

**THE POTENTIAL FOR DISCRIMINATION IN HEALTH  
INSURANCE BASED ON PREDICTIVE GENETIC  
TESTS**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON  
COMMERCE, TRADE, AND CONSUMER PROTECTION  
OF THE  
COMMITTEE ON ENERGY AND  
COMMERCE  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED SEVENTH CONGRESS

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# THE POTENTIAL FOR DISCRIMINATION IN HEALTH INSURANCE BASED ON PRE- DICTIVE GENETIC TESTS

WEDNESDAY, JULY 11, 2001

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON COMMERCE, TRADE,  
AND CONSUMER PROTECTION,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 12 noon, in room 2322, Rayburn House Office Building, Hon. Cliff Stearns (chairman) presiding.

Members present: Representatives Stearns, Shimkus, Bryant, Towns, DeGette, Capps, Gordon, and Eshoo.

Staff present: Nandan Kenkeremath, majority counsel; Marc Wheat, majority counsel; Brendan Williams, legislative clerk; and Bruce Gwinn, minority professional staff.

Mr. STEARNS. Good afternoon, everybody. I am pleased to chair a hearing on the potential for discrimination on health insurance based on predictive genetic tests. Genetic testing and genetic information is but one of many new technologies that will advance health care, provide better preventive medicine and counseling, unlock the causes and factors in diseases, make for better treatments and improve the delivery of services.

We can ensure that this new technology is a friend to patients and not something that they, in any way, need to fear.

In the future, genetic information will be an indispensable part of a medical file. We should not by regulation force health care plans or providers to create separate files of information that have to comply with one new regulatory regime after another or stifle the collection, dissemination or research of important information. At the same time, my colleagues, we should be cautious regarding the potential for discrimination based upon genetic tests.

There are current Federal prohibitions on discrimination based upon genetic information and the current privacy rules that already exist under Federal law. In the 104th Congress, during consideration of Health Insurance Portability and Accountability Act, Public Law 104-191, I worked to include the final language regarding genetic information within the provision prohibiting health insurance companies from denying coverage to an employee or a beneficiary on the basis of health status.

In 1997, I chaired the Task Force on Health Records and Genetic Privacy in which we held a meeting to gather testimony and infor-

mation from a variety of interested parties, including Dr. Francis Collins, Director of the Human Genome Project. We also heard from representatives of the insurance companies and the biotech and pharmaceutical industries and patient advocates. Given the technological advances in genetic testing we must find a way to ensure that such research is not impeded while also protecting the interests of the individual.

One conclusion upon which we agree was that advancing medical technology is crucial. However, it is the means of its application that must concern us today.

One problem we are faced with here is that science is beginning to realize that mapping the human genome and designing a predictive genetic test is a more daunting task than previously realized. Dr. J. Craig Venter of Celera Genomics whom we will hear from today was quoted as saying that last year "one gene leads to many different protein products that can change dramatically once they are produced." He was further quoted as saying, "that the environment acting on our biological steps may be as important in making us what we are as our genetic code." So one question which we will try to answer today is should an insurance company be able to deny medical coverage based on an individual's genetic profile, especially in light of recent information indicating we may not be as close to determining predictive genetic information as we once sought.

Having said that, I think that there is a general consensus that genetic information is personal, powerful, permanent and sensitive. That is a fundamental statement that goes to the center of this debate. The most important thing we can do is be thoughtful and deliberative in looking at these issues. It is our job to understand the regulations, recognize their application to the industry and acknowledge our duty as representatives in addressing this issue.

We had hoped to have a representative from the Department of Health and Human Services or the National Institute of Health appear before us today. However, they declined to do so for a number of reasons. I intend, however, to ask them questions, in writing, to Secretary Thompson, following this hearing and I invite members of this subcommittee to submit additional questions as well.

I am now, my colleagues, after our opening statements, we will welcome Representatives Slaughter and Morella, our good colleagues, both leaders, strong leaders in this debate and whose legislation is a leading contender. With their knowledge and resources, we are very pleased to have them here and I applaud their hard work and I thank them for testifying.

I'd also like to welcome our distinguished witnesses and look forward to their testimony. At this point, the ranking member, for an opening statement. Mr. Towns?

Mr. TOWNS. Thank you very much, Mr. Chairman. I'm delighted that the subcommittee has chosen to take up an issue that affects all Americans. New technology has allowed more advances in health science than ever before. Our pharmaceutical and biotechnology industries have been able to develop therapies which help fight HIV and AIDS, limit the impact of multiple sclerosis, lower cholesterol and even allow former Senator Dole to make a few dollars.

I am disturbed by the fact that hard working Americans across this country could be dismissed from their jobs or denied health coverage, solely based on genetic information provided through these new technologies. That is why we need to do something to protect our constituents from this practice. Genetic testing and the findings of those genetic tests can have many positive uses such as determining whether a person has a propensity for cancer, diabetes, Parkinson's disease or another debilitating illness, so that the patients can seek preventative treatment and measures to reduce their future risk.

Last, let me say that I am happy that this issue is finally getting the legislative attention that it deserves. I would like to commend not only my two colleagues, the gentle woman from New York, of course, Ms. Slaughter and the gentle woman from Maryland, Ms. Morella, who will be testifying before the committee today for their leadership on this issue, but I also would like to commend you, Mr. Chairman, for holding this hearing and I think that you're going about this the right way not just by moving very quickly, but sort of hearing from people and talking because this is a very, very serious matter and I think that your approach to it is a proper one and I look forward to working with you, and of course, my colleagues, on this issue.

Thank you again for holding this hearing and again I look forward to working with you and I yield back the balance of my time.

[The prepared statement of Hon. Ed Towns follows:]

PREPARED STATEMENT OF HON. ED TOWNS, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF NEW YORK

Thank you Mr. Chairman and I am delighted that the subcommittee has chosen to take up an issue that affects nearly every American in this country; the issue of Genetic Privacy and Discrimination.

New technology has allowed more advances in health science than ever before. Our pharmaceutical and biotechnology industries have been able to develop therapies, which help fight HIV and AIDS, limit the impact of multiple sclerosis, lower cholesterol, and even allow former Senator Dole the opportunity to make some money in his retirement. Technology also assisted scientists to map the human genome much more rapidly than initially expected. Yet these scientific gains also reveal information about patients that was previously either a private matter or impossible to discover.

I am disturbed by the fact that hard working Americans across this country could be dismissed from their jobs or denied health coverage solely based on genetic information provided through these new technologies. That is why we need to do something to protect our constituents from this practice.

Genetic Testing and the findings of those genetic tests can have many positive uses, such as determining whether a person has a propensity for cancer, diabetes, Parkinson's disease or another debilitating illnesses so that the patient can seek preventative treatment and measures to reduce their future risk. This, in my mind, is the proper use of genetic information.

Lastly, let me say that I am happy that this issue is finally getting the legislative attention that it deserves. I would like to commend not only my two colleagues, the gentlewoman from New York, Ms. Slaughter, and the gentlewoman from Maryland, Ms. Morella, who will be testifying before the committee today for their leadership on this issue, but I also want to commend you Mr. Chairman for holding these hearings and for not being a "Johnny Come Lately" to this issue. President Clinton asked that this issue be given more of a priority five years ago and I'm pleased to learn that the current administration wants to pass legislation protecting consumers' genetic privacy and prohibiting discrimination based upon one's genetic information.

I look forward to working with all my colleagues on this issue, in addition with members from industry to make sure that we report out a Commerce Committee

product this session and that we enact a bill this congress. Thank you Mr. Chairman and I yield back the balance of my time.

Mr. STEARNS. I thank Mr. Towns. Mr. Shimkus, you're recognized for an opening statement.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I want to commend my colleagues for being here and look forward to the testimony and appreciate their leadership on this issue. I know they would appreciate the visit I had from some breast cancer survivors in my District Office a couple of months ago and they've been very blessed in their clinical trials, but their concern was what about their children and their grandchildren and the safeguarding of data being conducted on these trials and the possible challenges to their future generations should the data and the genetic information fall into other hands.

So this is a challenging issue that we have to address and there should be an appropriate balance for science, but also for confidentiality and we all know that our biggest problem is health care coverage of all our citizens and we want to make sure that while we can continue using an employer-based health care system to provide insurance, that we don't scare them away by a lot of things that we plan and try to do here in Washington.

So I applaud your efforts. It is relevant to my constituents and I look forward to your testimony and the rest of the panel and with that, Mr. Chairman, I yield back my time.

Mr. STEARNS. The gentleman yields back the balance of his time. The gentleman from Tennessee, Mr. Gordon, is recognized for an opening statement.

Mr. GORDON. Thank you, just very quickly, let me add my welcome to our colleagues. I know that I joined Ms. Morella as her ranking member for a few years and know that she has a real interest in this subject and certainly my colleague and good friend, Louise Slaughter, we sat next to each other for several years, talked about these sorts of things and if anything, she is our in-house specialists by virtue of advanced degrees and a lot of work experience in this area and I think it has been demonstrated by the fact that you have gotten 252 co-sponsors, maybe even more than that by today, in a good bipartisan effort and so I look forward to hearing your testimony. Again, congratulate you for bringing this important issue to us.

Ms. SLAUGHTER. Thank you.

Mr. STEARNS. Ms. Capps for an opening statement.

Ms. CAPPS. Yes, thank you, Mr. Chairman. And I'm so honored to have our expert witnesses and our wonderful colleagues here today to testify. As we move further into the 21st century, scientific breakthroughs hold tremendous promise for the future of medicine. New advances that have cured previously fatal diseases, extended lives of millions of Americans and enhanced a quality of life. But unfortunately, as you two know very well, there's a danger involved with this progress and as medical science advances it, it is accompanied by greater threats to rights and civil liberties of patients.

New and better technologies also lead to new and better ways to take advantage of people. Superior understanding of life sciences lead to innovative ways to deprive individuals of their right to privacy and their access to care. I am an active supporter of medical



research, but I believe at the same time we have to balance promoting medical research against protecting the most important aspect of health care, sacred trust between patients and health care providers. As a nurse, I know that good medicine depends on a patient's willingness to seek out and share their personal health information with their doctors, nurses and therapists. No diagnosis or treatment is completely reliable without this kind of trust. But if they're not sure that this sensitive information will be kept confidential and will not be used against them, they're not going to be forthcoming. The success of the human genome project has added a very new element to this problem. The project allows us to better understand and predict some of the most intractable diseases that we face and this information can also be misused to cut costs, reduce financial liabilities and increase profit margins. It is possible that unscrupulous insurers and employers could use this information to avoid paying the higher costs for the health care of an individual. In fact, these institutions could deny coverage to a person based on the mere possibility that he or she might develop a costly condition and this would mean that while we may be able to help someone to avoid cancer or heart disease, that person might be denied all their basic health care so that a company can avoid the risk of potential paying for that treatment.

So I'm proud to be an original co-sponsor of the Genetic Non-discrimination Health Insurance and Employment Act offered by Representatives Louise Slaughter and Connie Morella. This bill would protect Americans from possible discrimination if genetic tests show they are predisposed to diseases like ALS, Parkinson's or cancer. Advances like the mapping of the human genome should bring powerful new tools to fight against disease, not become a source of fear for patients. If patients believe the results of their genetic tests will hurt them, they will be unwilling to take those very tests and this would ultimately block us from achieving the potential of breakthroughs like the human genome project. And so, Mr. Chairman, I appreciate your willingness to hold these hearings and hope that the Congress is going to pass swiftly H.R. 602. I yield back my time.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ED BRYANT, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF TENNESSEE

I also thank the chairman for this hearing, and I thank the witnesses for coming today. I am glad that this subcommittee will be looking into this issue. I am also a member of the Health Subcommittee, and as a member of that subcommittee, I have learned a great deal about the health care industry.

I have been amazed by the treatment available to people today to fight illnesses and diseases. The development of Genetic testing is an example of one these improvements. Over the next few decades genetic testing will become an integral part of health care, and I look forward to hearing from the witnesses about the benefits of this technology in regard to research, preventive care, and the delivery of care.

There are numerous benefits of genetic technology; however, a doctor's possession of this personal information, also brings into play a patient's privacy.

Included in HIPAA and the recently enacted medical privacy rule, there is a ban on genetic discrimination in determining the eligibility and rate setting in health insurance. Today, I look forward to hearing about the implementation of these bans. We need to look into these laws and see if there are any gaps in regulatory authority to address problems that may arise in discrimination in health insurance based on genetic tests.

However, in acting on this issue, the government should not hamstring the health care industry in a way that prevents it from taking advantage of this new technology. I have had the opportunity to look into the issue of Medicare reform, and I've seen many examples of instances when the government has made a process unnecessarily complicated. We should be sure that this does not happen while we work to insure that genetic discrimination in health insurance does not occur.

Again, I thank the Chairman for holding this hearing and our witnesses for coming today. I yield back the rest of my time.

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PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Mr. Chairman.

I commend you for holding this important hearing. This Committee has important expertise to contribute to addressing the evolving nature of health care, health insurance, and the privacy and use of medical information. Today's hearing combines many of these cutting edge concerns. As a general matter, our overall objective is improving the health of Americans. In this regard, genetic testing holds great promise. It will provide important information both for the counseling and treatment of individual patients and for research to identify the causes and factors in diseases. In the future, genetic information will be an indispensable part of a medical file.

We can protect privacy and assure that genetic information is used on behalf of patients. We must encourage, however, the free flow of general medical knowledge that will be derived from genetic tests. Also, whatever we may do to enhance protection from discrimination in eligibility or rate setting for insurance, we must take great care not to create an unnecessary bureaucracy that will chill the collection and use of genetic information on behalf of patients and for research. Moreover, it is important to evaluate the current Federal prohibitions on discrimination based on genetic information and the current privacy rules that already exists under Federal law. Federal regulation of health insurance and health care is already too complicated to add redundant provisions. We must make sure that what we do in this area doesn't add to the complexity.

Finally, we must always recognize that our private sector health insurance is a significant part of what helps provide Americans with great health care. Let's not take steps that will increase premium rates for small employers and, thus, unintentionally increase the number of uninsured Americans.

I am pleased that this hearing will begin a careful evaluation of the issues pertaining to genetic non-discrimination in health insurance. I look forward to hearing from today's witnesses to assist the Committee in these deliberations.

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PREPARED STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. Chairman, thank you for holding this important hearing on the potential for discrimination in the health insurance market based on predictive genetic tests.

With major scientific breakthroughs occurring everyday in the field of biotechnology and genetics, such as the mapping the human genome, we in Congress have the awesome responsibility of ensuring that this new technology is not misused. Clearly, genetic tests offer a way for modern medicine to pinpoint preventive care to those who may be genetically predisposed to certain medical conditions. By targeting preventive care we can improve the quality of life for many Americans who would otherwise suffer needlessly.

However, if Americans are afraid to use genetic tests due to the fear of genetic discrimination by either employers or insurers, the gains from this new technology may never be fully realized. This would be similar to having a cure to a common disease and simply throwing it away.

Clearly, perception is key. It is true that there is a patchwork of laws in place prohibiting the discriminatory use of genetic information in some circumstances. However, unless Americans clearly believe their genetic information is protected from prying eyes and discrimination, there will continue to be apprehension regarding the use of this new technology. That is why I want to commend the hard work of both Representatives Louise Slaughter and Connie Morella on this topic. This session, Representatives Slaughter and Morella reintroduced H.R. 602, the Genetic Nondiscrimination in Health Insurance and Employment Act, which would clearly ban discrimination in the workplace and in health insurance on the basis of genetic information. This bill unambiguously tells Americans that their genetic information

will not be used against them. I am proud to be one of 252 cosponsors of this bipartisan legislation and hope to see it passed this year.

I am also pleased to hear that President Bush has recently endorsed the concept of a ban on genetic discrimination. Representative Slaughter and Morella's bill is the best legislative vehicle for ensuring the passage of such a ban and I hope the President and the Republican leadership will work with Representatives Slaughter and Morella to ensure its passage this year.

Mr. STEARNS. I thank my colleagues and at this point we are pleased to welcome our two colleagues and ask them for their opening statement and we'll start with our distinguished colleague from New York. I always go left to right, but I'd be glad to go right to left.

**STATEMENTS OF HON. LOUISE M. SLAUGHTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK; AND HON. CONSTANCE A. MORELLA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND**

Ms. SLAUGHTER. Mr. Chairman, I thank you for the opportunity to testify at the hearing entitled "The Potential for Discrimination of Health Insurance Based on Predictive Genetic Tests." I'm pleased to be here, of course, with my good friend, Connie Morella. We were elected at the same time and we've been pretty much a matched set ever since, but she's a wonderful colleague and has been incredibly helpful on this bill and we're happy to discuss this with you.

Two hundred and twenty-five years ago, Thomas Jefferson drafted our Nation's Declaration of Independence to include the phrase "all men are created equal." He could scarcely have known that this statement would turn out to be a literal truth as well as a figurative one. With the completion of the mapping of the human genome, science has revealed to us the fact that human beings are 99.9 percent the same, regardless of race, gender or nationality.

The remaining 0.1 percent of the human genome accounts for all the human variation we see around us, from eye color to major disability. And while some of us may appear to have been blessed with better genes, none of us has perfect ones. Every person carries between 5 and 50 genetic flaws that predisposes him or her to a range of disorders.

Over the past few years, entire newsletters, medical journals, and on-line services have sprung up to cover the advances in genetic medicine. Along with these discoveries, we are seeing a corresponding increase in the number of genetic tests available to Americans. People can now take advantage of genetic tests that will help gauge their risk for breast cancer, colon cancer, and Huntington's Disease. In all, over 800 genetic tests are now available. In time, we expect that new therapies will be developed to target disorders based on our knowledge of the genetic information involved. Scientists will be able to focus treatment on diseases at the molecular level, alleviating side effects and other unintended consequences. We can anticipate a new way, an entirely new way, to provide health care at less cost and with fewer long hospital stays.

All of this great promise can only come to pass if genetic research can proceed forward unimpeded. Today, the greatest threat to genetic research comes from the potential for genetic discrimination: the misuse or abuse of genetic information. Indeed, many people

are reluctant to go into clinical trials because that information is not protected.

Today's hearing proposes to address the "potential" for genetic discrimination. Unfortunately, genetic discrimination is not just a theoretical possibility. It is already a reality. For example, in 1997, the New York Times reported the story of a woman who took a genetic test for early onset breast cancer. It came back positive. As a result, she decided to undergo a prophylactic double mastectomy. When she petitioned her insurer to cover this procedure, her request was denied. She then re-submitted her request, sending with it the results of her genetic test, which indicated a dramatically increased risk of cancer. Upon receiving the information, her insurer denied the request again, and canceled her policy. This is just one of dozens of cases.

This story encapsulates Americans' worst fears about the potential abuse of genetic information. As policymakers, however, we must look beyond the anecdotal stories to the fundamental policy issues at hand. In my judgment, genetic discrimination is grossly unfair for three key reasons.

