastern European, Jewish community.

Certain alterations of the BRCA1 and BRCA2 genes have been found in higher-than expected frequency among Ashkenazi Jews. And, researchers at Johns Hopkins University found a genetic mutation for colorectal cancer present in 6% of the Jewish community.

Because of our common ancestry, genetic researchers have become quite interested in studying the Jewish community. And needless to say, the Jewish community has become quite interested in the results of genetic research.

This research has been viewed by the Jewish community as significant progress in our general understanding of cancer, and for its potential to help members of our community manage their own cancer risk. We believe that this research will ultimately help everyone, Jew and non-Jew alike.

However, despite the promise of lifesaving medical breakthroughs, some implications of the research have raised concerns within the Jewish community—and not only for the diseases themselves. These concerns are primarily about genetic discrimination in insurance or employment.

Since the breast cancer research results first appeared, Hadassah has understood that fear of genetic discrimination might keep individuals from undergoing genetic testing to gain vital health information. We have heard this fear expressed, throughout the United States, in our Hadassah-sponsored community health forums and via frantic phone calls received by our National Headquarters.

Individual stories are easy to find. One of our Hadassah board members who has a strong family history of breast cancer will not take a genetic test, for fear her daughter may be at risk for discrimination. Such stories are reported regularly in the Jewish press.

Major national newspapers also report evidence of this fear. The New York Times featured a story entitled, "Genetic Testing Falls Short of Public Embrace," which detailed the status of what was to be a potentially $ 100 million-a-year commercial genetic testing market. The article claimed biotechnology companies that had developed tests to identify genetic mutations—like the ones found for breast cancer in the Jewish community—expected a deluge of clients. Instead, the companies reported that they had not seen much business in the past year. Individuals interviewed in the story stated that fear of discrimination played a key role in their decision not to take a test, even where they believed it could provide critical medical information.

A more disturbing article ran in Ha'aretz, the Hebrew language daily in Israel. The title of the story was "Come to Israel—to test your genes." It read, "A new kind of tourism is developing at Israel's oncology clinics which specialize in genetic testing . . ." It described the phenomenon of Americans traveling to Israel for genetic testing, where they are not afraid that insurance companies can get access to the results.

Even more frightening was the recent case regarding the Burlington Northern Santa Fe Railroad Company's use of genetic tests conducted without the knowledge or consent of its workers to garner information about their propensity to develop carpal tunnel injuries. Although there is no clear genetic mutation linked to carpal tunnel conditions, the company used genetic information to deny their employees' workers compensation claims. The company has acknowledged that it should not have conducted these tests. However, this case and others like it have heightened the fear of the consequences of genetic testing.

It is a terrible "Catch-22" that individuals who are simply seeking information to better care for their health may be denied the health insurance coverage they need to do so. It is particularly unfair with genetic information. The presence of a genetic mutation does not necessarily mean that the individual carrying it will ever get the disease. A significant percentage of those carrying a BRCA1 or BRCA2 mutation will never get breast or ovarian cancer. Nor does the lack of a genetic alteration indicate that an individual is risk-free.

Hadassah has recently become very concerned that fear of genetic discrimination could actually hamper genetic research, and we have some evidence that this is indeed occurring.

A few years ago, Jewish leaders in Boston were approached by researchers from the Dana Farber Cancer Institute, The researchers asked the Jewish community's leaders if they would be interested in helping involve the local community in further cancer genetics research, and proposed a theoretical study. Our leaders expressed concerns about the lack of adequate public policy protections against genetic discrimination, and politely declined on behalf of the community.

Another New York Times article quoted Rabbi Moshe Tendler, renowned medical ethicist at Yeshiva University and highly visible Orthodox leader as saying that "he would discourage Jews from participating in research until protections are passed." He said, "there's so much promise that I always walk gingerly when it means holding back any aspect of research. Yet, you have to weigh the risks against the benefits."

The Associated Press also cited an N.I.H. study in which 32 percent of women who were asked to participate in breast cancer genetic mutations research actually declined. Most of these women cited fear of discrimination and a loss of privacy as their reasons for not participating in the research.

I believe that some Jewish community members' fears about genetic testing and participation in research may result from some awareness of the history of insurance discrimination against African-Americans who carried the sickle cell anemia trait.

