



**Decoding the Genome, Genetic Predisposition to
Disease, and Health Insurance: What Do We Know and
Whom Do We Share It With?**

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Transcript*

PERRY: Good Morning. My name is Dan Perry. I am the executive director of the not-for-profit Alliance for Aging Research based here in Washington, D.C. We are a seventeen-year-old advocacy group trying to promote policies that will advance the frontiers of human biology in understanding both the relationship between the diseases that occur more commonly in the elderly and the fundamental biology of the aging process itself. It's our view that in a population that's going to see its over-sixty-five population double in the next twenty-five years, and its over-eighty-five population quadruple in that same period of time, and knowing of the disability and cost burden that comes from an explosion in the numbers of diseases such as Alzheimer's, cancer, Type II diabetes, stroke, vision and hearing loss, for example. We know that this is an area where public policy should be encouraging the most rapid advances and innovations in understanding how to intervene in the pathways of those diseases and rush as quickly as possible to patients the benefits of research that can keep them functioning longer. We also understand that without massive public support and without policies that channel that support to both increased funding for public sector and policies that encourage private sector innovations, we won't be able to meet the challenge of the graying of the baby boom generation, as surely we must.

In partnership with the American Association for the Advancement of Science (AAAS), the publishers of *Science* magazine, the Alliance for Aging Research, this year initiated a series of monthly Webcasts which have consisted of debates between some of the most far-reaching thought leaders on the subjects of bioethics, economics, and societal impact and repercussions that will come as we understand human aging on a more fundamental level. Today is the fifth in the series of these monthly Webcasts and they go under the heading of SAGE Crossroads. That's S-A-G-E, an acronym of Science of Aging Crossroads, and with this series of debates we also have a Web site where there are weekly updates on the news about research into human aging that comes from AAAS, and editorials, and chatrooms, and monthly live discussions.

Today we are delighted to be Webcasting from the BIO annual meeting. There is probably no more classic an example of how science and policy cross like hotwires than on the human genome project. Born of scientific initiative and funded by the federal government, it is probably *the* achievement of this generation, to have succeeded in mapping and sequencing the billions of parts of the human genetic road map. But it also raises serious and troubling questions. Now that we have this vast amount of information, these intimate details of human life and human biology, who owns this information? To what purposes can it be put? Will this be the servant of humankind or will this be a tormentor for people who find themselves with discrimination based upon their disease profiles? To help us unravel this thorny issue, we have been privileged to have as a moderator for all the cutting-edge debates for biology of aging and public policy the renowned American journalist Morton Kondracke. You are all familiar with Morton Kondracke from television, from magazines, and his national column "Pennsylvania Avenue." He is the executive editor of *Roll Call*, the feisty, independent newspaper on Capitol Hill and co-anchor of FOX News' "Beltway Boys." So I'm going to turn it over

to Mort Kondracke. I thank Mort not only for his involvement in this series of SAGE Crossroads debates, but also for his personal advocacy on behalf of medical research. He is simultaneously a director for both the Parkinson's Action Network and the Michael J. Fox Foundation for Parkinson's Research. For those of you who that want to spread the word about this, please log on to www.sagecrossroads.net. Not only will you be able to view this debate in a day or two, but you will also be able to see all those that preceded it. You will find news and information and updates on our debates still to come. Welcome to sagecrossroads.net and to this discussion. Mort, the show is yours.

KONDRACKE: Thank you very much, Dan. I'm delighted to be here, and thank you all very much for coming. The decoding of the human genome brought us into a new age of discovery and potential. It has also raised any number of questions and ethical dilemmas. Genetic medicine holds the promise of tailor-made medications for individuals, genetic therapy cures, and blood tests that can forecast our lifetime risks for disease. These possible outcomes hold many ethical questions that have to be discussed as we move into the future. As more is known about genetic predispositions to diseases, how much information should be available to insurance and health organizations, including Medicare? Will insurance companies insist on blood tests to determine genetic health before granting coverage? Observers fear that privacy violations or discriminatory employment and insurance practices will befall persons diagnosed with predispositions to disease. So that's our topic today. Also are the efforts to ensure privacy going to inhibit medical research? That's another topic we'll cover.

Our speakers are, first, Robert Cook-Deegan, who is the director of the Center for Genome Ethics, Law, and Policy at Duke University. Until July 2002 he directed the Robert Wood Johnson Foundation Health Policy Fellowship program at the Institute of Medicine at the National Academy of Sciences.

Cynthia Pellegrini is the chief of staff and legislative director for Representative Louise Slaughter, who is the chief House sponsor of the Genetic Nondiscrimination in Health Insurance and Employment Act. She's been with Congresswoman Slaughter since 1996, and has worked in various positions on Capitol Hill since 1993.

And Henry Desmarais who is senior vice president of policy and information at the Health Insurance Association of America (HIAA) where he directs analysis of proposed federal and state legislation, regulations, and other policy prescriptions that affect the health insurance industry.

I thought for an overview of the situation, Robert Cook-Deegan will start. Our format will be each of the panelists will have five to ten minutes to lay out their position on the matter and then we will have a discussion among us, and then you are invited after that to contribute questions. I think there are cards around, actually we have microphones here so that you can state your questions yourselves. I hope you'll contribute vigorously to this discussion and make it something that will explore the ramifications of this important subject through and through. So first Robert, why don't you go ahead and start with your overview.

COOK-DEEGAN: Let me just start by giving you a little bit of a history, first of genetics and then of the genome project and then of the very specific policy context we're talking about today. Let me just start by backing up to where we were in the 1960s and 1970s in the context of human genetics. I'm going to give a very quick overview of what's been happening in human genetics and the shift to the policy context. Genetics has changed a lot. The Human Genome Project is something that's been on the front page of every major news daily. Every newspaper probably has a story on genetics at least once a week now. So it's become a part of our culture in a way it had not been previously.

In the 1970s, when I was in medical school, I first cut my teeth on the concept of human genetics in the context of Alzheimer's disease. This was in the mid-1970s and Alzheimer's was not a household name. Those people who were looking at Alzheimer's disease saw it as a black box, and it was not considered to be genetic at all. I happened to be working at one of the medical schools that had gotten used to looking at pediatric diseases, that is childhood diseases, that were caused by single-gene defects. The idea was to search the literature and see if we could find a genetic form of Alzheimer's disease because if we could understand the genetic form of the disease, then we might understand what was going on with Alzheimer's disease more generally.

Now in the mid-1970s it wasn't a very smart thing to do. When we started this process there were seventy markers on human chromosomes, all of which were protein isomorphs and things like that—whether you could roll your tongue, whether your urine smelled funny after you ate asparagus. Those were the genetic markers that were actually used to do genetics. It's hard to believe. But there was faith that eventually the tools of genetics were going to catch up, so that is what happened. But there is one thing that you should observe. Genetics up until the 1970s was very much the sort of thing that people did in academic medical centers and if you had a genetic disease, it was the sort of thing that you were going to be referred to a specialist to do. And that really was the breeding ground for the first applications of all the miraculous technologies that grew up from the 1970s and then into the 80s.