As I stated above, every single human being is born with genetic flaws. As a result, we are all potentially uninsurable and potentially unemployable. By allowing discrimination to persist, we are simply punishing those people with the bad luck to have had the genes that were discovered first.

Having a given gene does not necessarily mean one will ever get sick. A genetic mutation only confers a higher or lower level of risk.

Our understanding of genetics is in its infancy. In most cases, we do not have a solid grasp of what it means to have a particular genetic mutation or how much risk is elevated. As a result, this information is useless as a basis for decisions about insurance coverage or premiums.

By banning genetic discrimination, we are simply asking insurers to continue covering the exact same people, under the exact same conditions that they are covering today. We're not asking them to insure a population with bad genes. I want to really enforce again that all of us are in that category.

Any congressional effort to ban genetic discrimination should adhere to four fundamental principles.

No. 1. It should ban discrimination in both health insurance and employment. If our goal is to make the American people comfortable in taking a genetic test, we cannot ban genetic discrimination in just one area or the other.

No. 2. It should contain strong provisions prohibiting the collection and disclosure of predictive genetic information without informed consent. Predictive genetic information should be a matter of privacy, not a matter of commerce.

No. 3. It should protect all forms of predictive genetic information, including family history. Much of our predictive genetic information comes from our knowledge of the disorders that run in our family. People need to be comfortable discussing this information with their health care providers and having it in their medical records without fear that someone else will see it and that they will be harmed by it.

No. 4. It should contain meaningful enforcement and remedies. It is not enough for Congress to pass a law but not punish violations. It's not good enough to say we wish you wouldn't do this. The abuse of genetic information represents a fundamental violation of an individual's person. It should be treated as such.

Representative Morella and I believe we have the legislative solution to genetic discrimination. We are proud to sponsor H.R. 602, along with 250 of our colleagues, the Genetic Nondiscrimination in Health Insurance and Employment Act. This bill has the support of well over a majority of the House of Representatives, as well as hundreds of outside organizations that I like to think represent anywhere from a quarter to a third of all of the people in the United States. We hope that your committee will act soon to pass H.R. 602 as quickly as possible.

Once again, Mr. Chairman, I thank you for the opportunity. Representative Morella and I both look forward to the day when social policy can keep pace with science. We hope that would have happened 5 years ago when we introduced this bill. We're kind of lagging behind. But Congress needs to pass a strong, meaningful, genetic nondiscrimination law and they need to pass one now.

Thank you.

[The prepared statement of Hon. Louise M. Slaughter follows:]

PREPARED STATEMENT OF HON. LOUISE M. SLAUGHTER, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, I thank you for the opportunity to testify at this morning's hearing, "The Potential for Discrimination in Health Insurance Based on Predictive Genetic Tests." I am delighted to be here this afternoon with my dear friend and distinguished colleague from Maryland, Rep. Constance Morella, to discuss this pressing health issue.

Two hundred twenty-five years ago, Thomas Jefferson drafted our nation's Declaration of Independence to include the phrase, "All men are created equal." He could scarcely have known that this statement would turn out to be a literal truth, as well as a figurative one. With the completion of the mapping of the human genome, science has revealed to us the fact that human beings are 99.9 percent the same, regardless of race, gender, or nationality.

The remaining 0.1 percent of the human genome accounts for all the human variation we see around us, from eye color to major disability. And while some of us may appear to have been blessed with better genes, none of us has perfect ones. Every person carries between five and fifty genetic flaws that predisposes him or her to a range of disorders.

Over the past few years, entire newsletters, medical journals, and online services have sprung up to cover the advances in genetic medicine. Along with these discoveries, we are seeing a corresponding increase in the number of genetic tests available to Americans. People can now take advantage of genetic tests that will help gauge their risk for breast cancer, colon cancer, and Huntington's Disease. In all, over 800 genetic tests are now available. In time, we expect that new therapies will be developed to target disorders based on our knowledge of the genetic information involved. Scientists will be able to focus treatment on diseases at the molecular level, alleviating side effects and other unintended consequences.

All of this great promise can only come to pass, however, if genetic research can proceed forward unimpeded. Today, the greatest threat to genetic research comes from the potential for genetic discrimination—the misuse or abuse of genetic information.

Today's hearing proposes to address the "potential" for genetic discrimination. Unfortunately, genetic discrimination is not just a theoretical possibility; it is already a reality. For example, in 1997, the *New York Times* reported the story of a woman who took a genetic test for early onset breast cancer. It came back positive. As a result, she decided to undergo a prophylactic double mastectomy. When she petitioned her insurer to cover this procedure, her request was denied. She then re-submitted her request, sending with it the results of her genetic test, which indicated

a dramatically increased risk of cancer. Upon receiving this information, her insurer denied the request again, and canceled her policy.

This story encapsulates Americans' worst fears about the potential abuse of genetic information. As policymakers, however, we must look beyond the anecdotal stories to the fundamental policy issues at hand. In my judgement, genetic discrimination is unfair for three key reasons:

As I stated above, *every person has genetic flaws*. As a result, we are all potentially uninsurable. By allowing discrimination to persist, we are simply punishing those people with the bad luck to have the genes that were discovered first.

*Having a given gene does not necessarily mean one will ever get sick*. A genetic mutation only confers a higher—or lower—level of risk.

*Our understanding of genetics is in its infancy*. In most cases, we do not have a solid grasp of what it means to have a particular genetic mutation, or how much risk is elevated. As a result, this information is useless as a basis for decisions about insurance coverage or premiums.

By banning genetic discrimination, we are simply asking insurers to continue covering the exact same people, under the exact same conditions, they are covering today.

Any Congressional effort to ban genetic discrimination should adhere to four fundamental principles:

1. **It should ban discrimination in both health insurance and employment.** If our goal is to make the American people comfortable in taking a genetic test, we cannot ban genetic discrimination in just one area or the other.
2. **It should contain strong provisions prohibiting the collection and disclosure of predictive genetic information without informed consent.** Predictive genetic information should be a matter of privacy, not a matter of commerce.
3. **It should protect all forms of predictive genetic information, including family history.** Much of our predictive genetic information comes from our knowledge of the disorders that run in our family. People need to be comfortable discussing this information with their health care providers and having it in their medical records.
4. **It should contain meaningful enforcement and remedies.** It is not enough for Congress to pass a law but not punish violations. The abuse of genetic information represents a fundamental violation of an individual's person. It should be treated as such.

Representative Morella and I believe we have the legislative solution to genetic discrimination. We are proud to sponsor H.R. 602, the Genetic Nondiscrimination in Health Insurance and Employment Act. This bill has the support of well over a majority of the House of Representatives, as well as hundreds of outside organizations. We hope the Energy and Commerce Committee will act to pass H.R. 602 as quickly as possible.

Once again, Mr. Chairman, I thank you for the opportunity to testify here today. Representative Morella and I look forward to working with you ensure that social policy keeps pace with science, and Congress passes a strong, meaningful genetic nondiscrimination law.

Mr. STEARNS. Thank you.

Ms. Morella.

#### **STATEMENT OF HON. CONSTANCE A. MORELLA**

Ms. MORELLA. Thank you, Mr. Chairman. I want to thank you and members of the subcommittee for this hearing. I want to particularly thank you for scheduling this hearing. I do think it's very important and it shows your continued interest in this particular issue.

I associated myself with the comments that you just heard from my colleague and good friend, Louise Slaughter. Actually, she's been tenacious in her dedication to this issue, having crafted this bill 5 years ago and being unrelenting in moving it forward and now more than ever we realize how important it is. But I am also pleased that you have invited J. Craig Venter from Celera to be here also who is a friend of mine and has his company in my District.

As you may recall, last summer in a special ceremony at the White House, the completion of the so-called “rough draft” of the human genome was announced. This was a significant milestone and has been compared to the incredible discoveries of Galileo.

The Human Genome Project, with its goal of producing detailed maps of the 23 pairs of human chromosomes and sequencing the DNA that make up the human genome, has identified genes responsible for diseases such as glaucoma, colon cancer, and cystic fibrosis.

With the identification of these genes, millions of Americans are renewed with hope for promising genetic therapies to cure their disease, or that of a loved one. We have witnessed in recent years the rapid pace of medical discoveries and growing optimism for a future with less human suffering.

However, in order to fulfill the promise that the mapping of the Human Genome holds, we do need to address the issue of genetic discrimination. For example, the presence of a cancer causing gene may indicate a predisposition, but it doesn’t guarantee that the person will contract the disease. How should an employer or insurer respond?

The ethical, social and legal implications of genetic advances have been the subject of intense scrutiny and concern. As scientific knowledge about genetics advanced, many researchers have expressed concerns about how this information will be used. While genetic information and genetic technology hold great promise for improving human health, they can also be misused.

Genetic information can be used as the basis for insidious discrimination. The misuse of genetic information can be a serious problem in terms of people’s access to employment and health insurance and the continued ability to undertake important genetic research. I believe, as do many others, that the misuse of genetic information has the potential to impede medical research. We know for a fact, it does.

Privacy and discrimination are two critical issues regarding genetics. The privacy interests of an individual and his or her genetic information is important and fundamental to all Americans and the protection of privacy can make discriminatory actions less likely. However, the approach would be to prohibit this potential misuse of the information by prohibiting discrimination.

These concerns have encompassed fears of discrimination in many aspects of life, including employment and health and life insurance. A study on discrimination found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military and schools were reported to have engaged in genetic discrimination against asymptomatic individuals. The discriminatory practices alleged included treating a genetic diagnosis as a preexisting condition for insurance purposes, refusal by an adoption agency to allow a woman at risk for Huntington’s Disease to adopt based on the woman’s genetic risk and termination from employment after disclosure of a risk of Huntington’s Disease. Similarly, another study reported that 22 percent of the respondents indicated that they or a family member were refused health insurance as a result of a genetic condition.

Mr. Chairman and members of the subcommittee, I've had the honor for the past 15 years to represent Montgomery County, Maryland. We call it the Human Genome Alley. My District is home to the National Institutes of Health and hundreds of biotechnical companies such as Celera. As a member of the House Science Committee, I chaired the Subcommittee on Technology for 6 years. Mr. Gordon was my ranking member for a number of those years and we held hearings on the Human Genome Project. The pace of discovery was rapid. The project is moving forward, but I've always had that concern about the possible misuse of genetic information and my colleague, Congresswoman Slaughter has moved ahead on that.

I've come to the conclusion that we need legislation that will, first of all, cover all genetic information, including family history, that predicts future health risks in healthy individuals, that it should prohibit both health insurers and employers from collecting predictive genetic information and from using it to discriminate in the health care system and the work place, that it should provide individuals who experienced genetic discrimination the right to seek redress through legal action with access to meaningful remedies and that it should ensure that those entities holding genetic information about individuals will not disclose it to third parties without the permission of the individual.

In closing, Mr. Chairman, and members of the subcommittee, I just want to bring to the attention of the committee something that you already know. It's what President Bush said about genetic discrimination in his radio address of June 23. "Genetic discrimination is unfair to workers and their families. It is unjustified—among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. 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." It couldn't have been better said.

Again, I want to express my appreciation to the committee, to you, Mr. Chairman, for establishing this hearing and for allowing myself and Congresswoman Slaughter to testify. I do realize that this is, in part, because I am the Republican sponsor for the Genetic Nondiscrimination Health Insurance And Employment Act, H.R. 602. It is a solid, bipartisan bill. I want to commend Congresswoman Slaughter again and hope that this wonderful subcommittee under your leadership, Mr. Chairman, will move such legislation ahead. Thank you.

[The prepared statement of Hon. Constance A. Morella follows:]

PREPARED STATEMENT OF HON. CONSTANCE A. MORELLA, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman, Members of the Committee, I am delighted to be here today and joined by my good friends Congresswoman Louise Slaughter and Dr. Craig Venter. I appreciate the opportunity to testify on The Potential for Discrimination in Health Insurance Based on Predictive Genetic Tests.

As you may recall, last summer in a special ceremony at the White House, the completion of the "rough draft" of the human genome was announced. This was a significant milestone and has been compared to the incredible discoveries of Galileo.

The Human Genome Project, with its goal of producing detailed maps of the 23 pairs of human chromosomes and sequencing the DNA that make up the human



genome, has identified genes responsible for diseases such as glaucoma, colon cancer, and cystic fibrosis.

With the identification of these genes, million of Americans are renewed with hope for promising genetic therapies to cure their disease, or that of a love one. We have witness in recent years the rapid pace of medical discoveries and growing optimism for a future with less human suffering.

However, to fulfill the promise the mapping of the Human Genome holds, we do need to address the issue of genetic discrimination. For example the presence of a cancer causing gene may indicate a predisposition but does not guarantee that the person will contract the disease: How should an employer or insurer respond?

The ethical, social and legal implications of genetic advances have been the subject of intense scrutiny and concern. As scientific knowledge about genetics advanced, many researchers have expressed concerns about how this information will be used. While genetic information and genetic technology holds great promise for improving human health, it can also be misused.

Genetic information can be used as the basis for insidious discrimination...the misuse of genetic information can be a serious problem, in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research. I believe, as do many others that the misuse of genetic information has the potential to impede medical research.

Privacy and discrimination are two critical issues regarding genetics. The privacy interests of an individual and his or her genetic information is important and fundamental to all Americans, and the protection of privacy can make discriminatory actions less likely. However, the approach would be to prohibit this potential misuse of the information by prohibiting discrimination.

These concerns have encompassed fears of discrimination in many aspects of life, including employment, and health and life insurance. A study on discrimination found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military and schools, were reported to have engaged in genetic discrimination against asymptomatic individuals. The discriminatory practices alleged included treating a genetic diagnosis as a preexisting condition for insurance purposes, refusal by an adoption agency to allow a woman at risk for Huntington's disease to adopt based on the woman's genetic risk, and termination from employment after disclosure of a risk of Huntington's disease. Similarly, another study reported that twenty-two percent of the respondents indicated that they or a family member were refused health insurance as a result of a genetic condition.

Mr. Chairman I have had the honor for the past 14 years to represent Montgomery County in Maryland, Genome Alley. My district is home to the National Institutes of Health and hundreds of biotechnology companies such as Celera. As a member of the House Science Committee, I Chaired the Subcommittee on Technology for 6 years. We held hearings on the Human Genome Project, the pace of discovery was rapid, the Project is moving forward., but I was always concerned with the possible misuse of genetic information.

I have come to the conclusion that we need legislation that will:

- cover all genetic information—including family history—that predicts future health risks in healthy individuals.
- 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.
- provide individuals who experience genetic discrimination the right to seek redress through legal action, with access to meaningful remedies.
- ensure that those entities holding genetic information about individuals will not disclose it to third parties without the permission of the individual.

Mr. Chairman, in closing I would like to bring to the attention of the Committee what President Bush said about genetic discrimination in his radio address on June 23.

“Genetic discrimination is unfair to workers and their families. It is unjustified—among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. 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.”

Again I would like to express my appreciation to the Committee to be able to testify today. I do realized this is in part because I am the lead Republican sponsor for the Genetic Nondiscrimination in Health Insurance and Employment Act, H.R. 602, a solid bipartisan bill. I hope as part of this oversight hearing that the many good merits of this bill will be recognized.

Thank you.

Mr. STEARNS. I thank the gentlelady.

We have someone, Ms. Eshoo from California, who was not here for the opening statements, but I'd like to give her an opportunity to have one.

Ms. ESHOO. Thank you, Mr. Chairman, I appreciate it. First, the warmest of welcome to my two, our two fabulous colleagues. I think they are part of the permanent women's hall of fame in the Congress for your work and I'm proud to support the bill.

To Representative Slaughter, this has been a 5-year effort, my colleagues, and she has been absolutely, totally, unswervingly on this for 5 years and we're going to pay attention to it. We have to.

And to Congresswoman Morella, of course you bring your credibility on a whole host of issues as the Republican sponsor of this.

I'd like to ask, Mr. Chairman, that the Washington Post article of Saturday, July 7, 2001 be made part of the record. It's "Keeping Genes Private." I think it's a very important piece that should be part of our record. And I also want to especially welcome Dr. Venter, The New York Times Y2K Man of the Year. Dr. Venter has distinguished himself in so many ways.

I'd also like to say something else in addition to what I'll submit for the record and that is when we had our bipartisan retreat earlier this year, and as one of the co-chairs of the effort, we turned to some of the leaders in our Nation to speak to us on three key top issues facing the American people. And one of them was this very area. Dr. Francis Collins was at the dinner that evening and as I sat next to him and he spoke of the overwhelming need for the Congress to address this, not a future Congress, we should stop this 5-year roll that we're on and not go into the sixth and seventh year and make it a decade where we're trying to catch up with the science that's already there for us to take advantage of. At any rate, I said to Francis Collins, come with me because at the table next to us was seated the Speaker and the Minority Leader and I said you have to be very succinct, you have to say in 1½ or 2 minutes to each one of them what you just told me. If there's anything to come out of this bipartisan conference, it should be the commitment of the 107th Congress to get this bill done. And both the Speaker shook his head. He asked very good questions of Francis Collins as did the Minority Leader. So we have the makings, the ingredients, Mr. Chairman, that right from this subcommittee where we set the original table for this legislation, we should distinguish ourselves on a bipartisan basis to move this bill. The American people will be forever grateful. Our great grandparents and great, great grandparents and great great grandparents should not become the sin of the present generation. Whatever we are predisposed to or of should remain in the realm of scientists, medical scientists, biotechnology professionals to help bring about how we address those thing, but it should not be held against us in the work place or any other place. So I want to thank these two great women for their faith in this issue and they are dogged and we should match it with what we can do here. Let's get this thing done.

So thank you, great members. The American people owe a great deal of gratitude to you. I couldn't mean it more. I respect you. I

admire you and thank you to the scientific community for the work that you've done in not only advancing America's best interests, but how proud we are of you that you're Americans and the best.

Thank you, Mr. Chairman. Let's do this.

Mr. STEARNS. Okay, and by unanimous consent, so ordered, to put in the record.

Ms. ESHOO. Thank you.

[The article follows:]

[Saturday, July 7, 2001—The Washington Post]

#### KEEPING GENES PRIVATE

President Bush surprised longtime advocates of a law against "genetic discrimination"—the use of genetic tests to deny people access to jobs or health insurance—by joining their cause last week. The president addressed the need for protection from abuses of this information, saying it amounts to "medical speculation" because a genetic predisposition to a condition does not mean it will develop: "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."

If this reasoning sounds familiar, it's because Mr. Bush's predecessor made the same arguments, issuing an executive order that barred the use of predictive genetic information in employment decisions throughout the federal workforce. That good policy remains in force, but it needs to be expanded to non-federal employees, something only Congress can do. The Republican House leadership, though, has declined for nearly five years to hold hearings on any of several genetic privacy bills, including one, written by Rep. Louise Slaughter (D-N.Y.), which has the high-profile endorsement of scientists Francis Collins and J. Craig Venter, the decipherers of the human genome.

