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GENETIC NON-DISCRIMINATION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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GENETIC NON-DISCRIMINATION

WEDNESDAY, MARCH 14, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:13 p.m., in Room B318, Rayburn House Office Building, the Honorable Fortney Pete Stark (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
March 07, 2007
HL–5

CONTACT: (202) 225–3943

Subcommittee on Health Chairman Stark Announces a Hearing on Genetic Non-Discrimination

House Ways and Means Health Subcommittee Chairman Pete Stark (D–CA) announced today that the Subcommittee on Health will hold a hearing on genetic non-discrimination. **The hearing will take place at 2:00 p.m. on Wednesday, March 14, 2007, in Room B–318, Rayburn House Office Building.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

One of the most significant scientific accomplishments in history has been sequencing the human genetic code—a breakthrough that is already transforming the battle against a broad range of medical conditions. As a result, scientists have identified genetic markers for a variety of chronic health conditions, increasing the potential for early treatment and prevention. Genetic tests provide information to diagnose conditions, guide treatment decisions and predict future risk of disease.

Alongside these benefits reside concerns about how genetic testing might be used. This threat has deterred the public and the scientific community from taking full advantage of the important opportunities that genetic information affords. Of particular concern is the potential for discrimination. 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 lack of a federal policy protecting genetic information has resulted in both actual and perceived acts of discrimination. It has also encouraged inconsistent legal responses to grievances associated with such discrimination. As the tax writing authority for the U.S. Congress, the Ways and Means Committee can enforce federal insurance laws that apply to ERISA plans, which provide health benefits to the vast majority of Americans. In addition, the Committee has jurisdiction over federal laws relating to Medigap policies.

In announcing the hearing, Chairman Stark said, **"No one should face discrimination in employment or be denied health insurance based on their genetic information. In order to ensure that genetic science reaches its full potential, patients need to trust that their information will be protected. Otherwise, people will rightly be reluctant to undergo genetic tests that could save lives."**

FOCUS OF THE HEARING:

The hearing will focus on the need for a federal policy to protect genetic information and legislation to achieve this purpose, specifically, the Genetic Information Non Discrimination Act.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*110th Congress*" from the menu entitled, "*Committee Hearings*" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). Select the hearing for which you would like to submit, and click on the link entitled, "*Click here to provide a submission for the record*." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Wednesday, March 28, 2007**. **Finally**, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman STARK. We will begin the hearing, and Congressman Camp has been otherwise detained and probably went over for the vote.

I will start, and thank you for being here to discuss the potential for genetic science and the need to protect genetic information.

We find that patients are reluctant to undergo genetic tests, unless they can be sure the results won't be used against them, and I don't blame them. Health insurers are in the business of not paying out money when they can avoid it, and so they have got an incentive to use whatever genetic information they can get to deny coverage or raise rates.

Employers can also use this information in hiring decisions and one of our witnesses will describe his victimization in that area.

We have got to ensure that patients and workers are protected against the discrimination so they can realize, as all of us should be able to realize, the benefits of genetic testing.

We have been deliberating this policy for 12 years. We made some improvements in HIPAA and many states have enacted some protection since then. The laws vary greatly and we should have, I think, comprehensive protections.

It appears we are close to realizing our goal to ban discrimination on the basis of genetic information and the Senate has passed similar bills. It is my understanding the administration supports the bill that is now moving through Congress. I look forward to working with my colleagues on this policy.

Congressman Johnson has graciously offered to put Congressman Camp's opening statement in the record. On the conclusion of that, we will hear from Dr. Collins, who is the director of the National Human Genome Research Institute at NIH in Bethesda.

But if you will withhold, and Mr. Johnson, would you like to submit Mr. Camp's remarks or put them in the record? It is up to you.

Mr. JOHNSON. If you don't mind, Mr. Chairman, I would just like to say that in his closing paragraph, he says, as this Committee considers the Genetic Information Nondiscrimination Act, I hope we will recognize that, with sufficient protection in place surrounding use of genetic information, the information can be used in positive ways that actually improve the lives of patients and we should not hinder these promising medical advances as we attempt to protect patients and employees. He thinks we can work together to do that.

I would like to insert the whole thing in the record.

Chairman STARK. Without objection, the opening statements will be in the record in their entirety.

[The information follows:]

I would like to thank all of the witnesses for testifying today about this important issue.

I think we are all in agreement that individuals should not be discriminated against on the basis of their genetic information. Insurers should not be allowed to use genetic "markers" to deny insurance coverage or increase out-of-pocket costs, nor should employers be allowed to fire employees simply because they possess a gene that could lead to a particular disease later in life.

However, the use of genetic information is not always harmful to patients. As we'll hear later from Dr. Corwin, advances in medicine have allowed doctors to tailor treatments in accordance with an individual's genetic information. Results from genetic tests allow physicians and other providers to better target preventive care and disease management techniques to those who need it most.

For example, a patient that possesses a gene for a type of colorectal cancer would be recommended to receive more frequent cancer screenings. Knowing this, the health insurer would know to approve coverage for these additional screenings because the patient would be at a higher risk of developing colorectal cancer. Early

detection and treatment has been proven to produce significant savings and improve quality of life.

As this Committee considers the Genetic Information Non-Discrimination Act, I am hopeful we will recognize that, with sufficient protections in place such data can to improve the lives of patients. These promising medical advances should not be hindered as we attempt to protect patients and employees. I am confident that we can both protect patient privacy and improve health care services.

With that, Mr. Chairman, I yield back the balance of my time.

Chairman STARK. Dr. Collins, why don't you proceed in any manner you are comfortable? I want to just tell our guests that Dr. Collins may have to zip out of here to make a plane, and we will excuse him at any time he feels it's necessary.

Proceed.

STATEMENT OF FRANCIS S. COLLINS, DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, NATIONAL INSTITUTES OF HEALTH

Dr. COLLINS. Thank you, Mr. Chairman. Good afternoon.

Yes, I am Francis Collins. I am a physician and a scientist. For the last 14 years, I have been at the National Institutes of Health and I have had the great privilege of leading the Human Genome Project, which many have considered to be the most important scientific undertaking that humankind has ever mounted, reading out the letters of our own DNA instruction book.

The purpose of this was to advance medicine, to improve the likelihood of people staying healthy and to treat disease more effectively when it occurs. We are making great progress.

The Human Genome Project accomplished all of its goals ahead of schedule and under budget in 2003 and, on top of that, we have now built several more new discovery engines that have put us in a position now to be able to discover what, in fact, are the hereditary factors in a long list of diseases that are particularly common in our population. In just the last 2 years, we have discovered major genetic factors for macular degeneration, one of the most common causes of blindness in the elderly; for prostate cancer, for Crohn's disease; and in a particular explosion of information happening right now about adult onset diabetes.

We have known that these are conditions that run in families, but now we are on the brink of very precisely identifying why that is and providing the opportunity to tell individuals who are at high risk about their risk, and therefore giving them a chance to reduce that risk by changing diet, lifestyle or medical surveillance.

This then puts us in a circumstance of being able to contemplate a future of truly personalized medicine. You wouldn't go to the shoe store and buy any old pair of shoes off the rack; you would want to be sure it was your size. Yet in medicine, we have often been forced to practice one size fits all because we didn't have the information about individual parameters to be able to do a better job. We are now able to do that in some instances, and that is growing by the day, not only in terms of predicting risk of disease but also being able to choose the right drug for the right person at the right time, based on their individual DNA sequence.

Yet there is a cloud on this horizon. The cloud gets darker and more threatening every day, and that is the risk of genetic discrimination.

Individuals who might wish to have this information about their own future risk of illness or about what drug they might best be treated with are terrified that if that information gets into the wrong hands, it may result in loss of their health insurance or potentially loss of their job. While there is, as the Chairman has indicated, effort under way in many states to deal with this, it is a patchwork of different kinds of laws with many exceptions. If we really want to protect the American public, we would have to do it with Federal legislation.

Twelve years ago, colleagues of mine and myself wrote a paper in the journal Science advocating for the importance of this kind of Federal legislation. It has been a long, hard slog getting to this hearing today where it does appear that finally there is momentum to see this happen.

Let me quickly put a human face on the issue. On the screen over here, you see a diagram of a family. You can tell who are boys and who are girls by the figures here. I draw your attention to the individual with the red arrow.

This woman came to seek advice because she had suffered from both uterine and colon cancer at a relatively early age, in her thirties. It turned out, so did her mother and so did her aunt.

After some investigation, it turns out that this is one of those situations where the precise DNA glitch could be identified. She was actually not sure she wanted that done because of her concern it might be used to take away her health insurance. But ultimately she decided to go through with it.

She was found to carry a specific misspelling in a particular gene, which confers this high risk of colon and uterine cancer to anybody in the family who carries that same glitch. The other people you see there in yellow are all at high risk of also having that same misspelling and a test is immediately available for them.

Yet, in this family, after much discussion amongst the family members, not a single one of them decided to take advantage of that test, even though we know that in this situation, knowing you're at high risk can be life saving, allowing you then to get into a program of annual colonoscopy starting at a very early age, picking up that early tumor while it is still easily treated.

So, this is a real example where the risk of genetic discrimination is probably going to cost somebody their life because of their fear of being able to get the information that they otherwise need. That is not just this family. A recent survey done by my colleague, Kathy Hudson, revealed a couple of weeks ago 93 percent of the American public, when asked the question whether this kind of genetic information ought to be available to employers or health insurance companies said, absolutely no. So, this is a widespread concern.

At NIH, where we do a lot of genetic research, fear of genetic discrimination is causing many people to decide not to participate in that research, which both deprives them of the opportunity to get useful information and deprives all of us of the results of the research.

So, we need to take action, and the sooner the better. Every day that goes by, we are missing out on opportunities. As this kind of information more and more moves into the mainstream, and it will

soon, it will have a dampening effect to say the least if people are afraid of obtaining this information about themselves.

This is about all of us. There are no perfect genetic specimens. We all have these glitches. We have the chance to find out what they are in a way that will benefit us. But we need to be assured that that is safe.

Thomas Jefferson wrote the words that you see over there on the Jefferson Memorial: "Our laws and institutions must go hand in hand with progress of the human mind."

Progress of the human mind has led us now to this remarkable point where we can read our own DNA instruction book. Our laws and institutions need to keep up with that, providing people with the kind of reassurance that this information is safe to obtain and won't be used against them. This is an issue of equity, of justice and of civil rights. You don't get to pick your DNA; it shouldn't be used against you.

The President of the United States in his visit to NIH earlier this year strongly endorsed the need for this legislation. Secretary Leavitt has been very much out in front of the promise of personalized medicine and the need for better policies to provide a safe harbor for people who wish to have the information as part of their medical care. So, all of us hope that this will be the year where the American people are given a gift by the Congress that is long overdue: Federal legislative protection against genetic discrimination.

Thank you very much. I will be glad to answer your questions.

[The prepared statement of Dr. Collins follows:]

Testimony
Before the
Subcommittee on Health
Committee on Ways and Means
United States House of Representatives

The Threat of Genetic Discrimination to the Promise of Personalized Medicine

Statement of
Francis Collins, M.D., Ph.D.
Director
National Human Genome Research Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Wednesday, March 14, 2007

Good afternoon, Chairman Stark and members of the Subcommittee. Thank you for the opportunity to speak with you today. I am Francis Collins, Director of the National Human Genome Research Institute (NHGRI) at NIH, part of the National Institutes of Health (NIH) within the Department of Health and Human Services.

It is my pleasure to be appearing before you today as you consider the Genetic Information Nondiscrimination Act of 2007. We stand at a critical time in the development of medicine: the mapping of the human genome has provided powerful new tools to understand the genetic basis of disease, but our ability to fully realize the promise of personalized medicine is limited by legitimate fear of how this powerful information could be abused. Many people are afraid that their genetic information will be used against them and are unwilling to participate in medical research or be tested clinically, even when they are at substantial risk for serious disease. More than ten years ago, expert advisors to the genome project concluded that federal legislation is needed to provide all Americans with protection against genetic discrimination in health insurance and employment. Without it, we may never realize the full potential of genomic research, and, more importantly, of individualized approaches to health care.

New Tools and Technologies

Since the completion of the Human Genome Project (HGP) in 2003, major advances in our understandings of the causes of disease have been appearing at an accelerated pace. As one example, the HGP enabled the development of the "HapMap," a detailed map of variations in the spelling of our DNA instruction books. Research supported by NHGRI has also led to orders of magnitude reduction in the costs of sequencing an individual's complete genome for medical

purposes. It is the vision of NHGRI that within the next ten years, the cost of sequencing the complete genome of an individual will be $1,000 or less. Should an individual so choose, this information could then be used as part of routine medical care, providing health care professionals with a more accurate means to predict disease, personalize treatment, and preempt the occurrence of illness.

New Findings in Genetics of Common Disease

Even before the $1000 genome becomes a reality, advances from genome research are already leading to important new understanding of the role of genetic factors in a number of common diseases. For instance, the HapMap made possible research that recently identified two major genes that influence risk for developing adult macular degeneration, a leading cause of vision loss in the elderly, with those at lowest risk having less than 1% chance of developing the disease, and those at highest risk a 50% chance. Other similarly derived recent discoveries include identification of variants in different genes that elevate risk for developing type 2 diabetes, Crohn's disease, prostate cancer, and Alzheimer's disease. Other new findings include the identification of genetic variants that predict whether or not a particular individual will respond well to drug treatment for disease, or will suffer a side effect. Each of these discoveries opens a new path toward diagnosis, prevention, and treatment, but the public will be reluctant to travel these paths if fair and reasonable protections against the improper use of genetic information are not in place.

NHGRI is currently involved in other groundbreaking initiatives, such as the Genetic Association Information Network (GAIN) and the Genes, Environment, and Health Initiative

(GEHI), that will accelerate understanding of the environmental and genetic causes of common diseases such as asthma, schizophrenia, cancer, bipolar disease, diabetes, and Alzheimer's disease. Increased understanding will in turn lead to better strategies for individualized prevention and treatment and enable the developement of personalized health care. NHGRI has also joined with NIH's National Cancer Institute in funding a joint project called The Cancer Genome Atlas (TCGA) to accelerate understanding of the molecular basis of cancer through application of genome analysis technologies. TCGA will provide new insights into the biological basis of cancer, and will help to optimize treatment and prevention strategies.

Already, healthcare providers can test whether some of us carry DNA variants that pre-dispose us to certain diseases, and new research efforts could help to expand this capability and possibly offer better opportunities for preventive measures. If illness does occur, doctors will have more powerful tools to identify the molecular causes, and to prescribe medicines based on individualized genetic information. This is our chance to transform medicine from "one-size-fits-all" to a potentially personalized approach.

Fear of Discrimination

As you can see, the science of genomic medicine is rocketing forward. But fear of genetic discrimination threatens to slow both the advance of such groundbreaking biomedical research and the integration of the fruits of that research into our nation's health care. If individuals continue to worry that they will be denied health insurance or refused employment because they have a predisposition to a particular disease, they may forego genetic testing that could help guide medical professionals to lessen their risk, simply because the test identifies them as having

such a predisposition. This is about all of us, as there are no perfect specimens at the DNA level; each one of us carries numerous gene variants that increase our risk of developing one disease or another. Therefore, each one of us is at risk for genetic discrimination.

Public concerns about the possible misuse of their genetic information by insurers or employers have been documented. A recent NIH study of families at risk for hereditary nonpolyposis colorectal cancer (HNPCC) (a particular form of colon cancer) revealed that the number one concern expressed by participants regarding genetic testing was about losing health insurance, should the knowledge of their genetic test result be divulged or fall into the "wrong hands." Nearly half of individuals with a 50% chance of having the HNPCC mutation cited fear of insurance discrimination as their greatest concern surrounding their participation in this study. Similarly, a recent survey of the personal attitudes of cancer genetics specialists showed that 68% of respondents would not bill their own insurance company for HNPCC or breast and ovarian cancer (BRCA) genetic testing due to fear of genetic discrimination, and 26% of respondents said they would use an alias when being tested.

NHGRI remains deeply concerned about the impact of potential genetic discrimination on both research and clinical practice. Unless Americans are convinced that their genetic information will not be used against them, the era of personalized medicine may never come to pass. The result would be a continuation of the current one-size-fits-all medicine, ignoring the abundant scientific evidence that the genetic differences among people help explain why some of us benefit from a therapy while others do not, and why some of us suffer severe adverse effects from a medication, while others do not.