So what were those technologies? Sequencing, recombinant DNA, and computing are the big three technologies that given rise to the genome project, and among those three technologies, what we have today of course is an incredible expansion of knowledge that has centered on creating information about human genetics. In the meantime, we have shifted from thinking about only those diseases that are inherited in families where we can tell that there is a broken gene because they're inherited the same way as Mendel's peas showed their inheritance patterns, to thinking about genetics being a part of every major disease, except maybe getting hit when you are crossing the street or getting in car accidents. And even there I think that we could come up with some genetic underpinnings to behaviors that are associated with the risk of getting into an accident.

So genetics has gone mainstream and in that context the Human Genome Project was something that really was a consequence of what was happening in science and technology. It was the idea of doing a concerted effort, a frontal assault on the human

genome. And it worked, right? What we have now is an immense amount of information about human genetics and it's being applied to virtually every disease.

Now take us back again to the 1980s. It was very clear that there was something special about genetics. Every time there's been a debate about having a national bioethics commission, every time there has been a debate about new technologies in medicine, genetics has been right there at the forefront. And partly as a consequence of a vigorous debate that went back to the recombinant DNA controversy and our experience with eugenics and racial hygiene right after World War II, and leading into World War II, there was a sensitivity to the social, ethical and legal implications of what was going on in science. So when Jim Watson was appointed the director of the NIH component of the genome project in late September of 1988, he announced that he was going to spend some of the money that was being devoted to genome research at NIH, he was going to focus some of that money on studying the social, ethical, and legal implications. As far as I know it was a precedent-setting move. I don't know of any other case where anyone has devoted funding to studying the impacts of science as part of the bundle of doing the science in the first place. At the very beginning it was abundantly clear that two of the things that had to be on the list to be studied were the issues that we are talking about today and are kind of woven together. One is the issue of genetic discrimination and the other is the notion of genomic privacy.

So let me briefly go through what we mean by those. There are two bodies of law that we think of immediately in connection with genetic discrimination. One is getting insurance, that is health insurance, disability insurance, long-term care insurance, and life insurance, at the very least. What does genetics have to do with that? Well, suddenly we might have technology that would subsequently predict someone's risk of subsequently developing a disease or in solidifying the diagnosis of an existing disease. Now for the genetic use in an existing disease it's not a new problem. But the predictive use of information for predicting future disability was something that was—it's not unique—it's not something that's completely new, it's not unique to genetics but it was very clear that genetics was going to intensify that aspect of a policy problem that already loomed in the background. So genetic discrimination came up as something that was worrisome. That's part one.

Part two is the other background risk was that we did have the experience of sickle cell testing in the 1970s because we did have the ability to do genetic tests for sickle cell starting in the late 60s, and it became quite mainstream by the 1970s and the roll out of that technology was not terribly smooth, to make an understatement. So the idea of genetic discrimination is that even though you don't choose your genes, information about you might make it difficult for you to get the kind of insurance that you want or the kind of job that you were seeking, because people would use the information about your future health risk to your detriment. Obviously linked to that concern about discrimination is a concern about privacy. That is, who gets access to the information? And it's actually two things—it's privacy and confidentiality. Privacy is whether you know data, and confidentiality is how it's shared among people, that is the relay of information from one group to another.

Is genetics different from other medical information? Well, yes and no. One thing that is different about genetic information that's obvious as soon as you think about it is that genetic information about one person in the family is also relevant to other members of the family. That is the main thing that is distinctive about genetic information. But the policy problem associated with predicted risk was the main thing that was associated with, that was the main potent value of genetic information. So from the very get go, in the ethical legal and social implications program, there was an intense focus on thinking about genetic discrimination and genetic privacy. As genes became discovered, starting in the mid-1980s, things like cystic fibrosis, breast cancer, colon cancer, ovarian cancer genes, and Alzheimer's genes, as they became discovered one-by-one, the policy process, because in part of the funding available through the ELSI program. In fact, there were empirical studies about how people were or were not getting genetic tests, how they were using the information. So we do have a body of information for policy-making that we would not normally have. So we have a body of empirical studies and a legion of scholars who have thought about these issues in advance. One of the consequences of that, of course, is that it has drawn the attention of policy makers.

I have a whole bunch of slides, but I am actually only going to use one, because I wanted to walk you through some of what's actually happened. I will touch on privacy in just a second, but for a moment let's just focus on genetic discrimination. Discrimination is the sort of thing that by its notion is something that you might deal with in the legal context. So the questions to me, looming in the background, are: how common is it? how severe is it? and how is it perceived to be? Those are three completely different domains of policy. The problem with trying to get a handle on this is—if you think about it—is we're probably never really going to know. It's a very, very hard thing to explore correctly. There were some grants given. There was some independent work done to try to get an answer to these questions, but it's rather unsatisfying to try to study something whose absence is what you desire.

The first surveys, for example, were done by asking folks who might have been subjected to genetic discrimination, "Do you think you've been discriminated against?" Now that's not a bad way to get a first fix, but you actually don't have very solid information because the only way to actually find out if that is happening is to go to the other side of the fence and find out how decisions were made about access to jobs and insurance. So it's a very difficult thing to understand and study empirically, but one thing we can say is that when we ask folks who are coming in and are part of these clinical trials and the other clinical research that's associated with the new genetic tests, as they become available—do they worry about them? The answer there is very clear, they do, particularly in cases like breast cancer where the genetic tests are especially relevant for young people at risk for a very high-risk disease and a very expensive disease that is highly perceived to be prevalent in our society. Although the genetic forms of breast cancer are very rare, breast cancer is not and those two factors have been conflated in the public mind. To become a perceived risk of a high risk of discrimination by women who are thinking about getting tested for the breast cancer gene, for example, the various breast cancer genes.

So stepping into this there are three levels of policy making that are immediately available. One is self-regulation. Where would that come from? That would come from the insurers and from the health plans, primarily—the groups that pay for health care and deliver the insurance products that people are seeking access to. So there is potential for self-regulation, in fact we've seen movement on that front just in the last year—a new standard being rolled out for health plans and thinking about how we are going to deal with discrimination. The states have stepped into the breach. This is taken from a database of state laws and was created by Georgetown University and the National Conference of State Legislatures. This is the database that is available online for free. You go in, and whatever state you are living in or whatever state you are thinking about policies in, you can go in and look across the bars and see what kind of statutes they have in various aspects of genetics relating to law.

I pulled out the database that links to genetic discrimination statutes and there are thirty-four states that have passed laws that are kind of general genetic discrimination statutes. Three states say you can only do it if there is an actuarial justification, so there's presumption against, but it can be overcome if there is some consensus in the actuarial community that is written or documented. Texas applies it to group plans, and Alabama has a statute that's specific to cancer, and if you add it up I think it is thirty-eight states, but it changes. It's impossible for a sole scholar to be able to follow it up. I think we are going to hear a little bit more about HIPAA and the action that is going on in the U.S. Congress, so I'm not going to say much about it except that there is action going on at the federal level. HIPAA does have stipulations in it for group plans that include more than fifty people. That's already in place. I think we are going to hear about the genetic discrimination statute that is waiting to be considered on the Senate floor, and then we'll see what happens in the House, and I hope that we'll hear a story on that in just a minute.