The Slaughter bill would bar employment discrimination based on gene tests and forbid insurance companies from using genetic information to deny coverage or adjust premiums. More important, no one could be forced to take a genetic test for either employment or insurance purposes—abuses that already are starting to be seen. It's true that insurers already set premiums based partly on guesses about future, not present, health; but genetic information at this stage adds little to such guesswork except an air of certainty that remains spurious. Some insurers are reported to have denied coverage merely because someone took a genetic test, the sort of overreaction that drives people away from taking the tests at all.

The president has not said exactly what he wants to see in a bill. But a law he signed in Texas overlaps significantly with what privacy advocates say they want, diverging mostly in how narrowly "genetic information" is defined. There's room here for a bipartisan bill that would extend significant protection to millions of people. Will House leadership unblock the topic?

Mr. STEARNS. Just briefly, I'd like to—I don't have so much questions for the two of my colleagues, but I would like to make a note that Ms. Eshoo has talked about that nothing has been done in this area and I would remind members that the Health Insurance Portability and Accessibility Act, HIPAA of 1996 added provisions specifically prohibiting discrimination based on genetic information for private group health plans and insurers offering coverage in connection with private group health plans.

This particular act was in the 104th Congress, so it already prohibits discrimination based on certain health information, including genetic information in the private group health market. In fact, in the first paragraph of this code it says "a group health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan may not establish rules for eligibility including continued eligibility of any individual to enroll under the terms of the plan based on any of the following health status related factors in relation to the individual or a dependent of the individual." And right out off the bat is genetic information.

So I call my colleagues' attention to the provisions in HIPAA of 1996 that say that a lot of the things you were talking about have been put in place with policy. Now the problem was the Department of Health, we tried to get a representative here to see how this policy is working and we were not able to do so for a number of reasons, but we intend to pursue this because this goes to the heart of the question. We have passed legislation. We have said that individuals and group individuals cannot be dismissed based upon genetics and in fact, they can't even be, their premiums cannot be adjusted because of genetic information that is revealed.

So we have that in place. Is it working? If it's not working, then obviously Congress needs to do something, but with that in mind I would like to say to both my colleagues that in looking at your legislation I think we have to see what is working first and continue to take the provisions of your legislation and move forward.

Now in my committee we can deal with the health insurance, but of course, on the employment side which I believe you have employment discrimination would go on John Boehner's chairmanship on his committee. So I'm hoping that you'll work with us on the discrimination on the health and perhaps you would work with Chairman Boehner on the aspect dealing with employment.

But I guess my only question to you folks are have you seen specific examples, not necessarily statistical and not something from 1997 or 1998, but has there been a proliferation of genetic discrimination out there enough for us to do an omnibus bill and if so, then why isn't the HIPAA Act of 1996 working and I'd be glad to—

Ms. SLAUGHTER. I'd like to respond to that, if I may. HIPAA in my estimation was somewhat misleading because it talked about the portability of insurance which was the main theme there. But it didn't mean that if you went from one job to another you took your insurance with you. It meant that if you were eligible at the job you had, and if your next employer offered insurance, which was not guaranteed, and if you could afford it, then you were eligible to have it. But it also said that you have to exhaust your COBRA coverage before you can get it and you had to have had 18 months of prior coverage. And people who didn't have any coverage prior are not covered at all. So they're still out there being discriminated against and as far as do we know that discrimination is taking place, yes, we do.

I'm sure you're aware of the Burlington Northern-Santa Fe case that just recently—in the news.

Mr. STEARNS. I've read that case.

Ms. SLAUGHTER. We've had numbers of cases.

Mr. STEARNS. But wouldn't you agree that they have due course process through the HIPAA Act? Just the paragraph I read—

Ms. SLAUGHTER. I wouldn't, no.

Mr. STEARNS. So you're saying that you don't think—

Ms. SLAUGHTER. I don't think that covers it at all. I don't think the genetic provision in there is nearly good enough and I really believe the fact that most people—which I thought was really the serious error on this bill—believed that if they were insured at one time they were going to be insured the rest of their lives. It's not the case. If you left your job, you left your insurance there, and if you went to another job and if they offered it, which was not cer-

tain, if they offered it, and second, if you could afford it, then you could be eligible because you had exhausted COBRA and you had been insured for 18 months.

Ms. MORELLA. I'd like to reiterate what you said, actually, because we looked into this. The law still only guarantees coverage if the individual can afford the plan being offered, which in some cases it can be astronomically marked up with that concept in mind.

Ms. SLAUGHTER. Because of genetics.

Ms. MORELLA. Yes. And if that person has already exhausted COBRA coverage and if the individual has had, as has been mentioned, 18 months of prior coverage, so people who had no coverage previously, had insurance through the individual market would be basically unprotected and there's no promise or provisions in HIPAA preventing insurance companies from requesting or requiring that an individual give up genetic information or protecting the privacy of genetic information.

Mr. STEARNS. I'm not an expert on this.

Ms. SLAUGHTER. There are a lot of loopholes.

Mr. STEARNS. And I'm just saying—

Ms. SLAUGHTER. I'm not either, but I mean on the surface, it looked great.

Mr. STEARNS. It says here group health plan and a group insurance issuer offering these plans, you can't change the premiums, based upon genetic information. You cannot dismiss anybody because of their genetic information and it's against the law. So I'm reading right from the statute, paragraph 1182(b)(1). So I'm saying that on the health side now that the law is in place and what we need to understand is it working. If it's not working, why not?

But I bring those to your attention because as you know both of us have been here a long time. We pass bills every year and we don't know how they're working and I think one of the things we have to do is find out the bills that we've passed, if they're working first, before we put new ones and that's, I was hoping in this hearing that would do this and I assure my colleagues that when I get these questions to the Department of Health and Labor, I'm going to provide them to you too.

Ms. MORELLA. Good, because this is the information that we were, we have been given.

Mr. STEARNS. I understand. Mr. Towns?

Mr. TOWNS. Thank you very much, Mr. Chairman. Mr. Chairman, let me request that all statements be made a part of the record.

Mr. STEARNS. By unanimous consent, so ordered.

Mr. TOWNS. Thank you. Let me first commend both of you on the outstanding work that you have done. But I do have a couple of questions. Why would you not divide it up in terms of health insurance and employment? The more committees that you have to refer a bill the more constraint it will have. Why wouldn't you break it up and leave health and insurance one place and of course, the education and work force in terms of the employment part in another?

Ms. SLAUGHTER. Well, we thought that both were equally important and that you couldn't do one without the other and really give full protection to people.

Also, there is one little item there that the Senate bill which is co-sponsored in chief by Mr. Daschle is the same bill that we have and has numerous co-sponsors and we understand that will be coming forward this year. So it took years of writing and perfecting this bill to get it where we thought we could really give the right protection to Americans.

Look, I'm a former scientist. The last thing in the world I would ever do is anything that would chill research. I see this whole new way of providing health care. As Connie said, since Galileo, at least since the germ theory of disease, we have not had anything as revolutionary as this.

The human suffering that can be alleviated with this research is overwhelming. The least we can do is not stop it in its tracks by having people so afraid, as they are now, that they will not be part of clinical trials. And the public's perception of it is that they are in for some trouble and let me give you one statistic here if I may. In June 2000 a Harris Poll said that 88 percent of Americans believe that people shouldn't pay higher or lower premiums on their predictive discrimination information. Ninety-four percent surveyed said insurance companies shouldn't have access to it. And a study conducted—this is one that I think is important—a study conducted by Northwestern National Life found that by the year 2000, which was last year, 15 percent of employers planned to get the genetic status of prospective employees and their dependents before making employment offers.

Mr. TOWNS. Right.

Ms. SLAUGHTER. So we saw them as equally important.

Ms. MORELLA. I don't see how you can separate the health discrimination from the employment when you think about the particular cases and how it overlaps. Dr. Francis Collins who is in charge of that Human Genome Project at NIH did appear at a news conference on this issue and he attested to the fact that clinical trials have been in trouble because of this concept of the shroud of discrimination.

Mr. TOWNS. Right. I don't want you to think for a moment that I'm saying they're both not important. I think the only thing I'm saying is that sometimes when you craft it in a way that you keep it from other areas, it has a tendency to move a lot faster. That's all that I was saying. I think that both of them are extremely important and no question about it. And I support that.

I guess the other thing though that I would sort of have, in terms of when it comes to penalties or damages awarded, I think that in your bill it goes to the Treasury. Why not to the individual?

Ms. SLAUGHTER. We thought that was the better thing to do. Actually, the individual has a right of recourse on there and I think that the Labor Department would be in charge of the arbitration to see where discrimination has taken place, but I don't know that it goes to the Treasury. I don't have any sense that it went to the Treasury. I think it went to the individual for damages.

Mr. TOWNS. No. My understanding is that it's the same as the Daschle bill.

Ms. SLAUGHTER. It is the same as the Daschle.

Mr. TOWNS. Then it goes to the Treasury? That's what I was wondering.

Ms. SLAUGHTER. Okay, civil penalties as Cindy points out go to the Treasury. Individual penalties go to the individuals if they are awarded.

Mr. TOWNS. Okay, I will do everything I can to try and help into moving this legislation. You can be assured of that.

Ms. SLAUGHTER. Thank you.

Mr. TOWNS. These are just questions that I have that—

Ms. SLAUGHTER. Right. We wanted to make sure that there was a penalty involved because we know without one, it's just useless.

Mr. TOWNS. Right.

Ms. SLAUGHTER. We worked to refine that several times and I worked with Senator Daschle's office on having the same bill that we could have before the House and Senate.

Mr. TOWNS. Right. Thank you. I understand that part because we can avoid a conference if we get it through.

Ms. SLAUGHTER. We sure could.

Mr. TOWNS. Thank you very much.

Ms. SLAUGHTER. If I could just get it on suspension, it would go through like a hot knife through butter.

Mr. TOWNS. Thank you very much.

Ms. SLAUGHTER. You're welcome.

Mr. TOWNS. Thank both of you.

Mr. STEARNS. Ms. Capps.

Ms. CAPPS. Thank you, and again, it's a true pleasure to be here and have this discussion going on today. I was very eager to be an original co-sponsor of this legislation precisely for the kind of discussion that's coming off today. We need to educate our colleagues, first, about the limitations of the HIPAA plan and its frailty. I understand it's being reviewed even now by the Secretary of HHS and the dramatic discoveries that have occurred with the genome project underscore the imperative nature of the legislation like this and perhaps just because it's also new it won't be the last piece, but surely, surely we can allow it to go unmarked up. It's got to come to the floor. This is an historic day I think today. I believe we should just push it through. We should keep it in concert with the Senate version and then begin to give, to empower our constituents and to empower patients.

I want to engage you in a discussion, a little bit, in the area of research because I think there is a fear by some research institutions that privacy sanctions that patients can hold on to will maybe on that side block research, so if you could comment a little bit on that we could add that to the mix of things because we need to have everybody on board with this. We need to have insurers aware that they're not saving money by withholding employment this way because as you pointed out, there is no one who doesn't have weak genes.

Ms. SLAUGHTER. Including the president of the insurance company.

Ms. CAPPS. Exactly. It's a matter of knowledge and being able to—we're actually going in the direction that is going to equip better, people better, to become better part of the work force, to be bet-

ter employees because they'll have more knowledge and be able to do the planning and the proactive work and it will lead us in that direction, but to the area of medical research.

Ms. SLAUGHTER. Medical researchers like to go through records, obviously, to find things that they want to research or information that they need. We don't want to stop that. It is our firm belief that they do not need to know, as they look through that record, who you are, where you live and where you work and who insures you.

Ms. CAPPS. So can we make assurances to—

Ms. SLAUGHTER. That's what the citizenry is worried about, that that's the kind of information that will get out. That's what we want to protect, their privacy, so that their name is not attached to that record so that they could lose their job or have other repercussions.

I mean I'm sure that a lot of people have been dismissed, not even understanding the reason why. But we have had some tragic cases of people who have gotten wonderful reports at work, progressing right along, highly thought of, who suddenly found that they had a disposition to a disease and they were suddenly fired. And that's not uncommon. I'm afraid it's getting even more common. And we do have the power here in Congress to stop that and I think we owe it to people to do it.

Ms. CAPPS. And I think it goes without saying that we have two women, members of—colleagues who are women that this is not—that men don't face these same limitations, but many of the issues that are being discussed in terms of characteristics that might be discriminated against happen to be those that women carry and that we need to do this for all the population, but sometimes it has to do with offspring and the role that women bear in caring for children and those that depend on them.

Ms. MORELLA. I've often said that if you knew that your grandmother, you had your grandmother's blue eye genes, do you want to know that you also have her cancer gene and that your employer knows and your neighbor knows and your health care provider knows and that's your concern—

Ms. SLAUGHTER. And your mother-in-law.

Mr. TOWNS. Will the gentlelady yield?

Ms. CAPPS. I will be happy to.

Mr. TOWNS. We're for this because, of course, you live longer than we do. We're for it.

Ms. SLAUGHTER. This could even the score. We might make that better for you.

Ms. CAPPS. I yield back.

Mr. STEARNS. I thank you and I thank our distinguished colleagues very much for taking your time and now we'll have the second panel. Ms. Mary Davidson, Executive Director of Genetic Alliance, Inc.; Dr. Donald Young, Interim President, Health Insurance Association of America; Dr. J. Craig Venter, Celera Genomics on behalf of Biotechnology Industry Organization; and Dr. Karen Rothenberg, Dean, Marjorie Cook Professor of Law, University of Maryland School of Law.

Let me welcome each of you to our second panel and we'll probably move from right to left.



Ms. Mary Davidson, if you are—at your convenience, we'll look forward to hearing your opening statement and welcome. Thank you very much for taking your time to be here to testify.

**STATEMENTS OF MARY E. DAVIDSON, EXECUTIVE DIRECTOR, GENETIC ALLIANCE, INC.; DONALD A. YOUNG, INTERIM PRESIDENT, HEALTH INSURANCE ASSOCIATION OF AMERICA; J. CRAIG VENTER, PRESIDENT AND CSO, CELERA GENOMICS; AND KAREN H. ROTHENBERG, DEAN, MARJORIE COOK PROFESSOR OF LAW, UNIVERSITY OF MARYLAND SCHOOL OF LAW**

Ms. DAVIDSON. Thank you very much. Good afternoon. My name is Mary Davidson and I'm Executive Director of the Genetic Alliance and I want to thank you for the invitation to present today on a topic that is very and near and dear to the hearts of everyone in my organization and I think to tremendous numbers of American public out there. And I'm here today to really talk about the urgent need for comprehensive genetic nondiscrimination legislation in health insurance as well as in employment.

Mr. Chairman, I request that my longer written testimony be added to the—

Mr. STEARNS. By unanimous consent. So ordered.

Ms. DAVIDSON. Thank you. I have two major points. New genetic discoveries offer an amazing potential for healthier lives, but Americans are afraid to use these tests and technologies because of their concerns about genetic discrimination. Congress has the authority and I hope the compassion and the will to create comprehensive legal protections that will give us the confidence we need to continue participating in research and to obtain testing and treatments for ourselves and for our families.

I'm here today representing consumers, individuals like you, me and our families and also on behalf of the Genetic Alliance, the largest international coalition of more than 350 genetic disease organizations and their millions of members.

Genetics is about all of us. Genetic diseases affect us all from cancer to sickle cell disease to heart disease to diabetes to Alzheimer's to the rare diseases. No one is untouched. This is the central message of the Human Genome Project.

However, the same genetics that connects us as one human family can also be misused by insurance companies and employers to deprive us of health care and jobs. We need a real safety net, not the haphazard, protective patchwork currently provided by HIPAA, the ADA and various State and Federal laws and regulations.

Let's put a personal face on this problem. Gail is a doctor with a family history of breast and ovarian cancer and she knew that she should have BRCA1 and 2 testing. These are predictive tests that indicate risk of breast and ovarian cancer in women of her background. Very genetic discrimination. She not only concealed her history from her doctor, but she took the tests under an assumed name and in the subsequent weeks a routine gynecological exam picked up a possible abnormality. Unaware of Gail, a doctor, Gail's family history, her doctor let it go, but had her doctor known about her history, a very different course of action would have taken place. Unlike many, this story has a happy ending. Gail took

charge of her medical care. She requested a follow-up study. Her genetic tests came back negative and everything turned out okay. Her story, however, is a wake up call for what might have happened.

It's hard to believe that here in the most advanced Nation on earth, even a doctor is taking a genetic test under an assumed name for fear of losing access to health care.

I'm also here today to represent those out there who don't yet know that all of us some day will have a genetic, a previous position, condition or disease some time over our lifetime because as others have said, it will soon be possible to identify the 40 or more mutations that scientists estimate that we all carry and this will lead to predictions for many more health problems and solutions and we will all be at greater risk for genetic discrimination under the current circumstances.

The Genetic Alliance maintains that predictive tests are not relevant to health insurance decision. First, we may never manifest the disease at all. Second, test results do not translate into health care dollar liability or work productivity scales on an individual basis. And in some cases like hemochromatosis, testing can even lead to treatments for an otherwise chronic, costly and even fatal condition. And finally, predictive information will soon become as universal as our imperfect genes, placing us all at risk for diseases as well as genetic discrimination.

The Genetic Alliance warns that the use of predictive tests in health insurance determination poses new and costly burdens to society. Individuals and families, as you have already heard, would be impacted in the most profound ways. Employees whose test results or medical treatments will increase group insurance premiums for their employers, in particular, small business employers, are less likely to be hired, promoted or retained and this is already happening. I think many of us already know the case of Terri Sergeant who was fired by her employer after 7 years, after the employer learned about her test results and the medical treatment that she would need to stay healthy and productive.

Research is already suffering because people are reluctant to sign up. We risk the creation of an uninsurable and unemployable genetic underclass at enormous public and moral and economic costs if individuals are excluded from health care and jobs on the basis of genetic makeup.

We recommend the following principles. One, we all possess imperfect genetic inheritances that will become equally transparent with tomorrow's technologies.

Two, health insurance and employment in this country are intrinsically linked and inseparable and legislation must protect both.

Three, we need strong protections of all information, medical and genetic.

Four, risk-based health insurance may not work in this new genomics age the way it's currently structured. The science is literally galloping ahead of our ability to understand the full meaning of this new information.

Five, without Federal protections, genetic discrimination has the potential to pose unfathomable social harms.

Just to close very quickly, in funding the Human Genome Project, Congress showed tremendous foresight. It now requires an equal measure of vision and courage to pass legislation that will allow people to benefit from the tests and technologies that are really the first fruits of that history endeavor.

You have before you H.R. 602 which we endorse as a major step forward, but we still more comprehensive legislation and we ask you, please, to take action in this area as soon as possible.

Thank you.

[The prepared statement of Mary E. Davidson follows:]

PREPARED STATEMENT OF MARY E. DAVIDSON, EXECUTIVE DIRECTOR, GENETIC ALLIANCE

Good afternoon. My name is Mary Davidson, Executive Director of the Genetic Alliance. The Genetic Alliance requests your assistance in enacting legislation that prohibits genetic discrimination.