In 2005, the Bush Administration issued a Statement of Administrative Policy supporting Senate passage of S. 306, the "Genetic Information Nondiscrimination Act of 2005." That bill never came to a vote in the House. In January of this year, the President visited the NIH and again called on Congress to pass a bill to protect Americans from genetic discrimination. We share the President's concern and commitment to this issue, and we are delighted to see this issue being taken up early in the 110th Congress. We are hopeful that this will be the year when the American people are given a gift that is long overdue – federal legislative protection against genetic discrimination.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee might have.

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

Director
National Human Genome Research Institute
National Institutes of Health
U.S. Department of Health and Human Services

Education:
University of Virginia, 1970 - B.S. (with Highest Honors);
Yale University, 1974 - Ph.D.;
University of North Carolina School of Medicine, 1977 - M.D. (with Honors)

Professional History:
1977-1981, Intern, Resident, Chief Resident in Medicine, North Carolina Memorial Hospital, Chapel Hill, North Carolina.
1981-1984, Fellow in Human Genetics and Pediatrics, Yale University School of Medicine, New Haven, Connecticut.
1984-1993, Assistant, Associate and then Full Professor of Internal Medicine and Human Genetics, University of Michigan, Ann Arbor, Michigan.
1987-1993 Assistant, Associate and then Full Investigator, Howard Hughes Medical Institute.
1993 to present, Director, National Human Genome Research Institute, NIH, Bethesda, Maryland.

Biographical Information:
Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project. With Dr. Collins at the helm, the Human Genome Project consistently met projected milestones ahead of schedule and under budget. This international project culminated in April 2003 with the completion of a finished sequence of the human genetic blueprint. From its outset in 1990, the public sequencing effort swiftly deposited all of its data into free, public databases for use by scientists around the world. Building on the foundation laid by the Human Genome Project, Dr. Collins is now leading the NHGRI effort to ensure that this new trove of sequence data is translated into powerful tools and thoughtful strategies to advance biological knowledge and improve human health.

Dr. Collins' own research initiatives have included the discovery of a number of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington's disease and the gene that causes Hutchinson-Gilford progeria syndrome, a dramatic form of premature aging. In addition to his scientific achievements, Dr. Collins is known for his continuing emphasis on the importance of ethical and legal issues in genetics. He has been a strong advocate for protecting the privacy of genetic information and has served as a national leader in efforts to prohibit gene-based insurance and employment discrimination.

Professional Organizations:
American Society of Human Genetics; American Society for Clinical Investigation; Association of American Physicians; Institute of Medicine; National Academy of Sciences; American Academy of Arts and Sciences.

Chairman STARK. As I understand it, most of us are not offered these tests at our regular annual physicals and so we don't have many cases of actual discrimination. People have suggested we wait until the testing is more universally performed. Would you have any comment on that strategy?

Dr. COLLINS. If you were standing in the middle of a train track and the train was headed toward you but it wasn't going to

hit you for another 10 minutes, I suppose you could decide to wait a little longer and see if you could just, in the nick of time, jump out of the way.

If, on the other hand, you are a thoughtful person or trying to preserve life, it would probably be better to make another plan.

Yes, you are quite right. Most of us have not yet been offered this kind of test. Even though there are a thousand tests available, they are mostly for rare diseases. As the family I showed you indicates, oftentimes the trigger is a very strong history and not all of us have family histories like the one I have shown you.

But increasingly, this is coming into the mainstream. Certainly with the proliferation of discoveries about diseases like diabetes and Alzheimer's, asthma, hypertension and so on that are happening right now, it is only a matter of time, a short period of time, before this does find its way into the kind of talk you are going to have with your physician in the next few years. Do you want to know about these risks? Many people will want to answer that, yes, and to be reassured that it is safe to do so.

Chairman STARK. Well, where do I go, Doc? Say, all right, I am a believer and I want to go have my DNA recorded and then I want somebody to tell me which of these ugly things are going to happen to me, is that available to people with an internist as a primary care physician or people in health plans, generally? What do you do if you want to do it?

Dr. COLLINS. At the present time, the first thing would be to collect a really detailed family history. Because family history is actually a genetic test that is quite revealing and actually free. You don't have to send off your DNA anywhere. Then a physician who is knowledgeable about genetics, which increasingly is more and more physicians—that is something we are working on—or a genetic counselor could look at your pedigree and say, okay, here are some particular things that we might want to think about testing for.

At the present time, that would be the trigger. We are not at the point where we yet have any tests that are being recommended for everybody as a screening test for future risk. Before taking that step, you want to be——

Chairman STARK. But even though you don't recommend it, is there one?

Dr. COLLINS. So, if you want to go to the worldwide web, you can find organizations that will market a lot of genetic tests to you at a certain price. I would be a little wary of those. If you look carefully, many of those are tests that have not been scientifically validated. They will also oftentimes, after offering you the test, try to sell you a nutritional supplement that will take—do something about your genetic deficiency. So, there is a little bit of a racket going on.

Chairman STARK. I can't get by the Viagra ads on the Internet, much less worrying about those guys selling me the other supplements.

Dr. COLLINS. These are in some of the same category, I am afraid. So, we are not quite there.

But, Mr. Chairman, I think again for some people we are there. For that family, we are there. You will hear from Mr. Escher on

the second panel, about how this kind of genetic testing was applied to him without his knowledge.

Again, why would we want to wait to fix this issue from a policy perspective until we have hundreds of millions of victims? If we can kill the risk here earlier on, we should do so.

Chairman STARK. Is there something we should do in Medicare, aside from this protection? I don't suppose Medicare pays for this yet. Is there something we should do that would encourage or accelerate the more generalized use of these tests for the benefit of those of us who are Medicare beneficiaries?

Dr. COLLINS. Sir, that is a great question. In fact, we have been in discussions with CMS about what would be the criteria to begin to reimburse for these genetic tests.

The Secretary's Advisory Committee on Genetics, Health and Society, SACGHS, has been meeting on a variety of topics like this and, in fact, issued a report about a year ago on coverage and reimbursement for genetic tests, which specifically addressed the question that you asked and, I think, made a number of points about what criteria Medicare might want to consider in making a decision about when to cover for these kinds of predictive genetic tests.

I think those are thoughtful recommendations. I think they are under serious consideration. It is, in fact, a very good thing that there is at a high level this advisory Committee that advises Secretary Leavitt about genetics, because this is coming along so quickly.

Chairman STARK. What does a genetic, you know, nice, broad, all-inclusive genetic test cost? To the closest thousand dollars.

Dr. COLLINS. That is a hard question, because both of the number of genetic tests is expanding quickly and the cost is coming down so fast. At the present time, you could test a specific place in your DNA sequence and ask whether it is a letter T or a letter C for something in the neighborhood of less than 50 cents. But, of course, on top of that you have to have quality control and you have to have somebody who is going to sit down with you and spend health professional time going over the meaning of the result.

So, I actually think it is not the cost of the test that is going to be limiting. It is going to be the other important aspects of that, as far as the delivery of that information, so that you can use it in a way that benefits your own health, instead of just giving you a laundry list that doesn't make sense.

Chairman STARK. Thank you.

Mr. Johnson, would you like to inquire?

Mr. JOHNSON. Thank you, Mr. Chairman.

You know, I appreciate the fact that people, including me, want their genetic information protected from the wrong eyes. This legislation that we are considering has a fairly broad definition of genetic information, including family history, which you say is important.

Dr. COLLINS. Yes.

Mr. JOHNSON. Do you think that is too much or not enough?

Dr. COLLINS. I think it is actually quite critical to include family history. As you can see from this example, a family that I talked

about, family history is often the trigger that initiates an examination that results in a genetic test being conducted.

You can imagine if legislation covered only the results of a test but not the family history, then the amount of protection being offered would be quite limited and almost nonexistent in a situation such as this sort. After all, the insurance company or the employer might say, well, it wasn't the genetic test that caused me to decide to jack up the premiums or to pass over this person for a promotion; it was their family history. Unless family history is included in the definition of genetic information, then essentially this bill would be toothless.

Some of the states have, I think, made that mistake and have bills that have genetic information that don't include family history.

Mr. JOHNSON. Yes, but what percentage of the family history, what percentage of the time does it actually come true that they pick up this problem?

Dr. COLLINS. Sure. Most of the time, family history is a clue but it is not certainly determinative of what is likely to happen.

Mr. JOHNSON. Right. Right.

Dr. COLLINS. Again, the point of the bill is to try to say if there is predictive information about somebody's likelihood of falling ill downstream, and they may well not fall ill downstream, that predictive information ought not to be used to take away their health insurance access or their access to a job. They ought to be judged on other——

Mr. JOHNSON. I know. But our job is to try to keep the insurance companies from doing just what you said. How do you do that?

Dr. COLLINS. The way this bill has been written, and it has been under construction now for many years in the many iterations that we have gone through over 12 years getting to this point——

Mr. JOHNSON. I understand that, and that has been one of the problems we have had.

Dr. COLLINS. I think it has carefully considered all the ways in which there might be loopholes to the protections that the public needs and expects and tried to cover those loopholes with things such as including the family history in the genetic information definition.

Mr. JOHNSON. Well, but you made the statement also, I believe, that it requires several if not a whole bunch of people to figure out the family history. How do you keep all that information confidential?

Dr. COLLINS. Again, it should not be confidential to the health care provider. Let us be clear, this bill, and it has some specific language in it that says this, should in no way be construed to interfere with the practice of medicine between the health care provider and the patient.

What this is saying, in terms of the health insurance provisions is that the health insurance company may not request or require that kind of information. If they happen to obtain it, which they might very well in the process of reimbursement for services, they are not to use that information in a discriminatory way that would cause that person to lose access to health care.

So, it is, I think, worded appropriately, so it doesn't get in the way of the delivery of medical care, because we all believe that ought to be better, not worse. But it puts in place protections against the misuse of the information in a discriminatory way.

Mr. JOHNSON. I think our lawyers will like it.

Thank you, Mr. Chairman.

Chairman STARK. Mr. Thompson, would you like to inquire?

Mr. THOMPSON. Thank you, Mr. Chairman.

Could we talk a little bit about how the folks' concern that they may be subject to discrimination is affecting efforts in regard to research?

Dr. COLLINS. Certainly. That is a very serious issue right now. This is not a hypothetical future risk. In fact, we have documented this over the course of more than 5 years.

At NIH, we run many research protocols where it is part of the protocol to undergo a genetic test, whether it is for colon cancer, as in this situation, or breast cancer or diabetes or a variety of other conditions. Individuals are intensely interested in those research protocols, especially if they have a family history and they are wondering about their own future risk.

We have documented that the most common reason why someone who is otherwise very interested and willing to join up to a research study decides to back away and that reason is genetic discrimination. Roughly a third of the people who would otherwise participate are now deciding not to, specifically because of this concern.

As a physician, I can't sit across from somebody expressing that concern and tell them that their concerns are unwarranted. At the present time, without this legislation, they are actually, I think, looking at a serious risk. Even though we are very careful about how we keep the information confidential.

This is permanent information. Once you have had a genetic test that shows something about your genome, that is going to be with you from now on. Without the assurance that it won't come back to bite you, some people just aren't willing to take the chance.

Mr. THOMPSON. Are those data quantifiable, or is this anecdotal?

Dr. COLLINS. They are quite quantifiable. So, I can submit for the record, three manuscripts that have been published that describe what those statistics look like. They all come up with this conclusion. It is about a third of individuals in these research studies who decide not to participate because of this specific fear.

Mr. THOMPSON. Mr. Chairman, I would like to ask that those documents be submitted for the record. I think that that is very important. Because it sounds like if this bill were to pass, that would fix a lot of this problem.

Dr. COLLINS. A huge sigh of relief would settle over the research community that we would no longer be in the embarrassing position of having to tell people that this is not a safe procedure to undergo. A huge sigh of relief would fall over some of the physicians who are currently in a position of having to advise patients with a high risk of breast cancer that if they are going to undergo

a BRCA1 test, they might want to do it under a false name. People are doing that right now.

Mr. THOMPSON. Great. I think that is important.

[The information follows: PENDING]

Mr. THOMPSON. Then the other question I have is, if the bill were to pass, are there any things in this that we should be concerned about as far as it would impact prevention and wellness programs that are offered by some health plans?

Dr. COLLINS. No, I don't believe that there is a concern there. Obviously, that was an issue in the drafting of this bill to be sure that we didn't discourage in any way wellness programs that employers——

Mr. THOMPSON. You feel that that has been well protected?

Dr. COLLINS. I believe that that has been very well protected by the way the bill has been written.

Mr. THOMPSON. Thank you, Dr. Collins.

I have no further questions, Mr. Chairman.

Chairman STARK. Mr. English, would you like to inquire?

Mr. ENGLISH. Thank you, Mr. Chairman, I would.

Dr. Collins, welcome. We are delighted to have you here and I am particularly delighted to be an original cosponsor of Representative Slaughter's bill.

Looking at the big picture, sir, can you tell us first of all what the current cost of a genetic test is? Second of all, if utilization increases, what likely impact is that going to have on the quality of genetic testing and its cost?

Dr. COLLINS. So, currently the costs are all over the place in terms of a specific test. As I mentioned earlier, the actual cost of being able to go and look at DNA from an individual and say, do you have a T or a C in that position has dropped profoundly and is in the neighborhood of less than a dollar.

But on top of that, there are many other costs that fit in, and I might mention that one of them is that some of these tests have been exclusively licensed to a single diagnostic company, which has tended to discourage competition, and so some of the tests have, in fact, remained more expensive than certainly on a technical basis you would expect they need to be. Including at least one that is up in the neighborhood of $3,500 for a genetic test.

But those costs will be coming down, and will be coming down rather quickly, I think, as the number of tests grows and the ability to multiplex them increases.

The wider availability of such tests, I think, would in fact drive costs down. It would certainly improve the possibilities of individualized prevention, something that we all hope and dream for. At the moment, if you are going to go to your physician and say, I think I want to practice better prevention, what should I do, you will get a sort of one-size-fits-all prescription, maybe a little bit tweaked by your family history or your blood cholesterol, but not in an individual way that would be possible with this new kind of information.

So, as we bring that more into the mainstream, I think that will have the potential of keeping all of us healthy for a longer period of time. Goodness knows, if we are going to sustain the costs of our

health care system, we have to do a better job of focusing on wellness instead of treating far advanced disease.

Mr. ENGLISH. Dr. Collins, that was going to be my next question. You know, assuming for a moment, I mean, there are a number of proposals out there for how to cure the health care system itself. But given the fact that most of them, I think, are grounded, whether they are based on a government model or a market model, most of them are grounded in achieving cost savings.

How would a broader use of this sort of testing contribute substantially? Can you give us an example of a utilization of this test that is just now on the horizon that could have a significant impact on the cost of health care?

Dr. COLLINS. My boss at the NIH, the NIH Director, Elias Zerhouni, is fond of pointing out the four P's of where we are going in terms of the practice of medicine, if we are going to drive down costs. That is personalized, preemptive, and predictive. All of those apply to what we are talking about here, as well as participatory, the fourth P; that is, getting everybody engaged in more attention to their own medical care.

I can give you an example right now where costs have already been documented to be reduced. Interestingly it is the same condition that is diagramed there on the screen, a condition called hereditary nonpolyposis colon cancer. This affects something like one in 500 individuals in this country who will carry a misspelling in one of these genes that causes colon cancer and sometimes uterine cancer as well.

We know that if we could identify those individuals, tell them of their risk, get each of them into a program of colonoscopy beginning at an early age, maybe age 35 instead of age 50, you can go through the calculations and they have even documented this now in real cases that have been followed for some time, that you will reduce substantially the downstream occurrence of metastatic colon cancer, which both costs productive years of someone's life and actually costs medical care dollars in great excess of what the colonoscopy would have cost. That is a published analysis that will tell you this is an approach that not only saves lives, it saves money.

Mr. ENGLISH. Thank you, Doctor, and thank you, Mr. Chairman. I yield back the balance of my time.

Chairman STARK. Mr. Becerra, would you like to inquire?

Mr. BECERRA. Thank you, Mr. Chairman.

Dr. Collins, thanks for being here with us. Let me ask a couple of questions regarding how far we extend the protection. I think most of us agree that we need to do more to protect individuals when it comes to the use of the information, genetic information. But we also want to make sure that because it is genetic information, it goes beyond just the individual but includes family members as well.

How far do we extend that? At what point do you say that you can't protect the great-great grandchild of the person whose genetic information was taken?