The final thing is genetic privacy. Now HIPAA is obviously about privacy, too. It does have some provisions in it about genetics, but there is a whole other body of law that has started to happen at the state level that's not quite as frequent. There aren't as many states that have passed genetic privacy laws, and the states have taken a more disparate approach to privacy. Some of them, like Florida, have said that genetic information created in the wake of a genetic test is actually handled as property of the person that the test is relevant to. Other states have handled privacy in very different ways on a spectrum out to rather weak protections and most states have not done anything that is specific to genetic privacy.

I would like to go back to two things I said at the very beginning. One is that for the most part, what's going on in genetics is very tightly tethered to what's going on throughout medicine. Genetic information is not completely unique in any aspects that I am aware of, but it is intensifying the debate about predictive risk in particular and about how information about one person in a family relates to information about another.

My final comment is that the landscape is itself changing. The role of genetics in medicine is changing very rapidly. To give you an example, we have thought about privacy mainly in the context of these inherited Mendelian diseases, where it is very clear

what the inheritance pattern in a family is. But what's going on in genetics more generally is we're using genes as tools to understand disease across the board. So what's happening in many, many, many diseases now is that we are beginning to use genetic profiling. Now that's a genetic test, right? But you are testing thousands of genes, thousands of alleles, for those genes in one single set of experiments. That begins to work itself to clinical practice in the form of pharmacogenomics or in the form of predicting risk of disease, and that's a different framework for thinking about genetic information, but that probably is our future. The upshot of that is that trying to disentangle genetic information from other medical information is going to be increasingly difficult in the coming decades. And with that I'll stop.

KONDRACKE: Thank you very much. That was a great overview. Henry Desmarais, go ahead and tell us what the insurance industry thinks about all this.

DESMARAIS: Thank you.

We've certainly come a long way in terms of genetics since the days when Mendel was growing flowers in his garden. But we are still at the infancy in terms of where we are going with all this increase in knowledge. I'm here and happy to be here to talk about this topic today representing the Health Insurance Association of America (HIAA). Our member companies not only provide health insurance or medical insurance to millions of people, but they are also involved in providing other health insurance products, like long-term care insurance and disability, income insurance, supplemental insurance, Medigap, dental, all of which have some relevance for the topic of genetics.

To get to right to the bottom line, two things have been raised. One is the issue of discrimination by insurers, and secondly the issue of privacy for genetic information. And I would just like to make a couple of simple points, which hopefully we can then elaborate on during the Q&A period.

First, there are already plenty of laws out there that attempt to address this rather vague notion of potential discrimination by insurers. The Health Insurance Portability and Accountability Act (HIPAA) several years ago was passed by Congress, and as part of that act set out some protections with respect to the use of genetic information by insurers. And it provides rather extensive protections actually for most Americans, because most of us get our health insurance through our employers where we have group coverage. And that act basically said that insurance cannot use genetic information to discriminate, to refuse to sell insurance to an individual within a group, to price differentially, to charge that individual more based on that information, to cancel insurance, to fail to renew insurance, and on and on. So there are plenty of protections out there for the vast majority of Americans in terms of their health insurance. So in terms of people coming to a clinic and expressing some vague uneasiness that maybe that information might be misused, I think a thing that we would suggest is a little bit of education about the existing protections that are already in place.

In terms of individual insurance, and there are roughly sixteen million Americans who get their insurance and buy it on their own, there it is true that HIPAA gives much less protection and that was a decision that the Congress decided to make. One thing that I would like to point out is that the individual insurance market is quite unique. It is very price-sensitive and also has more risk of adverse selection. What am I talking about? Let me use a very imperfect analogy just simply to make a point. Let's just say that there was a test that one could get to determine whether your house was going to burn down in the next twelve months and once you have the results of that test you could decide for yourself whether you needed fire insurance. So on the basis of that test you would determine when you would buy fire insurance. If you were a thinking person you would say, well I don't need it this year because my test was negative. And so you know you would make your decision on that basis. Well, obviously I'm talking about something that doesn't exist, but I am trying to make a point that we don't worry very much about the fact that fire insurance would not work if the only people who bought it were people who were going to have a fire in their homes that particular year. We all assumed our risk is small, but we want to protect ourselves from that risk, and so insurance is there to spread risk.

And so, as we look long-term, I think one of the concerns we have in particular with respect to the individual insurance market is the potential for reverse discrimination. Those that are calling for further restrictions against discrimination don't say a great deal about the potential for reverse discrimination. And again, what we are trying to do here is make sure that in the individual market the coverage is affordable for the people who need to purchase coverage on their own. Remember, when they do that they don't have an employer subsidy, so they are paying full cost. So the price of that coverage is an extremely important consideration for them. And so what we need, one of the roles that insurers in that market play, through underwriting and other mechanisms, is to price according to the degree of risk. With the obvious message being, buy your insurance early because then it will be there to protect you later if you do become sick and need care.

The second area that I would comment on is the area of privacy. It is also true that there are regulations already in place today, federal regulations, that protect personal health information. In fact, they only fully went into place roughly two months ago. I think a lot of us are still watching and waiting to see what the implications of all those regulations will be for things like research and health care and so on. But those regulations do apply to genetic information, and so in terms of privacy the point that we've been trying to make is that we don't believe there is a need today for further privacy protections that apply uniquely to genetic information. One of the reasons for that is every time you have new requirements there's a cost associated with complying. So if you are a physician's office or a hospital or a health plan or an insurer, if there is a new regulation that applies to some aspect of your business you are going to have to spend some energy and staff time to comply. One of the things we continue to worry about is that if we have one set of privacy rules for genetic information and a different set of privacy rules for other personal health information. Then the complexity increases monumentally.

Now we are already having trouble, quite frankly, because we have federal rules, we have state rules, and the way that Congress chose to handle privacy was to say if there are stricter state rules, they apply. So if you're an insurer, for example, doing business in fifty states, you have to somehow monitor the regulatory and legislative activities of the fifty states and go through some process to determine whether the regulation in that state is stricter than the federal rules. The more variety there is, in terms of trying to comply, the greater the costs. As you read every day, the cost of health insurance is going up, so anything that we can do to minimize those cost increases is something that we might favor.

So to come back to my earlier theme, I think what the signal we've been saying is that we would prefer that Congress does not enact any additional laws this year dealing with the issue of discrimination based on genetics. You notice one thing, in the earlier talk there were questions posed but never really answered. And that is despite all the searching that's been going on, it's my understanding that no one's yet found an example of discrimination by insurers based on genetic information. Even those who support additional regulations in this area haven't been successful in finding it. And those of you who are familiar with the Washington arena, if you want Congress to do something, one of the first things people do is find a series of problems. With respect to other issues Congress is wrestling with, like patient safety, people have been able to come forward and say, "Look at all these problems and these institutions," with respect to the problems with drugs, complications or other issues related to patient safety. So again, I think that we have been quoted as saying that we think that the law and the legislative proposals now in Congress are basically solutions in search of a problem. We think that it would be more prudent to defer any additional legislation at this point and let this whole field continue to evolve. And with that I will stop.

KONDRACKE: Thank you very much. Cynthia?

PELLEGRINI: Good morning, I'm delighted to be here. If you look at your program you will see that it says David Bowen to represent the Senate HELP Committee. I am not David Bowen. David's actually taller.