*Policy Development Outstripped by Escalating Genetic Discoveries*

Thanks to Congressional vision and your support for the Human Genome Project, these are remarkable and historic times. Earlier this year, the 3 billion letters of the DNA instruction book were published. And now scientists all over the world are using this genetic map to unravel the mysteries of heart disease, cancer, diabetes, mental illness, asthma, multiple sclerosis—since all diseases, with perhaps the exception of trauma, have a hereditary component. Already there are individuals and families whose lives have been touched in profound ways by biomedical technologies never before imagined.

From the perspective of science, medicine and policy, we are confronting a “brave new world” with entirely new challenges. Genetic research is moving at breakneck speed, taxing our ability to craft timely public policies that safeguard the promise of genetics to improve health. Surveys and polls tell us that the public is worried about the balance between benefit and harm posed by these new technologies. Based on these concerns, growing numbers of individuals and families have decided not to pursue genetic tests or services—the hard-earned products of genetics research.

*In the Midst of the Genetics Revolution, Healthcare Consumers Have No Safety Net*

I am here today to bring attention to these two central facts.

- *In the midst of the Genetics Revolution, people who could benefit from the new technologies are afraid to use them.* They are afraid to have genetic tests or participate in research because they fear losing their insurance and their jobs if their insurance companies and their employers learn the results of those tests.
- *Congress could put these fears to rest once and for all by enacting Federal legislation that makes it illegal for insurance companies to deny coverage and for employers to refuse to hire, promote or fire people based on genetic test results.* This would encourage people to take advantage of the rapid advances in genetic testing and other new technologies that can improve public health, alleviate human suffering and extend productivity.

These protections will ensure true nondiscrimination and facilitate the future sustainability of the biotechnology and healthcare industries.<sup>1</sup>

<sup>1</sup>Insurance Industry Sustainability: Research focusing not only on survival rates and the probability of future disease, but also on future health care needs and the availability, effectiveness, and potential cost savings of early intervention, is of great potential benefit. Not only would patients better understand their prognoses, but physicians could improve treatment modalities, and plan sponsors and insurers could better evaluate the appropriateness of covering specific tests, their likely impact on insurance costs, and their potential implications for risk classification in the individual market.

Some of the key questions that remain are:

- How accurately will genetic tests predict future health care needs?
- Will meaningful interventions be available for genetic disease?
- Will genetically based treatments become available?
- What impact will genetic technology have on overall medical care expenditures?

Policy-makers need a clear understanding of these issues so that proposals regulating the use of genetic testing information can find the best balance between the concerns of the public, the predictive ability of genetic test results, and the affordability of health insurance.

*Speaking on Behalf of the Genetic Alliance, Families and the Public*

I speak today on behalf of the Genetic Alliance—the largest genetics coalition worldwide, representing more than 300 lay advocacy, research, health professional, public and private sector organizations and their millions of members. The mission of the Genetic Alliance is to promote healthier lives for everyone impacted by genetics. Since 1986, we have worked to speed the translation of scientific and technological advances into quality healthcare and consumer-informed public policies. The Genetic Alliance Helpline and Discrimination Survey put us into daily contact with people with stories to tell about the benefits as well as liabilities of genetic testing. Annually, we're in touch with over 100,000 people about genetics and related issues.

I also speak today on behalf of known and unknown victims of genetic discrimination—individuals like Terri Seargent and Dave Escher, who have already felt the sting of genetic discrimination, and others out there who are struggling for their rights and still others who have chosen not to forsake their privacy and anonymity. Their struggles reaffirm the principle that “Genetic information is inherently personal and must be treated as confidential and proprietary.” (Alliance Guiding Principle)

*We're All At Risk. “Genetics Is About ALL of US”*

Finally, I am here today representing those who don't yet understand that “Genetics is about ALL of us.” Because every man, woman and child has some genetic predisposition, condition or disease resulting from inherited or acquired genetic changes.

Tests are currently available for approximately 700 genes, most of which are associated with relatively rare disorders. However, that number will soon grow to the thousands with an understanding of the genetics of more common health problems. For the most part, these will be predictive tests, opening windows to early detection and prevention of diseases currently thought to be untreatable. It will be possible to identify the 40 disease-causing mutations that scientists estimate that we all carry. And we will be able to search for diagnoses and predictors for multiple diseases, disorders and conditions, on the surface of one tiny microchip, perhaps available at our local drugstore. For every person identified with a genetic disease, there are usually 4 to 7 non-symptomatic family members who would benefit from the knowledge gained from a genetic test. This will also create an explosion in the ability to identify risk factors and make predictions for a broad range of health problems—from rare conditions to common complex diseases. This is wonderful and will help so many of us live healthier and more productive lives.

With this explosion comes a sense of greater risk for disease. *Our real risk has not changed, but our awareness of risk has.* And we don't even understand the exact implications of these newly identified risks. It may take us 100 years to determine whether certain risk factors are meaningful or not and to what degree, taking mitigating and co-mingling factors of other genes and the environment into account. *It is now even more apparent that genetic conditions are universal and we are all increasingly at risk for genetic discrimination.*

*What Is Genetic Discrimination?*

Genetic discrimination is the inappropriate use, or misuse, of genetic information in making health insurance and employment decisions. Discrimination based on predictive information is just one of several categories of misuse of genetic information that people are reporting.

*What Is A Predictive Genetic Test?*

These are tests for conditions like breast and ovarian cancer, Alzheimer's and Parkinson's Disease, Alpha-One, colon cancer and others. Test results indicate the risk or probability or likelihood of a disease occurring over our lifetime. Positive test results simply mean that one's risk is higher than the average person. The condition may or may not happen at all.

*Does Genetic Discrimination Based on Predictive Genetic Tests Really Happen?*

Through our Genetics Helpline and Discrimination Survey, people have come to the Genetic Alliance with their stories about the unauthorized use of genetic information in employment and insurance coverage decisions. This should not come as a surprise. We live in a society with a long history of discrimination based on ethnicity, class, gender, physical and mental impairment and now genetics. And we already witnessed the tragic consequences of discrimination based on sickle cell disease test results in the 1970's.

*If Genetic Discrimination Is A Serious Problem, Why Aren't People Coming Forward?  
Why Aren't There Any Test Cases?*

First, people don't know what to make of genetics—much less genetic discrimination. Without a sound scientific and social compass, they are unable to assess the fairness of the situation in which they find themselves. Second, our legal rights are equally obscure. State and federal laws and regulations make up a complex patchwork of protections that vary by state, health plan and employment situation and create major obstacles to legal action. Third, there are cases out there that have not yet seen the light of day. When people lose their health insurance or employment, they hold tight to the last vestiges of privacy and anonymity at all costs and are reluctant to get burned twice. Fourth, we know that the door is wide open for discrimination and that this potential will certainly increase with all the new predictive tests on the horizon.

*Is the Public Concerned about Testing and Research?*

We know that people are deciding not to have predictive tests and not to participate in research based on fears that insurance companies and employers will use this information to cancel healthcare insurance and deny them jobs.<sup>2</sup>

*Let's Put a Personal Face on this Growing Problem.*

Gail, a physician, knew about BRCA1 and 2 testing—predictive tests that indicate a predisposition to breast and ovarian cancers in some women. Because of a strong family history of breast and ovarian cancer, she opted to take the genetic test under an assumed name. In course of a gynecological exam and while she awaited test results, a possible abnormality on an abdominal ultrasound was noticed and confirmed by a radiologist. Because Gail's risk factors were not recorded in her medical record, he let it go. Had he known her history, a very different course of action would have been taken.

Fortunately, this story has a happy, though sobering, ending. Because Gail is a physician, she understood the problem and took charge of her own medical care. She requested a follow-up study, her genetic test came back negative and everything turned out to be OK. However this story is wake-up call for what MIGHT have happened.

Without a safety net, there was no way for Gail to use critical information about her own health without fear of discrimination and losing her health insurance. *It is hard to believe that in one of the most advanced nations on earth, we are driven to undergo anonymous genetic testing for fear we will lose our insurance and access to healthcare. Gail felt that she had no safety net.*

*Why the Potential for Genetic Discrimination Based on Predictive Tests?*

The door to discrimination is wide open because most state laws do not prohibit the use of predictive test information in health insurance determinations. About half of the states do provide some form of nondiscrimination protection. However, *in most cases, state protections are inadequate and do not address predictive information specifically.* State laws are generally described as a colorful, complex and inconsistent patchwork of definitions, provisions and right to action and often do not address predictive information specifically.

Looking to existing Federal protections, HIPAA's protective jurisdiction is also variable and inadequate, depending on whether someone belongs to an individual or group health plan or his employer is self-insured. In the individual market, there are no protections whatsoever. The genetic condition can be excluded or the premium set as high as the market and consumer can bear. *Because there are no restrictions or ceilings to the premium, access can be effectively blocked by pricing someone out of the market.* In the small group market, the group member is protected to the degree that rate hikes—resulting from member medical treatments or increased risk—are spread across the group pool. The employer is responsible for how the increased tab for premium increases is covered or shared with employees.

<sup>2</sup>Genomics and Managed Care: Preparing for the Revolution By: Carl Peterson [Healthplan 41(5):14-20, 2000. © 2000 AAHP "Concern among consumers is high. In a mid-June Time/CNN poll of 1,200 U.S. adults, three-quarters of respondents feared having health insurers gain access to disease predisposition data. An even greater number (84 percent) were concerned about government access to personal genetic information."

Genomics Research: However, Knowledge and Understanding Remain Modest Release Harris Interactive Polling Date:6/19/01 1,000 Adults polled June 2001 When asked what their greatest fears are, the answers given most often are that genetic information may be misused (45%)

In genetic testing studies at the National Institutes of Health, 32 percent of eligible people who were offered a test for breast cancer declined to take it because of concerns about loss of privacy and potential for discrimination in health insurance. May 2001

In the small business situation, these HIPAA protections result in serious potential vulnerabilities, both for the employee and the business owner. Increased premiums may threaten the solvency of a small business and put owners on the alert for employees whose medical condition and treatments are causing group rate hikes. In a small work environment, health and personal issues are sometimes common knowledge and the identified employee known to all. As has been well documented in the recent EEOC case involving Terri Sergeant and her former small business employer, HIPAA regulations leave both the employee and small businesses vulnerable to the misuse of genetic information in making employment decisions.<sup>3</sup>

With regard to protection under the Americans with Disabilities Act (ADA), people with predictive genetic information will probably not fare too well, given the trend in the courts over recent years. When Congress passed the ADA in 1990, Congress intended that the law would cover individuals with a broad range of diseases, such as epilepsy, diabetes, breast cancer, heart conditions and mental illness. Indeed, some Members of Congress even explained that the ADA would protect people who experience discrimination on the basis of predictive genetic information, on the grounds that such individuals would be “regarded” as disabled and hence covered under the law.<sup>4</sup>

Unfortunately, soon after the ADA went into effect in 1992, and culminating in a trio of cases by the Supreme Court in 1999, the ADA’s scope of coverage has been significantly restricted. Thus, in many cases, individuals with conditions such as cancer, epilepsy, diabetes, heart and respiratory conditions, mental illness, and a range of other health conditions, who have alleged discrimination based on such conditions, have been turned away at the courtroom door on the grounds that they are not sufficiently “disabled” to receive legal protection under the ADA.<sup>5</sup> In essence, the courts have required that to be covered under the ADA, an individual must be so debilitated by his or her impairment that it is difficult for the person to function at all. Moreover, if such an individual can take medication or receive a device (such as a pacemaker) that will enable the person to function, he or she will not be considered “disabled” under the ADA. In addition, even if an employer refuses to hire an individual expressly because of a health condition, this will not be sufficient to claim that the employer “regarded” the individual as disabled unless the individual can also prove that the employer believes many other employers would act the same way. *The same reasoning that has eliminated legal protection under the ADA for individuals with a range of health conditions will likely be used to deny coverage under the ADA for individuals with predictive genetic information or family histories regarding such conditions.*

#### *Predictive Tests Are Not Relevant to Decisions about Health Insurance Coverage*

First of all, the person may not ever manifest the condition. One’s actual risk depends on interactions with other genes and with the environment. There is just so much that we don’t know at this time and may never know, since we’re talking about tremendous levels of complexity.

Second, we don’t yet really know the exact level of risk indicated by the test results. The meaning of test results will evolve over time with longitudinal research that follows participants over their lifetime, assessing the interplay with other genes and the environment and the actual expression or incidence of the condition. And while the current risk percentages reflect scientists’ best guesses, this is not good

<sup>3</sup> Congressional Research Service Report for Congress RL30006: Genetic Information: Legal Issues Relating to Discrimination and Privacy The Health Insurance Portability and Accountability Act of 1996 P.L. 104-191, the Health Insurance Portability and Accountability Act of 1996, has been hailed as taking “important steps toward banning genetic discrimination in health insurance” but has also been criticized as not going far enough. The Act prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. However, the Act would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic testing, does not require them to obtain authorization before disclosing genetic information, and does not prevent them from excluding all coverage for a particular condition or imposing lifetime caps on all benefits or on specific benefits. In addition, this Act does not address the issues of the use of genetic information in contexts other than health insurance such as employment.

<sup>4</sup> See, e.g., 136 Cong. Rec. H4627 (statement of Rep. Waxman).

<sup>5</sup> For a comprehensive discussion of how the ADA’s coverage has been significantly restricted, see Feldblum, Definition of Disability Under Federal Anti-Discrimination Law: What Happened? Why? And What Can We Do About It?, 21 Berkeley Journal of Labor and Employment Law 91 (2000)

enough if the results can be used to deny health coverage and employment and disrupt productive lives.

Third, test results do not translate directly into healthcare dollar costs for any one particular person. Everything in medicine today is measured in terms of evidence-based and outcomes research and cost benefit analysis. However, the use of predictive test results to make health insurance decisions doesn't fit this paradigm. Predictive tests are not linear, black and white measures of healthcare dollar liability for you or me; currently they may have some meaning for pools of people, but not individuals. The science is too new and the variability of expression for two identical genotypes too great. We cannot measure healthcare dollars or future productivity based on computations using genetic test results as the yardstick.

Fourth, it is impossible to lump all predictive tests in one category. Health dollars could even be saved through the development of preventative treatments that forestall the occurrence of an expensive chronic conditions. In the case of hemochromatosis, for example, early identification could lead to phlebotomy treatments that stop the development of an otherwise insidious, chronic, expensive and possibly fatal condition.

And finally, *we all have flawed genes. With so many predictive tests already on the radar screen, we will all be at risk for genetic discrimination.*

*The Use of Predictive Tests in Health Insurance Determinations Puts People at Increased Risk for New Social and Medical Harms and Poses New Societal Burdens.*

First of all, the use of predictive tests in health insurance determinations impacts individuals and their families in the most personal ways—loss of privacy, healthcare, and employment. That is why people are choosing not to have genetic tests that could, in some cases, save their lives. This was the case with Gail and with countless others who choose to safeguard access to healthcare for their families by deciding not to risk their employment which provides their health insurance. We know that this strategy, while logical, can put the individual at medical risk, the family at financial risk, and sometimes results in serious, even fatal, health consequences.

Second, employers may fear hiring or promoting or retaining someone whose test results or recommended treatment threatens to raise the group insurance rate. We have already seen this happen in the case of Terri Seargent who was essentially symptom-free—jogging several miles every day—but was fired from her job after her employer learned about her positive genetic test results and preventative medical treatment.

Third, falling public confidence impacts everyone. We're all waiting for the benefits of biomedical research. However, without nondiscrimination assurances, people will not participate in the very studies that could lead to more precise interpretations of "risk" measures, better understanding about interplay between gene and environment and other genes, and the development of preventative treatments—sometimes for their own condition.

Finally, the real measure of genetic discrimination is the potential for broad societal impact and burden. If we systematically exclude individuals and families from healthcare and jobs on the basis of genetic make-up, we are risking the creation of an uninsurable and unemployable genetic underclass at enormous public, moral and economic cost.

*Genetic Alliance Recommends These Core Principles To Guide Policy Decision-Making*

- We all possess imperfect genes that will become equally and increasingly transparent with tomorrow's technologies.
- Health insurance and employment in this country are intrinsically linked. Legislation must address genetic nondiscrimination protections in both health and employment. They are inseparable.
- It is important to take a broad view of the implications and impact of predictive genetic test results for individuals and families and for the small business employer.
- Without Federal legislation protections, genetic discrimination will affect increasing numbers of individuals and families and pose unfathomable social harms. The focus of civil rights advocacy in the 21st century will be genetic discrimination.
- Risk-based health insurance may not work in this new genomics age. How can we have a risk-based health insurance system when the meaning of the risks that are being identified through new genetic tests is unknown? The science is

literally galloping ahead of our ability to understand this new information. And this distorts the usefulness of information resulting from genetic tests.

*Genetic Alliance Advocates for Comprehensive Federal Nondiscrimination Legislation Looking to HR 602 as a Model for Legislation*

- Legislation must cover all genetic information—including family history, medical tests and healthcare service records—which can be used to predict future health risks in healthy individuals.
- Legislation must ensure that those entities holding genetic information about individuals will not disclose it to third parties without the written permission of the individual.
- Legislation must provide individuals who experience genetic discrimination the right to seek redress through courts of law, with access to meaningful remedies.
- 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.

*Opposition to Unwarranted Discrimination in Health Insurance and the Workplace*

Finally, I want to point out that this testimony has focused on the hardships faced by those who experience discrimination based on predictive genetic information or family histories. However, we urge you to consider the fact that if these individuals are eventually diagnosed with a medical condition at some future point (whether such health conditions are genetically caused or not), they should also not be subject to unwarranted discrimination in health insurance and the workplace. As noted above, the reason people with predictive genetic information cannot rely on the ADA is because their brothers and sisters with actual medical conditions cannot rely on the ADA either.

This is why we can not stop at legislation like HR 602 alone without clarifying the ADA and considering the need for additional protective legislation. When a healthy individual tests positive for a gene that could cause a condition like Alzheimer's or bipolar disease, it is not always clear if signs of that condition have occurred. To ensure that people will not be afraid to seek treatment and receive a diagnosis, we need to assure them that, if a condition does manifest, their access to healthcare and employment will be protected.

*Safeguarding the Potential of Genetics to Improve Health.*

Completion of the sequencing of the genome is a wonderful and inspiring scientific accomplishment, however it has also accelerated the need for universal protections of genetic information that help to describe future risks for health and disease. Assurances against the abuse of personal genetic information will safeguard our hopes for improving public health through new genetics knowledge and technologies.

Congress demonstrated extraordinary vision in funding the mapping of the human genome. It requires an equal measure of vision and courage to pass the legislation that makes it possible for people to benefit from the new tests and technologies and creates a safety net for healthcare consumers. Otherwise, the remarkable achievements of the Human Genome Project will be rendered meaningless.

In a country founded on precepts which offer protections against discrimination, on the basis of sex, race or religion, we certainly have room for perhaps the most basic factor of all—our genes, representative of both our shared inheritance and the essence of our diversity.

*The Genetic Alliance calls for the unequivocal prohibition of genetic discrimination in health insurance and employment, and all other aspects of life. Every American—regardless of genetic inheritance—is entitled to the protection that Congress alone can provide.*

Thank you very much for this opportunity to present testimony on this important topic.