Dr. COLLINS. So, obviously, there is no bright line one can draw and say, well, family history is no longer relevant. When you get to that point, the way the bill has been written, it goes to the

fourth degree relative, which is to say if you're talking about me, you could be talking about my mother, that would be one degree; my aunt, that would be two; my cousin, that would be three; my first cousin, once removed, that would be four. That is a bit of an arbitrary dividing line, but it seems nicely inclusive of where most of the major risks are going to reside.

Mr. BECERRA. I think a number of folks would say that is going pretty far out, that first cousin once removed. At what point, are you stifling the ability to actually use information for valid purposes?

Dr. COLLINS. I hope not at all. Again, the purpose of this bill is simply to say that that kind of genetic, predictive information ought not to be used by a health insurance company, particularly in the individual underwriting market, or by an employer to make decisions that would discriminate against that individual.

But it is, I hope, absolutely clear that this in no way is intended to inhibit an interaction between a health care provider and their patient, trying to assess what is best for them as far as preventive care that is going to keep them healthy.

With regard to this fourth degree relative, again, just look at this family that is up there on the screen. While I won't try to count through all the relationships, there are certainly people in that family who are at high risk for colon cancer who are fourth degree relatives of other people with colon cancer, because it has really traveled through that family in a very devastating way.

Mr. BECERRA. Because this is science, this isn't two dice that we are rolling on a table, we feel pretty comfortable that we can make these predictions that we need that type of protection for purposes of nondiscrimination, because it is based on hard numbers and available data?

Dr. COLLINS. It will be based on hard numbers in the sense that you can make a prediction statistically based on somebody's position in the family and what you have learned about their DNA sequence, what their likelihood is of falling ill. But I should be clear about this.

Most of the genetic tests that are going to find their way into the mainstream of medicine in the next three or four or 5 years will not be yes/no; they will be, well, your risk is threefold higher of getting diabetes than somebody else. Or your risk of getting prostate cancer is threefold lower than somebody else. But you could still get it.

The idea here, though, is to be able to optimize where you pay your highest level of attention as far as your own prevention, instead of having everybody do the same thing, which is what we have largely been doing before. But most of these tests are not going to be deterministic; they are going to be predisposing.

Mr. BECERRA. I have one last question, Mr. Chairman, and Dr. Collins this is going to take you somewhat off base, so ratchet your brain a bit, because this is a different question. It still relates to genetic information.

I would like you to give me your thoughts, and if you can't give me too much right now, I would love to chat with you later on about this.

Right now, we are talking about not misusing this information, not taking it beyond the health care arena to make decisions. I have a concern that we are seeing more and more genetic information being withheld because of the ability to patent genetic information, genes, and therefore keep it out of the public domain unless you are able to pay the high price to get the information.

I know that is not necessarily the subject of this hearing, but I am wondering if you have any thoughts about the whole issue of patenting genes and genetic information?

Dr. COLLINS. Thank you, Mr. Congressman. Yes, I have a lot of thoughts about that and if we had more time, I am sure we could dig deeply into that. I am aware of the bill that you and Mr. Weldon have recently introduced on the topic of gene patenting.

This has been a subject of intense interest from the Genome Project's perspective. One of the things that we did to try to defuse what was a bit of a gold rush toward claiming parts of the human genome was to put all of the information that we derived on the Internet every 24 hours, basically making it prior art and therefore less likely to have IP claims upon it. But, of course, a lot of genes did get claimed anyway.

The NIH has worked hard, I think, to put out guidelines on this topic. I would particularly want to refer to the guidelines on research tools and also the guidelines on licensing of genetic discoveries because it is not just patenting, it is licensing that often either creates a good or a bad situation.

I think we make a mistake, though, when we think of patenting of genes as a moral issue. I think it is really a legal question. The real deciding question ought to be, is this benefiting the public or not? Because clearly there are instances in which a patent benefits the public by providing the kind of impetus for developing a product that the public needs.

One can cite the example of erithropoetin, for instance, as a very valuable pharmaceutical and those who developed that would tell you that a patent on the gene was essential from their perspective to invest the hundreds of millions of dollars that it took to get that drug to market. But is it reasonable to patent a gene where there is no therapeutic sort of pathway that is apparent? Many of us would say, no.

In more than 10 years of working on this issue, it shareholder become clear to me that it is extremely nuanced and there is no sort of straightforward, easy answer to the kind of important question that you have just asked.

I actually think, compared to where we were 10 years ago, there is a lot more sensibility out there. But we are living with the legacy of a lot of patents that were issued in the course of the last 10 years that, in retrospect, may not have necessarily been good for the public. How we sift through that thicket and try to continue to make progress is providing a bit of a challenge.

I am getting on a plane in about 3 hours to go to Europe to talk about an international project to try to inactivate every single one of the genes in the mouse, the mouse being our most important laboratory model. The biggest thing that is getting in our way is the thicket of patents about the technologies that have been developed to do this. It is actually creating quite a major headache. In retro-

spect, some of us wish that people had not been so quick to rush out there and claim those discoveries.

Mr. BECERRA. Thank you for the answer.

I yield back, Mr. Chairman.

Chairman STARK. Mr. Camp.

Mr. CAMP. Thank you, Mr. Chairman.

Dr. Collins, good to see you again. I am sorry, I apologize for being late to the hearing.

I appreciate your testimony, and obviously, this legislation has a lot of bipartisan support. It passed Education and Workforce with a voice vote. The idea of restricting insurers' use of genetic information or employers, for purposes to either deny people coverage or deny them employment is something that nobody wants to see happen.

But I have a question. You mentioned in response to a question that, obviously, having a health care provider and patient could be very, very helpful. The question I have is, if an individual has this information and needs extra cancer screenings or blood tests, their insurer is going to know because they are going to have something out of the norm.

How do we safeguard using genetic information for positive reasons and also preventing it being used for the bad reasons?

Dr. COLLINS. So, the drafting of this legislation very much seems to take that into very serious account in trying to get the balance right. Because, clearly, you don't want to discourage the use of what could be highly valuable information because something in this legislation seems to imply that it is improper.

Again, there is nothing in the legislation to say that a health insurer who learns about genetic information of one of the people that they cover is in trouble, as long as they did not request or require this and as long as they do not use this in a way to discriminate. But, clearly, they are going to obtain this information.

Employers may, by accident, obtain this information. There is clear language in here to say there is a safe harbor if this is genuinely something that was dug out improperly, that there is no culpability on the part of the employer for that.

I guess I take particular comfort in the language here, the rule of construction, which says, and I am quoting here: Nothing shall be construed to limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or family member of such individual undergo a genetic test.

So, they are trying very hard, I think, to make it clear what the goal is and what the goal is not. I think the way this is couched would accomplish that goal of encouraging the use of genetic medicine without allowing the discriminatory use, which will cause the public to stay away from it.

Mr. CAMP. As well, you're correct, not only will insurers get that information, but any employer will have copies of those insurance claims, they are going to have knowledge of any special test in the future that may be required because of a propensity for some kind of illness found out as a result of genetic testing.

Dr. COLLINS. Again, I think the bill makes it clear that employers who obtain that information as part of the routine practice of—

the fact that they are responsible for health coverage for many of their employees are not held responsible for that. That is not considered a violation.

It is considered a violation, on the other hand, if they require it or in other way put pressure upon the employee to go through a test that the employee was not planning to undertake.

Mr. CAMP. You also indicate in your testimony that if safeguards are not put into law, there could be not as many advances in scientific research in this area.

Dr. COLLINS. Yes.

Mr. CAMP. That you are finding some research participants are concerned the information that may be found will be used against them?

Dr. COLLINS. Yes, and there are well documented examples of that.

Mr. CAMP. Is there any indication that some people just don't want to know what their genetic information is?

Dr. COLLINS. That is certainly true. In particular, in a circumstance, of course, where there is nothing you can do about it, genetic tests can predict your propensity for future illness. People are particularly interested if that is then tied to an action they can take to reduce that risk. In fact, it is that kind of study that we are primarily conducting at NIH where there is a potential intervention. Most people want that information.

The kind where you can't do anything about it, there are some research studies of that sort. Certainly some people decline simply because that is not information they want.

Mr. CAMP. Just finally, I see my time is about to expire, but can you quantify the amount of research that might go forward if these safeguards are put in place? Is that possible to do?

Dr. COLLINS. In a certain sense, that we can already tell you that studies that offer people genetic information as part of the research protocol, a third roughly—and this has been true of several different studies—of the people who are offered the possibility of participating and who say they want to, basically then walk away because of their fear of genetic discrimination.

So, we would increase the participation overnight if we could assure people that that is no longer a risk. My hope is, it won't be long before we can do that.

Mr. CAMP. All right. Thank you very much again. Thanks for your testimony.

Dr. COLLINS. Thank you.

Chairman STARK. Ms. Tubbs Jones, would you like to inquire?

Ms. TUBBS JONES. Thank you, Mr. Chairman.

Good afternoon, Doc. How are you?

Dr. COLLINS. Good afternoon. Just fine.

Ms. TUBBS JONES. Good. My predecessor, the Honorable Congressman Louis Stokes, has a building named after him at NIH.

Dr. COLLINS. My laboratory is in that building.

Ms. TUBBS JONES. It is in that very building? I thought that it might be.

I want to speak to you about health disparities and the impact that genetic testing could well have on the high rate of health dis-

parity among African Americans and people in the majority in the country.

Tell me your impression as to whether this will assist in relieving us of disparities or perhaps elevate some of the disparities.

Dr. COLLINS. It is a very important question, and one that many of us have been wrestling with in terms of the most effective way to get the answers to the causes of health disparities, which we know continue and are vexing and troubling and do not show signs of going away any time soon.

Obviously, when you see a circumstance where a particular group is experiencing a higher rate of an illness or a more severe form of the illness, there are many reasons why that might be. Certainly access to health care often turns out to be a very significant one, as do other environmental circumstances such as diet, such as cultural practices. But, of course, genetics is always in there as a possible contributor.

We don't know in most instances whether it is an important contributor or not. Until we find out, it is hard to come up with a good prescription of how it is we can close these gaps as far as experiences of good health.

I will tell you one example. Prostate cancer. We have known for a long time that prostate cancer runs in families. We also know that prostate cancer tends to afflict African American males at a substantially higher rate and oftentimes at an earlier age. The question has been, what is that about?

Within the last year, there has been a discovery of a major gene that seems to be involved in prostate cancer risk, initially discovered in Europeans and subsequently, in a very careful study of African Americans, it looks as if it may be even more important in that group. So, in this one instance, we might have a clue that at least part of that health disparity ties into this particular genetic factor.

Now, that could be extremely useful to know in the sense that that genetic factor may predict a bit about how to follow those individuals and what kind of intervention might work. Instead of the one size fits all, well, you know, you should go to the doctor, you should have your PSA, maybe, maybe not, depending on who you ask. Now, finally, we are going to have more of a bright light shining on the cause of this illness. What I am saying for prostate cancer is now being attempted for diabetes, another disease of major health disparity.

Ms. TUBBS JONES. The true dilemma is that, historically, African Americans have been reluctant to participate in any type of research based on their experiences of discrimination in research in health care.

Dr. COLLINS. Understandably.

Ms. TUBBS JONES. To add to that, the genetic testing presents another level of concern.

I also am smiling because I am sitting here thinking about the fact that Reverend Sharpton has now learned that he is related to Strom Thurmond. I guess Strom is turning over in his grave, but just to think about the connection between—for majority and minority in terms of that.

But I really want to go back and focus—that was kind of a lightness in what I was talking about. But the reality is that discrimination, which may appear to be or a policy which maybe appear to be neutral on its face can have a discriminatory impact. That is why in litigation with regard to discrimination, we look to not only whether it is neutral on its face but whether it has a discriminatory impact.

I am just saying to you, based on my experiences in that and the fact that I am African American and represent a large population, and I know I speak on behalf of the Congressional Black Caucus on this issue, that as we walk down this road, we need to be particularly concerned about the impact that this could have on not only African Americans but other minorities in our country about access to health care and research and the like.

I thank you for your response. I think that we have an opportunity to really make a significant impact. But I am just trying to back up and say, pay close attention.

Dr. COLLINS. I am totally with you. I agree that is an issue that we ought to have at the top of our agenda as we see how personalized medicine begins to become a reality.

My hope would be that this bill, which takes genetic information off the table in important decisions about employment and health insurance, will be a step in the right direction.

Ms. TUBBS JONES. Because it looks like possibly—and Mr. Chairman I know I am over time and I am almost done—that as we provide health care to all Americans, the worry is that there will be those who will cherry pick the most healthy people and leave the people who need the most health care out in a pocket by themselves, which makes their health care so much more expensive.

I am hoping that, as we go down the genetic trail, we don't give people who want to discriminate another opportunity.

Dr. COLLINS. I completely agree we you. At the moment, they have that opportunity in certain loopholes. This bill aims to plug those.

Ms. TUBBS JONES. Thank you, Mr. Chairman. Thank you, Doc.

Chairman STARK. Thank you.

Mr. Emanuel.

Mr. EMANUEL. Mr. Chairman, thank you.

Dr. Collins, I will try not to make you late for your flight to Europe here.

Pretty much a lot of the other questions I was going to ask have been asked. So, if I could just narrow it down to just one particular subject, and that would be the overlap between the research you are talking about, genetic code, genetic information, and the area of medical records.

I am hoping our full Committee and this Subcommittee will deal with the issue of medical records, electronic medical records, and how do we want to do something over here and something over here and the two aren't either complimentary or cognizant of each other.

So it is not a specific question, how do you protect genetic information. But it is a specific question. If you could look forward, what guidance would you give to us? As I do think we have to deal

with medical records, electronic medical records that is. What information would you impugn to us or give to us so we do that right, so that we can accomplish both goals?

Dr. COLLINS. That is a great question and one that many of us——

Mr. EMANUEL. I will make sure my staff know, since they thought about it.

Dr. COLLINS [continuing]. Many of us are thinking about exactly that, and certainly Secretary Leavitt is both extremely persuasive about the need to hurry up here with electronic health records and also very committed to this idea of personalized medicine. So, this is being discussed at a very high level in the Department of Health and Human Services.

That includes, by the way, a serious discussion about how we should take genetic information that is going to find its way into these electronic records and standardize it so that you could actually make some sense out of it when you are trying to compare across different databases.

For me, as a researcher, the chance that over the course of the next few years we might be able to learn an awful lot more about the interaction between genes and the environment will mean that we need to have standard ways of keeping track of both environmental exposures and genetic information in an electronic form.

I think actually these things dovetail quite nicely. Because the fact that you are trying to develop an electronic health record with a standardized way of incorporating genetic information provides you the opportunity to put it into a field that is appropriately labeled so there will be no ambiguity here about whether this is something which ought to be protected by this particular nondiscrimination bill.

As opposed to the current rather messy medical records system, where you might have to sift through many pages of hand-scribbled notes to even be quite sure what is in there that ought not to be used by a health insurance company in doing individual policy underwriting.

So, my hope would be that if we have a system that can actually better incorporate and better label the information about each of us in our medical care, that will facilitate the process of avoiding the kind of discriminatory actions that otherwise could happen.

Mr. EMANUEL. Mr. Chairman, I don't have any other questions. I do think that as we look at the notion of electronic medical IT, electronic medical records, this information, I think, will be very important in guiding us as we start to develop that piece of legislation, which I know has been a priority for you and something we discussed in the last congress.

Chairman STARK. Thank you.

Mr. Pomeroy, would you inquire?

Mr. POMEROY. Thank you, Mr. Chairman. I have no questions. I just commend Dr. Collins for the wonderful presentation he gave the National Prayer Breakfast. I completely enjoyed it. I wish you had brought your guitar today; maybe you could have regaled some of this testimony in song. But you did a wonderful job and I have also enjoyed the testimony. I have no questions to add to it.

Thank you.

Dr. COLLINS. Thank you.

Chairman STARK. Thank you. Have a safe trip. Don't forget your passport.

Dr. COLLINS. I won't get very far if I do.

Thank you all very much.

Chairman STARK. Thank you, Doctor.

We will now have a panel inform us about various aspects of this issue. Ms. Karen Pollitz, who is the project director at Georgetown University Health Policy Institute; Ms. Sharon Terry, who is the president and CEO of the Genetic Alliance; Mr. David Escher, formerly in the employ of the Burlington Northern of Reno, Nevada, and Dr. William Corwin, the Medical Director of Clinical Policy, the Harvard Pilgrim Health Care service on behalf of America's Health Insurance Plans.

Why don't I ask you to testify in the order in which I called you.

So, Karen, welcome back to the Committee. Why don't you proceed to enlighten us any way you would like.