But I work for Congresswoman Louise Slaughter, and she has sponsored genetic nondiscrimination legislation for the past several years in the House of Representatives. I want to cover a couple of points as briefly as I can so that we can get to the discussion. I think there are some critical issues that we should review. First is, should we pass genetic nondiscrimination legislation at all? Is this worth doing? And Congresswoman Slaughter's answer is a resounding yes. We absolutely have to address this problem.

Congresswoman Slaughter issued her first bill on this issue in December of 1995, so that's seven and a half years ago now. She's been toiling in the wilderness, if you will, for some time. When she first started talking to her colleagues about this issue they really looked at her and said, "You know, Louise, you need to get out more. This is very interesting, but it's not something that we need to worry about here and now." Well, in the intervening few years we've gone from being way ahead of the curve to, in my boss's

view, behind the curve. In her opinion, this should have been taken care of already. We shouldn't be discussing it any more.

Is genetic discrimination happening? Well, again, the answer is a very qualified yes. In fact, our office has encountered a number of people who have come to us and said, "Yes, I have been the victim of genetic discrimination in health insurance in employment." And we say to them, "We're working on this issue, we want to help you out. Will you come and talk to people? Will you come and talk to members of Congress? We need you." And they say, "Absolutely not. I've already had my privacy violated; I've already been victimized. I'm not going to talk to anybody else." It is very difficult to say to an individual, "Will you come and tell the world how difficult it was to lose your privacy?" It's counter-intuitive.

Now, discrimination, admittedly, is not widespread. This is not happening all over the place, but wouldn't it be nice for Congress to get ahead of the curve for a chance? Wouldn't it be good if we addressed a problem before it was endemic? And while discrimination itself may not be happening that often, the fear of it is having a major impact on people's health care decisions. We talked repeatedly to genetic counselors, to physicians, to cancer doctors, who said either "I have people who want to take genetic tests but they won't because they fear that the information is going to get in the wrong hands," or "I have patients that want to take genetic tests, they're doing it anonymously, though, or they're doing it under assumed names. And they're keeping the results confidential." They're not putting the results in their medical record. I was at a talk not too long ago where a doctor discussed a patient friend of his who had not disclosed the results of her genetic test, then went and had a screening exam that would have been read very differently if the screener had known of her genetic predisposition. And in fact her cancer was not caught until stage three or four.

So this fear is having a real impact on people's daily lives and having an impact on their health care decisions. If you've ever watched the "Simpsons" you may have seen Homer laughing at the misfortune of others and saying, "That's funny because it isn't me." Well, this has the potential to be every one of us. There is no perfect genetic specimen. We all have genetic flaws. Sooner or later we will discover them in ourselves, or in our children, our loved ones. And by not having a genetic discrimination law in effect right now we are essentially punishing the people with the bad luck to carry the genes we discovered first.

Let's say for the sake of argument that I've convinced you that we need to have genetic nondiscrimination laws. In that case why should we have a federal law? There are a couple of good arguments in Congresswoman Slaughter's view.

The first is that we end a national statement of policy. We need to draw some type of law in the sand. This is an issue that is already creating a national dialogue. We need to have a statement as a society, as a people, as a nation, that is firm on how we are and are not going to use this incredibly sensitive information. Second, as Robert pointed out, the states are already doing this, but they're doing it in a very haphazard patchwork. If you've ever had the chance to review some of the state laws out there, they're a mess.

They're all over the ballpark. Each one of them is reinventing the wheel over and over. Some of them cover very narrow areas, some of them have very broad definitions. They're all over the place.

On the federal level, we could do two different things. We could provide some uniformity to those state laws by providing a floor, at least, that we could work from. This will always help one of the arguments that Henry raised with companies that are forced right now to comply with all these different state laws. We could at least provide some level of uniformity so they only have to follow one standard and then make little variation off that.

Thirdly, states can't regulate ERISA plans. Any health insurer that's covered by the federal health and pensions laws, ERISA, is exempted from state regulations. So states can pass all the laws they want, they're still going to fail to cover thousands of their residents who are working for companies that offer self-insured health insurance plans.

Finally, the federal Health Insurance Portability and Accountability Act, HIPAA, has a lot of loopholes. HIPAA was a very good law for what it wanted to do, but in fact adding genetic information, genetic discrimination, to HIPAA was a very last minute addition. It was almost an afterthought, put in at the eleventh hour. "Oh yes, we're going to insure portability when you go from one job to another. Oh, and we shouldn't let them drop a plan based on genetic information." So it was kind of thrown in there, and there are still a lot of loopholes for people who aren't going to be covered by HIPAA.

Alright then, if we're going to pass a federal nondiscrimination law how should we do it? Well, I'm glad you asked. So I want this bill that would ban genetic discrimination in health insurance and employment and I want to make two things clear. We don't address long-term care, disability coverage, some of the other kinds of health insurance, definitely not fire insurance. We are very careful to limit the bill, in addition, only to people who want to get a genetic test or find out they have a predisposition but have not yet been diagnosed. So this is for people who have a pre-diagnosis. Pre-treatment. Once you are passed diagnosis, you ought to be covered better by HIPAA and in the workplace by the Americans with Disabilities Act, in theory.

Right now there are a couple of different initiatives in Congress. There is the bill that's sponsored in the House of Representatives by Congresswoman Slaughter and in the Senate by Senators Daschle and Harkin. The Senate folks have been working very hard with their Republican colleagues, and they will produce a compromise bill. It is in my boss's judgment not perfect. But we should not let the perfect be the enemy of the good. So she is at least tentatively right now backing that bill, watching it as we move through the process. We were hopeful that this bill would be voted in the Senate before the July 4 recess, which will start this weekend. Unfortunately it looks like that's not going to happen, but it's not because the support is falling away from the bill, it's because of some procedural problems that have come up.

It's been argued that we should not ban discrimination because some people may get a genetic test and then actually wait until they need coverage and rush out and purchase it, and that that's unfair to the health insurer. While that argument has some logic on its surface, I think it ignores the reality of how and why people actually buy insurance coverage. First is that most people buy health insurance through their employer. You get a job, you're offered health insurance, you sign up or you don't. As time goes along, maybe you've got coverage through a spouse or something, you change your mind to sign up for it after all. But people are out there, in my view, saying "Well, I'm going to ignore the next flu season or not worry about SARS or West Nile or infectious diseases. I'm not worried about breaking my leg or getting hit by a bus, but I've got this genetic disorder, but I'm not going to buy health insurance until I think that that's going to kick in." That's not why people buy health insurance. They buy it to cover their family members, they buy it to cover their kids, they buy it to cover their next cold or if throughout the year they step on a nail or something horrible like that. They're not thinking twenty years down the road.

There's an argument that we need to keep coverage affordable. So we need to allow genetic information to flow freely so that information for the coverage will stay affordable. If you think that coverage isn't affordable, try paying your own catastrophic health bills. We can keep coverage affordable if we structure our risk pools properly. And we can do that without knowing whether there is a possibility that someone might develop a genetic disorder in five, or ten, or twenty years. Most people are given a health plan for five years or less. We don't need genetic information in the vast, vast majority of those cases to know if that person is going to get sick or not.

I'm going to stop there and give back the microphone to Mr. Kondracke.

KONDRACKE: Great. I'm going to start the cross-talk with Dr. Cook-Deegan, who has a specific example, and then we'll discuss among ourselves, and then we'll bring you in.