Mr. STEARNS. Thank you.

Dr. Young for your opening statement.

**STATEMENT OF DONALD A. YOUNG**

Mr. YOUNG. I am Dr. Don Young, Interim President of the Health Insurance Association of America. I'm pleased to be here today to discuss concerns about the potential genetic discrimination in health insurance. HIA is well aware of the public apprehension about the use of genetic information in the insurance marketplace.



At the same time, there's a great deal of misinformation about this matter. Nine out of 10 Americans with private insurance coverage receive it through the employer-based group market in which no information on genetic testing or individual health status is used to determine eligibility for coverage or to set individual premium rates. Further, Federal law already provides significant protections to consumers. Under HIPAA, health insurers offering coverage in connection with group health plans cannot use genetic information or the results of a genetic test to refuse to cover employees or their family members, refuse to renew coverage, charge covered employees or their family members higher premiums, impose pre-existing condition waiting periods or cancel coverage. The remaining 10 percent of Americans purchase their private insurance through the individual market. Under HIPAA, insurance carriers offering coverage in the individual insurance market are also subject to substantial restrictions on the use of genetic information or the results of genetic testing.

In addition, the majority of States have passed laws to protect individuals who undergo genetic testing. Additional legislation is unnecessary given current insurer practices. Independent research confirms that health insurers are not either asking for or using genetic test results in their underwriting decisions, even in those States where no genetic testing legislation has been enacted.

Many of the so-called genetic nondiscrimination proposals contain definitions of genetic testing that are often unnecessarily broad. While they purport to apply to newer genetic technologies they frequently sweep in tests and information collection practices that have routinely been used by insurers for many years to ensure that premiums are fair to all purchasers. The result would be to prohibit generally accepted principles of the individual insurance market that have served consumers well for many decades. Although well intentioned, if enacted, these proposals would hurt the very people they are intended to help. For many people premiums would unfairly rise and as experience resulting from similar State laws as clearly demonstrated, many people would not purchase individual insurance leading to more uninsured Americans.

We're also concerned about proposals that would apply restrictions on the use of genetic information on insurance products not covered by HIPAA, such as disability, long term care and supplemental insurance. These products are very different than medical expense insurance. Individual applicants would have the opportunity to favor themselves at the expense of other policy holders by making purchase decisions based on risk characteristics that are known or suspected by them, but unknown to the insurer. Current Federal law including HIPAA privacy rules and the Gramm-Leach-Bliley Act also require health insurers to protect the confidentiality of personal health information including genetic information.

HIPAA's members are increasingly concerned about the multiplicity of Federal and State laws governing the privacy of personal health information. It is becoming increasingly costly to our customers to comply with all these differing and at times conflicting Federal and State requirements. Additional requirements specific to genetic information would further increase the cost of health insurance without adding to the substantial privacy protections now

in place. In addition, by requiring an artificial segregation of an individual's medical record, such requirements could lead to harmful medical errors and lost opportunities to provide preventive care and will establish a harmful precedent of allowing selective reporting by providers.

Given the emerging nature of the new technologies, the importance of the individual market to Americans who cannot get insurance through the work place, the already high costs of coverage and the demonstrated lack of any abuse by health insurers, it is vital that we avoid premature action that would undermine access to affordable health care coverage in the future.

It is also important that the public policy debate be carried on in a way that does not feed unjustified public fears about insurers' use of genetic information and thus discourage people who could benefit from these new tests from undergoing them.

I would be pleased to any questions you may have on this very important topic.

[The prepared statement of Donald A. Young follows:]

PREPARED STATEMENT OF DONALD A. YOUNG, INTERIM PRESIDENT, HEALTH INSURANCE ASSOCIATION OF AMERICA

*Introduction*

Chairman Stearns, distinguished members of the committee, I am Dr. Donald A. Young, Interim President of the Health Insurance Association of America (HIAA). I am very pleased to be here today to discuss concerns about the potential for genetic discrimination in health insurance. HIAA is the nation's most prominent trade association representing the private health care system. Its more than 300 members provide health, long-term care, dental, disability, and supplemental coverage to more than 123 million Americans. It is the nation's premier provider of self-study courses on health insurance and managed care.

HIAA is well aware of the fact that there is considerable public concern about the potential for genetic discrimination in the insurance marketplace. At the same time, we are convinced that there is a great deal of misinformation about this matter. In particular, we believe that calls for federal legislation to address this issue fail to appreciate the extensive array of federal and state laws already in place, and the potential negative consequences of additional federal requirements. In this regard, it appears that advocates for increased government regulation of the private health insurance market often overlook the need for the appropriate balance of risk and cost in a voluntary health insurance market. I would like to begin by summarizing current legal protections against genetic discrimination in the health insurance sector and the inappropriate disclosure of genetic information.

*Current Legal Protections Against Insurance Discrimination*

Current federal law already provides significant protections to consumers. Let us first look at group health insurance coverage. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), employer-sponsored group health plans and health insurance issuers offering coverage in connection with group health plans cannot:

- Refuse to cover employees or their family members based upon genetic information or the results of a genetic test;<sup>1</sup>
- Refuse to renew coverage based upon genetic information or the results of a genetic test;<sup>2</sup>
- Charge covered employees or their family members higher premiums based upon genetic information or the results of a genetic test;<sup>3</sup>
- Impose pre-existing condition waiting periods upon employees or their family members based upon genetic information or the results of a genetic test;<sup>4</sup> or

<sup>1</sup>HIPAA Title I, Subtitle A, Part 1, Section 101 (ERISA Section 702(a)(1)).

<sup>2</sup>HIPAA Title I, Subtitle A, Part 1, Section 102 (ERISA 702(a)(1)) (for individual enrollees); HIPAA Title I, Subtitle A, Part 1, Section 102 (PHSA Section 2712) (for groups).

<sup>3</sup>HIPAA Title I, Subtitle A, Part 1, Section 101 (ERISA Section 702(b)(1)).

<sup>4</sup>HIPAA Title I, Subtitle A, Part 1, Section 101 (ERISA Section 701(b)(1)(B)).

- Cancel coverage based on genetic information or the results of genetic testing.<sup>5</sup> In highlighting these existing protections, it should be noted that about nine out of 10 Americans with private health insurance coverage receive it through some type of employer-sponsored arrangement.<sup>6</sup>

HIPAA also speaks to the issue of genetic discrimination in the case of individual health insurance coverage. Under HIPAA, insurance carriers offering coverage in the individual insurance market cannot:

- Deny coverage to individuals previously covered by employer-sponsored group health plans;<sup>7</sup>
- Impose preexisting condition waiting periods on such individuals based on genetic information or the results of genetic testing;<sup>8</sup> or
- Cancel coverage to people covered under individual health insurance policies based on genetic information or the results of genetic testing.<sup>9</sup>

These protections are substantial. Nevertheless, Congress was extremely careful with the restrictions it placed on the individual market for two reasons:

1. The individual insurance market is about one-tenth the size of the group market,<sup>10</sup> and families generally purchase individual coverage voluntarily with their own after-tax dollars. Congress was concerned that imposing significant new restrictions on insurers offering policies in the individual market would reduce, rather than expand, coverage in this relatively small and fragile market. The unique and fragile nature of this market has been well documented,<sup>11</sup> as have been the unanticipated consequences of prior efforts to “reform” this market.<sup>12</sup>
1. While federal laws predating HIPAA set certain requirements for health benefit coverage in the employer-based market, it traditionally has been the role of the states to regulate insurance in the non-group market.

In addition to the federal protections outlined above, the majority of states have passed laws to protect individuals who undergo genetic testing. As a result, insurers that offer policies in the individual market are generally limited in their ability to use genetic information in risk classification and risk selection.

#### *Current Health Insurer Practices*

A recent Public Policy Monograph issued by the American Academy of Actuaries notes that private health insurers do not require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions.<sup>13</sup> Similarly, a survey conducted in 1998 found that no HIAA member company requires applicants to undergo genetic testing in determining whether to offer or renew major medical coverage, and that our members had no plans to do so. In addition, the survey found that member companies do not exclude coverage for certain benefits or establish differentials in premium rates or cost-sharing for coverage on the basis of genetic information. Independent research confirms this—health insurers are not “either asking for or using presymptomatic genetic test results in their

<sup>5</sup>HIPAA Title I, Subtitle A, Part 1, Section 101 (ERISA Section 702(a)(1)).

<sup>6</sup>William S. Custer and Pat Ketsche, *The Changing Sources of Health Insurance*, HIAA, December 2000.

<sup>7</sup>HIPAA Title I, Subtitle B, Section 111 (PHSA Section 2741).

<sup>8</sup>HIPAA Title I, Subtitle B, Section 111 (PHSA Section 2741(a)(1)(B)).

<sup>9</sup>HIPAA Title I, Subtitle B, Section 111 (PHSA Section 2742).

<sup>10</sup>*The Changing Sources of Health Insurance*.

<sup>11</sup>American Academy of Actuaries, *Risk Classification in Individually Purchased Voluntary Health Insurance*, February 1999; U.S. General Accounting Office, *Health Insurance for Children: Private Individual Coverage Available, but Choices Can Be Limited and Costs Vary*, GAO/HEHS-98-201, August 1998; U.S. General Accounting Office, *Private Health Insurance: Millions Relying on Individual Market Face Costs and Coverage Trade-Offs*, GAO/HEHS-97-8, November 1996; American Academy of Actuaries, *Providing Universal Access in a Voluntary Private-Sector Market*, February 1996.

<sup>12</sup>Stephen Zuckerman and Shruti Rajan, “An Alternative Approach to Measuring the Effects of Insurance Market Reforms,” *Inquiry*, Spring 1999, page 44; William S. Custer, *Health Insurance Coverage and the Uninsured*, HIAA, January 1999; Frank A. Sloan and Christopher J. Conover, “Effects of State Reform on Health Insurance Coverage of Adults,” *Inquiry*, Fall 1998, page 280; Melinda L. Schriver and Grace-Marie Arnett, *Uninsured Rates Risk Dramatically in States with Strictest Health Insurance Regulations*, The Heritage Foundation, August 20, 1998; Jill A. Marsteller et al., *Variations in the Uninsured: State and County Level Analyses*, The Urban Institute, June 11, 1998.

<sup>13</sup>American Academy of Actuaries, *Genetic Information and Medical Expense Insurance*, June 2000.

underwriting decisions,” even in states where no genetic testing legislation has been enacted.<sup>14</sup>

#### *Current Privacy Protections*

Some pending genetic nondiscrimination proposals include provisions that would impose special confidentiality requirements regarding genetic discrimination. Once again, however, current federal law already speaks to the confidentiality of personal health information, including genetic information. For example, the preamble to the HIPAA privacy rule, published December 28, 2000, specifically notes that genetic information is included in the term “protected health information” and subject to sweeping new requirements governing the use and disclosure of health information by health plans; health care clearinghouses; and doctors, hospitals, and other health care providers. In addition, the Gramm-Leach-Bliley Act (GLBA), enacted November 12, 1999, requires health insurers and other covered financial institutions to protect the privacy of nonpublic personal information. In the case of insurers, the statute delegates the enforcement of these requirements to state insurance authorities, and states are now considering legislative and/or regulatory responses to GLBA. Furthermore, the National Association of Insurance Commissioners has adopted a model regulation to guide state policy makers in complying with GLBA’s privacy requirements.

I should note that HIAA’s members are increasingly concerned about the multiplicity of federal and state laws governing the privacy of personal health information. It is becoming increasingly costly for our members to sort through and comply with all of these vary requirements, especially when an insurer does business in a large number of states. This cost ultimately is borne by consumers in the form of higher premiums. It is for this reason that HIAA has called for federal preemption in the case of privacy requirements. For purposes of this hearing, suffice it to say that HIAA strongly opposes additional federal requirements that would uniquely govern the privacy of genetic information. This would only further complicate an already difficult situation. HIAA member companies believe it is important to treat all medical information—including genetic information—equally to assure strong and uniform confidentiality protections. In this regard, I think it is important to note that health insurers have an excellent track record of processing literally hundreds of thousands of information transactions daily, with virtually no violations of patient confidentiality.

One final point is in order. It is increasingly critical that providers in an integrated system share health information and communicate about such information in order to treat patients effectively and avoid harmful medical errors. Genetic information, including the results of predictive genetic tests, is an integral and inextricable part of the medical record of each patient. This information can and should be used by providers and health plans to ensure that prevention—often the most effective type of care—is provided. Early detection, identification, and treatment are often critical to success. In addition, as the technology of genetic testing becomes more sophisticated, health professionals will need to know the results of genetic tests to avoid harmful medical errors. To require genetic information to be segregated and kept “private” in an effort to avoid the perceived risk of discrimination would thus be contrary to the best interests of the patient.

#### HIAA CONCERNS

Given current federal and state restrictions on the use of genetic information in the health insurance sector, HIAA opposes additional legislation in this area. We have a number of concerns regarding such proposals.

#### *Individual Health Insurance*

HIAA is concerned about genetic nondiscrimination proposals that are at odds with the fundamental principles of the individual health insurance market and go beyond the restrictions imposed by HIPAA. In the individual health insurance market, each person must decide whether or not to participate based on the perceived value of coverage, i.e., the relationship of the premium they must pay to their perception of their risk of loss. In this market, risk selection (whether or not to accept an application for insurance and issue a policy) and risk classification (ensuring that the policy provisions and premiums charged are consistent with the level of risk involved)—together known as underwriting—are important for consumers and health insurers alike. For consumers, underwriting ensures fairness among purchasers of

<sup>14</sup>Mark A. Hall and Stephen S. Rich, “Laws Restricting Health Insurers’ Use of Genetic Information: Impact on Genetic Discrimination,” *American Journal of Human Genetics*, January 2000, p. 293.

insurance since their premium reflects the likelihood of needing health care services. In addition, underwriting protects the solvency of the insurance program, making it possible for the insurer to fulfill the promise to pay claims as they become due. No less important, underwriting helps stabilize and hold down premiums by avoiding the effects of adverse selection. For insurers, underwriting protects the insurer's financial health by allowing premiums to be set at a level commensurate with the expected level of claim cost. This financial health is necessary to ensure ongoing operations and the continuing ability to develop and market new products. In short, both consumers and insurers benefit when the insurance system can offer financially sound, competitively priced products to a broad range of consumers.<sup>15</sup>

In enacting HIPAA, Congress expressly, and wisely, refused to impose federal price controls, or to extend additional guarantee issue requirements, to individual insurance products. Such controls and requirements would impede the ability of insurers to engage in legitimate risk assessment activities that are necessary to set premiums commensurate with actual risk. Laws prohibiting insurers from accurately weighing the risks of offering coverage at a certain price in the individual insurance market—for example, by proscribing the use of information on health status—would compromise the ability of insurers to remain financially viable and to meet their obligations to existing policyholders. States that have enacted guaranteed issue and some form of community rating in their individual health insurance markets have experienced significant increases in the price of indemnity insurance options, and are seeing a drop in the number of people covered in the individual market. For example, following the adoption of community rating and guaranteed issue in New Jersey in 1993, average rates for the most popular individual indemnity health plans rose to more than double the national average of rates for similar coverage. During 1996 alone, the number of people with individual coverage in the state declined 17.2 percent, and the number of families covered declined 37 percent.

To sum up, in a voluntary, individual insurance market, restrictions on the ability of insurers to evaluate applicants and charge appropriate premiums will simply result in higher average premiums and fewer consumers purchasing coverage. At a time when more than 42 million Americans lack health insurance, this would certainly not be a very prudent course of action.

#### *HIPAA "Excepted Benefits"*

HIPAA also is concerned about proposals that would apply restrictions on the use of genetic information on insurance products not covered by HIPAA, such as disability, long-term care, and supplemental insurance. Disability income, long-term care, supplemental insurance and other HIPAA excepted benefits are commonly purchased by individuals—much more frequently than is the case for comprehensive medical expense insurance. In general, these insurance products are also held for longer periods of time, and are more sensitive to biased or adverse selection based on long-term health prospects. Consequently, restrictions on risk selection and risk classification would be much more detrimental for these types of coverage.<sup>16</sup>

While there appears to be considerable concern about the potential for insurers to discriminate against consumers based on genetic information, there appears to be a conspiracy of silence regarding the potential for individual consumers to use genetic information in a way that disadvantages insurers and their other policyholders. The potential for such "biased selection" or "adverse selection" is especially a risk in the case of insurance products that are voluntarily purchased by individuals, who can choose the timing of their insurance purchase, as well as the extent and duration of coverage. In these cases, individual applicants have the opportunity to make decisions that favor themselves at the expense of the insurance program by making purchase decisions based on risk characteristics that are known or suspected by them but unknown to the insurer. If the insurer is unaware of a risk characteristic, it cannot be reflected in the premium charged, and applicants with that characteristic will on average contribute less to the insurance pool than they receive from it. Without the ability to properly assess the risk, insurers would see more and more high cost individuals purchase coverage at an average premium level. As this occurred, premiums would rise for all policyholders, some of which might find that the value received for their premiums no longer justified continued coverage.

Of course, biased or adverse selection is not necessarily an intentional deception on the part of the consumer. It can also occur if the insurer fails to inquire about a health condition, or is prohibited from doing so. In any case, this situation would be akin to one in which you had a test that would indicate how likely it is that a

<sup>15</sup> *Risk Classification in Individually Purchased Voluntary Health Insurance.*

<sup>16</sup> *American Academy of Actuaries, Risk Classification in Voluntary Individual Disability Income and Long-Term Care Insurance, Winter 2001.*

fire would occur in your home and used that information to time the purchase of fire insurance.

#### *Definitional Problems*

Another problem arises with proposed definitions of such terms as “genetic test” and “genetic information,” which are often unnecessarily broad. While these definitions purport to apply to newer genetic technologies, they frequently sweep in tests and information collection practices that have been routinely used by insurers for many years, especially in the individual health insurance market. For example, some proposals define the term “genetic information” in a way that includes information gathered when asking about an individual’s family history. Similarly, some proposals include a definition of “genetic test” that could be construed to include routine tests such a blood pressure reading, even including “the analysis of...phenotypes,” which would include almost any observable characteristic of an individual. In fact, *Dorland’s Illustrated Medical Dictionary* defines phenotype to include “the entire physical, biochemical, and physiological makeup of an individual as determined both genetically and environmentally.”

Furthermore, while some proposals provide a “safe harbor” for routine laboratory tests, the language used may not be adequate. This safe harbor language is often circular, only protecting those tests to the extent they do not constitute “genetic tests” as defined by the bill. It is unclear how a safe harbor excludes anything from the scope of “genetic tests” if it does not apply to genetic tests. In any event, the current definitions are unnecessarily vague and seem likely to encourage litigation.