STATEMENT OF KAREN POLLITZ, PROJECT DIRECTOR, GEORGETOWN UNIVERSITY HEALTH POLICY INSTITUTE

Ms. POLLITZ. Thank you, Mr. Chairman, Mr. Camp, Members of the Subcommittee. I am Karen Pollitz, and I direct research on private health insurance at Georgetown University's Health Policy Institute. I am pleased to testify today about genetic discrimination in health insurance and about H.R. 493, also known as GINA, which would prohibit it.

Congress and the states have already taken some steps to end genetic discrimination in health insurance but work remains to be done. For example, with HIPAA in 1996, Congress prohibited insurance companies in the small group market from denying coverage to any small employer based on any health status reason, including genetic information. HIPAA also limited the imposition of preexisting condition exclusion periods in all group health plans and prohibited pre-ex based on genetic information in all group health plans.

However, HIPAA did not set any limits on what employer groups can be charged in terms of premiums based on the health status of members of the group.

Congress has also limited medical underwriting in Medigap or Medicare supplemental insurance. Seniors who apply for Medigap policy within the first 6 months of Medicare eligibility cannot be turned down or charged more based on their health status.

After this open enrollment period, however, seniors may face medical underwriting in the Medigap market. Federal law protections also do not apply to disabled beneficiaries under the age of 65, although more than 20 states do limit medical underwriting by Medigap insurers for these individuals.

In the past, critics have questioned the need for Federal law prohibition of genetic discrimination in health insurance arguing that very few such instances of problems have yet been documented. However, it is important to remember, as Dr. Collins just said, that very few individuals have undergone genetic testing to date.

For example, since genetic testing for hereditary breast and ovarian cancer became clinically available via the BRCA1 and 2 tests

in the mid-nineties, 75,000 individuals have been tested through the commercial lab that holds the patent on these genes and approximately 9,000 have received a positive test result. So, there aren't that many people yet to be discriminated against.

My colleagues at Georgetown and I recently completed a study on individual health insurance market underwriting practices with respect to genetic information. We asked 23 individual health insurance companies to medically underwrite hypothetical applicants.

Four pairs of applicants were presented. Within each pair, one applicant had received a positive genetic test result indicating higher risk of future disease. In seven instances, five of these 23 responding medical underwriters said they would take an adverse action based on genetic information. They would turn the applicant down, charge them more, or permanently exclude coverage for their preexisting condition, which was the genetic information.

We also asked underwriters what action they would take based on an applicant's receipt of genetic services, which is mentioned in GINA. Specifically, we asked them to consider an applicant with a BRCA1 mutation whose doctor had discussed or recommended preventive surgery to reduce her future risk of cancer. Thirteen underwriters responded to this question. Of those, five said that they would take an adverse action based on even a discussion of risk reduction options and 10 of 13 said they would take an adverse action if the doctor had recommended an intervention to reduce risk.

Our research findings confirm that patient fears about genetic discrimination in health insurance are not unfounded. A Federal law prohibition on medical underwriting based on genetic information in all types of health insurance is reasonable and good public policy.

Finally, Mr. Chairman, I would just note there was discussion earlier today and concern has been raised at prior hearings that H.R. 493 would prevent insurers from using genetic information for medical appropriateness review of claims. It does not.

Current law, health privacy rules, expressly permit the use of personal health information including genetic information for medical appropriateness reviews and H.R. 493 does not disturb that authority. The bill does prohibit insurers from requiring an individual to undergo a genetic test. That's different. The decision to undergo a test is very personal and impacts not only the patient but potentially members of their family. As you heard Dr. Collins say, some people don't want to have the test. So, that decision under the bill rests with the patient.

But once a patient has undergone testing, the information about the results of that test can be available for appropriate uses by insurers.

Thank you very much for your time today.

[The prepared statement of Ms. Pollitz follows.]

GEORGETOWN UNIVERSITY

Health Policy Institute

Testimony of Karen Pollitz
Research Professor
Georgetown University Health Policy Institute
on
Genetic Discrimination in Health Insurance

U.S. House of Representatives
Committee on Ways and Means
Subcommittee on Health

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Chairman Stark, Representative Camp, and Members of the Subcommittee, my name is Karen Pollitz. I am an adjunct professor of public policy at Georgetown University and direct research on private health insurance at Georgetown's Health Policy Institute. I am pleased to testify today on the subject genetic discrimination in health insurance.

For more than a decade, scientific and public policy leaders, including the Secretary's Advisory Committee on Genetics, Health, and Society, have called on Congress to enact comprehensive legal prohibitions on health insurance discrimination:

> "[The Committee] heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing."[1]

Without question, a prohibition on genetic discrimination challenges a key construct in medically underwritten health insurance. In return for premium payments, insurers promise to protect consumers against the cost of unknown, future medical risks. Insurers use medical underwriting to distinguish known risks that will not be covered. Eventually, scientific advances may render this construct obsolete, and all people will be able to discover one or more of our future health risks through genetic testing – rendering us all "uninsurable." By protecting our

insurability, however, GINA also makes it more likely that the medical benefits promised by genetic science come to pass with the discovery of more effective treatments, cures, and preventive therapies for many serious and expensive health conditions.

Current law prohibitions are incomplete

Congress and the states have already gone a long way toward ending genetic discrimination in health insurance, though work remains to be done. There is not yet comprehensive protection against genetic discrimination in health insurance. Comprehensive protection will prevent all health plans and health insurers in all markets from turning people down, charging them more, or excluding or limiting covered benefits based on genetic information. Only federal legislation can accomplish this goal.

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), setting federal minimum standards for private health insurance, including a requirement that employer-sponsored group health plans may not exclude participants based on genetic information or other factors relating to health status. HIPAA also prohibited group health plans from imposing pre-existing condition exclusion periods based on genetic information. However, HIPAA did not prohibit individual market health insurers from underwriting on the basis of genetic information, nor did it limit insurers in any market from varying premiums on that basis.

Since HIPAA, 43 states have prohibited use of genetic information by individual market health insurers. (See Appendix A) Most have enacted statutory prohibitions, which vary. Some state laws, for example, prohibit medical underwriting based on genetic test results, but not on family history. A few states prohibit insurers from denying coverage based on genetic information, but permit premiums to be surcharged. Interestingly, most state insurance regulators would enforce a broader prohibition on genetic discrimination than plain statutory language might otherwise indicate. For example, most say insurers cannot underwrite based on family history, even when this is not specifically included in the state law definition of genetic information.

However state laws do not apply to group health benefits offered by so-called self-insured employer plans because a federal law called ERISA preempts state regulation in this area.

Congress is now considering HR 493, the Genetic Information Nondiscrimination Act (GINA.) This important legislation was introduced to establish comprehensive national standards that protect against genetic discrimination in health insurance and employment. Title I of this bill would prohibit discrimination against members of employer-sponsored group health plans based on their genetic information, including receipt of genetic services. The group market provisions of Title I would also prohibit insurers from charging employer groups higher premiums based on genetic information about members of the group. Group health plan and health insurance standards in HR 493 are drafted in both ERISA and the Public Health Service Act. In order for these standards to be enforceable similar to other federal group health plan standards, amendments to the Internal Revenue Code would be needed, as well. Title I of HR 493 also prohibits genetic discrimination in individual health insurance, and in Medicare supplemental insurance policies.

Comprehensive prohibition of genetic discrimination in health insurance is needed.

Some in the insurance industry have testified that federal legislation is not necessary, arguing that there is no evidence that insurers engage in genetic discrimination.[2] According to one industry expert,

> "There is good research out there showing that people *believe* employers, health insurers, doctors and the family dog are using genetic information against them. [But] health insurers are not using genetic information. There is a very real public fear but it is unfounded. That information is not being used against people today."[3]

However, it is unlikely that medical underwriters in health insurance have had many opportunities to discriminate based on genetic information. The science of genetic testing is still

young, and relatively few individuals have undergone predictive genetic testing in the U.S. For example, genetic testing for hereditary breast/ovarian cancer via *BRCA1 and BRCA2* testing is one of the better known and more widely used predictive genetic tests. Since this genetic test became clinically available in the mid 1990s, about 75,000 individuals have been tested through the commercial lab which holds the patents on these genes, and approximately 9,000 have received positive test results.[4] Many, if not most of those patients with positive test results likely were insured by employer-sponsored group health plans, where discrimination based on health status is already largely prohibited.

Even so, as causative genes associated with increased susceptibility to common diseases, such as asthma, heart disease, and cancer are identified, the number of tested individuals will grow considerably. It is therefore important to understand how health insurers would respond to genetic information about applicants for coverage when they encounter this information in the medical underwriting process.

Background on Medical Underwriting

Individual health insurance plays a small but important role in our nation's system of health coverage. People often turn to this market when they cannot get health benefits from an employer or when they are ineligible for public programs such as Medicare or Medicaid. In 2005, over 17 million people in the U.S. were covered by individual health insurance, or 6.6 percent of the non-elderly population.[5] On average, over a three-year period, one in four adults buys or seeks individual coverage.[6]

Individual health insurance is medically underwritten in most states. This means applicants for coverage must submit information about their current and past health status – for example, whether they have been diagnosed with medical conditions such as diabetes, dates of and reasons for recent physician visits, names and dosages of recently prescribed medications,

etc. Health insurance applications typically do not include specific questions about genetic test information nor about family health history.

On as many as half of individual health insurance applications, underwriters make a decision to issue or decline coverage based solely on health status information provided on the application.[7] For other applicants, additional information may be required. All applications for medically underwritten health insurance policies require written consent to release any medical records and to submit to further medical examinations that may be requested. Most often additional medical information will be sought directly from the applicant (for example, a telephone interview to determine results of a recent pap test), or her physician. Less frequently, applicants may be required to take a physical examination or submit samples of urine, blood, or saliva for testing. A 2001 report on medical underwriting practices found that in the course of 420 applications for coverage studied, underwriters requested further specific medical histories 179 times, attending physician statements and/or copies of patient medical records 140 times, samples of blood, saliva, or urine for laboratory testing 46 times, and paramedic physical examination of the applicant 21 times.[8] Other experts on individual health insurance market underwriting suggest patient medical records are typically requested on 20 percent of applications, while a very small portion of insurers (estimated at fewer than one-in-ten) may request records on more than 40 percent of applications.[9] It is in this additional investigation of an applicant's medical history and health status that information about genetic testing is likely to be discovered. Underwriters can come across medical information they did not specifically seek. Once disclosed, however, they are obliged to consider, evaluate, and act upon all available information.

The actions underwriters may take on an application fall into three main categories.

- Coverage may be offered, or the applicant may be turned down.
- If offered, coverage may be priced using a standard rate premium, or a premium surcharge may be applied.

- If offered, the policy may include all covered benefits, or certain benefits may be specifically limited or excluded. For example, the insurer may apply an exclusion rider,* or increase the policy's annual deductible.

Underwriter responses to genetic information

Last year, my colleagues and I partnered with Beth N. Peshkin, a senior genetic counselor and associate professor of oncology at Georgetown's Lombardi Comprehensive Cancer, to conduct a study of medical underwriting practices in the individual health insurance market as they relate to genetic information. Our team also worked with private risk management consultants to design and implement this study. This project was supported by a grant from the Nathan Cummings Foundation.

Professional medical underwriters from 23 insurers – some local and some multi-state – volunteered to participate in a survey about medical underwriting practices and genetic information. Survey participants were senior health underwriters from 23 companies that sell individual health insurance. Sixteen worked for national, commercial insurers that write coverage in multiple states; seven worked for nonprofit Blue Cross Blue Shield plans. The size of participating insurers varied, though according to data from the National Association of Insurance Commissioners, three of the participating insurers rank among the top ten health insurance companies based on national market share, and eight rank among the top 25 companies.[10] Participants and their employing insurers were promised anonymity.

Our survey asked participants to underwrite eight hypothetical applicants for coverage. The applicants were arranged in pairs that were almost identical except one person in each pair had received a positive genetic test result. For each pair of applicants, medical information was provided that would likely prompt further investigation by underwriters. The survey noted when

* An exclusion rider is an amendment to the insurance policy that specifically excludes coverage for a named health condition. Sometimes exclusion riders also eliminate coverage for body parts or systems that a health condition might affect.

genetic test result information was discoverable via patient medical records or other follow up inquiry. The hypothetical applicants presented in the survey were:

- Ann and Brenda -- healthy 29-year-old women who receive regular annual mammograms well before the age of 40 when such screening is recommended for the general population. Upon review of medical records, it is clear that both Ann and Brenda have a family history of breast cancer. In addition, Brenda has inherited a *BRCA1* mutation, meaning her lifetime risk of breast and ovarian cancer is significantly elevated, though not certain.
- Clarice and Donna -- 48-year-old women who are ten-year breast cancer survivors. Both women recently had preventive surgery to remove their ovaries. Upon review of medical records, it is clear that Donna's reason for undergoing surgery was a genetic test result from 2003 which was positive for mutation in the *BRCA1* gene, meaning her lifetime risk of a second breast cancer is significantly elevated, but not certain.
- Evan and Fritz -- 52-year-old men in good health. Both receive regular blood tests to monitor blood iron levels. In follow up telephone interviews both men acknowledge a close family history of Hemochromatosis, though blood tests for both men have consistently been negative for elevated blood iron levels. Fritz has also undergone genetic testing with a positive result, meaning his blood iron levels may eventually increase and need to be managed.
- Galen and Howard -- 44-year-old men in excellent health. Both of their insurance applications disclosed a recent consultation with a cardiologist, and both take several nutritional supplements daily. Medical records indicate Galen sought his checkup after a neighbor his age died suddenly of a heart attack. Howard's visit was prompted by an online genetic testing company report that said he has gene variants that put him at risk for heart disease. The cardiologist questioned the validity of the

tests and assured him the gene variants found are commonly observed in most people.

Survey participants were asked what underwriting action(s) they would take in response to each of the hypothetical applicants. Five of the 23 underwriters responded in seven instances that they would treat applicants differently because of their genetic information. For Brenda, the hypothetical applicant with a BRCA1 mutation, insurers # 7, #8, and #23 said they would, respectively, offer Brenda coverage at a surcharged premium, deny her application, and offer a policy with a rider excluding coverage for all diseases and disorders related to her breasts. For hypothetical Donna, a ten-year breast cancer survivor with a BRCA1 mutation, insurer #11 would reject her application. Insurer #1 said consideration of the application from hypothetical Fritz would be postponed pending provision of additional medical information, while insurer #8 would deny Fritz's application. Finally, insurer #8 would postpone consideration of Howard's application pending provision of additional medical information.

In addition to these actions, in two other instances underwriters (for insurers #7 and #21) were uncertain as to the appropriate underwriting action and said they would need to consult their medical directors. (See Table 1)

The good news is that most underwriters said most of the time that they would not act based on genetic information. Most said this is because their company policy is to underwrite on the basis of a definitive diagnosis and treatment, and they do not underwrite on the basis of family history or genetic information in the absence of a diagnosis. Most underwriters believed their company policy had been adopted pursuant to laws prohibiting this practice. (Those from multi-state insurers said their company's policy would apply even in those states that have not yet enacted legislation.)

Nevertheless, survey findings are also consistent with patient and policymaker concerns that genetic discrimination in health insurance can happen today and could pose a problem in the

future. When asked whether they would take adverse action based on genetic information in the absence of legal prohibitions, many underwriters answered yes.

Table 1. Underwriter Response to Hypothetical Applicants With Genetic Information
[Applicants *italicized* had positive genetic test results]

Insurer	Ann	Brenda	Clarice	*Donna*	Evan	*Fritz*	Galen	*Howard*
1						Pend. Unable to offer without diagnosis.		
2								
3								
4								
5								
6								
7		Premium surcharge (25%)						Unsure. Would refer to Medical Director.
8		Deny				Deny		Pend until further evaluation completed
9								
10								
11				Deny				
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								Unsure. Would refer to Medical Director.
22								
23		Rider disease/disorder of breast						

Note: Table shows only those underwriting actions which differed between applicant pairs based on genetic information.

Underwriter responses to genetic services

Legislation before you today also prohibits health insurance discrimination based on receipt of or request for genetic services – a term which includes genetic counseling to interpret or assess genetic information. Some patients with inherited risk of disease today have options – ranging from lifestyle changes to preventive therapies or surgery – to reduce that future risk and may

consider those pursuant to genetic testing. As part of our research, we asked underwriters to participate in a follow up survey that also tested their reaction to genetic services. The follow up survey sought additional information about one of the hypothetical applicants with a *BRCA1* mutation, who would also have been counseled about options for reducing her inherited risk of breast and ovarian cancer. Underwriters were asked, "If Donna's medical records indicated her doctor had discussed or recommended options to reduce her risk of future breast cancers (for example, prophylactic surgery) what underwriting actions would you take on her application?"