COOK-DEEGAN: Let me ask Henry, was the HIAA in favor of the HIPAA restrictions? And what happens at the state level when a legislature wants to adopt nondiscrimination language? Does the insurance industry try to help it or try to stop it?

DESMARAIS: Well, first, I wasn't with HIAA back in the days of HIPAA, so I'm not absolutely certain. Our general view is that we tend to oppose additional regulation of the insurance sector. What we did exactly at that time I'm not sure. I think the point that Cynthia made about the fear issue is certainly there. And I'm not sure a new or additional federal law is going to be able to address fear. She told you correctly that most people buy insurance through their employers. There is a federal law in place today that says that an insurer cannot refuse to cover employees or the family members based upon genetic information or the results of a genetic test, may not refuse to renew coverage based on genetic information or the results of a genetic test, may not charge cover employees or their family members higher premiums based upon genetic information or the results of a genetic test, may not impose pre-existing condition waiting periods upon new employees or their family members based upon genetic information or the results of a test, and may

not cancel coverage based upon genetic information. So in terms of fear and laws, we have a law and it applies. I bet if I was to ask who here has insurance through their employer? I bet the vast majority of you do. So there is already a law applied. I think that is our concern. We are not sure there is a need for a new law at this point. We are not sure that a new law is going to address a vague fear. And there are some potential unintended consequences that could flow from this kind of regulation. In particular if it is eventually applied to other types of insurance products that do lend themselves to adverse selection.

KONDRACKE Do you want to respond?

PELLEGRINI: Sure. In Congresswoman Slaughter's work she has spoken to, again, many, many different people—be it patients, or health care providers. And they are all coming to her and saying the same thing: "Please pass a federal nondiscrimination law, because we won't get genetic tests and we won't recommend genetic tests for our patients, in many circumstances, until the law is there."

KONDRACKE: Can I stop you there?

PELLEGRINI: Sure.

KONDRACKE: Why isn't the answer to that problem, "Well there is a law on the books"? "Did you know about HIPAA?"

PELLEGRINI: Well, that is part of the answer and HIPAA is a very good law for the people it does cover. But it doesn't cover everybody. There are a number of different groups of people who fall through the gaps.

KONDRACKE: It leaves roughly ten percent uncovered.

PELLEGRINI: Right. So for instance, if you haven't previously been with a large employer or one that is covered by the bill and you come into a plan that is covered by HIPAA, its provisions don't apply to you. So say you're a student and you're getting your first job, HIPAA may not apply. You have a genetic predisposition to a certain disease and you have been unemployed for a certain stretch of time and then come into a large employer, you may not be covered by HIPAA. As far as the premiums go, you can't be charged a different premium as an individual within a group, but HIPAA does allow an insurer to raise the premium of the entire group. So let's say you work for Joe's hardware store and they have twenty employees and one of the employees has a child with cystic fibrosis. The premiums could skyrocket for that entire small group because that child has an expensive genetic disorder. So the fear is very real. What we're being told repeatedly by the health providers and patients alike is that they want a federal law, they need a federal law, and they won't feel comfortable until they get one.

KONDRACKE: Henry, do you want to respond at all?

DESMARAIS: No, I think he's ready with his examples. Yeah, Bob, go ahead.

COOK-DEEGAN: I thought it might be useful just to focus on an example that is kind of a perfect storm in connection with the new genetic technologies. So I'm just going to lay out a conceptual framework for why we are talking about this and why it matters.

Alzheimer's disease, you all know, is fairly common. It's a late-onset disease with a fairly high risk, and what we discovered a little over ten years ago now is that the risk of Alzheimer's disease is affected by a gene. There are these very rare inherited forms, but they account for a very small fraction of the patients, one in twenty. The one genetic factor that is associated with Alzheimer's disease is a gene called apoprotein E. It comes in three flavors: 2, 3, and 4. I don't know what happened to 1. But if you have one copy of the 4 your risk goes up, and if you have two copies of the 4, your risk goes way up for eventually getting Alzheimer's disease. But there are lots of people who get Alzheimer's disease and do not have a copy of the 4. Then there are some people with the 4-4 allele who don't get Alzheimer's. So it's a susceptibility that affects the risk, but doesn't tell you whether you're going to get a disease for sure.

So how common is Alzheimer's disease? It is common and the epidemiology is a little squishy, but the risk associated with Alzheimer's disease seems to suggest that if we got rid of this risk factor, whatever it is, it would account for up to a quarter to half of the cases of Alzheimer's disease. So if you are an actuary, this is a very potent risk factor. You're going to have to take it into account. So it's a sizable fraction of the risk. That's part one.

Part two is if what you are thinking about is selling long-term care insurance, what do you spend money on under long-term health insurance? You spend it for assisted care in a nursing home. You look at who are in nursing homes—people with severe dementia account for a very high fraction of people in nursing homes, and Alzheimer's disease accounts for a majority of those people. So with this test you have a significant fraction of cases for which it's relevant for predicting this. And it is the thing that predicts expenditures quite strongly. It's the single disease that is most closely associated with payout in the long-term care insurance policy, and moreover, you have a voluntary individual market. So people are kind of coming and deciding if they should get long-term insurance one person at a time instead of their employer or working group. This is the usual market for long-term care insurance.

What's the result of that?

The result is in this situation it's very predicable what's going to happen. People with apo E4 are going to have a higher risk, they're going to have to pay higher premiums, or the insurers are going to assume that everybody that they confront is going to know that they are apo E4 positive and are going to price accordingly. It's going to stratify the market. Or it's going to kill the market, depending on how it's structured. So the market's not dead in long-term health insurance so it's probably stratified. Rob Korsky has written about this in the literature, and this is just what happens.

And what is wrong with that? Well, maybe nothing. If you think this setup is fine then this is what is going to happen. If you have E4 allele then you'll probably pay more for long-term health coverage if we leave things this way. And we can't do anything about bullets one and two here. We can't do anything about the risk of Alzheimer's disease that we know about, and we can't do anything about the need for nursing home care except constrain it, right? We can have policies that reduce the likelihood of getting into a nursing home but eventually people get sick, and they are going to need care.

What we can do is think about how we structure the market. That's what these nondiscrimination statutes are talking about. If it's a voluntary individual market you've got a very severe problem. What can we do? We can pass rules about what information is allowed for use. Or you could pass a mandatory insurance law like we do for car insurance so that everybody has to buy insurance. That insures that the pool is universal and that whole pool is taken into account. But those are really the only choices that are out there. If what we have is an individual, voluntary market for insurance. So upshot. A new genetic technology has an economic impact and it presents us with a policy dilemma. So I just thought that it nice clear example.

KONDRACKE: What is the reality now as to Alzheimer's and long-term care insurance and genetic testing? And do long-term care insurers ask for a blood test?

COOK-DEEGAN: No. The way it usually works is that when you get an individual insurance policy it's not that they have to ask for a test. What they want is access to whatever medical information the person seeking insurance has about their own risk. And it has to be structured that way in a private voluntary market. So no, they are not mandating the test, but if you have knowledge about your risk, it's going to be in your medical records and they are going to have access to them.

KONDRACKE: Henry?