The American Academy of Actuaries monograph cited earlier summarizes the problematic nature of overly broad definitions as follows:

If a ban on information obtained from “genetic tests” defines such tests to include medical history, routine physical examinations, and other routine laboratory testing, it would severely hamper individual medical expense insurance underwriting. Since some individuals’ health risks would be unknown, the pool of insurance purchasers might soon include a disproportionate number of people with higher-than-average anticipated medical expenses. This biased selection would cause premium rates to rise, making individual medical expense insurance even less affordable than it is now.<sup>17</sup>

#### *Evolving Technology*

It is important to remember that genetic technology is still evolving and we do not know what its ultimate capacity or impact on society will be. Given the demonstrated lack of use of genetic information and existing legal protections, HIAA believes it would be premature at this time to enact additional legislation, locking-in certain legislative parameters in the face of the rapid evolution of these genetic technologies.

#### *Conclusion*

In conclusion, HIAA opposes federal legislation intended to prohibit discrimination based on the use of genetic testing or genetic information because:

- It is overly broad, covering information on current health status that insurers have used for many years. Even where a particular proposal includes a “safe harbor” for routine laboratory tests, the language used is circular in nature or unduly vague.
- It is unnecessary given current federal and state laws, including those governing the confidentiality of personal health information.
- It is unnecessary given current insurer practices.
- It could restrict the ability of insurers to set appropriate premiums and would be unfair to many consumers, who would be forced to give up their individually purchased insurance.
- It could inappropriately restrict an insurer’s ability to assess and select risk for individual insurance products or HIPAA “excepted benefits.”
- It would be risky to lock-in certain legislative parameters given the rapidly evolving field of genetic testing.

The public sensitivity about the use of genetic information is understandable, given that genetic technology is new and unfamiliar. However, insurer use of genetic information is subject to the same restrictions as is any other type of personal health information. Independent research confirms that individuals are not being denied access to coverage based on genetic test results. Given the emerging nature of the new technologies, the fragility of the individual market, the high cost of coverage, and the demonstrated lack of any abuse by health insurers, it is vital that

<sup>17</sup> *Genetic Information and Medical Expense Insurance.*

we avoid premature action that would undermine access to affordable health care coverage in the future. It is also important that the public policy debate be carried on in a way that does not feed unjustified public fears about insurers' use of genetic information and thus discourage people who could benefit from these new tests from undergoing them.

Mr. STEARNS. Thank you.  
Dr. Venter, for your opening statement.

#### STATEMENT OF J. CRAIG VENTER

Mr. VENTER. Good afternoon. My name is Craig Venter. I'm the President and Chief Scientific Officer of Celera Genomics, headquartered just up the road in Rockville, Maryland. Chairman Stearns, members of the subcommittee, thank you for this opportunity to testify on behalf of myself and the biotechnology organization of which Celera is a member. If you have no objections, I would like to insert my written comments into the record and make a brief opening comment.

Mr. STEARNS. By unanimous consent, so ordered.

Mr. VENTER. Thank you. I'd also like to start by thanking Congresswomen Slaughter and Morella for their tremendous leadership on this issue and speaking out so well on it.

I'm a scientist who has been at the forefront of the genomic revolution and like many of my colleagues in the private industry and public genome project, I'm concerned about the misuse of genetic information. With the dawn of a new era of medicine and science, now that we have sequenced and assembled the nearly 3 billion letters of the genetic code that make up the human genome, I believe this basic knowledge that we're providing to the world will have a profound impact on the human condition and treatments for disease and our view of ourselves in the biological continuum. However, one of my continuing concerns is about having this information, is that someone would want to use this new knowledge as a basis of discrimination.

Much has happened in the 3 years of Celera's history when the PE Corporation, now Applera and I launched Celera in June 1998 our goal was to sequence the human genome and build an information company to provide researchers in industry and academia with new information for genomic discoveries. Today, we're using that information in a massive effort to understand the products of our genes, proteins that go into build a new kind of pharmaceutical company that will incorporate all this new information and technologies for faster, cheaper therapeutic discoveries. We've seen major changes in the last 3 years.

Just 1 year ago, Francis Collins and I—Francis is the head of the public funded genome effort at NIH—stood before the world at the White House with President Clinton to announce our respective progress on the human genome. We both individually selected to talk about genetic discrimination as the biggest concern for the future of research in this field. In fact, a CNN-Time poll conducted that morning reported that 46 percent of Americans believe that the impact of the human genome project would be negative.

Most are pleased that President Bush has recently voiced his concerns about genetic discrimination and to do something about it.

Clearly one of the ways we can combat this fear is through higher science literacy, but education, while important, can only do so

much. I believe that new laws are critical in order to maximize the medical benefits from new genomic discoveries, in part, from misunderstandings about what these discoveries can lead to.

Sequencing the human genome showed us that there were fewer genes than earlier estimates. The fewer genes means more complexity, not less. This shows that we're clearly much more than the sum totals of our genes, just as society is greater than the sum total of each of us. Biology is not based on the idea that there is one gene, one protein, one disease. Our physiology is based on the complex, seemingly infinite interactions amongst all our genes and the environment, just as our civilization is based on the interactions amongst all of us.

This information should help dispel the notion of genetic determinism. There's a tendency to think of DNA as the perfect predictor of an individual's future health. Many years of work in genomics has taught me one must discuss the genomic context of the environment. I do not believe the human condition can be seen as merely a manifestation of individuals DNA sequenced information and that computation that goes with such sequenced information. Individuals need to be assured that arbitrary subjective conclusions will not be based on the analysis of their DNA.

It's ironic that approximately 1 week prior to Celera's publication of the human genome, an event that should have given all of us great joy and optimism for the future, an agency of the U.S. Government, EEOC had to go to court for the first time to block a private employer from compelling its employees to submit to genetic testing for work-related injuries, in this case, carpal tunnel syndrome, on the threat of dismissal for noncompliance.

It was clear that this was just bad science as well as bad policy showing that discrimination is not based on fact. It's usually based on ignorance.

We sometimes hear the following question, why should in the insurance company not be allowed to use tests or information from an individual's genome, DNA, in making its decisions? Don't they already do things with high blood pressure or smoking? In response, it's important to note that DNA is not like other tests. An individual's DNA is, in a sense, the ultimate personal identifier and from a technical point of view there's virtually no limit to what one's examining DNA can lead to once a sample goes to a testing lab.

Some individuals clearly fear that use of such tests will affect their livelihoods and standing in the community. Moreover, other family members, because they share a certain amount of DNA, may be affected by the decision without their consent or even knowledge.

I'm excited by the promise that the genomic era in science and medicine brings. We are working at Celera to turn this information into new diagnostics and new therapeutics so people can benefit directly from this information. We all need to work together to ensure that fear does not inhibit people from taking advantage of these new discoveries. I, along with BIO, urge Congress to draft carefully worded legislation that would prohibit discrimination in health insurance based genetic discrimination and testing.

Thank you.



[The prepared statement of J. Craig Venter follows:]

PREPARED STATEMENT OF J. CRAIG VENTER, PRESIDENT, CELERA GENOMICS, ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to testify today about this critically important topic.

Good afternoon. My name is Craig Venter. I am President and Chief Scientific Officer of Celera Genomics, headquartered in Rockville, MD. In August of 1998, the PE Corporation, now known as the Applera Corporation, and I launched Celera Genomics. Our initial goal was to sequence the human genome and to build an information business to provide researchers in industry and academia with an integrated information and discovery system for genomic information. Today we are using that information and an industrial scale effort to understand the products of our genes—proteins—to build a new kind of therapeutic company that will integrate genomic, proteomic and genetic variation information together with new technologies for faster and cheaper disease-related discoveries. I am testifying on behalf of myself and the Biotechnology Industry Organization (BIO). BIO represents almost 1000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations.

We have all been dazzled over the past few years at the pace of scientific discovery. At Celera we are very proud of our role in sequencing the human genome and the mouse genome. That was just the beginning. Using this information, even more will become known about how our bodies develop, function, and change.

This information will be enormously powerful. Armed with these data, scientists will be able to identify the biological basis of disease.

Understanding the function of genes in key cellular processes has become an important basis for creating new drugs and therapies. This information could, for example, tell us how and why certain diseases afflict certain people. It could also tell us why certain medications are safe and effective for some people, but cause adverse reactions or are ineffective for other people with the same diagnosis. This information could lead to the development of cures and treatments for diseases that affect tens of millions of Americans and their families.

The results of this research are likely to be a more “personalized” medical paradigm than exists today. Drugs and therapies are likely to be more targeted as we learn more about the impact and role of genes. While medicine will become more individualized based in part on the genetic code it will be based on statistical information in contrast to deterministic information. I believe, as does BIO, that this new paradigm is likely to be extremely effective in improving the lives of millions of Americans and their families.

We are on the verge of a true revolution in medicine. But there is a chance it will not happen as we hope. It will not be a failure of the science. There is increasing evidence people fear their genetic information will be used to deny them health insurance or a job. This fear is keeping them from seeking medical help. If people believe that a new system of individualized medicine will lead to denial of health insurance or other benefits, they will not take advantage of what the new system could offer. The revolution at hand may not be realized because people are afraid to take part in it.

BIO has long supported federal legislation aimed at alleviating these fears. At Celera we started the push for legislation on genetic discrimination long before we announced the first assembly of the human genome. People must have confidence they can take advantage of technological developments without fear that the information gained from this technology will be used against them.

Mr. Chairman, we want to encourage people to get information about their health and take necessary steps to improve their lives.

BIO, as I have in the past, supports national legislation to ensure that individuals’ personal medical information, including genetic information, is safeguarded against misuse. For example, BIO strongly supported barring discrimination on the part of group health plans based on “genetic information” during congressional consideration of the Health Insurance Portability and Accountability Act (HIPAA). We must assure the public that the great promise of biotechnology research will not be tarnished by abuses of this technology. I am proud of the fact that BIO worked effectively in 1996 to secure enactment of an amendment to HIPAA that provided these important protections against discrimination by health insurance companies based on “genetic information” about the individual. But HIPAA does not cover the individual insurance market. On behalf of BIO and myself I believe these protections should be expanded to this market.

BIO has also consistently supported federal legislation—and now regulations—that create federal standards to protect the confidentiality of, and safeguard against misuse of, all personal medical information including genetic information.

With the implementation of the HIPAA medical privacy regulations, individuals have much greater assurance that genetic information created and used in the health care context will not be disclosed to employers, insurance companies or other third parties without the specific authorization of the individual. Protecting individuals from the misuse of this information—genetic discrimination—is complimentary to HIPAA regulations that make the information harder to get.

As with most complex issues, however, as Congress debates legislation to protect individuals from genetic discrimination, there are other critical issues to consider. Please keep the following issues in mind:

- In legislating to prevent genetic discrimination be careful not to restrict biomedical research
- Leave the debate about price controls for another day
- Use updated definitions

#### *Promote Critical Biomedical Research*

As noted, BIO believes that individuals' personal medical information must be safeguarded against misuse. While we must protect patients' rights, however, it is critical to allow important medical research to go forward. We are already beginning to see the results of biomedical research. As of today, 117 biotech products have helped a quarter billion people worldwide. Another 350 biotech medicines targeting more than 250 diseases are in late stage development. These products target unmet medical needs.

Mr. Chairman, BIO and I believe protecting patients and promoting critical research are mutually attainable goals. Federal policy must ensure the achievement of both.

Health researchers often use and share health care information, including genetic information. Therefore, federal policy must not impose barriers to use of these data. Consequently, any federal proposal to prohibit genetic discrimination must be carefully written to ensure that research uses of information are not inhibited.

#### *Price Controls*

Just as BIO cannot support price controls on products of its members, it has concerns about federal legislation that would regulate the price of insurance products.

#### *Update Definitions of Key Terms*

Genetics is a new and dynamic field. By legislating on genetic discrimination, Congress is charting new territory. Whatever action Congress takes will have large ramifications. Future regulations and legislation—at the federal and state levels—are likely to be based on this proposal.

As Congress addresses this complex issue, therefore, it is essential that it draft legislation carefully define terms such as “genetic information”.

#### *Conclusion*

In sum, genetic information is extremely valuable. Armed with the information these technologies will provide, patients could make lifestyle and medical care choices that would have otherwise been unavailable. In addition, the knowledge gained by research used to develop new tests and the information gleaned from those tests will lead to new drugs and therapeutics to treat disease and maintain health.

However, public anxiety could limit its potential. BIO and I have long supported federal legislation that will ensure that a person's individual medical information, including genetic information, cannot be misused. Consequently, we support carefully drafted legislation prohibiting discrimination in health insurance based on genetic information.

Thank you for the opportunity to testify today. I'll be happy to answer any questions you may have.

Mr. STEARNS. I thank you.

Dean Rothenberg, welcome, for your opening statement.

#### **STATEMENT OF KAREN H. ROTHENBERG**

Ms. ROTHENBERG. Thank you. Good afternoon, Chairman Stearns and members of the subcommittee. It's a pleasure to be here today and it's always a challenge to go last because if you have to listen

very carefully to what everybody said before you and second to the questions and then decide that everything you wrote may not be exactly on point or has already been said. So if I can also ask permission I will put my statement into the record.

Mr. STEARNS. By unanimous consent, so ordered.

Ms. ROTHENBERG. Thank you. And I thought maybe talk a little bit more informally trying to address, if I might, some of the points that are already made and some of the questions that have already been asked.

I've been asked, I think, specifically, to focus on the legal and public policy implications. Prior to being Dean and I'm hoping to continue in this area for many years I was running the law and health care program and the University of Maryland and for the last 7 years we have been doing research and scholarship on the ethical, legal and social implications in genetics, in particular, studying various State and Federal approaches to issues of genetic privacy and discrimination, both in the insurance and employment context. And there's two good studies over here or maybe they left, the Congresswomen and a number of Members of Congress who have expressed a lot of interest in this area, including the chairman who has really been a leader as well.

Mr. STEARNS. Thank you.

Ms. ROTHENBERG. Based on these experiences then I thought what I could do is to put into context first where we are at the State level, so we know what we need to do, if anything, at the Federal level, then give you a little bit of perspective of where we are with HIPAA from my perspective, and where we are with the HHS privacy rules so then we can figure out what, if anything, we still need to do and then make some suggestions of where I think we may at a Federal level need to go as a matter of public policy.

But before going to the details, the very first question is do we need to worry specifically about genetics? And I think there's been a lot of debate about is it any different than medical information, what is it that's special. I think that we could argue with the scientists about whether it's any different or not than other sorts of medical information, but as a social issue in our society it is different. And that's because we've had a history of discrimination based on genetics that goes back many, many years. And many of us are still alive to remember it. Some of us didn't remember it, but it's still in our memory. And two, the other thing about genetic information as stated earlier, it isn't just information about us. It's information about our blood relatives, some of them that we might not even have relationships with, but it goes into the future and continues into the future.

So with those two points I think it is special enough for a number of States now up to 40 to have actually passed anti-discrimination and privacy integrated approaches to dealing with problems in both the health insurance and the employment arena. And of the 18 members on your subcommittee, I'm proud to say that in 15 of those States including the chairman's, there is legislation on the books and they vary to some degree, but every one of those State laws has an integrated approach that includes provisions of both anti-discrimination and privacy protections.

Now before we're patting ourselves on the back that, in fact, we've solved it in up to 40 States and we only need to worry about the 10 that haven't yet passed a law, it's important to know that up to one-third of the population in those States would not be protected by those laws because they are covered through ERISA self-funded plans and the ERISA pre-emption does not allow State laws to kick in. So we have a patchwork of approaches State by State and we have an ERISA pre-emption which prevents a number of people in each of those States from being protected. Again, it's very deliberate that they, in fact, have both anti-discrimination and privacy protections integrated.

Now let's look at HIPAA just for a minute. HIPAA was a great and significant step forward as a matter of public policy. Now why was that? One, it was significant because it's the first piece of legislation that used the term genetic information. I mean it recognized that there is something about genetic information that might need some special protection. And as stated by the chairman, it specifically dealt with discrimination and eligibility and in premiums and continuing eligibility. I think Dr. Young mentioned that as well. But something else was really significant as a matter of social policy that you did with HIPAA and that is that you said that genetic information will not be deemed a pre-existing condition in the absence of the diagnosis of the condition. Now what does that mean and why is that so important? What that says is if you have a positive test, a predictive test for let's say BRCA1, for example, you're not sick. You don't have a pre-existing condition. So if 10 months later, you develop breast cancer they can't hold coverage from you because you had a pre-existing condition. So as a matter of social policy, the chairman and his colleagues said you should not be discriminated against or not be deemed sick and I think that is very significant as a matter of public policy. The problem is that HIPAA in itself still has a lot of gaps. I think my time is running out, but I can conclude at this point and we can come back to that.

Mr. STEARNS. We can come back to that.

Ms. ROTHENBERG. Thank you.

[The prepared statement of Karen H. Rothenberg follows:]

PREPARED STATEMENT OF KAREN H. ROTHENBERG, DEAN AND MARJORIE COOK  
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Good afternoon, Chairman Stearns and members of the Subcommittee. It is a pleasure to be here today. I am Karen H. Rothenberg, the Dean, Marjorie Cook Professor of Law, and the founding Director of the Law & Health Care Program at the University of Maryland School of Law. I have been working for the last seven years on issues directly related to genetic testing and its legal, ethical and social implications, and I have written numerous publications on genetics and related legal issues in health care. Over the last few years I also contributed to a series of studies on legislative approaches to genetic information in both health insurance and workplace contexts which were published in Science.

My remarks will focus on the legal, ethical, and public policy implications related to the potential for discrimination in health insurance based on predictive genetic testing. Toward this goal, I will first examine whether genetic information is different than other types of medical information and whether it requires a special public policy approach. I will then examine what role legislative approaches may play in addressing the use, misuse, and privacy of genetic information, particularly in the health insurance context. I will conclude that effective genetic nondiscrimination legislation requires a comprehensive approach, including strong privacy protections and enforcement mechanisms, at the federal level.

Genetic information is personal, powerful, predictive, pedigree-sensitive, permanent, and prejudicial. As a result, it is information people commonly wish to keep private, although DNA databanks and computer technologies make protecting people's privacy increasingly difficult. Most individuals expect that all medical information should be protected. The potentially harmful risks associated with genetic information may demand that we pay special attention to its use, misuse and privacy.

While most Americans are optimistic about the use of genetic information to improve health, many are concerned that genetic information may be used by insurers and employers to deny, limit or cancel their health insurance. This concern is affecting the choices individuals make about their own health care and their decisions whether to participate in research. In a Time/CNN poll conducted in June, 2000, 75% of those polled indicated they would not want their health insurance company to have information about their genetic code.

Genetic information has implications not only for the individual, but also for his or her blood relatives, including parents, siblings, cousins and future offspring. Thus, the intergenerational impact of genetic information (and inheritability) makes the risk for misuse, including stigma and discrimination, significant and unique. Genetic information may be linked to certain ethnic and racial groups, many of whom have suffered from discrimination and eugenic policies that historically were "justified" by genetic findings. For example, restrictive immigration laws against Eastern Europeans in the 1920s, sterilization policies, Nazi atrocities, and insurance and employment discrimination against carriers of the sickle cell trait were justified by the power of genetic information. Even the discovery in the mid-90s of specific gene mutations that may be associated with higher rates of breast and ovarian cancer in the Ashkenazi Jewish community has raised concerns about how this information may be used to discriminate against them. The African American and Indian communities are also very concerned about behavioral genetic studies on violence and alcoholism.

