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Genetic Testing in Health Insurance

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Summary: Great advances are being made in the area of genetics. Potential uses include the cloning of humans, the farming of body replacement parts and improving the knowledge of an individual's predisposition to medical conditions. This session explores the use of genetic testing in the health insurance business.

MR. RICHARD A. KIPP: This morning we're going to talk about genetic testing in health insurance. I don't know if you've been following some of these stories, but certainly there's been an awful lot of interest generated by the Human Genome Project and also from the pharmaceutical industry, which has been exploring the use of genetics in its biotech drug designs. So I think the subject is fairly topical, and, of course, there are implications to the health insurance industry with all this kind of attention and all the new tests and so forth that will arise from having done the research on the genome.

The other angle into all of this from a testing and new information perspective is, of course, the privacy aspect of it, which has been something we've been wrestling with in regard to other insurance information recently, most recently due to the Health Insurance Portability and Accountability Act. If you've been watching the news a little bit, there are also other legislative bills at the national level as well as at the state level that have been trying to deal with the proliferation of and the protection of genetic information. We'll touch on some of that today and try to wrestle a little bit with some of those issues.

We've assembled a panel that is going to lead us through the discussion today. We

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have two people who have very different backgrounds. Stephanie Newhart has a master's in genetic counseling from the University of California Berkeley and is currently working as a genetic counselor at Kaiser Permanente California. The majority of her work consists of prenatal genetic counseling, and she's involved in pediatric and adult counseling as well. Other areas of interest for her include cancer genetics, neurogenetics, inherited lipid disorders, and I'm sure a whole list of other issues that she has to deal with for the patients she sees. Our second panelist is Tom Wildsmith. He is currently a policy research actuary with the Health Insurance Association of America (HIAA) located in Washington, D.C. His duties include analyzing legislative and regulatory proposals for the potential impact on the insurance industry, so he'll be able to give us a little bit of the industry perspective on this issue and lead us through some discussion about that. He's been with HIAA since 1995.

Before we get into the serious part of the presentation, I don't know whether you would agree that maybe we've opened a can of worms—or maybe it's Pandora's box—but certainly there's going to be some serious consequences to having unraveled the human genome. As we explore all the testing and the treatment opportunities that we'll see over the next few years, I think it's going to be a very interesting world for us as health actuaries to live in.

MS. STEPHANIE NEWHART: I want to provide you with some basic understanding of genetics as well as some current information about what we're doing right now with genetic testing. At the end, I'll kind of give you some information about where we're going in the future with genetic testing. Hopefully during the course of the talk you'll begin to appreciate all the complexities that come with genetic testing and interpreting those genetic test results.

First of all, I'll start with some of the really basic stuff about genetics. Our bodies are entirely made up of cells, and in each of those cells are chromosomes. We have 23 pairs of chromosomes or 46 chromosomes total. We inherit one of each chromosome pair from our mother and one of each chromosome pair from our father. On those chromosomes are genes, so the myriad genes lying along those chromosomes are just instructions to our body that tell us a little bit about how we develop and who we are. So there's a difference between what is a chromosomal disorder and what is a genetic disorder.

Chromosomal disorders are something that pertains to the actual structure of the chromosome or the number of chromosomes that are present. So again, we have two of every chromosome, and if there's some imbalance in that, where there's some additional chromosome present such as in Down Syndrome, the extra genetic material in that extra chromosome causes mental retardation, physical problems and potential increased risk for health problems as well. With a genetic disorder, it particularly pertains to that specific gene or gene change.
There's also a difference between what is genetic and what is hereditary. Genetic is

just a broad term for anything that pertains to the genes, whereas hereditary means something that can be passed on in a family. An example I like to use is cancer. We know that all cancer is genetic. There are changes that occur in our genes that allow tumors to form and that can then possibly proceed to cancer, but there are specific cancer syndromes that may increase our risk for cancer. We know that cancer is not hereditary, so if our mother or father has cancer, it doesn't necessarily mean that we're going to get that same type of cancer. But if cancer runs in the family, especially a particular type of cancer, then family members may be at an increased risk for developing that type of cancer.