Only 13 underwriters responded to these follow up questions. Of those, five indicated they would take an adverse action in response to Donna's doctor having discussed risk reducing options, while ten of 13 said they would take an adverse action if the doctor recommended a significant medical procedure to reduce inherited risk. (See Table 2) Interestingly, when the same question was posed to state insurance regulators, most said their laws would also protect against genetic discrimination based on these kinds of patient-physician communications. (See Appendix B)

Table 2. Underwriting Actions for Donna Based on Interventions to Reduce Breast Cancer Risk (Counseled vs. Recommended)

Insurer	Underwriting Action	
	Doctor discussed prophylactic surgery to reduce risk	Doctor recommended prophylactic surgery to reduce risk
1		Postpone
2	Probably Rider	Probably Rider
4	Rate	Rate
6	Rider	Rider
7		Rider or Deny
10		Deny
11	Deny	Deny
12		Rider
14		
15		
16		Postpone
17	Deny	Deny
20		

Limitations of Methodology

The small number of self-selected survey respondents means results cannot be interpreted as representative of the entire health insurance industry. In addition, because the survey asked questions about only three genetic tests, results provide no information about how underwriters might respond to other types of genetic information or inherited risks. Other study design aspects may have biased results. For example, survey respondents came from a self-selected sample of those who participate in a professional underwriting study group and who tend to be more senior, expert, and informed about issues. In addition, the survey clearly identified the issue being studied, potentially biasing respondents to answer "correctly." On the other hand, survey vignettes also made obvious applicants' genetic information. Therefore results do not shed light on how well underwriters recognize, or overlook, this information when they encounter it in practice. Nevertheless, the responses of so many mainstream insurers provide important insights into industry underwriting practices related to genetic information.

Policy implications

Industry experts and others have urged that health insurance discrimination based on genetic information happens rarely, if at all, today, and there is evidence to support this contention. The low incidence of predictive genetic testing in the general population is one key reason. In addition, prohibitions in more than 40 states may discourage insurers from actively seeking out information about applicants' genetic status or from acting upon such information when it is discovered in the course of underwriting. Most carriers surveyed said they do not underwrite based on genetic information.

However, findings showed that some individual market insurers would act on genetic information if they discovered it. In seven of the 92 decisions tracked by this study, an insurer used genetic information as the basis for their action to decline/postpone, limit coverage or surcharge premiums.. These seven decisions were limited to five of the 23 insurance carriers and

were spread across all four applicants with genetic information. One of these respondents expressed uncertainty as to the meaning of one of the genetic tests. Experts in the field of genetics have long called for "vigorous educational efforts" within the insurance industry to improve understanding about genetic information. Findings from this study suggest such education could be beneficial. Comprehensive federal legislation could also reinforce and strengthen state restrictions and promote a uniform standard within the health insurance industry to never use genetic information in medical underwriting.

From the insurer perspective, medical underwriting in individual health insurance is based on a key premise: the insurer promises to cover an individual's future health care risks, but only if the applicant discloses known risks today. Public policy has insisted on an exception for genetic information – protecting this information, at least partially, because the clinical significance and promise of this science is so profound. Policymakers will have to decide how comprehensive and uniform protections should be. In so doing, they will have to consider the problem of health insurance discrimination in light of what genetic testing means for patients today and what it is likely to mean in the future. Advances in genetic science may make possible dramatic improvements in medicine and public health that can reduce or prevent the incidence of many serious and expensive health conditions. For that day to come, patients will need assurances that they can both learn their genetic status and take appropriate actions to reduce their risk and improve their health without endangering their insurability.

APPENDIX A

State Prohibitions on Use of Genetic Information in Medical Underwriting, Individual Health Insurance Market

	Prohibited Underwriting Action											
	Application asks about:			Deny coverage based on:			Raise premium based on:			Exclusion rider based on:		
State	Family history	Received genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referral for genetic services (incl. counseling or testing)	Positive genetic test results
AL*						√			√			√
AK												
AZ*					X	√		X	√		X	√
AR*		X	X		X	X		X	X		X	X
CA*			√			√			√	√	√	√
CO		X	√	X	X	√	X	X	√	X	X	√
CT	X	X	X	X	X	√	X	X	√	X	X	√
DE				X	√	√	X	√	√	X	√	√
DC	X	X	X	X	√	√	X	√	√	X	√	√
FL		√	√	X	√	√	X	√	√	X	√	√
GA						√						√
HI	X	X	√	X	√	√	X	√	√	X	√	√
ID			√		X	√		X	√	√	√	√
IL*	X	X	√	X	X	√				X	X	√
IN		X	√	X	√	√	X	√	√	√	√	√
IA												
KS		√	√	X	√	√	X	√	√	X	√	√
KY			√		√	√		√	√	√	√	√
LA	√	√	√	√	√	√	√	√	√	√	√	√
ME				√	√	√	√	√	√	√	√	√
MD	X	X	√	X	√	√	X	√	√	X	√	√
MA	X	X	X	√	√	√	√	√	√	√	√	√
MI		√	√	X	X	X	X	X	X	√	√	√
MN		√	√		√	√		√	√	√	√	√
MS												
MO*		X	X	X	X	X	X	X	X	X	X	X
MT			√		X	√		X	√	X	X	√
NE												
NV		√	√	X	√	√	X	√	√	X	√	√
NH		√	√		√	√		√	√	X	√	√
NJ	√	√	√	√	√	√	√	√	√	√	√	√
NM				√		√	√		√	√		√
NY				√	√	√	√	√	√	√	√	√
NC		X	X	X	X	√	X	X	√		X	X
ND					X			X			X	

	Prohibited Underwriting Action											
	Application asks about:			Deny coverage based on:			Raise premium based on:			Exclusion rider based on:		
State	Family history	Received genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referral for genetic services (incl. counseling or testing)	Positive genetic test results
OH			√			√			√			√
OK +				X	X	X	X	X	X	X	X	X
OR	√	√	√	X	X	√	√	√	√	√	√	√
PA	**	**	**	**	**	**	**	**	**	**	**	**
RI	X	√	√	X	√	√	X	√	√	X	√	√
SC				X	√	√	X	√	√	X	√	√
SD												
TN		X	√		√	√		√	√		√	√
TX				X	X	√	X	X	√	X	X	√
UT		√	√	X	√	√	X	√	√	X	√	√
VT				√	√	√	√	√	√	√	√	√
VA				X	√	√	X	√	√	X	√	√
WA	√	√	√	√	√	√	√	√	√	√	√	√
WV												
WI		√	√		√	√		√	√		√	√
WY				X	X	X	**	**	X	**	X	

Source: Statutory research by Georgetown University and responses of state insurance regulators to Georgetown survey conducted in May-June, 2006. Regulators in five states did not respond to the survey: California, Mississippi, New Mexico, New York, and Vermont. In these states, table only indicates prohibitions found in statutory language.

√ indicates prohibition found in state statute.

x indicates state regulator confirms practice is prohibited, but practice is not specified in statute.

** Regulator did not answer this question. No statutory prohibition found.

+ Additional state notes below:
Alabama prohibitions only apply to genetic information about risk of cancer.
Arizona prohibitions unless "applicant's medical condition and history and either claims experience or actuarial projections establish that differences in claims are likely to result from the genetic condition."
Arkansas prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."
California prohibits insurers from denying "enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer."
Illinois allows an insurer to "consider the results of genetic testing…if the individual voluntarily submits the results and the results are favorable to the individual."
Missouri prohibits insurers from inquiring "to determine whether a person or blood relative of such person has taken or refused a genetic test or what the test results of any test were…" except with approval of the applicant to consider this type of information.
Oklahoma prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."

APPENDIX B
State Prohibitions on Use of Genetic Information in Medical Underwriting,
Individual Health Insurance Market

	Prohibited Underwriting Action					
State	Deny coverage based on:		Raise premium based on:		Exclusion rider based on:	
	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options
AL +	X	X	X	X	X	X
AK						
AZ +						
AR +	X	X	X	X	X	X
CA +					√	√
CO	X	X	X	X	X	X
CT	X	X	X	X	X	X
DE	X	X	X	X	X	X
DC			X			
FL	√	√	√	√	√	√
GA	X	X				
HI	X	X	X	X	X	X
ID	X	X	X	X	√	√
IL +	X	X			X	X
IN	X	X	X	X	√	√
IA						
KS	X	X	X	X	X	X
KY	X	X	X	X	√	√
LA	X	X	X	X	X	X
ME	√	√	√	√	√	√
MD	X	X	X	X	X	X
MA	√	√	√	√	√	√
MI	X	X	X	X	√	√
MN	X	X	X	X	√	√
MS						
MO +						
MT	X	X	X	X	X	X
NE						
NV	X	X	X	X	X	X
NH	X	X	X	X	X	X
NJ	√	√	√	√	√	√
NM						
NY	√	√	√	√	√	√
NC	X	X	X	X	X	X
ND						

Prohibited Underwriting Action						
State	Deny coverage based on:		Raise premium based on:		Exclusion rider based on:	
	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options
OH	X	X	X	X	X	X
OK +	X	X	X	X	X	X
OR	X	X	√	√	√	√
PA	**	**	**	**	**	**
RI	X	X	X	X	X	X
SC	X	X	X	X	X	X
SD						
TN						
TX	X	X	X	X	X	X
UT	X	X	X	X	X	X
VT	√	√	√	√	√	√
VA	X	X	X	X	X	X
WA	√	√	√	√	√	√
WV						
WI	X	X	X	X	X	X
WY	**	**	**	**	**	

Source: Statutory research by Georgetown University and responses of state insurance regulators to Georgetown survey conducted in May-June, 2006. Regulators in five states did not respond to the survey: California, Mississippi, New Mexico, New York, and Vermont. In these states, table only indicates prohibitions found in statutory language.

√ indicates prohibition found in state statute.

x indicates state regulator confirms practice is prohibited, but practice is not specified in statute.

** Regulator did not answer this question. No statutory prohibition found.

+ Additional state notes below:
Alabama prohibitions only apply to genetic information about risk of cancer.
Arizona prohibitions unless "applicant's medical condition and history and either claims experience or actuarial projections establish that differences in claims are likely to result from the genetic condition."
Arkansas prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."
California prohibits insurers from denying "enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer."
Illinois allows an insurer to "consider the results of genetic testing…if the individual voluntarily submits the results and the results are favorable to the individual."
Missouri prohibits insurers from inquiring "to determine whether a person or blood relative of such person has taken or refused a genetic test or what the test results of any test were…" except with approval of the applicant to consider this type of information.
Oklahoma prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."

End Notes

[1] Letter to Secretary Tommy Thompson, May 3, 2001, at http://www4.od.nih.gov/oba/sacgt/ltr_to_secDHHS5-3-01.pdf.
[2] See, for example, "Testimony of the HIAA on Genetic Testing," before the Senate Committee on Labor and Human Resources, May 21, 1998. See also "Testimony of John Rowe, M.D., Chairman and CEO, Aetna Inc.," before the House Judiciary Subcommittee on the Constitution, September 12, 2002.
[3] As cited in "Genetic testing: consumers fear it will be used to deny coverage and raise premiums" *Risk and Insurance*, April 14, 2003.
[4] http://www.myriadtests.com/provider/mutprev.htm
[5] U.S. Bureau of the Census and Bureau of Labor Statistics, 2006 Current Population Survey Annual Social and Economic Supplement.
[6] Duchon, L., et.al., "Security Matters: How Instability in Health Insurance Puts U.S. Workers at Risk," The Commonwealth Fund, December 2001.
[7] Personal communication with Kathy Thomas and Ben Chaput, risk management consultants specializing in the individual market, January 20, 2007.
[8] Karen Pollitz, Richard Sorian, and Kathy Thomas, "How Accessible is Individual Health Insurance for Consumers in Less-Than-Perfect Health?" Report to the Kaiser Family Foundation, June 2001.
[9] Thomas and Chaput, personal communication, January 20, 2007.
[10] National Association of Insurance Commissioners, "Accident and Health Insurance Industry 2004 Market Share Report by State and Countrywide," © 2005, NAIC. Accessed November 30, 2006. http://www.naic.org/documents/research_stats_market_share_health_sample.pdf

Chairman STARK. Thank you.

Ms. Terry, would you like to proceed?

STATEMENT OF SHARON F. TERRY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENETIC ALLIANCE

Ms. TERRY. Chairman Stark, Representative Camp, and Members of the Subcommittee, thank you for the opportunity to testify here. Representative Slaughter, Biggert, Eshoo and Walden demonstrate robust vision and courage to introduce again the legislation that will make it possible for Americans to benefit from new genetic tests and technologies.

My name is Sharon Terry, and I am the president and CEO of Genetic Alliance, which is a coalition of more than 600 disease support groups. Mine is not a chosen profession, I have been assigned it, since my two children have a rare genetic disease for which there is no treatment and I long for the day that we can have many people enter research.

I am also the chair of the Coalition of Genetic Fairness and I have worked on this legislation for 12 years myself, since Chairwoman Slaughter first introduced it. With others present here, I founded the Coalition for Genetic Fairness to support this legislation and we have had a long and uphill battle.

We are several hundred organizations strong and include members from every sector of society, disease support groups, health professional organizations, women's leadership groups, labor groups, academic, and most significantly companies like Affymetrix, IBM and Twentieth Century Fox. We have compromised and conceded a great deal during these years and I believe that the bill before you is fair and well balanced.

Many Americans fear that genetic information may be used by insurers and employers to deny, limit or cancel their health insurance and/or to discriminate against them in the workplace. As

ance and/or to discriminate against them in the workplace. As more genetic tests become available, there is real concern that this genetic discrimination will increase. More than 40 states have enacted legislation on discrimination and more than 30 states have enacted it in the workplace health insurance in the first case.

Despite the presence of these state laws, only comprehensive Federal legislation can guarantee that everyone in the United States will be protected. This legislation will prohibit the use of genetic information as a basis of charging more for health insurance, limit the collection of genetic information by employers and insurance, limit the disclosure of genetic information by employers and insurers and apply to individual health insurers except if covered by the portability provision.

In 1997, following a number of papers, some by Dr. Collins and others, and symposia calling attention to genetic discrimination, Chairwoman Slaughter and Senator Snowe introduced companion bills in the House and Senate. Over the next few years, there were several senate hearings, reintroduction of the bill in both chambers.

President Clinton first endorsed the legislation and then signed an executive order to prohibit discrimination. Meanwhile the Secretary's Advisory Committee on then Genetic Testing and the Coalition for Genetic Fairness among other bodies called for the passage of the legislation.

In 2000, Dave Escher and others experienced discrimination, which he will tell you about after me.

At the start of the 108th Congress, the bill was radically overhauled. We, the proponents of the legislation, were told that if we could give up the strong protections and remedies in the bill, it would move. The new bill narrowed the definition of genetic information, specifically excluding protections for genetic tests related to manifest disease. In addition, it required claimants to exhaust administrative state and Federal EEOC procedures before seeking court damage and limit the amount of punitive damages that can be awarded.

The new compromise version, heavily compromised, passed the U.S. Senate in 2003 by a vote of 95 to zero but was never taken up in the House.

In the 109th Congress, the Genetic Nondiscrimination Act of 2005 passed 98 to nothing in the Senate. It was introduced again in the House in March of that year and the bill was referred to the three Committees, yours being one. It saw no action. President Bush released a statement of administrative policy supporting the legislation twice.

The bill has again, this Congress, 110th, been introduced in both chambers. The Senate Committee on Health, Education, Labor and Pensions has approved it and the Senate will bring it to the floor for a vote soon. As you know, the other two Committees of jurisdiction here, and yours, have taken swift action which we appreciate.

My passion for more than a decade has been fueled by the faces and the voices of the hundreds of individuals who have contacted us, fearing for their children, their families, their jobs, their insurance. Men, women and children, families from communities all

across this country have told us their stories and in some cases pleaded for us to help them.

In 2003, Heidi Williams of Kentucky suffered discrimination when her children were denied health insurance from Humana because they are carriers of alpha-1 antitrypsin deficiency. Her third grade daughter wrote to her representative here in the house: Please help my mom stop people from treating others unfairly.

Aren't health and disease enough to worry about? We cannot afford to also worry about discrimination based on our mutations, silent mutations with no signs or symptoms. This is simply about preventing the misuse of genetic information.