An individual's genetic makeup is unique and cannot be altered. Even though a predictive test result is not a diagnosis, it is still powerful information and there is risk for misinterpretation by both providers and patients. People may believe that their fate is predetermined genetically and there is nothing they can do to change it.

The fear of genetic discrimination in the health insurance context is a reality. It is argued that individuals who might otherwise choose genetic testing will decline it based on their fear that they or their family members will not be able to obtain or maintain health insurance coverage. As a result, the future of research on the benefits and risks of testing for genetic conditions, including susceptibility to such common diseases as cancer and heart disease, may also be inhibited. Thus, now that the mapping of the human genome has been accomplished and as new genetic tests emerge, policy makers need to evaluate the development of legislative and regulatory strategies to address these concerns.

In the 1970s, a few states began to pass legislation that addressed genetics issues recognizing even then the potential for discrimination. North Carolina, for example, passed legislation prohibiting health insurers from refusing to issue insurance or charging higher premiums based on the sickle cell trait or hemoglobin C trait. By 1991, a new generation of state legislation began to evolve with the passage of a Wisconsin law prohibiting health insurers from:

- requiring or requesting an individual or a member of the individual's family to obtain a genetic test;
- requiring or requesting directly or indirectly into the results of a genetic test;
- conditioning the provision of insurance coverage or benefits on genetic testing; or
- considering genetic testing in the determination of rates.

This approach attempts to integrate protection against discrimination in insurance practices, coverage, benefits, and rates with some privacy protection for the individual and his/her family. Similar approaches have been incorporated to varying degrees in legislation passed in 39 other states. Conversely, a dozen states have no legislative protections in place regarding health insurance. In fact, of the 18 states represented by the members of this subcommittee, three states have no legislation that addresses genetic nondiscrimination in health insurance. As for the 38 states with legislation in this area, the states vary regarding the substance of the protections they afford. This creates a patchwork of protections within our nation.

The development of public policy to address genetic information and health insurance must be analyzed in the context of a complex and inadequate health insurance system, the uncertainty about the future scope and impact of genetic testing, and the political realities of a pluralistic society. The current patchwork of state legislative approaches does not provide a comprehensive solution to genetic discrimination and health insurance.

Just a few years ago, with the exception of a few states, these laws focused narrowly on genetic tests, rather than more broadly on genetic information generated by family history, physical examination, or the medical record. Now the trend is to include family history into the definition of genetic information. Meaningful protection against genetic discrimination requires that insurers be prohibited from using all information about genes, gene products, or inherited characteristics to deny or limit health insurance coverage.

Second, a large proportion of the population receives health benefits from self-funded plans not subject to state insurance laws. The federal ERISA preemption prevents a statewide approach to regulating the use of genetic information by all plans providing health benefits.

With these policy considerations in mind, as early as 1995 the following recommendations were developed by the National Action Plan on Breast Cancer (NAPBC) and the Working Group on Ethical, Legal and Social Implication of the Human Genome Project (ELSI) for both state and federal policy makers to protect against genetic discrimination:

1. Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment or contribution requirements.
2. Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information, or an individual's request for genetic services.
3. Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
4. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

The recommendations further provide that genetic information be defined as "information about genes, gene products, or inherited characteristics that may derive from the individual or a family member." Insurance provider is defined as "an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded." These recommendations remain valid today.

As you know, in the last few years, a number of members of the Senate and the House have taken a leadership role in introducing federal legislation that integrates these recommendations. Although none of these proposals have passed, they have influenced other health insurance legislation. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, specifically prohibits a group health insurance plan from using "genetic information" to establish rules for eligibility or continued eligibility. It also provides that genetic information shall not be treated as a preexisting condition "in the absence of the diagnosis of the condition related to such information." Thus, a healthy woman who tests positive for a BRCA1 mutation would not be deemed to have a pre-existing condition related to breast cancer and this genetic information could not be used in the determination of eligibility for a group insurance plan, including self-funded plans. This is a significant first step in the evolution of federal legislation, but it is only a first step, and gaps remain.

Of course, this incremental approach to health care reform does not provide the comprehensive protection outlined in the NAPBC/ELSI recommendations. It does not prohibit insurers from requiring or requesting genetic testing or requiring or requesting the results of genetic testing. Thus, the burden is on the individual to prove that the insurer did not use genetic information to deny coverage or affect the terms and conditions of insurance. Nor does it prevent a plan from excluding all coverage for a particular condition, or imposing lifetime caps on all benefits or on specific benefits. It appears that this form of discrimination against women with breast cancer and/or a genetic predisposition to breast cancer, for example, would be permitted as long as plan characteristics are not "directed at individual sick employees or dependents." Absent other contractual and legal protections, plans could exclude, for example, prophylactic surgery specifically. HIPAA provides even less protection for employees not in group plans and provides no coverage for the uninsured. Thus, even if the uninsured had access to genetic testing, the risk of future insurance discrimination would be a reality. In addition, the uninsured would not benefit from genetic information if they could not afford to pay for the related prevention and intervention strategies, including more frequent mammograms and surgical interventions.

State anti-discrimination statutes also integrate various levels of privacy protection. At the federal level, the recently published HHS Privacy Rule fails to provide the kind of protection that can be uniquely afforded by strong anti-discrimination

legislation. For example, whereas the Privacy Rule protects individuals from the unauthorized release of their health information, it does not prevent inquiries into their genetic makeup. This is a gap that must be filled. Meaningful privacy protections must prohibit insurance companies from requesting or requiring genetic information, and performing genetic tests.

Finally, federal legislation must include a strong enforcement provision, so that individuals who experience genetic discrimination or privacy violations not only will have the right to seek legal redress, but will have access to meaningful remedies.

Perhaps our greatest public policy challenge will be to determine when, if at all, it will be appropriate to make the transition from predictive testing for high-risk individuals and families within a research context to testing for the general population. Will the commercial market promote testing for the general population before we have been able to carry out the benefit/risk analysis even in the high-risk population? As the flow of genetic information increases, so too will the risk of its misuse. Should testing be restricted until we enact anti-discrimination and genetic privacy legislation nationwide? What implications will testing have on cancer surveillance and prevention strategies within our healthcare system? How will individuals be able to integrate predictive testing results with health behavior, lifestyle, and environmental factors that may significantly contribute to cancer morbidity and mortality? These questions have no simple answers.

Thus, given the varied state approaches that have developed in recent years, and the noteworthy but incomplete federal approaches, it is imperative that we develop comprehensive federal strategies to protect the public. For today, we face the onset of a revolution. Federal legislation stands to offer a pre-emptive strike in favor of genetic privacy and against genetic discrimination, potentially helping individuals to avoid doing battle alone in the health insurance arena.

Thank you.

Mr. STEARNS. I thank you.

When I come to my questions I'm going to start off with trying to understand what the genetic tests mean and then I would like to go to this HIPAA and talk about it. And then I'd like to go a little bit to the reality of how do insurance companies actually go to price this and talk some of that. Dr. Young, you can help me.

But Dr. Venter, I want to go to some things that I have off the internet that you have said publicly, so I'll just read a little bit of these.

"Our understanding of the human genome has changed in the most fundamental ways. A small number of genes, some 30,000, support the notion that we are not hard wired. We now know the notion that one gene leads to one protein and perhaps one disease is false." Is that true, that one gene leads to one protein and one disease. Is that false?

Mr. VENTER. There are examples where that does occur, but they're extremely rare.

The scientific community and the public has been misled by the early successes in genetics thinking those were general rules.

Mr. STEARNS. That is fundamental to our discussion and the American people have to realize that. If I do a DNA test and I find a gene, that gene and one protein that it develops is not going to do a disease. In fact, you go on to say a little later that "one gene leads to many different protein products that can change dramatically once they are produced. And we also know that the environment acting on our biological steps may be just as important in making us what we are as our genetic code."

Do you say that's still true?

Mr. VENTER. Absolutely.

Mr. STEARNS. Okay. So you take my DNA. You look at it. The protein is not just one protein. You sort of indicate there could be

perhaps be 300,000 proteins that are developed from these 3,000 genes. Again, I'm quoting from you.

Mr. VENTER. Yes.

Mr. STEARNS. So the probabilities that exist between the environment and the 300,000 proteins or whatever the number of proteins that are developed from one gene make it extremely difficult, I suspect, to determine a predisposition with any guarantee. Is that true?

Mr. VENTER. I think that's very much along the right lines and I think a lot of people here have used the right language. They've talked about probabilities, not yes or no answers.

Mr. STEARNS. Probabilities. Okay.

Mr. VENTER. And probabilities can be—there are very high probabilities or very low probabilities, but they don't mean that you get a disease and they won't mean that you won't get a disease.

Mr. STEARNS. Okay, that's very fundamental to our discussion. Could I safely say contrary to Dr. Francis Collins that the genome has not yet been fully decoded?

Mr. VENTER. I think his agency is still working on closing a number of gaps.

Mr. STEARNS. Dr. Francis Collins has been out there saying it's been decoded and mapped and I'm saying from what you have just told me between the environment and those proteins that we cannot accept on a probability statistical basis determine a predisposition if we do a DNA.

Mr. VENTER. Is your question do we thoroughly understand the human genetic code? The answer is absolutely not. It will take most of this century to even approach that.

Mr. STEARNS. The discussion that there's going to be rampant discrimination based upon predisposition after taking a DNA test is not accurate because we don't know what that means. Is that true?

Mr. VENTER. The difference that I would make is, in fact, the cases are discrimination has not been based on knowledge, just in the railroad case.

Mr. STEARNS. Okay.

Mr. VENTER. The employees at the railroad—

Mr. STEARNS. It's very important for the American people to understand that—

Mr. VENTER. Their discrimination was based on absolute ignorance in that case, not based on genetic knowledge.

Mr. STEARNS. Yes.

Mr. VENTER. But the company thought that by using genetic knowledge they would have a basis of discriminating. It turns out they were just fundamentally wrong in their reasoning.

Mr. STEARNS. The railroad was ignorant.

Mr. VENTER. But it doesn't mean there was no discrimination.

Mr. STEARNS. Based upon all scientific evidence, we do not have a strong understanding of what a DNA test means in terms of a predisposition toward a disease. That's my point.

Mr. VENTER. We do with some diseases. There are some extremely rare genetic disorders where it's very clear cut scientifically, for example, with the Huntington's Disease gene, if you have a certain number or a triplet repeat, the likelihood of getting Hun-



tington's Disease is so high, it's the closest we'll ever get to a yes/no answer. Most diseases and most human conditions will not fall in that degree of probability.

Mr. STEARNS. Okay. Let me change the subject a little here.

Ms. Davidson, both you and Mr. Young note the provisions of HIPAA which already prohibit discrimination of eligibility and premium contribution based upon genetic information. Specifically, HIPAA prevents any group health plan or insurance provider in connection with a group health plan from refusing to cover employees or their family members based upon genetic information or results of genetic testing.

Now is HIPAA sufficient? I mean do we need another and I would say to Mr. Young first, Dr. Young, do we need another full genetics bill like our colleague, Slaughter, and our colleague Connie Morella talked about? In the health area, I'm not talking about employment because basically this committee is dealing with health.

Mr. YOUNG. No, we do not. We have HIPAA, but we also have Gramm-Leach-Bliley which we haven't talked about today and we have the various rules and regulations in the States and it's important when we come back and talk about insurance, not only are there privacy and nondiscrimination provisions, but there are very strong rate setting provisions as well and we can return to that later. We do not need additional legislation.

As I said in my testimony, it will harm the people we're trying to help.

Mr. STEARNS. Ms. Davidson?

Ms. DAVIDSON. Thank you for your question. Let me just take a quick second just to tell you that my answers to this are really informed by the fact that we run a genetics help line so we receive calls from the public numbering somewhere between 3,000 to 4,000 calls per year from people who are having genetic tests who have concerns about genetics as well as who have been diagnosed with genetic conditions. From time to time we certainly get an increasingly number, actually, of questions asking about insurance coverage and HIPAA coverage. The two vulnerabilities that we're seeing in particular is certainly in the individual market and part of this may reflect the fact that I have two children in their 20's. They're just entering the employment market and had not, if I didn't know as a parent how important it was that they stay on COBRA and have this continuous coverage, they might actually have difficulty. My son was in the position of setting up his own business and in an individual market because HIPAA doesn't provide protections there, it does provide premiums, but there's no ceiling on the premium and the other point of vulnerability, if I can just take 1 second is also in small businesses, because again, this goes back to why, how insurance and employment are linked because in a small business people's medical information is often known to everyone and again the case of Terri Sergeant was one where her employer found out about her premium, about her medical care and was concerned about possible increases to the group premium and dismissed her.

Mr. STEARNS. We're going to go a second round here, but I want to get the ranking member, Mr. Towns, because my time has expired.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me just start with you, Dr. Young. You mentioned Gramm-Leach-Bliley, but it's my understanding that most of the States have not actually adopted it. I think it's like maybe 5 or 6 States have moved forward, others have not.

Mr. YOUNG. No, it's moving very quickly.

Gramm-Leach-Bliley led to the National Association of Insurance Commissioners developing a model law which we supported. And that model law now is being enacted across the States.

Mr. TOWNS. How many States, Dr. Young? Because just as a matter of a few weeks ago, it was only a few States that actually had adopted it.

Mr. YOUNG. Virtually all the States currently have privacy rules on the book. Many of them go back to the 1980 model and they are changing those to update them to Bliley, but those laws are in place. All that's happening now is the updating of them to the GLB.

Mr. TOWNS. I don't want to get into this kind of—the State of Iowa has said we're not going to do it, period. There are some problems, but that's for another day, another hearing. But I just don't want you to mislead anybody by saying that that's a catch-all and a for-all. It's just not. And I just want to make that point.

Mr. YOUNG. We'd be happy, if you want me to submit for the record, a listing of the States and their current status.

Mr. TOWNS. I would like to have it. I'd appreciate that.

Do all genetic tests have to be approved by the FDA, Dr. Venter?

Mr. VENTER. I'll defer to others here, but my understanding is no.

Mr. TOWNS. Dean Rothenberg?

Ms. ROTHENBERG. There is a dispute about how much authority the FDA has, but right now there are a lot of genetic tests that have no regulation under the FDA.

Mr. TOWNS. Do you think that the legislation being put forward by Congresswoman Morella and Congresswoman Slaughter is actually needed?

Ms. ROTHENBERG. I was hoping to be able to finish in the analysis of both HIPAA and its gaps as well as the HHS Privacy Rule that we do need the law and the reason is because where HIPAA started in the right direction, it doesn't have in it any type of protection with respect to requiring or requesting genetic testing. It also has very little protection. I would disagree with Dr. Young, about the individual market, and of course, those that are uninsured that want availability for genetic testing, if they then want to get insurance at a later date, it becomes problematic. It is the beginning of protection in the anti-discrimination area for group health plans and Chairman Stearns is right that we don't really have a lot of data on how it is being utilized in part because how would anybody know individually if there was a problem if you don't have any restriction on the information that they can collect? How would an individual know, in fact, or even a group know? You can't have an individual distinction with respect to the premium differential, but you can raise the whole premium on the group after you've gotten information. I don't think Dr. Young would disagree with that, but how would anybody even know and the reason

why you need a different type of protection is because discrimination with genetics is different than race and sex. You don't know when you see it. So if you want to argue that you've been discriminated against based on race, you're not giving up that part of any privacy. If you want to argue that you've been discriminated against based on predictive genetic information, you've got to give up your privacy to make the anti-discrimination claim and one of the reasons why this new legislation attempts to integrate both limiting who gets the information with discrimination protections is it fills that gap and the HHS Privacy Rule doesn't do it either because it just relates to health care providers. It doesn't relate to insurance companies and it doesn't relate to information about getting genetic information. It just deals with protecting information in the record. So that's, I think, why you need either to amend what you've already got or to have a comprehensive Federal approach that matches what they're attempting to do at the State level.

Mr. TOWNS. Yes, Dr. Young? Thank you very much, Dean.

Mr. YOUNG. Health insurers don't ask about predictive genetic testing and about genetic make up. As I said, 90 percent of people get their coverage from the large employer market and there is no information about any kind of health status is asked or requested for because the group is large enough that the risk can be spread across a large group.

When talking about the individual market which is 10 percent or so, our interest there are simply knowing are you sick today? The overwhelming number of people who buy insurance in the individual market, I'm sure like Ms. Davidson's family, are very healthy and we need to be able to set the lowest rates possible, this is a very, very price sensitive market. It tends to be younger people. It tends to be people at low income and if they look at rates that are high they are going to forego the insurance. We've seen the experiment in the States where States have tried to guarantee, issue and community rating much of what this legislation would do and there, the number of uninsured has climbed dramatically because people forego their insurance. It's not the insured leaving the State. It's individuals will not buy since this is voluntary and they pay for it after tax dollars.

Second, people who are insurance products in the health arena are generally in those products for 2, 3 or 4 years. It's unusual that people have the same product over a long period of time. We simply have no interest from a health insurance point of view in knowing if somebody is going to develop Huntington's Disease or Alzheimer's 10, 15 or 20 years from now, so we want to know where they are today.

As to Dean Rothenberg's question who's looking at the rates, I can assure you State regulators are looking at the rates. When you come in for rate increases either a block of business in the individual market and the rate increases for the whole block, you cannot have rate increases for a single person or single out two, three or four once the policy has been issued.

Likewise, in a small group market the States know the insurance in their States and they look very carefully at those rates and there can be long periods of time where you don't get a rate increase be-

cause the State is looking at it and asking for more information. There is a great deal of oversight of this industry at the level of the States, both in terms of discrimination and pricing of the product, but I'll come back to it again. The point I made earlier, you're going to harm the people you're trying to help. If you raise overall rates, then people who are low income are going to forego buying in the individual insurance market. We know that because experience has shown it.

Mr. TOWNS. You'll leave that statement in the record, harm the people they're trying to hurt?

Mr. YOUNG. No, no. Trying to help. You'll harm the people you're trying to help. Let there be a correction.

Mr. TOWNS. Okay, fine.

Mr. STEARNS. The gentleman's time has expired. The gentleman from Illinois, Mr. Shimkus?

Mr. SHIMKUS. Thank you, Mr. Chairman. It just shows you that Mr. Towns is listening to the answers.

Mr. YOUNG. And I appreciate that.

Mr. SHIMKUS. I know, that's very good. I'm sorry for being in and out, but I've just been in the back room and I appreciate the panel here and this great debate and also learning about group versus the individual market. I've picked up some things.

Insurance companies do, based upon good record, at least automobile insurance, good record, health insurance may do non-smokers. There may be some alcohol-related provisions that affect the rate structure, am I correct?