DESMARAIS: A couple of observations. We still haven't found evidence that companies are using this information at this point. One of the reasons they tell us, among other things—and we're talking about long-term care insurance here, where there are no federal rules at the moment, and where I don't think rules are being contemplated either in the House or the Senate, so let's be clear about that. They're really focusing on medical insurance. But the issue is that if it's good enough for medical insurance, why isn't it good enough for other aspects of the voluntary market? The other thing to remember from the medical perspective is that only rarely are we finding a single gene guaranteeing that you will develop an illness in a certain point in time. In most cases it's a very complex situation and there's a very complex interplay between other genes that you have, the environment, and what you do to yourself along the way. It's really not like we can have a little print out that says on such and such a date you're going to have Alzheimer's because, as was pointed out first, there's a lot of things that go on. And there are a lot of people that have Alzheimer's for which we're not sure yet there's any genetic component whatsoever.

So I think there are some difficult issues here, and I'm glad you focused on the voluntary market aspect because I think it is what distinguishes individual insurance, medical insurance and also disability, income insurance, and life insurance, etc., where much of it is purchased an individual at a time—and where that particular market is extremely fragile. States have tried various kinds of reforms and what happens is that they increase the cost of coverage and fewer buy the insurance because they have to buy the whole bill, because their employer is not there to help them in that particular case. I think that's what we're worried about. How do we balance these interests? I understand the discrimination concern, but how do we make sure we have insurance there? That we suddenly don't have a situation where the only people buying, in my example, fire insurance, are people who know their house will burn down because they have a print out?

KONDRACKE: So what about Cynthia's point?

DESMARAIS: Who buys it? We have a potential issue that as a societal perspective how we're going to handle it because we're not prepared. Certainly, I don't think Ms. Slaughter's prepared to say you must buy medical insurance or you must buy long-term care insurance, because that's another way to deal with this potentially, but not a very popular way.

PELLEGRINI: My point on why people buy insurance does not apply at all in this circumstance. I think people who suspect that they are likely to develop a chronic disease such as dementia, Alzheimer's, Huntington's, Parkinson's, anything in that general vein, I think they are much more likely to go out and buy long-term care insurance, life insurance and disability insurance. So I think the solution for those products has to be completely different than what we are proposing for health insurance.

KONDRACKE: So you acknowledge the point of gaming the system. What is the situation on life insurance, by the way?

PELLEGRINI: Right now there's nothing that's happening on life insurance in Congress and there's not much that's proposed. I think the life insurers are very pleased about that. Their great concern with our bill is that the structures, the approach in our bill will be applied in insurance. And that's really not a valid approach. One thing that has been tried, kind of giving us a model perhaps, is in Great Britain. If you want to buy a life insurance policy, I'm going to oversimplify here, but if you want a standard policy you don't have to provide genetic information or anything, even if you have it in your possession. If you want something above a standard policy, a premium or extensive policy, then you have to provide that information. That may be one approach that we may consider in the future.

KONDRACKE: Let me ask you about the employment discrimination aspects of the situation. If there is limited evidence and only anecdotal and sort of non-public evidence that you've sighted of insurer discrimination, what is the evidence on employer discrimination?

PELLEGRINI: Actually, I think the evidence is much more solid on employer discrimination. We have a number of very well documented cases where it has occurred.

KONDRACKE: The most famous of which is the Burlington railroad situation.

PELLEGRINI: Right.

COOK-DEEGAN: That case involved carpal tunnel syndrome and twenty workers were subjected to sort of secret genetic testing. This sounds like a weird case. It doesn't sound like industry in general across the country is genetically testing its potential employees to see whether they might be a cost factor or raise their health insurance rates. This sounds like a weird individual case. What other cases can you sight?

PELLEGRINI: Well the Burlington Northern case, as Morton points out, was a case where these workers filed disability claims for carpal tunnel syndrome from working with jack hammers and repetitive motion-related disorders. They were subjected to genetic tests without their knowledge or consent. Presumably if any of them had come up with the gene positive for the genetic mutation in question the railroad was then going to use that information then to deny their claims. Now on the face of it, beyond this it was junk science. None of them fit the profile for having the kind of disorder that the gene would have caused. You read this in the paper and you think, "Who could've thought this was a good idea?" This is the stupidest thing you have ever heard in your life. But the fact of the matter is, it did happen.

KONDRACKE: But are there any other cases besides this sort of outside case?

PELLEGRINI: Sure. There were a couple of others. There was one in North Carolina of a woman who thought she had allergies and went and got tested and turned up with a disorder called alpha-1 antitrypsin deficiency, which had killed her brother. She had thought previously that it was a disease that only affected men. She went and started getting preventive treatments for the disorder that were going to keep her healthy and functional. She had an office-type job. She scheduled the treatments on her vacations and weekends, so that her employer shouldn't have even known they were happening. But the information did get to the employer and she was summarily fired.

These things are happening. If we can't accurately use this information for medical purposes right now, how much more so is it unfair to use this information to discriminate for employment purposes? When employers are making employment relation decisions, under federal law what they are supposed to be examining is whether the person is able to fulfill the duties of their job. The fact that a person might develop colon cancer in ten years should be totally irrelevant to those decisions.

KONDRACKE: Bob?

COOK-DEEGAN: The only other case that I know of that has gone to actually being tested in court is, ironically, at one of the DOE-funded national labs that was doing sickle

cell testing without the knowledge of one of their employees. But that's ironic because the Department of Energy has an ethical, legal and social implications research program, and it was focusing on employment discrimination. So this was a left-hand not knowing what the right-hand is doing. But again, the underlying point is these are funny cases because they are dumb decisions made at a low level. But it is evidence that bad things can happen. The looming question is, how big of a problem is it? The really big question for us is how big of a problem will it be in the future compared to how it is now? And I don't know how you think about that.

KONDRACKE: Let me ask you, how many diseases are there for which there are genetic markers for which people are routinely tested for? And what do you think the future is like in this regard? I mean, how long will it be before genetic screening becomes part of our physical exam and part of the blood test as part of the physical exam?

COOK-DEEGAN: Right now there are probably three hundred or so genetic diseases for which you could think of at least in some context where there is some genetic test in at least a specific family or two. But what's going on in science isn't that. We've moved beyond Mendel. We've moved beyond these inherited diseases. So do I think most people are going to have a genetic test done in connection with a physical illness, in ten years? I would be surprised if we weren't doing a lot of genetic profiling for routine medical treatments. I really would. It's going to help you make clinical decisions. Does this person expressing genes 1, 2, or 3 that predicts whether they've got a well-behaved breast cancer or a badly behaved breast cancer? I think we'll be doing a lot of that for a lot of diseases. It's genetic information, but it's not genetic information that we are talking about now—it's much more complicated. But it's also much more pervasive.

DESMARAIS: We shouldn't minimize all the ethical issues that we've raised about getting genetic tests for things we can't do anything about, or who is going to pay for genetic tests when you are looking for one in a million. There are a lot of complex issues we aren't addressing here.

KONDRACKE: Which we can, so why don't you raise them?

DESMARAIS: Well I am. This is an area of clash between the insurance community and others, because there are researchers and others who would like for the insurers to pay for all the genetic tests that they would like to use. When we are talking about pure screening tests, many policies, especially in the individual insurance market, don't cover those kinds of things. And so that's a clash. If they do cover them, then there is a cost dimension that all of us have to pay as we pay our share of the premiums. I think there are issues for the providers community to decide, "Should I recommend a test even though I can't do anything about it?"