This is also about special interests. Let us put the special interest of all Americans above all else. Every one of you and each of your loved ones is at risk for some disease. We cannot yet easily reduce that risk, as Dr. Collins has said, but it is in your hands to reduce the risk of discrimination associated with that information.

At the end of the day, we are relying on you to make it possible for individuals to use their genetic information for the health purposes it was elucidated. I have faith that you will relieve our burdens, your burdens, all our burdens, and I look forward to your good work. Thank you.

[The prepared statement of Ms. Terry follows:]

Testimony of

Sharon F. Terry

President and CEO, Genetic Alliance

Chair, Coalition for Genetic Fairness

Ways and Means Committee

Subcommittee on Health

March 14, 2007

Sharon Terry, Coalition for Genetic Fairness

Chairman Stark, Representative Camp, and Members of the Subcommittee,

thank you for the opportunity to testify here. Representatives Slaughter, Biggert, Eshoo and Walden demonstrate robust vision and courage to introduce again the legislation that will make it possible for Americans to benefit from new genetic tests and technologies.

My name is Sharon Terry. I am president and CEO of Genetic Alliance, a coalition of more than 600 disease support groups, and I am chair of the Coalition for Genetic Fairness. I have worked on this legislation for 12 years, since Chairwoman Slaughter first introduced it. With others present here, I founded the Coalition for Genetic Fairness to support this legislation – and we have had a long and uphill battle. We are several hundred organizations strong and include members from every sector of society – disease support groups like Facing Our Risk of Cancer Empowered; healthcare professional organizations like the American Society of Human Genetics, National Society of Genetic Counselors, and American Academy of Pediatrics; women's leadership groups like Hadassah, The Women's Zionist Organization of America, labor groups such as the National Workrights Institute, academia such as Brown University; and most significantly, companies like Affymetrix, IBM, and Twentieth Century Fox. We thank them and those of you, who year after year, supported this legislation. We are impatient to see it pass. We have compromised and conceded a great deal during these years, and we believe that the bill before you is fair and well-balanced.

Many Americans fear that genetic information may be used by insurers and employers to deny, limit, or cancel their health insurance, and/or to discriminate against them in the

workplace. There have already been a few documented cases of such discrimination, and as more genetic tests become available, there is real concern that such discrimination will increase. Most states have now enacted health information privacy legislation. In addition, more than 40 states have enacted legislation on discrimination in health insurance and more than 30 states have enacted legislation on genetic discrimination in the workplace. Despite the presence of these state laws, only comprehensive federal legislation can guarantee everyone in the United States protection from genetic discrimination. Such legislation will also significantly enable biomedical research involving human subjects and genetic information, because it would greatly reduce the fear of misuse of such information.

This legislation will:

- Prohibit the use of genetic information as a basis for charging a group more for health insurance.
- Limit the collection of genetic information by employers and insurers, and prohibit them from requiring an individual to take a genetic test.
- Limit the disclosure of genetic information by employers and insurers.
- Apply to individual health insurers except if covered by the portability provision.

History of the Issue on a National Level

Starting with the sequencing of the human genome, there has been concern that the information gleaned from the very inheritance of human beings is kept safe. In 1995[1],

[1] Genetic Discrimination and Health Insurance: an Urgent Need for Reform published in Science, October 20, 1995, Vol. 270: 391.

and again in 1997[2], Dr. Francis Collins published papers on the issue of discrimination and the need to safeguard the nation. In 1996, in between these two papers, NIH-DOE ELSI National Action Plan on Breast Cancer held a workshop on genetic discrimination in employment, and Genetic Alliance published the consumer perspective on genetic discrimination in the journal Science[3]. In 1997, Chairwoman Slaughter and Senator Snowe introduced companion bills in the House and the Senate. Over the next few years, there were several Senate hearings, reintroduction of the bill in both chambers, adding Senators Daschle, Harkin, Dodd, and Kennedy as sponsors in the Senate. President Clinton first endorsed the legislation and then signed an executive order to prohibit discrimination in federal employment. Meanwhile, the Secretary's Advisory Committee on Genetic Testing and the Coalition for Genetic Fairness, among other bodies, called for passage of the legislation and observed the escalating issues around genetic discrimination. We find ourselves facing this issue head on in the case Dave Escher shared with us, which resulted in the settlement against Burlington Northern Santa Fe Railway.

At the start of the 108th Congress, the bill was radically overhauled. We, the proponents of the legislation, were told that if we could give up some of the protections and remedies in the bill, it would move. The new bill narrowed the definition of "genetic information," specifically excluding protections for genetic tests related to "manifest disease." In addition, it required claimants to exhaust administrative state and federal EEOC

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[2] Genetic Information and the Workplace: Legislative Approaches and Policy Challenges published in Science, March 21, 1997, Vol 275: 1755-1757.
[3] *Genetic Discrimination: Perspectives of Consumers*, published in Science, October 25, 1996, Vol. 274. no. 5287, pp. 621 - 624

procedures before seeking court damages, and limits the amount of punitive damages that can be awarded. This new compromise version passed the U.S. Senate in 2003 by a vote of 95-0, but was never taken up in the House.

In the 109th Congress, the "Genetic Information Non-Discrimination Act of 2005" (S.306) passed 98-0. Representatives Biggert, Slaughter, Ney, and Eshoo introduced an identical bill, H.R. 1227, in the House, on March 10, 2005. The bill was referred to the Committee on Education and the Workforce, the Committee on Energy and Commerce, and the Committee on Ways and Means. It saw no action. President Bush released a statement of administrative policy supporting the legislation.

The bill has again been introduced in both chambers. The Senate Committee on Health, Education, Labor, and Pensions has approved it and the Senate will reportedly bring it to the floor for a vote soon. As you know, the other two committees of jurisdiction in the House and yours have taken swift action on the bill in the 110th Congress.

The Faces of Genetic Discrimination

My passion for more than a decade has been fueled by the faces and the voices of the hundreds of individuals who have contacted us, fearing for their children, their families, their jobs, their insurance. Men, women, and children – families from communities all across this country – have told us their stories and in some cases, pleaded for us to help them.

Sharon Terry, Coalition for Genetic Fairness

In 2003, Heidi Williams of Kentucky called me when her children were denied individual health insurance from Humana, Inc. Heidi has alpha-1 antitrypsin deficiency, an autosomal recessive genetic disease. Humana rejected the children's application stating that since the children were carriers of alpha-1 antitrypsin, Humana could not cover them. With our help, Heidi explained in an appeal that carriers of genetic conditions are not affected by the condition, but Humana again denied her children health insurance. I then called a reporter from a prominent national newspaper and told her Heidi's story. The reporter called Humana and Heidi received notice of retroactive coverage late that same night. This year, Heidi's daughter Jayme Williams wrote this letter to her congressman:

Dear Congressman Ron Lewis,

My name is Jayme Williams, and I am in the fifth grade and live in Cecilia, Kentucky. My brother and I are carriers of Alpha-1 Antitrypsin Deficiency, a defective gene in our DNA that can be passed on to our future children. While my brother and I both have only one defective gene, my mother was given two, one by her mother and one by her father. The two genes make my mother's lungs very sick. My brother and I were denied health insurance because we carry mutations in the Alpha-1 gene.

My mom tells our story because other people are too afraid to tell theirs. Discrimination makes people very afraid. When people are discriminated against, they are sometimes told they will lose something they need if they speak out against the people causing the discrimination.

Sharon Terry, Coalition for Genetic Fairness

I think you should support the bill that is before the House of Representatives that would make it illegal for anyone to do this to another person in the USA. My mom says that everyone is created equal, and deserves to be treated fairly. Please help my mom stop people from treating others unfairly.

Sincerely,

Jayme Williams

Let resonate these heart-felt words from a young girl who cannot imagine that carrying a mutation in a gene makes her uninsurable. I assured her that we would continue to work hard so that she and others like her are not discriminated against again.

I am also reminded of Becky Fisher, who shares a mutation for inherited breast cancer with many in her family. Having watched her mother, aunts, and cousins die of breast cancer, and she herself surviving cancer, she thinks only of her daughter, who was brave enough to be tested, and says of her:

One of the not-so-good things is that having a documented genetic mutation makes her vulnerable to more than just a devastating illness: she also faces the heavy burden of never knowing whether or when she will legally be asked to take a genetic test as a condition of employment, be lawfully fired from a job because of the high

cost of her potential medical care, or be legitimately denied health insurance on the basis of her genetic predisposition to disease.

We are all Heidi and Becky's children; we all carry mutations for dozens of diseases, and we are all vulnerable. Aren't health and disease enough to worry about? We cannot afford to also worry about discrimination based on these mutations, silent mutations, with no signs or symptoms. This is simply about preventing the misuse of genetic information, that which makes up every one of us, our shared inheritance, and that which makes each of us unique.

This also about special interests. Let us put the special interest of the health of all Americans above all else. Every one of you, and each of your loved ones, is at risk for some disease or another. We cannot yet easily reduce that risk, but it is in your hands to reduce the risk of discrimination associated with that information. At the end of the day, we are relying on you to make it possible for individuals to use their genetic information for the health purposes for which it was elucidated. Some might say that Dr. Collins and his colleagues have done the hardest work, but we understand that balancing the policy needs of a nation is also difficult – you are pulled and pushed in many directions. Please measure your decisions against 'what truly matters' when voting in committee and the full House floor in the next weeks. Please remember that none of us have any choice over our ancestry, our different abilities, or our genetic makeup. As a nation we do have a choice about how we treat that information.

Sharon Terry, Coalition for Genetic Fairness

Every American is affected by this legislation. Beyond health insurance companies', trade associations', and employers' needs, all those who carry genetic mutations they did not choose are asking us to take necessary measures to alleviate the burden discrimination — and the fear of discrimination — places on our nation. I have faith and hope that you will chose to relieve their burdens, my burden, your burden. I look forward to the good work you will do over the coming weeks. Thank you.

Biography

Sharon is President and CEO of the Genetic Alliance, a coalition of over 600 disease specific advocacy organizations working to increase capacity in advocacy organizations and to leverage the voices of the millions of individuals and families affected by genetic conditions. She is the founding Executive Director of PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE). Following the diagnosis of their two children with pseudoxanthoma elasticum (PXE) in 1994, Sharon, a former college chaplain, and her husband, Patrick, founded and built a dynamic organization that fosters ethical research and policies and provides support and information to members and the public.

She is at the forefront of consumer participation in genetics research, services and policy and serves as a member of many of the major governmental advisory committees on medical research, including the Food and Drug Administration Cellular, Tissue and Gene Therapies Advisory Committee and the Advisory Committee on Heritable Disorders and

Genetic Diseases in Newborns and Children. She served as an Ethical Legal and Social Implications Research Advisor of NHGRI/NIH, the National Institute of Arthritis Musculoskeletal and Skin Diseases Council and currently is liaison to the National Advisory Council for Human Genome Research. She is a member of the board of directors of the Biotechnology Institute and on the advisory board of the Johns Hopkins Genetics and Public Policy Center funded by the Pew Charitable Trusts. She serves on the boards of the Coalition for 21st Century Medicine, the Personalized Medicine Coalition, DNA Direct, and the Center for Information and Study on Clinical Research Participation. She is the chair of the Coalition for Genetic Fairness, composed of advocates, healthcare providers and industry working to enact effective federal policy to prohibit genetic information discrimination. She is also chair of the Social Issues Committee of American Society of Human Genetics. In 2005, she received an honorary doctorate from Iona College for her work in community engagement and haplotype mapping.

Ms. Terry is a co-founder of the Genetic Alliance Biobank and serves as president of its board. It is a centralized biological and data [consent/clinical/environmental] repository catalyzing translational genomic research on rare genetic diseases. The BioBank works in partnership with academic and industrial collaborators to develop novel diagnostics and therapeutics to better understand and treat these diseases. Along with the other co-inventors of the gene associated with PXE (ABCC6), she holds the patent for the invention. She co-directs a 19-lab research consortium and manages 52 offices worldwide for PXE International.

Sharon Terry, Coalition for Genetic Fairness

Sharon feels strongly that advocates, working together and partnering with professionals and industry, can generate the energy and mechanisms necessary to realize the promise of biomedical research. Her work with the Genetic Alliance over the past few years has particularly focused on genetic literacy, research protections, biosample repositories, technology translation, genetic nondiscrimination, accessible services and youth issues. She has published widely on these issues. Sharon is committed to facilitating technical assistance to advocacy organizations, so that each organization benefits from the wisdom of the other. Sharon lives with Patrick and their two children in Maryland.

Chairman STARK. Thank you, Ms. Terry.

Mr. Escher, would you like to tell us about your experiences, please?

STATEMENT OF DAVID ESCHER, RENO, NEVADA

Mr. ESCHER. Yes. Thank you. My name is Dave Escher. I am 53 years old, and I had been employed by Burlington Northern Santa Fe Railroad for over 26 years, as well as a member of the Brotherhood of Maintenance of Way during that time.

I was born and raised in Herndon, Kansas, a small northwestern town in Kansas, with a population of 200 people. I graduated from high school in 1972 and began my career with Burlington Northern in 1976 and had that career abruptly end in 2002.

I married my wife, Deb, in 1986. I have three daughters, Kelsey, Kara and Kristyn. We now live in Reno, Nevada, after relocating three-and-a-half years ago from McCook, Nebraska.

My jobs within the company during that 26 years included such positions as laborer, truck driver, assistant foreman, machine operator and foreman. I was appointed to the Division Safety Committee and continued to serve on that Committee for over 12 years. I held such positions as maintenance of way representative, vice Chairman, and safety and health facilitator up to the time of my departure from the company.

I was also selected as the McCook Division Safety Employee of the Year in 1994. I had always had a great working relationship with all my coworkers as well as those in upper management levels.

Prior to my departure from the company, I began experiencing numbness, pain, and tingling sensations in my right hand. When the numbness began to move through my hand and up into my arm

and upper bicep, I went to see a doctor, who referred me to a specialist. It was determined that I had developed work-related carpal tunnel syndrome, for which surgery was necessary.

After meeting with the operating surgeon, I received a letter from corporate headquarters stating that they were not satisfied with the initial test results and that they required further testing. In a subsequent visit to a neurologist, I once again had my hands X-rayed and another nerve conductor study was performed. The results again confirmed that I had carpal tunnel syndrome and that surgery was required and that the condition was work-related.

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

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

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

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

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

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

I was also fearful of the fact that no one could tell me where all the vials of my blood had been dispersed. What information was being learned about me, who was going to receive this information, and how it could be used to discriminate against not only myself but my family when they go out into the workplace? The constant worries, where would I go to find another job at this point in my life, and would I be able to obtain insurance for my family, seemed to me insurmountable. It was a very trying time in my life.

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

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

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

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

It is my personal belief that individuals are hired on the basis of their abilities and their capability to do the job, not on the basis of their genetic makeup or their genetic history.

It has now been 5 years since I had the opportunity to testify before the Health, Education, Labor and Pension Committee in regard to genetic testing. To this day, I have never received confirmation of what happened with the five vials of blood taken from me. I have been denied health insurance since I am on a railroad occupational disability, and there are still no laws protecting individuals from an employer demanding an employee be genetically tested.

There have been many important events that have occurred in this time period, most notably 9/11 and the aftermath which followed. As important an event that this has been in our Nation's history, I still strongly believe that the need for the passage of legislation that protects all Americans from genetic discrimination is as important today as it was 5 years ago.

Mr. Chairman, through the tactics of deception, intimidation, lying and stealing, the company to which I had given 26 years of my life took from me something they can never give back, and that is the very essence of my being, my genetic makeup.

In conclusion, if employers, insurance companies, and the like are able to have this type of power and control over their employees and clients, then who will be able to have a job or affordable insurance, if any insurance at all?

I thank the Committee for the opportunity to testify and I urge enactment on legislation to protect American citizens from genetic discrimination. Thank you.

[The prepared statement of Mr. Escher follows:]

Testimony of David Escher

Before the Subcommittee on Health

Committee on Ways and Means

United States House of Representatives

On the Genetic Information Nondiscrimination Act (H.R.493)

March 14, 2007

Chairman Stark, Members of the Subcommittee, thank you for inviting me to testify before you today.

My name is Dave Escher. I am 52 years old and had been employed by Burlington Northern Santa Fe Railroad for over 26 years and was a member of the Brotherhood of Maintenance of Way during that time. I was born and raised in Herndon, a small town in northwestern Kansas with a population of 200 people. I graduated from high school in 1972, began my career with Burlington Northern in 1976, and ended that career in 2002. I married my wife Deb in 1986, and have three daughters, Kelsey, Kara, and Kristyn. We now live in Reno, Nevada after relocation three and a half years ago from McCook, Nebraska.