Mr. YOUNG. Generally, it is simply—we're talking in the individual market, this question has already been asked in the large group market. In the individual market it's generally are you sick now? Do you expect to have major surgery in the near future? Have you been in the hospital in the last year? It is health status kinds of information. They may ask about alcohol. They may ask about smoking. They may ask about other personal behavioral kinds of things.

Mr. SHIMKUS. Ms. Rothenberg, you mentioned and I'm just trying to get some information, behavioral genetic studies on violence and alcoholism. Can you explain what you mean by that?

Ms. ROTHENBERG. What the term means?

Mr. SHIMKUS. Right. And how it ties in, I guess, to my previous question of a concern. If you're saying through genetics we can make some implication on future behavioral aspects which may affect cost pricing in the insurance market.

Ms. ROTHENBERG. Yes. Actually, most of the studies with respect to behavioral genetics haven't made it through as far as I know in the insurance market. I think Dr. Young would agree with me on that.

Most of those concerns have been expressed in research, genetics research that is now being done based on certain population groups. And this brings me back to a point you raised earlier about the breast cancer community and their concerns, particularly the Ashkenazi Jewish community which has a lot of concern about genetic discrimination because many of the earlier studies with respect to the breast cancer gene were associated with a particular ethnic group, the Jewish community, and there was concern in that

community about what impact it might have on buying in certain markets. There's been assurances from the insurance company that there isn't of that going on.

I would like to correct, however, that in the individual market if anybody has looked at an application the very first question it usually asks you is have you had any medical tests within the last 5 years and it doesn't say in parens exclude predictive genetic tests, end parens. And the reality of it is is that the individual consumer doesn't really know how to answer that question and that's a very generic question. So I think that's one that would need further clarification.

In the future, if we continue to do tests with respect to behavioral traits, there's nothing that would prevent an insurance company from asking those questions or even asking for the tests right now. I don't think they would do that. I don't think it would be wise, but there's no law that would prevent it.

Mr. SHIMKUS. The other great balance and we're going to be going into that debate in the next couple of days here in Washington is the whole debate over employer response over health care group coverage and the cost and 42 million uninsured Americans right now.

Dr. Young, what do you see as far as the ability of the insurers working with employers if we then move to behavioral genetic studies or other aspects, is this—or even the tort aspects that could evolve. What's that do to the cost of affordable health care?

Mr. YOUNG. The insurance industry and particularly its customers, the Americans, are facing substantial challenges in terms of various regulations and legislation. We've been regulated primarily at the State level and regulated quite heavily over the years. What is new beginning with HIPAA and now the other legislations being considered is a second layer of the Federal regulation. That is certainly a substantial contribution in driving up costs. The CBO estimate for the Patient Bill of Rights of 4.2 percent, in fact, translates into \$230 billion over 10 years. That's a lot of money that the American public is going to have to pay for.

We are also seeing increasing mandates. There's mandates in HIPAA. There's mandates in Federal legislation and increasing mandates at the State level for services, many of whom services are good, very good services, but the question is do people want to purchase them and will people forego insurance because of that. The major growth area in the uninsured are people who work, who are offered insurance through the work place and who decline it because even the 20 percent or 25 percent that they have to pay is too much for them in terms of their low incomes, so costs and factors driving costs are very important components. As I said earlier, at the State level in the individual insurance market, the consumer buys the product out of their own pocket. It's entirely voluntary and they are very, very price conscious and will turn down insurance or not purchase it if the price doesn't look right to them.

Mr. SHIMKUS. And I will just end with my time, Mr. Chairman, to say if the additional costs of additional regulation would be filtered back into the health care delivery system or the funding of our hospitals to adequately pay for our professionals, that's one thing, but I am concerned about the excessive regulation and the

spiraling costs and the inability for people to have some coverage which is critical in the high cost medical field that we have today. That's the balance and I appreciate the panel and Mr. Chairman, I yield back.

Ms. CAPPS. The gentleman's time has expired. The gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman, I have an opening statement, if I might ask unanimous consent to be able to just add it to the record.

Mr. STEARNS. So ordered.

Mr. BRYANT. I apologize to the panel. We were in and out as Mr. Shimkus said quite a bit. I haven't been in yet, but I have to leave fairly shortly to go to another meeting, but I did have a chance to review some of the testimony and I want to thank you all for being here.

Ms. Rothenberg, I think you're down on the end there. I thought you were supposed to be down at this end. I finally identified you. In your written testimony you state that a predictive test result is not a diagnosis and I think I agree with that. But do you believe that or do you not believe that a health care plan should not provide genetic counseling to help patients plan their health care and if so, wouldn't this require tests, this type of test for the patient? Do you think there should be some results, some positive results, some preventative type action involved in this?

Ms. ROTHENBERG. I think the taxpayers and Congress would not have invested in the Human Genome Project if we didn't think it held out the promise for a better life for all of us. And not to have to be in a situation where we would all be afraid about getting a test. Wouldn't that be a shame, in fact.

What I think the principle, the underlying principle that should be determined in responding to your question is to ask all other things being equal, does it make sense for an individual to get that information and that requires an informed consent process between their health care provider and themselves.

I would not want a situation in which an insurance company could require you to have to take a predictive genetic test in order for them to then make a determination about whether they're going to pay for a particular procedure. And there have been cases in which prior to approving prophylactic mastectomies for women, providers, insurance companies said well, you need to have a genetic test. If you don't have the predisposition for, you don't have BRCA1, you don't have BRCA2, you don't have BRCA3, what is the rationale for a prophylactic mastectomy. I don't think that is a rampant problem, but I think the determination about whether to get a genetic test should be a medical determination, not a determination made by an employer or an insurer.

Mr. BRYANT. Thank you. Dr. Young, I also agree with the concept of insurance, a company ought to be able to fairly evaluate the risks they're about to insure before they take that on. I think that's common sense and I think most people understand that. And so we are put in a difficult position here.

As I listened to your testimony I agree with you that you tend not to look long term, that you're interested in the information today and more what's current. We've heard testimony here before

I think where, particularly insurance companies, HMOs, usually don't keep patients very long, or keep insurance very long. There's quite a turnover there. So sometimes we see the preventative care side of it neglected because you're not going to have that person long enough term to really be the beneficiary of that good preventative care. And I think we're talking about this a little bit here. You bring in genetic testing and that really complicates the matter.

If there's a question somewhere in those comments, I'd like for you to answer it, but from the perspective of the insurance company and this type of testing and how it would relate maybe to preventative care and is it from a risk insurable standpoint, is that feasible for companies to do that, health care companies?

Mr. YOUNG. Once the individual has insurance, we can't deny their coverage and that's as it should be. I think the issue that Dean Rothenberg raised was a very good one and I think in that situation it was of the breast and the individual who wanted a bilateral mastectomy and are they or are they not at increased risk? I think in that situation if that is an important question to be addressed, the doctor should request the test. That's the appropriate mechanism. That kind of interaction should be done between the doctor and the patient. The insurance company will have a responsibility to see whether the employer's coverage covered it or not. Most benefits are covered commonly across all insurers, but not all and that's entirely the purchaser and the employer who makes that decision, but in the example given, I think that it's a very reasonable question to ask and in my mind one the doctor should have asked with the patient before it ever came up to the insurer.

Mr. BRYANT. My time is about to run out. But I think we all agree too that we want to keep as many people insured as we can. Forty-two, 43 million are uninsured and many of the people insured today are insured through small companies, smaller companies, smaller plans.

Mr. YOUNG. Yes.

Mr. BRYANT. And I can understand where you've got a big plan and you don't even look at the questionnaire, you just insure the person. Many cases, they're smaller plans where you do have to assess individual conditions because you just can't jack up the rates in a small plan because you've got fewer people and they're paying this.

Mr. YOUNG. That's the small group market, so employers, 5 people, 10 people, 15 people, 20 people. There again you cannot eliminate the coverage. You cannot deny Ms. Jones or Mr. Smith or somebody else coverage because of their health condition, but what the insurer does do each year as part of its annual renewal in setting a premium it looks at all the factors that affect that group. But in setting the premium, you look at rising drug costs and make your best guess for next year, you look at rising physician fees and make your best guess and you look at the experience of that small group in terms of its utilization. A group of people who are 25, 30, 35 is going to have a lower experience rating than a group that's more heavily wedded to people who are 50 to 55. But having said that again I need to stress those rates are subject to review and approval by State Insurance Commissioners. Those rates are simply not granted without oversight and review.

Mr. BRYANT. Mr. Chairman, I think my time is exhausted.

Mr. STEARNS. I thank the gentleman. Dr. Venter, I think your written testimony states that genetic information is not different from other medical information. You further state that it is an integral part of the medical information. Is that still—is that true?

Mr. VENTER. When it's medically related. Genomic information in all of our genetic code is not necessarily medically related to a disease.

Mr. STEARNS. Right.

Mr. VENTER. But when there's a specific test done either for predictive measures or diagnostic measures, then it's definitely medical information in my view.

Mr. STEARNS. I think what I'm trying to get to is do we need to have a broader concept of privacy of medical information and not have different or conflicting rules for different type of medical information? For example, maybe 50 years ago people wouldn't want their cholesterol levels known, they wouldn't want their blood pressure known. They wouldn't want their pulse known. And they would think that that would require a whole new privacy whereas today, it's not considered. It's private, but it's not considered with the enormous impact if somebody knows your cholesterol level or your heart beat or your pulse. So I guess my question is do you think we need a broader concept of privacy of medical information to in effect, which I think Mr. Bryant was talking about when we talked to Dr. Rothenberg, Dean Rothenberg, about the idea of genetic counseling to help patients plan their health care because somewhere if I have problems and I could determine from my genetics it was a problem I'd want counseling on what to do.

Mr. VENTER. Well, you've talked about preventive medicine and I can give you a wonderful example. A few years ago we found three new genes in collaboration with Burt Vogelstein at Johns Hopkins University that are linked to colon cancer. We can now measure in the population and there's tests commercially available to determine whether somebody has an increased risk of getting colon cancer from these mismatched DNA repair enzyme changes. But by measuring those genetic changes, we cannot determine who's going to get colon cancer and somebody might mistakenly say well, this person has a greatly increased risk of colon cancer, therefore their medical coverage is going to cost a lot more. In fact, it empowers that individual to then be aware of early symptoms for colon cancer and even get annual colonoscopies because colon cancer is readily treatable if it's caught early. So it changes the nature of the information in terms of empowerment of individuals.

At the same time, this earlier discussion about whether there was a genetic basis of behavior, we've been there in the past history of the U.S. in the 1930's with eugenics. The biggest fear that most of us have in the scientific community is just bad science and bad interpretation of the information. So at what stage does it become medical information? If somebody thinks that it's related to criminal behavior, measuring something in your genetic code, that's got nothing to do with medical outcomes. It probably has nothing to do with actual outcomes, but the discrimination is based on what people assume.



Mr. STEARNS. Let's take a more specific case example of a managed care program. So Aetna gives you a managed health care program. It includes insurance company, they provide all the doctors and all the patients and everything and they sit down with you to counsel you and they find out, based upon what you said that you have colon cancer. Shouldn't they know that to tell you to have a colonoscopy on a regular basis? I'm just taking the devil's advocate now. It seems like a managed health care insurance care would want to know this so that they could say to you, by golly, we're going to save your life. Instead of a colonoscopy every 10 years, we're going to have it every 2 years on your or every 3 years to see if there's polyps.

Mr. VENTER. I'm not sure we're disagreeing on this issue. I think that would be extremely valuable information for the medical practitioners to know and perhaps even for getting the tests. Right now there's problems in insurance companies covering annual colonoscopies for people over 50, let alone if you're 20 years old and you know you have a greatly increased risk of getting colon cancer, but it could lead to decreased medical cost because it would be preventive measures.

Mr. STEARNS. Dr. Young, any comment you might have?

I guess what I'm trying to do is see if we need to have a broader concept of privacy of medical information or do you think the way we're going now is satisfactory?

Mr. YOUNG. Medical information needs to be protected. We do not disagree with that. The public is very concerned about this and I think as I said and as other witnesses have said, they may be forgoing tests and studies that are important to their health because of their concern, so we need to alleviate that concern. The legislation though that's in place, I think, goes a very, very long way in doing that already and the risk is in doing additional harm. In terms of medical records, the physician should have access to information. Our medical system today is very complicated. It's no longer one doctor that sees a patient. There may be several. There may be physical therapists. There may be laboratory people. Information is out there. We have to protect it, but it should be used to help the people. Health insurers use that information for things like sending out reminders to people to come in and get their asthma drugs if they haven't had their drug filled or to come in for their annual Pap smear or their mastectomy screening or their prostate screening. We need to protect that information, but that's not to say it shouldn't be used when it's necessary to improve care. It's used for chronic disease management programs, care management programs. So we have to protect it. We have to reassure the public, but we should not do something that is not in the patient's interest in terms of how that information is used and I think we have a lot of regulations out there now and I don't see the need for additional legislation, particularly that which would segregate the information.

Mr. STEARNS. Okay, my time is expired. The gentleman from New York.

Mr. TOWNS. Thank you very much, Mr. Chairman. Dr. Venter, let's see, how do I want to phrase it? Do most of your trade associa-

tion make tests that can be used to identify genetic disposition with respect to certain diseases?

Mr. VENTER. I'm not in a position to answer that. I don't know. I would assume not.

Mr. TOWNS. You are representing the trade association, aren't you?

Mr. VENTER. I'm here on behalf of myself and the BIO organization. We can get information for you from the BIO representatives.

Mr. TOWNS. Because I would think if you're representing them, you have some knowledge of who might be—

Mr. VENTER. Well, you know in your own case you don't have infinite knowledge of all the people you represent.

Mr. TOWNS. That's true, but I have a general idea because they keep reelecting me.

Mr. VENTER. My election is only for a day.

Mr. TOWNS. The question I guess I wanted to ask was what happens to the information? Who do they sell it to?

Mr. VENTER. I don't think I'm the—as a leading scientist in this field the person to be able to answer the question on what diagnostic companies do with the information. Usually, they provide it back to the physicians and the health care provider that ordered the information in the first place.

Mr. TOWNS. Anybody might be able to help me with this because I have a funny feeling here.

Ms. ROTHENBERG. I think you're asking a very good question and I think it gets to the point and the question that Chairman Stearns asked and that is what is left that still needs to be covered that isn't already covered with the privacy rules? And what isn't yet covered anywhere except in a patchwork at the State level is that nothing prohibits the insurance companies from requiring or requesting information or requiring testing. That doesn't mean they're going to do it, but there's nothing that prohibits it.

Second, nothing in the privacy rules speaks to insurance companies. The focus is on health care providers, unless those are the same, or employers who happen to be the insurers.

So in your situation, there is not a Federal way to approach that problem right now. You're absolutely—you're asking the right question.

Mr. TOWNS. Thank you. Do you want to make a comment on that, Dr. Young?

Mr. YOUNG. Yes. I think part of the issue here is traditional State regulation versus the Federal and what we need to do. Part of it though is how one specifies the definition of genetic information and that definition now is extremely broad which will encompass almost everything that is health status. We've heard that everybody has genetic defects, everyone has genetic problems, so how do you craft that legislation that will not do harm in terms of using information in the individual's own personal welfare, whether it's the doctor or whether it's in making insurance and benefit coverage decisions? That would be the real challenge.

Ms. ROTHENBERG. Well, under the proposal though to the best of my knowledge, it allows for written authorization from the individual, but they just have to be told what it's going to be disclosed

for, so that the individual gets to decide where the information goes, rather than somebody else without their knowledge.

Mr. TOWNS. Could the employer purchase it?

Mr. YOUNG. I'm sorry?

Mr. TOWNS. Could the employer purchase this information?

Mr. YOUNG. No, that is also prohibited in terms of the employer doesn't have access, by and large, to the medical records of the employee. Now they can ask for written consent and get that kind of information, but we would not feedback that kind of personal information. We would generally not even have that kind of information. All we have are the claims, so we know what encounters have occurred and what we've paid for, but we don't have additional information other than that in the overwhelming number of circumstances.

Mr. TOWNS. I've been around this place a long time. When you hear one situation you always feels like there are 100 situations. I'm thinking about the Burlington Northern situation. I just sort of feel there's a lot of others. We know about this because it's highly publicized, but the point is that how many more are there out there? That's the question.

Mr. YOUNG. Well, the Burlington, of course, was not a health insurance issue.

There has been research that's looked at this. There's been research that has failed to show—

Mr. TOWNS. Why is that not a health issue?

Mr. YOUNG. I'm sorry?

Mr. TOWNS. Why do you say—it's genetic. I don't understand the statement you made.

Mr. YOUNG. Okay. I think in the discussion that is going on and a point that you made earlier to the Congresswomen is that the problems facing health are different than the problems facing life insurance, the problems in terms of employers are different than health. The issue is the same, but how one deals with those problems and the solutions one comes up with will be tailored differently for the wide audience the legislation would apply to.

Mr. TOWNS. I agree, yes. Ms. Davidson?

Ms. DAVIDSON. Yes, I just wanted to speak to the question about whether there have been sufficient studies in this area because I would suggest that there have not been and it really is time that we take a very sound thorough and in-depth look and that's one of the things that my organization is beginning to do on a pilot basis. There have been other, a couple of other pilot studies, but I don't think that they really have given us the kind of information that we need.

But again, I would come back to not only is this happening on an anecdotal basis, but it is happening in a handful of cases of very brave people who have essentially given up on their privacy and the privacy of their family and their extended family to come forward and be public about their particular circumstances, but it really comes back to the issue of whether or not and I appreciate your questions, Mr. Chairman, whether or not the combination of HIPAA and State and Federal regulations and laws, whether that really gives a sufficient safety net for consumers.

If I can take 1 second also, just to come back to the whole question of information and the question also about services because it is so critical, it is so critical that people are able to access the medical care that they need, the genetic tests that they need, the counseling that they need and that their concern really be on obtaining that and getting the best medical care possible. I think where I would like to see legislation move is not on controlling information because we all know, we've all been in that doctor's office trying to collect the information so we can maximize our 15 seconds. What is so important here, really, is that there be assurances that the information be protected, not that it be controlled, because that will stop research. That will really inhibit quality health care.

Mr. TOWNS. I agree. Thank you very much, Mr. Chairman, you've been very generous with your time.

Mr. STEARNS. Let me first of all thank my distinguished ranking member for his participation and thank our second panel for your participation and also for waiting. I think what we've had today is very illuminating and a very comprehensive coverage of a lot of the issues that we failed to talk about here in Congress on genetic privacy, so I'm glad at least finally to have this hearing. This might be something that we should have additional hearings on. I think we have touched some very sensitive subjects, but I think we can all agree that if the States march out with individual genetic privacy bills that the Federal Government is going to have to step up to the plate and do something so that we don't have companies and individuals all having to comply with 50 different States so that if nothing else, the Federal Government might have to do something to bring all this in so that we pre-empt the States with Federal legislation, but at the same time I think we pointed out how important this is for the individuals who have the genetic testing, but at the same time we have to protect their privacy. So I want to thank all of you and the committee is adjourned.

[Whereupon, at 2:02 p.m., the subcommittee was adjourned.]