In 1998, there was enough community-wide concern about potential discrimination to prompt Hadassah, the Jewish Council for Public Affairs, and the National Human Genome Research Institute to convene a meeting in Washington which brought together the top rabbis and leaders from nearly every religious movement and significant organization in the Jewish community. The goal of the meeting was to "ensure the continued participation in the Ashkenazi Jewish community in critical genetic research within a framework where risks to the community are considered and minimized."

Some leaders present at that meeting expressed the concern that even the regular-albeit sometimes imprecise—news reports of the research findings might stigmatize Jews. They posited that this could lead some individuals, insurance companies, or employers to believe that Jews have more genetic mutations or are at greater risk for cancer than other groups.

They were afraid that because the Jewish community is being studied early, its members will be early victims of genetic discrimination.

Now of course it is not true that Jews have any more genetic alterations than anyone else. We know that every human carries a handful of genetic alterations that may confer some sort of disease or negative trait. So everyone is potentially at-risk for genetic discrimination. Though the Jewish community is highly concerned about this issue, it is not a Jewish issue. It is a human issue, No one should have to make the choice between health information and health care. No one should lose a job because of their genotype. The pace of life-saving cancer research should not be slowed because potential subjects are too afraid to participate.

Genetic discrimination in insurance and employment must be prohibited by law. For several years now, Hadassah has been working vigorously for the passage of state and federal law to prevent genetic discrimination.

Hadassah believes that there are four key components in particular that are required to make genetic nondiscrimination legislation. The four components are:

- A broad definition of genetic information that includes family history, an individual's genetic tests, and analysis of DNA, RNA, chromosomes, proteins, and metabolites.
- The inclusion of health insurers and employers to guarantee that predictive genetic information is not collected and used to discriminate in the health care system and the workplace.
- Legal repercussions for those providers and employers who do discriminate based on genetic factors. Remedying the situation by reinstating the insurance or job is not enough. Hadassah believes that individuals should have the right to bring private right of action in state courts.
- A privacy component. Genetic information must not be released to health plans or health issuers, employers, the Medical Information Bureau or any other groups that disseminate or collect insurance information.

Hadassah supports S. 318, the "Genetic Nondiscrimination in Health Insurance and Employment Act," sponsored by Senator Tom Daschle (D-SD), which contains these four necessary provisions.

Proper public policy needs to keep pace with this rapidly evolving area of research. Hadassah urges the Committee and the Senate to act now to insure that genetic science advances, rather than limits, health care options for all Americans.

Again, I thank you for this opportunity and for your leadership on this vital issue.

PREPARED STATEMENT OF THE AMERICAN CIVIL LIBERTIES UNION, RONALD WEICH, LEGISLATIVE CONSULTANT

Mr. Chairman and Members of the Committee: My name is Ronald Weich. I am a partner in the Washington D.C. law firm of Zuckerman Spaeder LLP and I serve as a legislative consultant to the American Civil Liberties Union (ACLU). I am pleased to submit for the record of this hearing the views of the ACLU on the subject of genetic privacy and nondiscrimination.

The ACLU is a nationwide, non-partisan organization of nearly 300,000 members dedicated to protecting the principles of liberty, freedom and equality set forth in the Bill of Rights to the United States Constitution. For almost 80 years, the ACLU has sought to strengthen civil rights and civil liberties in all aspects of American life.

We commend the Committee for its attention to the important issue of genetic privacy. Recent scientific advances in understanding and mapping the human genome present opportunities for improved medical care, but also pose challenges to principles of privacy and non-discrimination.

Genetic tests reveal the most intimate and personal health-related information that exists about any individual. While all medical information should be treated as private, genetic information is uniquely sensitive because it may reveal so much about an individual, including the individual's genetic predisposition to medical conditions. Individuals should be allowed to control such quintessentially personal information, and should be empowered by law to shield such information from third parties.

In addition to establishing the privacy of genetic information, federal law should prohibit discrimination in employment or insurance based on genetic information. There are three reasons why Congress should take immediate steps to prohibit the use of such information by employers or insurers:

- First, it is inherently unfair to discriminate against someone based on immutable characteristics that do not affect their ability to perform a job.
- Second, the mere fact that someone has a genetic predisposition to a health condition is an unreliable basis to act on the risk that he or she will actually develop that condition in the future. Genetic tests do not show with certainty that any individual will eventually develop a disease or how severe their symptoms might be.
- Third, the threat of genetic discrimination leads individuals to decline genetic screenings and other health services to avoid revealing information that may be used against them. For example, the Journal of the American Medical Association reports that only 57 percent of women at risk for breast cancer seek genetic testing, and 84 percent of those who decline the test do so because they fear genetic discrimination. Dr. Frances Collins and other leading genetic scientists have warned that progress in the field of genetic medicine depends on the willingness of individuals to submit to genetic tests without fear of discrimination.