My jobs within Burlington Northern Santa Fe Railroad included such positions as laborer, truck driver, assistant foreman, machine operator, and foreman. I was appointed to the Division Safety Committee and continued to serve on that committee for over 12 years. I held such positions as maintenance of way representative, Vice Chairman, and safety and health facilitator up to the time of my departure from the company.

I was also selected as "The McCook Division Safety Employee of the Year" in 1994. I had always had a great working relationship with all my co-workers as well as those in upper management levels.

Prior to my departure from the company, I began experiencing numbness, pain, and tingling sensations in my right hand. When the numbness began to move through my hand and up my arm into my upper bicep, I went to see a doctor who referred me to a specialist. It was determined that I had developed work-related carpal tunnel syndrome, for which surgery was necessary.

After meeting with the operating surgeon, I received a letter from corporate headquarters stating that they were not satisfied with the initial test results and that they required further testing. In a subsequent visit to a neurologist, I once again had my hands x-rayed and another nerve conductor study performed. The results again confirmed that I had carpal tunnel syndrome, that surgery was required, and that the condition was work-related.

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

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

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

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

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

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

I was also fearful of the fact that no one could tell me where all the vials of my blood had been dispersed. What information was being learned about me, who was going to receive this information, and how could it be used to discriminate against not only myself, but also my family, when they go out into the workplace? The constant worries, "where would I go to find another job at this point in my life," and be able to obtain insurance for my family, seemed to me insurmountable. This was a very trying time in my life.

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

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

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

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

It is my personal belief that individuals are hired on the basis of their abilities and capabilities to do the job, not on the basis of their genetic make-up or genetic history.

It has now been over 5 years since I first had the opportunity to testify before Congress in regard to genetic discrimination. To this day, I have never received confirmation of what happened with the vials of blood taken from me. I have been denied health insurance since I am on a railroad occupational disability, and there are still no laws protecting individuals from an employer demanding an employee be genetically

tested. I still strongly believe that the need for the passage of legislation that protects all Americans from genetic discrimination is as important today as it was five years ago.

Mr. Chairman, through the tactics of deception, intimidation, lying, and stealing, the company to which I have given 26 years of my life took from me something they can never give back, and that is the very essence of being - my genetic make-up.

In conclusion, if employers, insurance companies, and the like are able to have this type of power and control over their employees and clients, then who will be able to have a job or affordable insurance, if any insurance at all?

I want to thank the Subcommittee for the opportunity to testify, and I urge enactment of legislation to protect American citizens from genetic discrimination. Thank you.

Chairman STARK. Thank you very much.
Dr. Corwin . . .

STATEMENT OF WILLIAM CORWIN, MEDICAL DIRECTOR, CLINICAL POLICY, HARVARD PILGRIM CARE, ON BEHALF OF AMERICA'S HEALTH INSURANCE PLANS

Dr. CORWIN. Thank you, Mr. Chairman, Mr. Camp, Members of the Subcommittee. My name is Dr. William Corwin. I'm a physician, a medical director for clinical policy at Harvard Pilgrim Health Care, which is a not-for-profit health plan that provides insurance plan options to more than a million members in Massachusetts, New Hampshire and Maine.

Harvard Pilgrim has been named the number one health plan in America for three consecutive years, according to a joint ranking by the U.S. News and World Report and the National Committee for Quality Assurance.

I appreciate this opportunity to testify on behalf of America's Health Insurance Plans, which is a national association representing nearly 1,300 health insurance plans, providing coverage for more than 200 million Americans.

Health insurance plans work on a daily basis to promote appropriate use of medical and genetic tests, to help clinicians and patients make informed health care decisions and improve health outcomes. We agree with the sponsors of H.R. 493 that health care consumers should not face discrimination on the basis of their genetic makeup and that genetic makeup should be protected from unauthorized disclosure. Our policies and programs reflect this belief.

We have submitted written testimony that focuses on three broad areas. First, examples of how health insurance plans are promoting the appropriate use of genetic tests to improve patient care. Second, opportunities for improving H.R. 493. Third, our support for strong protection with respect to nondiscrimination in the confidentiality of genetic information.

In the next few minutes, I would like to provide some examples of how health insurance plans are promoting the use of genetic information to help enrollees receive the highest quality evidence-based care possible. I also will briefly comment on H.R. 493.

Through early detection, disease management programs and other improvement initiatives, we are working to identify individuals who can benefit from early intervention and the evidence based treatments for specific illnesses and diseases. Genetic information including the results of genetic tests is just one more very sophisticated source of data that clinicians and health insurance plans are using to ensure that patients receive appropriate preventive care, coordination of services and very early treatment for their medical conditions.

I would like to highlight two specific examples of how genetic tests are being used to improve patient care.

In February of this year, in 2007, the Food and Drug Administration approved a new genetic test called MammaPrint, which indicates whether a woman with breast cancer is likely to have a relapse. This test allows physicians to tailor therapy for individual patients, as Dr. Collins mentioned, and administer chemotherapy to only those patients who would benefit. At the same time, the test allows physicians to identify patients who would not benefit from chemotherapy and should not be subjected to risky and costly treatment.

Another test, the Cytochrome P450 enzyme, is genetically coded. The identification of the presence or absence of this genomic marker enables a physician to evaluate a patient's ability to process many different medications, adjust the doses intelligently, and avoid any of the potential adverse drug reactions in patients who either metabolize a drug too quickly or do not metabolize this drug at all. This test also is used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy.

Health insurance plans may request that this test be performed before authorizing a course of therapy or treatment to ensure the appropriate evidence-based care is being provided to meet the patient's individual needs.

Health insurance plans are also using genetic test results to promote preventive screening and disease management programs. These programs can help to improve health care for individuals who have tested positive for a genetic disease or who have a family history of a specific disease or condition. For example, individuals who have a gene for the familial form of colorectal cancer, as we heard described earlier, can receive coverage for more frequent preventive screenings.

As scientists acquire a greater understanding of the role that genes play in disease and develop more targeted therapies, more targeted treatments and possibly even cures, preventive screening and disease management programs can be tailored to improve the

outcomes for these individuals. These therapies will become even more important in the future.

We appreciate the interest many Subcommittee Members have shown in passing additional legislation addressing use and disclosure of genetic information. As you do so, we urge you to fully evaluate the implications of any additional requirements or prohibitions and ensure that new legislation does not unnecessarily restrict the use of information needed to promote appropriate health care decisionmaking.

Working with AHIP, our industry association, we have reviewed H.R. 493 and identified several areas where we believe changes are needed to ensure that genetic information is available to health plans so we can continue to ensure appropriate coverage decisions and design targeted disease management programs to improve the quality of patient care.

We do not oppose the bill and we agree with its intent. However, once enacted, there will be a variety of interpretations about the bill and how its requirements would apply in various settings. To avoid any confusion, the Health Insurance Plans would like to encourage the Subcommittee Members to ensure that the statutory language clearly reflects your intent for enacting this legislation.

In conclusion, I want to emphasize that the Health Insurance Plans are strongly committed to ensuring that genetic information is used to help clinicians and patients make informed health care decisions, at the same time maintaining strong protections in the area of nondiscrimination and confidentiality.

We appreciate the opportunity to testify, and I am open to questions. Thank you very much.

[The prepared statement of Dr. Corwin follows:]

Testimony on

Genetic Information and Testing

By

William Corwin, M.D.
Medical Director, Clinical Policy
Harvard Pilgrim Health Care
on behalf of
America's Health Insurance Plans

Before the
U.S. House Committee on Ways and Means
Subcommittee on Health

March 14, 2007

I. Introduction

Mr. Chairman, Mr. Camp, and members of the subcommittee, my name is Dr. William Corwin. I am the medical director for clinical policy at Harvard Pilgrim Health Care. Harvard Pilgrim Health Care is a not-for-profit health plan that provides a variety of insurance plan options to more than a million members in Massachusetts, New Hampshire and Maine. Harvard Pilgrim provides innovative approaches to health improvement and disease management, unique online tools that speed and simplify key transactions for employers and providers, and personalized health support.

Harvard Pilgrim was named the #1 health plan in America in three consecutive years according to a joint ranking by *U.S. News & World Report* and the National Committee for Quality Assurance (NCQA). The November 6, 2006 edition of *U.S. News & World Report* ranked the nation's best health plans and determined that Harvard Pilgrim continues to lead the country for member satisfaction and quality of care. Harvard Pilgrim is the only health plan to earn the nation's top rating from NCQA three years in a row. Harvard Pilgrim's HMO and PPO plans have been recognized by J.D. Power and Associates for providing health plan members with an outstanding member experience for a third consecutive year.

Harvard Medical School and Harvard Pilgrim Health Care jointly sponsor The Department of Ambulatory Care and Prevention (DACP). This is the nation's only medical school department that is jointly sponsored by a health plan. The DACP is actively engaged in both research and teaching. The DACP leads in the creation and dissemination of new knowledge and skills essential to maximizing the health of defined populations within available resources. Research conducted by the DACP is routinely vetted through the Harvard Medical School Institutional Review Board process.

I appreciate this opportunity to testify about issues relating to genetic information and testing, including H.R. 493, the "Genetic Information Nondiscrimination Act of 2007" (GINA). I am testifying today on behalf of America's Health Insurance Plans (AHIP), which is the national association representing nearly 1,300 health insurance plans providing coverage to more than

200 million Americans. AHIP's members offer a broad range of products in the commercial marketplace – including health, long-term care, dental, disability, and supplemental coverage – and also have demonstrated a strong commitment to participation in public programs.

Health insurance plans are working on a daily basis to promote the appropriate use of genetic tests to help clinicians and patients make informed health care decisions and improve health outcomes. We agree with the sponsors of H.R. 493 that health care consumers should not face discrimination on the basis of their genetic makeup and that genetic information should be protected from unauthorized disclosure. Our policies and programs reflect this belief.

Our testimony today will focus on three broad areas:

- examples of how health insurance plans are promoting the appropriate use of genetic tests to improve patient care;
- opportunities for improving H.R. 493, the "Genetic Information Nondiscrimination Act of 2007"; and
- our support for strong protections with respect to nondiscrimination and confidentiality of genetic information.

II. Improving Patient Care Through the Appropriate Use of Genetic Tests

Health insurance plans are strongly committed to helping their enrollees receive the highest quality care possible. Through early detection, disease management programs, and other quality improvement initiatives, we are working on a daily basis to identify individuals who can benefit from early intervention to guide patient-centered care and choices while supporting the best evidence-based treatment for specific illnesses and diseases. Genetic information, including the results of genetic tests, is just one more sophisticated source of data that clinicians and health

insurance plans are using to ensure that patients receive appropriate preventive care, coordination of services, and early treatment for their medical conditions.

Health insurance plans encourage appropriate genetic testing for individuals who are at risk of certain genetic conditions for which there are specific interventions for prevention or treatment. Such tests can provide information that may positively affect the course of an individual's treatment. The following are several examples of how genetic tests are being used to improve patient care:

- According to guidelines issued by the National Institutes of Health (NIH), the treatment for hepatitis C patients should be extended – from 24 weeks to 48 weeks of therapy – but only in cases where a viral genotype guide has been identified in an individual. In this situation, a genetic test can determine whether the patient could benefit from an additional 24 weeks of therapy and thereby help the clinician prescribe a more effective course of treatment. The health insurance plan will need to know whether the genetic test was performed in this situation in order to authorize and/or pay for the extended course of therapy for the individual.

- In February 2007, the Food and Drug Administration (FDA) approved a new genetic test, a MammaPrint, which indicates whether a woman is likely to have a breast cancer relapse. This test allows physicians to tailor therapy for individual patients and administer chemotherapy to only those patients who would benefit. At the same time, the test allows physicians to identify patients who would not benefit from chemotherapy and should not be subjected to this risky and costly treatment. This new test will help guide the treatment of roughly 100,000 women each year who are diagnosed with early stage breast cancer.

- Breast cancer patients can benefit from HER-2 genetic tests that indicate whether their tumors would be responsive to herceptin therapy. Significantly, this test also allows physicians to identify patients who would face adverse side effects, including increased risk of heart disease, if they received herceptin therapy that is not appropriate given their genetic makeup.

- Another test, the Cytochrome P450 enzyme, is genetically coded. The identification of the presence or absence of this genomic marker enables a physician to evaluate a patient's ability to process many different medications, adjust dosages intelligently, and avoid potential adverse drug reactions in patients who either metabolize a drug quickly or do not metabolize a drug at all. This test also is used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy. Health insurance plans may request that this test be performed before authorizing a course of therapy or treatment to ensure that appropriate care is being provided to meet the patient's individual needs.

- Genomic signatures can be used to drive gene profiles from cell-lines that predict drug sensitivity for difficult-to-treat malignancies such as lung cancer. Genomic signatures will direct the choice of drug therapy as determined by the tumor's biology and not a "best guess" about what "might" work in an individual's situation.

To help patients understand the appropriate use of these and other genetic tests, health insurance plans are partnering with physicians and other providers to ensure that enrollees have access to informational materials about the impact of genetics on health care. This consumer education is helping to increase patient awareness about the availability of coverage for genetic tests and services as well as treatments and therapies that can be used to combat and treat genetic diseases and conditions. The value of this information can reduce unneeded anxiety about possible gene mutations or genetic diseases and conditions.

Health insurance plans are using genetic test results to promote preventive screening and disease management programs. These programs can help to improve health care for individuals who have tested positive for a genetic disease or who have a family history of a specific disease or condition. For example, individuals who have the gene for the familial form of colorectal cancer can receive coverage for more frequent preventive screenings. As scientists acquire a greater understanding of the role genes play in disease and develop more genetic therapies and possibly even cures, preventive screening and disease management programs can be tailored to improve outcomes for individuals. This ability will become even more important in the future.

Individuals also benefit from research projects that health insurance plans conduct to examine the genetic and environmental factors that influence common diseases such as heart disease, cancer, diabetes, high blood pressure, Alzheimer's disease, and asthma. By combining the genetic, health, and survey information from hundreds of thousands of members into databases, researchers hope to gain a deeper understanding of what combinations of genes and environmental factors influence the risk of complex diseases.

Such research projects meet the highest scientific standards and comply with the legal requirements for privacy and confidentiality, including the requirements applicable to federally-funded research projects under HIPAA (e.g., 45 C.F.R. 164.508, 512(i)) and other applicable legal provisions. One example is a project being conducted by another AHIP member, Kaiser Permanente of Northern California's Division of Research. In that project, individual participation in the research is completely voluntary and individual genetic information will not be used in genetic studies without written consent. The data will be used only for research purposes and ultimately is expected to yield findings that will enable the medical community to be more precise in pinpointing the causes of disease and tailoring treatment for patients.

III. Opportunities to Improve H.R. 493

We appreciate the interest many subcommittee members have shown in passing additional legislation addressing the use and disclosure of genetic information. As you consider such legislation, we urge you to fully evaluate the implications of any additional requirements or prohibitions and ensure that new legislation does not unnecessarily restrict the use of information needed to promote appropriate health care decision-making.

Working through AHIP, our industry association, we have reviewed H.R. 493 and identified several areas where we believe changes are needed to ensure that genetic information can continue to assure appropriate coverage decisions and be available to improve the quality of patient care. We would like to publicly state that we do not oppose the bill and agree with its

intent. However, once enacted, the bill will be interpreted by clinicians, non-clinicians, individuals, lawyers, courts, and other interested persons who can take various interpretations of Congress' intent and how the requirements can apply in various settings. To avoid any confusion, health insurance plans would like to engage subcommittee members in a dialogue about our suggestions for clarifying the statutory language of the bill. We respectfully offer the following issues for your consideration.

- **Medically-indicated testing should be encouraged to promote consumer access to appropriate coverage and treatment.**

  As currently drafted, section 101 of the bill could limit consumer access to life-saving treatments because it prohibits health insurance plans from "requesting or requiring" an individual or a family member of an individual to undergo a genetic test. This prohibition can be read as restricting the ability of a health insurance plan to request this information, even when it is needed to determine the appropriate course of treatment and evaluate the patient's eligibility for coverage.

  As noted in the previous section, a genetic test is needed to determine whether hepatitis C patients could benefit from an additional 24 weeks of therapy under NIH guidelines. However, by prohibiting plans from requesting or requiring this test, H.R. 493 may cause some individuals to forego coverage for the extended therapy that is needed to effectively treat their particular condition.