I'm going to talk about basic modes of inheritance. There are more complex modes of inheritance that I'm not going to get into today. One of them is autosomal recessive inheritance, where again we have two copies of every gene, and if those copies of those genes are changed in some way, that results in the development of that condition or that disorder. Autosomal dominant inheritance is one where all we need is a change in one of our copies of that gene to result in the development of that disorder. X-linked inheritance is a little bit more complicated. We have in those chromosomes a pair of sex chromosomes. We know that women have two X chromosomes and men have an X and a Y chromosome. If there's a change on one gene along that X chromosome, women have another X chromosome that sort of compensates for that, but men don't have another X chromosome; so we tend to see X-linked disorders more often in males. Polygenic inheritance just refers to certain diseases in which many genes need to be involved in order for that condition to be developed. And the last one is multifactorial inheritance, which is a large part of birth defects and disorders in general. This has many genes involved or a gene in particular that's involved with the combination of the environmental factors that increases the chance for that condition or does increase the presentation or the severity of that condition.

There are two things that lead to the variability that we see within families and between families for genetic conditions: penetrance and expressivity. Penetrance refers to, if we have a specific change in the gene, the likelihood that we're going to actually present with one or more symptoms. So if we have a specific gene change, are we going to present with a specific phenotype or a presentation of that symptom; whereas expressivity is if I have the genotype and I'm going to present with those symptoms, what's the severity and how many symptoms am I going to present with. So both those things play a role in the variability of many different genetic conditions.

There are a few unique qualities to genetic testing. One of them in particular is very important in that genetic test results do not just pertain to that individual who is having that genetic test. Testing often is relevant to many other family members. It can be relevant to close family members and even extended family members. They can be at increased risk for genetic conditions, or we could identify them as carriers of genetic conditions. We can also identify healthy people as carriers. We're doing more and more population screening, screening of at-risk ethnic groups, identifying

people who aren't presenting with any symptoms as carriers of that condition and at risk of potentially having a child with a particular genetic condition. Testing can also be used to predict the risk. So if we know that there's a family history of cancer, for example, we already know that that person among that family may be at increased risk, but a genetic test result can tell us that, yes, this person has a genetic change that greatly increases their risk for cancer and can predict their possibility of presenting with symptoms.

There are many, many limitations to genetic testing, most of which I'm not going to mention today, but I will touch upon a few of those in my presentation. With genetic testing and being a genetic counselor, of course, I'm going to stress genetic counseling and education for those family members and for people who are considering genetic testing. It's important prior to and following testing that people understand the information this test is going to provide for them and for their family members, and what the test result means when they get that.

I've broken down genetic testing into a couple of different categories. There are screening tests versus diagnostic testing, and then I'll also talk about diagnostic versus predictive testing and also versus presymptomatic testing. First of all, a screening test is just a test that gives us some more information about a person's risk or the increased likelihood that they could have a genetic condition or a child with a genetic condition, whereas a diagnostic test tells us yes or no, this person does or does not have this specific condition. So a diagnostic test can be used when somebody who is already presenting with symptoms comes to our clinic, we think that the symptoms may be genetic related, so we do a test to see if there is a gene change related to those symptoms. Whereas with someone who comes in with a strong family history of particular symptoms or a particular genetic condition, then we can do predictive testing to see if maybe a 20-year-old who comes in has a family history of Huntington's disease, which has a later onset in adulthood. So they may want to come in and find out if they may have the condition and may present with symptoms later on in life. Presymptomatic testing is one that can be used in cancer-type testing, so if there's a family history of cancer, we can see if a person carries a gene change that puts them at increased risk for developing those types of cancers prior to their developing cancer.

Genetic testing can be done at any point during a lifetime and even prior to life. I'll talk about preimplantation genetic diagnosis (PGD) as well as prenatal screening and diagnostic testing, testing that's done before a woman's pregnancy, which includes screening and pregnancy screening, and diagnostic testing that can be done during the pregnancy. There is also newborn screening, which is mostly a state-funded or state-run program that can influence test results and the outcome for that individual. Pediatric diagnostic testing I'll touch upon, and adult testing I'll try to focus a little bit more on today, because that's really an area where we're getting a lot more information. And I think the general population is more interested in having the tests done, and you may hear more about them as time goes along.
So PGD is what I'll start with. It is a test that can be done prior to the embryo's

being implanted into the uterus, and there are a couple different methods or ways that this can be done. There are several steps that are involved. One of them includes giving the women a hormone that allows them to produce multiple eggs. Now, that hormone treatment can put the women at risk for medical problems, some of them severe and possibly death. So we want to educate people about those risks as well as about what they're testing for. Cycles can cost as much as $30,000, and it often takes more than one cycle to allow this testing to proceed and allow a pregnancy to proceed and actually carry on to term. PGD is not typically a benefit covered by health insurance. Part of it may be covered; maybe they'll cover the in vitro fertilization (IVF), or maybe they won't cover the IVF part but will cover the PGD part of it.