In recent years a number of states have enacted genetic privacy laws, but the ACLU believes that a comprehensive federal law is needed to ensure that all Americans are protected from this unacceptable form of discrimination. For this reason, the ACLU has endorsed S. 318, "The Genetic Nondiscrimination in Health Insurance and Employment Act," introduced by Senator Daschle, Chairman Kennedy and others earlier this year.

The ACLU supports S. 318 because it meaningfully addresses the serious threat to civil liberties posed by new genetic technology. It prohibits genetic discrimination in all aspects of employment, including hiring and compensation. It prohibits insurers from restricting enrollment or adjusting fees on the basis of genetic information. And it prohibits both insurers and employers from requiring genetic testing.

During the recent debate on the Patients Bill of Rights (S. 1052), the Senate adopted by voice vote an amendment offered by Senator Ensign on the subject of genetic discrimination. There are several reasons why we believe S. 318 provides superior protection against genetic discrimination than the Ensign amendment.

The most important respect in which S. 318 is preferable is that it bans discrimination by employers as well as health insurers. In contrast, the Ensign amendment only prohibits discrimination by insurers, leaving individuals vulnerable to discrimination in hiring and promotions. Without protections in place in both areas, individuals have reason to fear that their genetic information could be used against them.

Also, the definition of genetic information in the Ensign amendment is narrower than the corresponding definition in S. 318. The Daschle-Kennedy bill protects information gleaned from all genetic tests, even if the test was not administered for the purpose of obtaining genetic information. In contrast, the Ensign amendment explicitly does not cover information derived from a test administered in order to "detect symptoms, clinical signs, or a diagnosis of disease." Similarly, the Ensign amendment contains an exception that would permit health plans to obtain genetic information "for purposes of diagnosis, treatment or payment"—terms which are not defined in the amendment—while S. 318 contains no such exception.

Finally, S. 318 grants individuals a more complete judicial remedy than the Ensign amendment. Unlike S. 318, the Ensign amendment requires individuals to rely on overworked government agencies to vindicate their rights, at least initially, and limits the penalties levied on violators.

It has been suggested by some that S. 318 may be unnecessary because the Americans with Disabilities Act ("ADA") already prohibits employment discrimination based on genetic information. We agree that Congress intended the ADA to prohibit genetic discrimination. Unfortunately a series of court decisions, notably Sutton v. United Airlines, Inc., 527 U.S. 471 (1999), has narrowly defined the term "disability" under 42 U.S.C. Sec. 12102 (2) and has thereby limited the scope of ADA protections. Individuals who are symptomatic but not disabled can no longer rely on the protection of the ADA, and individuals with a genetic predisposition to an illness that has not yet manifested itself are also likely to fall outside the ADA's protected class.

While we continue to believe that the ADA should be read to prohibit genetic discrimination, we believe it is entirely appropriate for Congress to clarify its intent to outlaw this pernicious practice. At this critical juncture, new legislation is needed to eliminate any ambiguity regarding protections for this most personal of information.

Indeed, whether in the course of this genetic non-discrimination bill or as a separate initiative, Congress should strengthen the ADA by overturning Sutton and similar cases that interpret the Act too narrowly. Congress should make clear that unwarranted discrimination against anyone on the basis of disability is impermissible, whether the victim of discrimination is: (1) actually disabled; (2) symptomatic but not disabled; or (3) genetically predisposed to a disability or medical condition but not symptomatic. Enactment of a genetic non-discrimination law would be welcome in that it would extend civil rights protection to non-symptomatic individuals, but such a law would inadvertently create a gap in federal law in which discrimination against individuals in the middle category (symptomatic but not disabled) will still be permissible.

In sum, the ACLU believes that Americans should be judged on their actual abilities, not their potential disabilities. No American should lose a job or an insurance policy based on his or her genetic predisposition. We urge Congress to adopt S. 318, the Genetic Nondiscrimination in Health Insurance and Employment Act, and to take such other steps as may be necessary to ensure the privacy of genetic information.