KONDRACKE: Are there specific cases now where Cadillac or maybe Rolls Royce insurance plans that cover genetic screening?

DESMARAIS: Oh yeah. There are plans, certain tests would be covered, or would be covered under certain circumstances. Not necessarily for someone walking in off the street, but for someone who has some kind of known family history or some kind of condition it would make sense. Or therapy. The selection of a chemotherapeutic agent might depend upon the results of the test. I mean, those things are covered, but it does vary. It's like any other coverage that you have in your health insurance. It's not uniform and some plans will cover it and some won't.

PELLEGRINI: Just one side issue. We shouldn't ignore the fact that some of this routine genetic testing is happening. Whether it's newborn screening or things like the fact that a routine battery of blood tests like a CBC will turn up iron levels. Excessive levels of iron can indicate hereditary hemochromatosis, which is a genetic condition. In drafting Congresswoman Slaughter's legislation, we have grappled with all of these issues extensively. And the definitions are shifting.

KONDRACKE: And so this is covered in your bill but not the Senate Bill? Are you requiring such testing or protecting against it?

PELLEGRINI: Never requiring testing. We prevent insurers and employers from requiring that an individual take a given genetic test. But we only deal with how the information can or cannot be used once it's in possession.

KONDRACKE: Let me cover one other area that we've neglected until now, and then I'll throw it open to questions. And that's the privacy element. Are there downsides in the privacy protections in HIPAA? In other words, I've heard it said that medical research, epidemiology could be inhibited by the restraints on the dispersal of information that's in people's medical records.

COOK-DEEGAN: I think we don't know yet. HIPAA was changed from its original form, and its implementation regulations are different as a consequence of a debate about access to research data. The fact is that I am hearing a lot of complaints about HIPAA from the folks that I talk to, but probably ninety percent of those are from folks who deliver medical care. There are—it is going to make it, you're going to have to do things that you didn't have to do before you can disclose data and make them accessible to research outside of your own institution. So will that get in the way of some research? The answer to that is almost certainly yes. The question is, how big of a problem will it be? I think we don't know. So we've raised the bar on privacy which was the intention but that has secondary consequences for the research system. And I think that we'll find out.

DESMARAIS: I will add only that our sense is that we used the word fear a number of times. My sense is that the provider community is in great fear now of somehow of being found in violation of the privacy regulations that are already there. So I think you should ask your questions to all of us in six to twelve months in terms of what the impact is. I think that that is part of the reason we are arguing. We shouldn't be adding additional

privacy laws and regulations at this point in time until we better understand what we have wrought from the ones that are already being implemented.

KONDRACKE: I have one final question. Why would it not be advisable for the federal government to set one standard across the country so that you don't have this disparity between states? As I understand it, if a state has a higher standard than the federal standard in your bill, than the state standard is the one that is followed, applies. Why not just push everybody to the same level?

DESMARAIS: It's an excellent question. And we've been favoring a single federal standard, but a single standard in two ways. I shouldn't pull out your medical record and say, "Oh, this item on line one is the set of federal rules that apply, line two is a different set. And you keep track of which is which." Unfortunately, Congress has so far been unwilling to provide a single federal standard for privacy. They've allowed variation from state to state, if it is stricter. You can't imagine how difficult it is to sit down and try to determine all the state regulations and laws and even judicial cases, and try to sort out which item is stricter in that state versus the federal standard. And since the states can change their laws, it's a moving target. So we, as the insurance industry, favor a single uniform privacy standard because it would simplify everybody's life. And I think it would actually produce better protections, because the variations produced today are almost inviting a compliance problem down the road.

KONDRACKE: Cynthia?

PELLEGRINI: I'll just make one side point, which is that, no personal offense to Henry, but HIAA is trying to have it's cake and eat it too. It tries to say, "We want one uniform standard" and then we say, "What should the standard be?" and they say, "Nothing."

DESMARAIS: That's not true. We have supported the federal privacy regulations. We've asked that the federal regulations that are in place today be made as the national standard. And so far Congress has been unwilling to do that. I understand why, and there are people, there are states rights folks, and there are people who believe "Well let California have stricter laws than other states," so there is this debate. But the complexity that creates, and the costs that you know, it's really a question of whether you want to spend your health insurance dollar trying to comply with fifty state laws on privacy as opposed to a single uniform law that everyone would be able to follow.

KONDRACKE: OK, I really want to throw this open now to the audience. Please feel free to quiz the panel. Ron Bailey?

BAILEY: Hi, nice to see you again. I'm Ron Bailey with *Reason* magazine.

Part of this discussion, as I understand, while we're currently worried about genetic discrimination, I suppose, but it seems a little short sighted because twenty years hence people are going to be rushing to get these kinds of tests done because they are going to want to get taken care of. Genetic profiling will be incredibly useful for me to figure out

what I need to do to make sure that I have a healthy lifestyle, so that I don't come down with some kinds of things that I might do otherwise. And it seems to me that we also by providing these rules and regulations, now, we may be killing off an industry that may be clinically useful for us later, twenty years from now, to improve ourselves.

What we're worried about now is the insurance problems, what I'm worried about later is health care problems, actual provision of health care.

KONDRACKE: Henry?

DESMARAIS: Could you expand a little about the killing off part?

BAILEY: Sure. The problem is that right now if the testing industry is killed off, for example, we can't use any of the information, right? Then the insurers can't use it, the patients can't use it, and the doctors can't use it.

DESMARAIS: Hold on. I don't think anyone said that we couldn't use the information in a medical context. I think what we've been talking about is using it in an underwriting process. So I haven't heard any laws against use of genetic testing in the medical context.

COOK-DEEGAN: Right, and I think the evidence is just the reverse. I think the industry is blossoming and there's lots going on.

BAILEY: OK, perhaps I misunderstood something. But what I am concerned about is not what, wait, let me think about the question a bit more before I confuse anyone else.

(Laughter)

PELLEGRINI: If it helps, BIO, since we are at the BIO convention, BIO does support the Senate compromise bill, right now.

KONDRACKE: Anyone else? Please, thank you.

AUDIENCE MEMBER: Hi, I'm with the Human Genome Institute at NIH. I wanted to get back to the point that we are just at the beginning of the genomic era, you know we now have a sequence, and that's the real concern in terms of the need for this legislation. This whole field is blossoming so much and everyone really will be having access to genetic tests in the future and we want to make sure that we're preventing a problem in becoming one in the future rather than wait for this huge problem to occur. I think that we want to get to this problem before it really happens.

Also, I'm also curious about what the insurance industry is thinking about in terms of the costs of covering these genetic tests and what you think that some of the implications are there, because I would suspect that that's almost a bigger concern for us rather than discrimination suits. How are people going to be able to afford these?