There are many reasons or indications why someone may want to come and get PGD. A woman may have had multiple miscarriages, or she may have done IVF but hasn't been successful. She may want to try PGD to increase her likelihood of getting a normal pregnancy and carrying a pregnancy to term. Also, women who are 35 and older are at increased risk for chromosome abnormalities, so women of that age group may decide to have PGD rather than going ahead and getting pregnant and then doing testing during the pregnancy, because they may not want to terminate a pregnancy but feel more comfortable with doing PGD. So those two groups of people comprise most of the people who will come and get PGD.

There are some other people who actually come to the PGD clinics. Some of them include people who are at high risk for Mendelian disorders, again with the autosomal recessive or autosomal dominant or X-linked inherited disorders. So if they have a family history of a particular condition, or maybe they're identified as carriers of a particular condition and are known to be at increased risk of having a child with a particular genetic condition, then PGD may be available for them. Also, some people come because they have a child with a genetic disorder already, and they want to have another child who is free of that genetic disorder who can possibly be a blood or marrow donor for that person. One of the things you may have heard of is stem cells, and we know that we can use stem cells from the umbilical cord of a baby rather than going in and doing a bone marrow transplant to actually help with some genetic conditions such as sickle cell disease. So people may come if they have a child with sickle cell disease; they may want to have another child who is free of that disease and is a human leukocyte antigens match or a donor match for that other child, so they could potentially provide treatment for that other child.

There are also people who have chromosome translocations. This means that one side of a chromosome is attached to another part of a chromosome, and this can cause problems when we're forming our egg and our sperm cells, affecting the equal separation of those chromosomes. Again, like I said earlier, if there's an imbalance in the number of chromosomes, then that causes problems for the baby, and so people who are known chromosome translocation carriers are at increased risk of having babies with an imbalance in those chromosome numbers. Adult onset

disorders are very controversial for PGD testing and for prenatal diagnosis at this point, and I'll talk about some of those adult onset disorders a little bit later.

I will now move on to carrier screening, which is something that's typically offered to specific at-risk, high-risk ethnic groups. One example is carrier screening for cystic fibrosis for Caucasian couples. One in 25 people is a carrier for cystic fibrosis in that population. One in 10 African Americans is a carrier of sickle cell, and one in 30 Jewish persons is a carrier for Tay-Sachs disease. So right now these are some of the particular populations that we're offering carrier screening for, for these specific diseases, but there are many other diseases that are less common in these populations. Cystic fibrosis is also common in African American populations and Hispanic populations, but not at as high of a frequency as it is in Caucasian populations, so we're not offering those ethnic groups carrier screening at this point.

The detection rates and residual risks of being a carrier vary for all these conditions. For some of them you can completely eliminate their carrier status, such as sickle cell testing. It's a very accurate test. We can identify carriers with almost 100 percent accuracy. It's very important to note that about 80 percent of carriers will not have a family history of the disorder, so that's why we're offering it to people who are high-risk ethnic groups, even if they don't have a family history of that disorder.

So most of these conditions, if not all of these conditions, are autosomal receptive diseases, so those parents need to be carriers of the condition in order for them to be at risk of having a child with a genetic disorder, and that risk is about 25 percent. Most of them are untreatable conditions. We don't have cures for a lot of these genetic disorders. It's simply management of the symptoms, and most of these conditions that we're testing for result in early adult or childhood death.

So what do we do with these couples in which we know that both of them are carriers? We can obviously offer them adoption. They can choose not to have a pregnancy. They can choose to use a sperm or egg donor to potentially reduce their risk if they're picking a less-at-risk population group. They can use prenatal diagnosis. I'll talk in more detail about what sort of testing we can offer to a woman who we know is at increased risk of having a child with a genetic disorder. They can potentially also use PGD to assess their chances of their fetus's being affected.