PREPARED STATEMENT OF THE NATIONAL WORKRIGHTS INSTITUTE

Mr. Chairman and Members of the Committee: Thank you for allowing the National Workrights Institute to submit testimony on the subject of "Genetics Research Issues and Non-Discrimination in Health Insurance and Employment." The National Workrights Institute is a national, private, non-profit organization and the only organization of its kind in the United States dedicated exclusively to expanding and preserving human rights in the American workplace.

During the past several decades, our collective knowledge of human genetics and its impact on our health has multiplied as procedures for identifying, analyzing and manipulating DNA have advanced. The federally funded Human Genome Project has identified hundreds of specific genes and their role in our development and has announced jointly with Celera Genomics the completion of a working draft of the sequence of the human genome. Among the many benefits of these efforts are the ways they may influence preventive health, reproductive planning and eventually therapies to cure illnesses with a genetic component. While no one can deny that this knowledge may be a blessing in finding cures to diseases with genetic origins, including Alzheimer's, Huntington's and many forms of cancer, the immediate consequences of such advances have lead to a number of forms of individual discrimination.

The ability to identify individuals based on genetic characteristics necessarily predates the ability to use this information in the treatment of the corresponding diseases. Furthermore, genetic information only indicates a predisposition or susceptibility to future illness; such information does not necessarily indicate when an individual will develop symptoms or how severe the symptoms will be. In fact, many people who test positive for genetic mutations associated with certain conditions will never develop those conditions at all. Many individuals identified as having a hereditary condition are, indeed, healthy. Genetic information does not necessarily diagnose disease.

Yet we have already encountered the use of genetic information as the basis for discrimination both in the health insurance industry and employment. In a 1996 Georgetown University study of 332 families belonging to genetic disease support groups, 22 percent of the respondents stated that they that they had knowingly been refused health insurance and 13 percent stated that they had knowingly been terminated from their jobs because of the perceived risks attributed to their genetic status.

The U.S. Department of Labor has found that genetic screening in the workplace is on the rise. In 1982 a Federal Government survey found that approximately 1.6

percent of surveyed companies were using genetic testing for employment purpose.[1] This accounted for more than 1,500 U.S. companies. In a similar survey conducted by the American Management Association in 1997, that figure had risen to 6 percent of responding employers (well over 6,000 companies).[2] Additionally, the Council for Responsible Genetics has documented hundreds of cases where healthy individuals have suffered insurance and workplace discrimination on the basis of genetic information.[3]

For example, take the case of Christine Demark, a sales representative with an exemplary record. She was fired when her employer found out that she was at risk for Huntington's disease. The employer had been notified by a co-worker of Christine's that she had been going to the required counseling before undergoing testing. Subsequently, she was demoted to a customer service position and eventually fired because of this testing. Or consider the case of Jamie Stephenson whose entire family was denied health insurance after two of her children were diagnosed with fragile X syndrome, a variable condition involving mental retardation.[4] Consider further the three year old child who had recently been identified with the predisposition for MPS syndrome whose insurance policy was terminated by the family's private health insurer despite the fact that the family had been on the policy almost a year before diagnosis. After an extended negotiation involving the retention of a lawyer and threat of a lawsuit the policy was reinstated, but only after a rider was added that would exclude coverage for many common MPS-related complications.[5] Indeed, consider further the pregnant woman whose fetus tested positive for cystic fibrosis and whose managed-care health plan limited coverage for her pregnancy and future child while offering full coverage should she choose an abortion.[6]

As the cost of testing rapidly declines and the number of conditions that can be tested for increases, genetic testing may become as common as drug testing is today. Already current statistics for genetic testing rates do not account for the recent advances in identifying the genetic basis for breast cancer and other common genetically related conditions. Indeed, if one really doubts this growing trend of genetic discrimination consider asking an insurer or employer the following question: "If an inexpensive and accurate test existed that would indicate that an individual had a predisposition to a particular illness that would cost thousands of dollars to treat and limit their ability to perform would you be interested conducting such testing?"

Insurance practices such as exempting "preexisting conditions," limiting coverage, charging higher premiums for higher perceived risks, refusing to issue policies or changing existing insurance policies will continue to have a serious impact on people said to have a genetic predisposition to develop cancer or some other condition. It should be important to note that health insurance companies have already allocated the total cost of health care among all their subscribers (called risk pooling). Our knowledge of genetics and our ability to identify some genetic predispositions are relatively new. The incidence of genetic predispositions in the American population, though, has remained unchanged.

