

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

---

---

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

FIRST SESSION

JULY 11, 2001

**Serial No. 107-46**

Printed for the use of the Committee on Energy and Commerce



Available via the World Wide Web: <http://www.access.gpo.gov/congress/house>

U.S. GOVERNMENT PRINTING OFFICE

73-729PS

WASHINGTON : 2001

---

For sale by the Superintendent of Documents, U.S. Government Printing Office  
Internet: [bookstore.gpo.gov](http://bookstore.gpo.gov) Phone: (202) 512-1800 Fax: (202) 512-2250  
Mail: Stop SSOP, Washington, DC 20402-0001

COMMITTEE ON ENERGY AND COMMERCE

W.J. "BILLY" TAUZIN, Louisiana, *Chairman*

MICHAEL BILIRAKIS, Florida	JOHN D. DINGELL, Michigan
JOE BARTON, Texas	HENRY A. WAXMAN, California
FRED UPTON, Michigan	EDWARD J. MARKEY, Massachusetts
CLIFF STEARNS, Florida	RALPH M. HALL, Texas
PAUL E. GILLMOR, Ohio	RICK BOUCHER, Virginia
JAMES C. GREENWOOD, Pennsylvania	EDOLPHUS TOWNS, New York
CHRISTOPHER COX, California	FRANK PALLONE, Jr., New Jersey
NATHAN DEAL, Georgia	SHERROD BROWN, Ohio
STEVE LARGENT, Oklahoma	BART GORDON, Tennessee
RICHARD BURR, North Carolina	PETER DEUTSCH, Florida
ED WHITFIELD, Kentucky	BOBBY L. RUSH, Illinois
GREG GANSKE, Iowa	ANNA G. ESHOO, California
CHARLIE NORWOOD, Georgia	BART STUPAK, Michigan
BARBARA CUBIN, Wyoming	ELIOT L. ENGEL, New York
JOHN SHIMKUS, Illinois	TOM SAWYER, Ohio
HEATHER WILSON, New Mexico	ALBERT R. WYNN, Maryland
JOHN B. SHADEGG, Arizona	GENE GREEN, Texas
CHARLES "CHIP" PICKERING, Mississippi	KAREN MCCARTHY, Missouri
VITO FOSSELLA, New York	TED STRICKLAND, Ohio
ROY BLUNT, Missouri	DIANA DEGETTE, Colorado
TOM DAVIS, Virginia	THOMAS M. BARRETT, Wisconsin
ED BRYANT, Tennessee	BILL LUTHER, Minnesota
ROBERT L. EHRLICH, Jr., Maryland	LOIS CAPPS, California
STEVE BUYER, Indiana	MICHAEL F. DOYLE, Pennsylvania
GEORGE RADANOVICH, California	CHRISTOPHER JOHN, Louisiana
CHARLES F. BASS, New Hampshire	JANE HARMAN, California
JOSEPH R. PITTS, Pennsylvania	
MARY BONO, California	
GREG WALDEN, Oregon	
LEE TERRY, Nebraska	

DAVID V. MARVENTANO, *Staff Director*

JAMES D. BARNETTE, *General Counsel*

REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

CLIFF STEARNS, Florida, *Chairman*

NATHAN DEAL, Georgia	EDOLPHUS TOWNS, New York
<i>Vice Chairman</i>	DIANA DEGETTE, Colorado
ED WHITFIELD, Kentucky	LOIS CAPPS, California
BARBARA CUBIN, Wyoming	MICHAEL F. DOYLE, Pennsylvania
JOHN SHIMKUS, Illinois	CHRISTOPHER JOHN, Louisiana
JOHN B. SHADEGG, Arizona	JANE HARMAN, California
ED BRYANT, Tennessee	HENRY A. WAXMAN, California
STEVE BUYER, Indiana	EDWARD J. MARKEY, Massachusetts
GEORGE RADANOVICH, California	BART GORDON, Tennessee
CHARLES F. BASS, New Hampshire	PETER DEUTSCH, Florida
JOSEPH R. PITTS, Pennsylvania	BOBBY L. RUSH, Illinois
GREG WALDEN, Oregon	ANNA G. ESHOO, California
LEE TERRY, Nebraska	JOHN D. DINGELL, Michigan,
W.J. "BILLY" TAUZIN, Louisiana	( <i>Ex Officio</i> )
( <i>Ex Officio</i> )	

(II)

## CONTENTS

---

	Page
Testimony of:	
Davidson, Mary E., Executive Director, Genetic Alliance, Inc .....	21
Morella, Hon. Constance A., a Representative in Congress from the State of Maryland .....	10
Rothenberg, Karen H., Dean, Marjorie Cook Professor of Law, University of Maryland School of Law .....	38
Slaughter, Hon. Louise M., a Representative in Congress from the State of New York .....	7
Venter, J. Craig, President and CSO, Celera Genomics .....	35
Young, Donald A., Interim President, Health Insurance Association of America .....	28

(III)

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

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

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

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

#### *Promote Critical Biomedical Research*

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

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

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

#### *Price Controls*

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

#### *Update Definitions of Key Terms*

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

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

#### *Conclusion*

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

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

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

Mr. STEARNS. I thank you.

Dean Rothenberg, welcome, for your opening statement.

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

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

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

Mr. STEARNS. By unanimous consent, so ordered.

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

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

Mr. STEARNS. Thank you.

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

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

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

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

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

Mr. STEARNS. We can come back to that.

Ms. ROTHENBERG. Thank you.

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

PREPARED STATEMENT OF KAREN H. ROTHENBERG, DEAN AND MARJORIE COOK  
PROFESSOR OF LAW, UNIVERSITY OF MARYLAND SCHOOL OF LAW

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

Thank you.

Mr. STEARNS. I thank you.

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

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

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

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

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

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

Do you say that's still true?

Mr. VENTER. Absolutely.

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

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

Mr. VENTER. Yes.

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

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

Mr. STEARNS. Probabilities. Okay.

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

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

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

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

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

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

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

Mr. STEARNS. Okay.

Mr. VENTER. The employees at the railroad—

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

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

Mr. STEARNS. Yes.

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

Mr. STEARNS. The railroad was ignorant.

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

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

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

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

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

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

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

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

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

Mr. STEARNS. Ms. Davidson?

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

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

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

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

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

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

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

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

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

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

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

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

Mr. TOWNS. Dean Rothenberg?

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. TOWNS. Okay, fine.

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

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

Mr. YOUNG. And I appreciate that.

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

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

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

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

Ms. ROTHENBERG. What the term means?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. STEARNS. So ordered.

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

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

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

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

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

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

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



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

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

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

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

Mr. YOUNG. Yes.

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

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

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

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

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

Mr. STEARNS. Right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. TOWNS. Could the employer purchase it?

Mr. YOUNG. I'm sorry?

Mr. TOWNS. Could the employer purchase this information?

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

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

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

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

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

Mr. YOUNG. I'm sorry?

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

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

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

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

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

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

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

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

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