DESMARAIS: Well, it's not only a concern of ours, it's a concern of all the people who buy coverage: the employer community, the individuals, and the individual market. As you know, the cost of coverage has been climbing considerably over the last several years. I think we've hit the peak and I think costs are going to come down, but we're still talking about pretty substantial increases and so that is going to be a societal challenge. I mean, if we are talking about an additional cost over and above or these are going to substitute, will some of this testing really actually allow us perhaps some offsetting efficiencies in the way we manage people. Or the use of...will delay complications, but certainly every time you talk about adding to the cost of coverage, it raises issues. And you know there is some evidence, and it's probably not the best, but every time you add to the cost there are people who fall off. There are employers who drop coverage, there are individuals who stop buying their policy. And that's a major societal issue that I think we're all struggling with right now: what do we do about these uninsured? I keep saying to people, insurers are more than happy to sell any policy you want to buy. The problem is that you probably can't afford the kind of Cadillac policy that somebody might want to devise for you because you just can't do it. So the most perfect coverage that no one can afford is not very good coverage at all. And so it's a constant balancing act and that's why there continues to be innovation in the way benefits are designed and the whole way people are trying to manage the health insurance coverage.

KONDRACKE: Yes, go ahead, answer.

PELLEGRINI: Just as an aside, this is going to be a huge challenge to the government programs, too. Medicare, Medicaid, you know, CHAPUS, all the government sponsored programs, CHIP, the child health insurance program, and in addition to the actual tests, these tests can't happen in a vacuum. You really have to have genetic counseling with them so that people understand the results of the tests accurately. Because when you are talking about gradations of risk, these genes are not black and white. You are going to get sick, you're not going to get sick. And you know we've already seen cases, people making dreadful decisions based on the fact that they didn't understand the information they were given. So genetic counseling will be a part of it too.

COOK-DEEGAN: And if I could, Tim, to reinforce your point about—the last point was really payment, right? What are you going to paying for it? If we've been worried about genetic discrimination and genetic privacy for the last ten years, those have been the real things that have gotten the most policy attention, then my guess is that for the next ten years that question is going to be the central question. And the real question underlying that is what is the clinical value of the genetic information that is going to be coming out of these tests? If we believe, and I do believe, that genetic information is going to be influential in an awful lot of clinical decision making, it suggests there are going to be a lot of these things. But as I look out there right now there are a lot of technologies, there are thousands and thousands of genes whose function is being discovered even as we speak. And that's a pretty complicated situation and our process for thinking about the clinical utility of tests, diagnostics tests and predictive tests, the capacity of thinking through those problems is pretty limited right now. We do have the report of the Secretary's Advisory Committee on Genetic Testing from a few years ago. And I guess

we've now got the Secretary's Advisory Committee for Genetics, Health, and Society. I think that's one of the issues they're going to have to be thinking about is coverage and reimbursement, those are the huge issues in the next decade.

DESMARAIS: Allow me to speak to that for just a second. A very common response when faced with this is for states to mandate coverage of certain tests or certain services. And they have certainly done that. We've got 1,500 mandates today that the states have imposed that have to be in an insurance policy. Know however, that their reach only applies to people who don't get coverage, who are not getting coverage from a self-insured plan. Most employers are self-insured today, so that when the state does that it is only touching certain individuals that may buy insurance, an insurance product through the small group market or the individual market. But every time you mandate something it adds to the cost of coverage. There's always a trade-off. The more costly the coverage, the less people can afford it, and so there's a balancing act and people haven't found a perfect way to deal with this yet. We've got a number of challenges, and I don't want to be flip, but if the past is any guide, I can pretty well guarantee that insurance won't cover everything everyone wants it to cover and won't pay as much as they want it to pay. But then if it did, then we might not have anybody who was insured.

AUDIENCE MEMBER: I'm with AstraZeneca. If you listen to what Mark McClellan has been saying, this is going to explode very quickly. It's starting now. In our industry we are trying to use this information to pinpoint patients who will benefit best from our particular medicines. But to touch upon the secondary sources, where this information is going to come up from, and you haven't actually touched upon our particular source, where we're now being mandated almost to the point of, for drug approval, going out and identifying patient populations and excluding populations who might have an adverse event or might not benefit from a particular kind of treatment. So now we have a federal government, FDA, coming through saying we have to have these tests, so that means that we have to go back to the population and give the tests. This is the secondary source of this information that we actually are not well equipped to handle right now, and I don't think the insurance companies are going to be able to handle the onslaught of our information coming into this.

Are there any other sources of these genetic information bands that we're not currently thinking about that might come into the system, where we might push the insurance companies to not be able to handle the privacy issues or not be able to enable the physicians to use the information properly? You mentioned the genetic counseling. I don't think that's been well-addressed as well.

PELLEGRINI: Well, I can tell you right now that in Congresswoman Slaughter's legislation and in the Senate bill right now we do not differentiate among sources of the information. We say, wherever it came from, it cannot be used either in health insurance or employment to discriminate. It doesn't matter if a person, and this is a concern that was raised, for example, by employers, well what if you're reading the paper one morning and you find out that your employee's parent just died of colon cancer, you've got genetic information. Well, that's perfectly feasible, that's an understandable concern.

Now that you've got the information, though, you can't use it to discriminate. As long as you are not using that in a discriminatory fashion, the fact that you have it is not, in and of itself, a violation, and then it must be, of course, it must be maintained confidentially.

DESMARAIS: You know what is curious here—and I only say this to make an observation—is that when we buy insurance, we have a bigger house, it's more expensive, we have a fancier car, it's more expensive, if we have a car that has a higher risk due to accidents, it's more expensive. On the other hand, when we approach medical insurance there is this squeamishness that if I have a higher risk somehow I shouldn't have to pay for it. And I understand this. But where it breaks down most severely is in the individual market because if I'm voluntarily buying insurance and I am a low-risk individual, I don't want to have to pay more because I am subsidizing someone at a higher risk. So we have this tension in the system that emanates there and yet we are uncomfortable with it. Yet we are more comfortable with it when we are dealing other sectors of the economy where there is higher risk. No one thinks twice that if I'm a smoker I should pay more for life insurance than if I'm a non-smoker. But somehow in the life insurance arena we get a little more squeamish about it.

PELLEGRINI: Well, I think that where that stems from is that you can choose your car, and you can choose your house, and you can choose to smoke, and you can build your house in a flood plain if that's what you really want, but you can't choose your genes and right now there is nothing much that we can do about them. You know we can't fix them.

KONDRACKE: Yes sir, last question. We are almost out of time.

AUDIENCE MEMBER: It seems to me that many of the problems that we've been discussing today would go away if there were universal coverage or at least an individual mandate. I'm just interested in your perspectives and your thoughts on what the political barriers are that prevent that from happening?

KONDRACKE: From my point of view the barrier to it happening is largely political. And you know, everybody is talking about it and I think this is an issue that is rising to the top of the national agenda, driven, not nearly by liberals who want to make sure that everyone has health insurance, but by employers who are unable to keep up with the rising cost of health insurance. Something is going to happen; I don't think anything is going to happen any time soon. But I think it's going to be a major issue in the 2004 presidential election. But you know, getting something actually done is going to be deferred to 2005 at least.

Does anyone else have any comments on this subject? There is endless debate about the model. There are ideological differences, there are financial and economic differences, and it's all going to be hashed out. At the moment it looks as though there is a preference for doing things incrementally, but other people say that we will never solve the problem if we do it incrementally, we have to do it globally. And that's another difference between all the parties. So I think it's at some distance away, although I think something will happen, but I just don't know when.

Thank you to the panel.

I think this has been fascinating and it's not going to go away. We are grateful to you for coming and listening and your questions, and for you, the SAGE crossroads audience, thank you very much for tuning in.

Thanks.

End.