There is little evidence that the insurance industry will be adversely impacted in any significant way by limiting their access to genetic information. Actuarial data used by the insurance industry already accounts for the probability that someone will get sick on the basis of his or her membership in a specific group, identified by age, sex, profession, and other criteria. Adverse selection is not a serious problem with respect to health insurance. The vast majority of medical care is not discretionary; people do not need more medical care because they have insurance. Buying health insurance is a multi-factorial process. Health insurance decisions occur with much frequency, involve estimates of needs over short periods and involve relative price uniformity. Consumers with private knowledge that they are at high risk cannot enrich their heirs at insurer's expense by purchasing very large health policies (as they can with life insurance). The net effect of these factors is that no data let alone formula for acquiring data has been developed to measure adverse selection in health insurance. It should be noted that a significant additional factor in this analysis is the fact that since genetic information only represents a series of varying probabilities of contracting the corresponding disease it is likely to create at best

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[1] "The Role of Genetic Testing in the Prevention of Occupational Disease." Office of Technology Assessment, April 1993.

[2] American Management Association.

[3] "Statement of Position on Genetic Discrimination," Council for Responsible Genetics.

[4] "A Case of Discrimination" Genewatch, vol. 7, Feb. 1992, p. 9.

[5] "Individual, Family, and Societal Dimensions of Genetic Discrimination: A case Study Analysis," Geller, Alper, Billings, Barash, Beckwith, and Natrowicz, Science and Engineering Ethics, Vol. 2, Issue 1, 1996.

[6] "Incidents of Genetic Discrimination: A Case Study." Dr. Paul Billings.

weak adverse selection pressures in the market. While the costs for individuals who use large amounts of care will exceed the premiums they have paid, the insurer will recover these loses from the premiums of those who use less. The responsibility in enacting effective genetic nondiscrimination legislation is to do what is correct in principle as long as there is not substantial industry impact. All indications are that such would be the case in passing strong genetic anti-discrimination legislation.

Current statutory protections are inadequate in protecting individual privacy and preventing genetic discrimination. To date fifteen states do not have any statutory protections against genetic discrimination. Even among those that do such protections are not comprehensive; some states only prohibit discrimination in health insurance or in the workplace or only for specific genetic traits.

Federal protection is also limited. The most important such law concerning genetic discrimination is the Americans with Disabilities Act. The ADA prohibits employers from discriminating against those with "physical or mental impairments which substantially limit a major life activity" (or those that have a record of or are regarded as having such an impairment) so long as their condition does not make them incapable of performing their job.

The ADA does not specifically discuss genetic predispositions and there is a substantial risk that asymptomatic individuals are not protected from genetic discrimination in employment. Such individuals only have a predisposition to future illness, are currently healthy, and may not necessarily ever become disabled (as defined by the statute) by a genetically related condition. This potential lack of coverage has become a more real possibility as recent Supreme Court cases have narrowly interpreted the ADA and indicated that the Court is clearly of the mindset that the ADA was not intended to protect large segments of the populace. The class of those potentially affected by genetic discrimination is certainly not a small segment of the population; every citizen of the United States has at least several genetic mutations which may at some point be linked to disabling conditions. The EEOC has taken the position in its interpretative regulations that such a person is covered against discrimination when that discrimination is due to the perception that they are predisposed to become ill. The EEOC interpretation, however, has not been tested in court and the Supreme Court has struck down several EEOC regulations in this area.

One situation that the ADA regulations do not address is when a person is an unaffected carrier for a recessive or X-linked mutation. This person never will manifest a genetically based disease, but does carry a mutation. However, if this person mates with another person who is a carrier, there is a 25 percent chance that the offspring will carry a mutation that may result in the manifestation of an illness. The ADA is silent on how to treat such a carrier.

Another such situation concerns people who do not themselves have a genetic mutation, but who have a family member who does. Employers who provide medical insurance for employees' dependents have a financial incentive to discriminate in such situations. It is unclear at best, however, whether this type of discrimination violates the ADA.