  Looking to the future, unforeseen advances in medical treatment and technologies may lead to many additional circumstances where health insurance plans will need to request genetic tests to determine whether customized therapies or treatments are warranted. Therefore, we urge the subcommittee to consider changes that would allow proper uses of genetic tests while at the same time meeting the bill's original goal of prohibiting genetic discrimination.

- **Health insurance plans should be allowed to request "genetic tests" to promote preventive screening and disease management.**

Another concern is that this legislation would prevent health insurance plans from continuing to use genetic tests to promote preventive screening and disease management programs.

We are proud of the success health insurance plans have achieved in promoting preventive health care services to keep Americans healthy, detect diseases at an early stage, and avoid preventable illnesses. Plans also have been proactive in developing innovative disease management programs to improve patient care and health outcomes for persons with diabetes, congestive heart failure, and other chronic conditions.

Because of these private sector initiatives, millions of Americans are healthier and enjoying a higher quality of life. Congress should be making every possible effort to support these initiatives. Unfortunately, H.R. 493 could stifle health insurance plans from utilizing genetic tests to identify patients who may benefit from specific types of preventive screening or disease management services.

For example, a person who has the gene for the familial form of colorectal cancer could benefit from earlier or more frequent screenings for the disease. As genetic science advances over the next decade and beyond, health insurance plans will have a legitimate need to use genetic testing to identify these persons and ensure that they receive the necessary screening and early intervention to detect and treat cancers for which they are highly susceptible.

Current law allows health insurance plans to use genetic testing in this manner, but H.R. 493 could prevent plans from taking such proactive measures on behalf of their enrollees. We urge the committee to change the bill to ensure that it does not unintentionally undermine preventive health care services and disease management programs.

- **A clearer, more precise definition of "genetic information" would promote optimal patient care and help avoid unintended consequences for consumers.**

We also are concerned that H.R. 493 includes an excessively broad definition of the term "genetic information." As currently written, this definition could apply to diseases, tests, and conditions that are completely unrelated to genetics.

Another problem is that the bill's definitions arguably could apply to certain conditions – such as obesity or high cholesterol – that are not genetic, but may be linked to a person's family history. Even though there is no connection to a specific gene for these conditions, the bill in its current form could be interpreted to prevent health insurance plans from requesting tests that could help patients avoid or overcome health problems caused by obesity or high cholesterol.

These are serious issues with far-reaching implications for health care consumers. As this bill moves through the legislative process, we urge the subcommittee to define "genetic information" with greater clarity and precision.

- **The threat of litigation can be alleviated by clarifying that Title II of the bill, encompassing employers and unions, does not cover the administration and operation of employer-sponsored group health plans.**

Although the bill includes separate titles addressing health insurance issues (Title I) and employment issues (Title II), the legislative language of Title II could be interpreted to include the terms of an employer-sponsored group health plan as an employer practice that could be the basis for a discrimination complaint. Specifically, section 202 states that it is an unlawful employment practice for an employer to "discriminate against any employee with respect to the compensation, terms, conditions, and privileges of employment." This language can be interpreted as applying to a health benefits plan or health coverage sponsored or offered by an employer. Some employers may be discouraged from offering employee health benefits to avoid the threat of litigation. It is our understanding that the Title II provisions were not intended to cover health benefits plans and we suggest that the language be clarified to ensure that employer-sponsored group health plans are not covered under the Title II language.

We also would like to bring certain technical issues to the subcommittee's attention. It is our understanding that the sponsors of H.R. 493 do not intend for the bill to cover long-term care products. Also, the bill may be read to effectively create "two classes" of health information, creating barriers to optimal patient care and the advancement of a national health information infrastructure. AHIP is communicating with subcommittee members and staff about these and other significant issues.

IV. Industry Support for Nondiscrimination and Privacy Protections

It is important for the subcommittee to understand that genetic information is not used to deny or cancel coverage or set premiums. At the same time, health insurance plans are accustomed to and understand the importance of protecting the privacy and confidentiality of individually-identifiable health information, including genetic information. Our industry's practices reflect our strong support for provisions of current law that: (1) prohibit discrimination against individuals based on their genetic information; and (2) protect the confidentiality of patient-identifiable genetic information.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits employers and health insurance plans in the group market from using the results of genetic tests to deny coverage or set different premium rates for individuals who participate in group health plans. HIPAA specifically prohibits group health insurance plans from:

- refusing to cover employees or their family members based on genetic information;
- refusing to renew coverage based on genetic information;
- charging employees and their family members higher premiums based on genetic information; and

- canceling coverage based on genetic information.

In addition to providing these nondiscrimination protections, HIPAA established an effective framework for health insurance plans, health care providers, and health care clearinghouses to protect individuals' health information. In addition, a number of state privacy laws impose similar restrictions on the use and disclosure of health and genetic information by health insurance plans.

The following examples highlight some practical examples of how these privacy protections apply in real-life settings:

- HIPAA prohibits health insurance plans or health care providers from disclosing information about an individual's genetic tests to an employer who sponsors a health insurance plan.

- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for the individual's treatment.

- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for coverage determinations – such as to determine whether coverage for a genetic test or genetic service will be authorized or paid for by a health insurance plan.

- HIPAA permits individuals to authorize a health insurance plan or health care provider to disclose their genetic information to a person who would otherwise not be entitled to receive the information (e.g., to a family member interested in learning about the individual's genetic conditions).

V. Conclusion

Thank you for considering our perspectives on these important issues. Health insurance plans are strongly committed to ensuring that genetic information is used to help clinicians and patients make informed health care decisions and, at the same time, maintaining strong protections in the areas of nondiscrimination and confidentiality. We appreciate this opportunity to testify and we stand ready to work with the subcommittee on this and other health care priorities facing our nation.

Chairman STARK. I want to thank all of you. My assumption is that the first three witnesses are in support of the bill and that Dr. Corwin is in support of the bill with conditions. I guess I would just like to figure out whether we're in a general hearing nit picking or whether there are some major issues here.

You guys are hooked up with Harvard, right?

Dr. CORWIN. In name only.

Chairman STARK. In name only? All right.

Dr. CORWIN. Separate entity. It used to be part of the Harvard Community Health Plan way back.

Chairman STARK. Okay. I don't suppose there are any laws now—and I don't know what the Massachusetts health bit—if I come in and you tell me that I have to have a colonoscopy and I say I don't want to, you are not going to kick me out of the plan, are you?

Dr. CORWIN. No, sir, we are not. It's your choice.

Chairman STARK. I mean, you are not going to send me to jail.

Dr. CORWIN. No, sir.

Chairman STARK. So, wouldn't the same thing prevail if you told somebody, well, we think the indication is you have this condition or that condition, and I think in your testimony you said maybe you want to get an extra 30 days of treatment that could be identified as necessary with genetic testing. Was that yours?

Dr. CORWIN. That is ours.

Chairman STARK. Okay, that was your testimony.

Dr. CORWIN. Yes, sir.

Chairman STARK. Wouldn't medical ethics say to you if I said, no, you think I probably would need the 30 days, but I ain't going to take the test, wouldn't medical ethics say well you ought to go ahead and give me the extra 30 days of treatment just in an abundance of caution?

Dr. CORWIN. What our concern is, sir—this is a very good question, first of all.

What our concern is, that when Dr. Collins's future research becomes even more sophisticated, that we will soon be at a point in time where what is called pharmacological genetic signatures, or pharmacogenetics, will allow us to take a look at a panel of chemotherapeutic agents on one side and a panel of genetic interpretation on the other side of a grid and help predetermine which

chemotherapeutic agent is most likely to be able to help you in your treatment.

It is our understanding and our concern that, in the wording of this bill that, as it stands at this point in time, that requesting or requiring someone to undergo that kind of testing as a health plan, to help guide their therapy to the most appropriate level, to ensure they get the most appropriate medication and not the most—best guess, which is not good medicine at this point in time and not evidence based, that we wouldn't be able to do that.

Chairman STARK. Okay, now, I think you hit on the operative word. I don't know as there is anything in the bill, although I must say I would have to read it more carefully than I have, that would stop you from requesting it. But as to requiring it, I don't know that there are any tests that you can require anyway, and I don't know that, under law. I guess you could say you withhold certain treatments.

I don't know, I certainly wouldn't want to see anything in this bill that would interfere with the delivery of the best medical care that your physicians could determine for your beneficiaries. I do see the exciting prospects of being able to be much more accurate in determining what kinds of pharmaceuticals should be used. We get in a big fight with Amgen about EPO. How much EPO should you give somebody in dialysis. I think I know, but I think it is determined more by money than it is by medical science.

But be that as it may, I don't want to get in the way. If there are specific issues, then I think you are going to have to, and I hope you will, sit down with our legislative counsel and your lawyers and see if we can come to some kind of an agreement that——

Dr. CORWIN. We are more than willing to work with you on this and we would love to do that.

Chairman STARK. Because if we could work those sorts of things out, you guys would favor the bill.

Dr. CORWIN. Yes, sir.

Chairman STARK. Well, I will assure you that we will do our best to see that we don't get in the way of physicians practicing the best medicine they know how. Now I can't assure you that I am going to be able to put something in this bill that is going to pound sense into the heads of your patients, who may often choose not to listen——

Dr. CORWIN. My patients have been refusing to listen to me for a long time about a lot of things.

Chairman STARK. I can lead that horse to water, okay, but that is about as far as I think we could get.

So, I appreciate you raising those issues and I hope that, with your forbearance and cooperation, we could take care of those. As long as you see them as technical corrections.

Dr. CORWIN. We feel they are technical corrections, yes, sir.

Chairman STARK. I think that that we could handle.

I want to especially thank Mr. Escher for raising concerns. I know it is difficult, when we talk here in generalities of people not wanting to release private information. It is even more difficult, often, to come in a public forum such as this and talk about your family and your personal involvement. But it is important, and so you are to be thanked for the inconvenience and however you feel

about our invading your personal privacy. But by being willing to step forth, you do us all a service and I want to thank you, in particular.

Ms. Terry and Ms. Pollitz, I thank you for your help and support in this. We may have as we try and move this along—we have to report this by the 23rd?—we are on somewhat of a time schedule to see if we can report this out by the end of the month. So, we may want to call on all of you, if we can, over the next week or two to see whether we can wrap this up into a form that will have broad support.

With that, I would like to recognize Mr. Camp for any inquiries he would like to make.

Mr. CAMP. Thank you, Mr. Chairman. Again, thank you for holding this hearing.

I want to thank you all for coming and taking the time to do that, especially Mr. Escher. Again, it is difficult to come and talk about personal issues. Hopefully, we won't make you come in another 5 years, we will have resolved this issue. Ms. Terry, after 12 years of effort, I hope we can.

Dr. Corwin, I did want to just point out, there is a limitation on genetic testing in the bill, but it does say an insurance plan shall not request or require an individual or a family member of such individual to undergo a genetic test. So, it looks as though they can't even request it.

But then you go further down in the rules of construction and it seems to go the other way and says in the rules of construction that a health care professional who is employed and is providing health care services may notify an individual of the availability of genetic testing. So, there is a bit of a construction problem here that I think—I would think the rule of limitation overplays the rule of construction, so I don't know if you want to comment on that, Ms. Pollitz?

Ms. POLLITZ. Actually, if you continue on, the bill also protects health care professionals to request that they undergo, they just also can't require as well.

Mr. CAMP. Under the rules of construction.

Ms. POLLITZ. Yeah.

Mr. CAMP. Yes. Oh, no, I understand that and I mentioned that.

Dr. Corwin, there is a limitation on insurance companies requesting, but in the rules of construction they say that physicians and professionals employed by an insurance company can notify individuals of the desire for a genetic test.

What does that do in terms of your understanding?

Dr. CORWIN. I am not a lawyer, so I would have to defer to my colleagues who have helped me try to understand this bill as best as possible. My understanding is that the health insurance plans would be prohibited from requesting and then requiring.

Again, we do not employ physicians. Physicians are merely the end product of the delivery of health care. The——

Mr. CAMP. I am sorry.

Dr. CORWIN [continuing]. The testing that we would be requesting.

So, again, we get into the situation within our plan where we are trying to help improve the long-term, evidence-based process, de-

crease the variation in the practice of medicine. To your point earlier in terms of getting to that wonderful state where we have electronic medical records that do all the reminding for us, it is a great future place to be.

But at this point in time, health plans have a very significant component in terms of filling gaps in care in the busy office practice in terms of reminders, both to patients who don't want to have their colonoscopies done for obvious reasons, not a comfortable procedure to undergo. If they have to be done more frequently, it is less comfortable to have to undergo those procedures.

In the same token, we like to be able to remind physicians that they have panels of patients who require these tests. Being able to encourage that and use this information in that way that if it is available in a generic way at some point in the future, to the Chairman's comment, at some point in time there will be tests that will be available that will help us with this.

Mr. CAMP. Yes, I would be happy to yield.

Chairman STARK. As another nonlawyer, what I am hearing here, some from my staff and some from—that there are some legal differences and niceties between saying, if you recommend to me to take the test, that is okay. But if you request it and I don't, then I might be in danger of being kicked out of the club. That I don't want.

So, I mean, those are terms of legal differences that I think we have to work out, because I am happy to have you recommend to me, even be a pest and remind me. But I don't want to lose my health insurance.

Dr. CORWIN. We don't disagree with that interpretation.

Chairman STARK. Those are—okay.

Mr. CAMP. I agree with the discussion, the way it is going. I mean, obviously, on the whole concept of the bill, I think we have general agreement on. We just want to make sure that as we look to the future—and I thought Dr. Collins was pretty eloquent in his statement that we do need to personalize health treatment. That that can be a real help to the future in terms of addressing health care needs and costs and other things, and obviously making sure people get the care they need.

But the word request is okay with doctors, it is notify with insurance providers, it is request or require up in other language. I think we just need to get together and find out what the commonality should be so that we don't have an unintended consequence later when maybe this becomes a very hopeful tool in helping people.

But the main purpose of the bill is to protect people from the misuse of this information, which I think is the real concern initially. We don't have the technology to really use it as a health care preventive measure right now as much as we would like. But as Dr. Collins also testified, that is coming, and we don't know how soon that will come.

So, I appreciate all of your testimony. Thank you very much. Thank you, Mr. Chairman.

Chairman STARK. Thank you.

I just had one other question of Dr. Corwin, and maybe Karen could answer. In Dr. Collins's testimony, I asked him about how

much it cost, and he indicated that there are services out there that would be glad to accommodate me and also recommend Herbalife and a lot of other good things for me to take if they found something that didn't seem quite right.

Are we going to be opportuned by, quote, services who want to get out and sell this kind of program to the public and then come and ask us to have Medicare pay for it? Are there any of those services that are valid? Or do we have to wait a while until they are more developed? Can you comment on that?

Dr. CORWIN. I would be glad to, and it is an excellent question. I don't know the future answer to that, but currently there are some, for lack of a better term, fly by-night services that do offer those things.

There are many very good companies who are offering genetic tests at this point in time. But as Dr. Collins indicated, these are companies that have patented certain components of the human genome which have raised the price. To answer your question about the pricing, they can be anywhere from, depending on how good your contracting people are, from a couple hundred dollars up to $5,000. Many of these companies hold the patent on specific tests which limit the access to that one company, so there is a lack of competition and that is an issue for us on the payer side in keeping the overall cost of medical care down. So, I think that is a future concern.

We will have to sort through the latter part of your question, which is how do we decide if these programs are really very good and whether they really do offer anything. It would be our hope that we would be able to use the evidence of science to help us determine what tests are appropriate, when they are appropriate, how they should be best utilized and hopefully keep them in the realm of the primary care practices of our specialists and our primary care physicians and away from people who may take advantage of other people's concerns, which is obviously something that does happen, unfortunately.

Chairman STARK. Is it in the public interest to patent this stuff?

Dr. CORWIN. I think that is a politically hotbed question. I would say with all due respect to our private enterprise system that as long as it is competitive, we may be able to keep those prices down. Right at the moment, it does not feel like a competitive environment.

Mr. CAMP. Mr. Chairman, we do have—and this is fairly off the subject, but we do have patenting of tax advice, which we have held hearings on in the Committee on, so we have got some real extensions of patent law that are occurring out there.

Chairman STARK. Do you suppose they could patent politicians?

Mr. CAMP. I think that would be a very scary thought.

Chairman STARK. I want to thank all of you again, and we will conclude the hearing. Thanks very much.

[Whereupon, at 3:37 p.m., the hearing was adjourned.]

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