Most importantly, the ADA does not protect the privacy of employees and does not prevent employers from obtaining genetic information; it only prevents them from using the information. Under the ADA, an employer who has made a "conditional job offer" is free to conduct unlimited medical investigations of the applicant. This can include collecting information that the employer cannot legally use. This allows employers to learn about an applicant's genetic status without violating the ADA. Once an employer knows that a potential employee is likely to require expensive medical care, the employer can find some excuse not to hire that person. While employees will sometimes be able to correct this injustice in court, the right answer is to prevent it from ever happening. This can only be accomplished by keeping genetic information out of the hands of employers.

Additionally, the Health Insurance Portability and Accountability Act of 1996 (HIPA or Health Care Law) provides some federal protection against genetic discrimination when an employer provides medical insurance. It does so by preventing a group health plan from applying a waiting period on preexisting conditions if the condition was not diagnosed or treated within six months before the plan's waiting period. If a genetic problem was diagnosed or treated within the previous six months, the maximum waiting period can be only 12 months. Nevertheless other forms of health insurance are not covered. Genetic privacy and equal access to insurance necessarily compete with the insurance industry's desire to write insurance based on sound actuarial data. Indeed, the underlying foundation of the insurance industry is the ability to discriminate based on such data. Insurance companies are ever vigilant to minimize their risks. Nevertheless there is no epidemic of genetic conditions and they exist at a fairly stable incidence in our society. In fact, actuarial tables used by the insurance industry already reflect the incidents of genetic conditions as part of their risk pooling. Still, demand for policy holders within the industry can lead to an assessment spiral where one company will offer discounts for those persons who submit to genetic tests and consequently soon all companies will adopt such practices in order to become competitive. The incentives to discriminate within the insurance industry remain as underwriting practices become more strict and are structured to identify and insure only healthy individuals.

Legislation is the only way to address the privacy of genetic information and the accompanying discrimination. Incidents of individuals avoiding necessary testing in fear that the information obtained from the tests will be made public are already well documented. It is vital that legislation be enacted with a definition of genetic information that is broad enough to include all the sources of information from which an employer or insurer might learn about an employee, policy holder or applicant's genetic condition. Many proposed definitions have unintentionally omitted important sources. For example, among the most common ways for an employer or insurer to learn that someone is at risk for a genetic illness are by learning that other family members have contracted the disease or that the person has requested genetic counseling. Definitions which focus on testing do not cover these situations. Additionally, many proposals prohibit only discrimination on the basis of genetic information. While this provision is essential, it does not offer adequate protection. Given the substantial costs involved in providing medical care and other benefits to those who contract genetic diseases, if employers or insurers are permitted to collect genetic information about employees, policy holders and applicants, some of them will use it, even if this is not legal. Even where discrimination does not occur, the employee or insured party has still suffered a loss of privacy.

With this in mind, the National Workrights Institute strongly urges the following principles be addressed in order to have strong and effective genetic non-discrimination protection.

Coverage/Definitions:

Legislation must cover all genetic information—including family history - that predicts future health risks in healthy individuals.

Scope:

Legislation must prohibit both health insurers and employers from collecting predictive genetic information including information and from using it to discriminate in the health care system and the workplace.

Strong Enforcement:

Legislation must provide individuals who experience genetic discrimination the right to seek redress through legal action, with access to meaningful remedies.

Privacy/Disclosure:

Legislation must ensure that those entities holding genetic information about individuals will not disclose it to third parties without the permission of the individual.

As public concern mounts with the growth of medical technology, it is crucial that restrictions be placed on the accumulation of genetic information by employers and insurers. Without meaningful privacy safeguards and protections against discrimination, the benefits of genetic testing will ultimately be lost as individuals avoid tests in the fear of adverse consequences. The National Workrights Institute urges the prompt enaction of a legislative remedy.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF MEDICAL GENETICS, MICXHAEL S. WATSON, PHD., EXECUTIVE DIRECTOR

The American College of Medical Genetics represents over 1000 doctoral level Clinical Geneticists and Genetics Laboratory Directors in the United States who are Board certified by the only board of the American Board of Medical Specialties that is specific to this area of medical practice, the American Board of Medical Genetics. The College is pleased that discussions of these important issues are beginning and is submitting this letter and its Position Statement as testimony for the committee to consider in its deliberations. Although the magnitude of discrimination based on genetic information is somewhat unclear, the perception of this problem by the American public is quite real. It has already caused significant problems with regard to the publics willingness to seek genetic services and to participate in research and clinical investigation into the genetic components of disease. We welcome your attention to this important issue and offer any assistance we can provide.

The American College of Medical Genetics believes that fears of genetic discrimination in health insurance and employment have a negative impact on willingness to seek genetic services and to participate in genetic research. These decisions, based on fears of discrimination, could keep individuals from having services that could protect their health and that of family members by prevention and treatment of disease. Comprehensive federal legislation is needed to protect all Americans. The goal of such legislation should be to enhance the safe and effective integration of genetic services, including genetic testing, as an inseparable part of the health care system. The American College of Medical Genetics believes that:

- All Americans should be protected by genetic 0nondiscrimination legislation addressing both health insurance and employment.

Protection against genetic discrimination in health insurance is needed for individuals covered by all public and private programs, whether through group or individual plans, and regardless of the mechanism by which the program is regulated.

Protection against discrimination in employment must cover the many participants in the process including employers, employment agencies, labor organizations, and training programs, and at all steps of the employment process.

- Legislation must not impede the ability of individuals to make maximal use of genetic information in their health care and employment decision-making. It must not limit the access of health care providers to genetic information needed to ensure that the care provided is beneficial and specific to the needs of the individual.
- Like all health information, the privacy of genetic information must be adequately protected. Protection against unfair discrimination based on genetic risk for disease is achieved only by strategies that restrict use of genetic information in enrollment and rate setting.
- There are significant uses of genetic technology in evaluation and management of conditions that are not familial. For example, DNA analysis is used to evaluate cancer cells for acquired mutations that can help to characterize the tumor and guide treatment. Legislation should recognize that there are different types of genetic tests, and avoid creating new barriers to use of those elements of genetic technology that do not create unique or novel risks.
- It is not easy to define "genetic test," "genetic information" and "genetic services" for legislative purposes. Key and occasionally contradictory points to consider include:

Definitions must be sufficiently broad to accommodate the wide range of what is known about classical single gene disorders and the contribution of multiple genes to common, complex diseases.

Definitions must be sufficiently flexible to avoid becoming rapidly outdated by new developments.

Definitions must be sufficiently narrow and clear to avoid confusion in application of statutory protection in the current system of health delivery.

Definitions must avoid creating arbitrary distinctions that unfairly exclude some individuals from protections afforded to others.

- Protected genetic information must include that based on evaluation, testing, and family histories of individuals and their family members.
- Legislation should include enforcement to ensure compliance.
- When there is clear evidence that genetic factors contribute to an individual's vulnerability to unavoidable environmental workplace exposures, and testing is available to determine if an individual is at increased risk, employees and potential employees should be made aware of the availability of such testing, and fully informed of the implications of testing.

The American College of Medical Genetics believes that no American should have to choose between having a genetic test that could be important to his/her life, and avoiding a genetic test to save a job or protect health insurance coverage.

PREPARED STATEMENT OF THE NATIONAL HEMOPHILIA FOUNDATION

The National Hemophilia Foundation (NHF) applauds Chairman Kennedy and the Health, Education, Labor and Pensions Committee for hearing testimony today on the urgent need for passage and enactment of legislation to protect consumers from genetic discrimination by insurers and employers.

NHF strongly encourages Congress to pass this year the genetic nondiscrimination bill sponsored by Senate Majority Leader Tom Daschle and Congresswoman Louise Slaughter (D-NY). The Genetic Non-discrimination in Health Insurance and Employment Act (S. 318/H.R. 602) has the support of 23 Senators, 252 House cosponsors, and more than 200 organizations. The bill would prohibit enrollment restrictions and premium adjustments on the basis of predictive genetic information, including family history, and prevent discrimination in hiring, compensation, and other personnel processes. The bill also would protect the privacy of individuals by limiting disclosure of predictive genetic information by employers.

Access to health insurance, health care, and employment is of critical concern to persons with hemophilia and other bleeding disorders. Hemophilia and other bleeding disorders are genetic conditions that impair the ability of blood to clot effectively. Persons with hemophilia and other bleeding disorders manage their disease with costly life-sustaining treatments and comprehensive preventive care.

NHF strongly supports genetic research in hopes of finding a cure for hemophilia and other bleeding disorders. S. 318/H.R. 602 ensures that genetic information will be appropriately used to provide early detection and prevention of disease rather than to limit access to insurance and employment. NHF urges Congress to take swift action in passing this urgently needed legislation.

Senator DODD. With that, the committee is adjourned.

[Whereupon, at 11:06 a.m., the committee was adjourned.]

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