There are a lot of concerns out there for the potential for genetic discrimination, and this comes up with carrier screening as well. So in this case we're thinking about couples who are identifying at risk. Perhaps we've identified their fetus or that child as having a genetic disorder, having a particular genetic disorder during pregnancy, and that child may never present with symptoms. An example would be for cystic fibrosis. If both parents are carriers of a mild mutation, we know that they are presenting with symptoms, but if the child carries two mild mutations, they

may never present with severe symptoms of cystic fibrosis. However, we've already identified them as having cystic fibrosis, and that could be potentially damaging for that child later in life in getting health and life insurance.

The cost is extremely variable for testing these conditions. It depends on what technique is used and what we're testing for, and it can range anywhere from $85 to something cheap like doing a hemoglobin electrophoresis, which is used to test for sickle cell traits, to something more expensive where we're looking for particular changes in genes that are specific to that population.

One of the more common things that's offered to women during pregnancy is, I think, called multiple marker screening, which is just a blood test. They look at certain things in the mother's blood that are made by the baby or the placenta, and then assess what are the chances this baby could be affected with a genetic condition; most of those are chromosomal disorders such as Down Syndrome or Trisomy 18 Syndrome, which is another chromosome abnormality. Most of this screening right now takes place in the second trimester; however, they're coming up with new ways to test the pregnancy in the first trimester with a combination of these ultrasound findings and blood test results and the mother's age. Most of these programs are partially state funded or fully state funded. In California it's a fully state-funded program, and they screen for various abnormalities. It varies from state to state on what they screen for.

With a positive result we know that this pregnancy is an increased risk, so what do we do with these women? We can offer a woman diagnostic testing to determine whether this baby has or does not have this specific chromosome abnormality or genetic condition that we're concerned about. We can offer her a detailed ultrasound to take a closer look at the baby, and obviously offer her some counseling around that test result and what that means for her pregnancy.

One of the things that people don't really think of as a screening test, but is a screening test during pregnancy, is ultrasound. So with ultrasound we can identify particular things that may not be specific birth defects such as a heart defect, but if we see a couple things that look a little unusual on ultrasound, that could give us an indication that the baby could have a genetic condition. An example of this is what's called increased nuchal thickening. There's a thickening of the skin at the back of the neck or a fluid between the skin at the back of the neck, and if that's abnormally large, that's associated with an increased risk for Down Syndrome, and this can be measured in the first and second trimesters. So based on that, if we know that the pregnancy is at increased risk based on some ultrasound findings, we can offer a diagnostic test or maybe a more detailed scan to take a closer look at the baby. So if we know a woman's child is at increased risk for Down Syndrome based on what we've seen on ultrasound, we may want to offer her an amniocentesis during the pregnancy to tell us, yes, this baby does or does not have that genetic condition. The cost of an initial 20 minute routine ultrasound during pregnancy is about $800 more or less, but if she's having a detailed ultrasound,

that could be more, because it takes a longer time for us to look at the baby, and often a radiologist is involved in that process.

So what are some indications for a detailed ultrasound? One of them is if a woman has been exposed to a particular medication during pregnancy, or drugs or alcohol perhaps, we may want to look at the baby a little bit closer to give us an idea if there's a birth defect present. An example of this is that women who take anticonvulsants during pregnancy have an increased risk of having a baby born with a spine abnormality, so we would want to take a closer look at that spine at some point during the pregnancy. Also we know that women who have specific conditions during the pregnancy could place the pregnancy at increased risk. An example of this would be uncontrolled diabetes. If a woman has diabetes that isn't well managed or controlled during pregnancy, she does have a substantially increased risk for having a baby born with particular birth defects. Also, for a woman who has the multiple marker positive screen result, we may do a detailed ultrasound, as we also would if she's had an abnormal ultrasound at some point during a previous pregnancy. If she had an ultrasound done at 16 weeks and they think they saw something unusual, we may want to do an ultrasound in a couple of weeks to reevaluate that pregnancy to see if it's progressing or getting more severe. Also, if the family has had a previously affected child with a condition that we know can be identified by ultrasound, or if there's a family history of a particular birth defect that we know can potentially be identified by ultrasound, we may want to offer a detailed ultrasound for that woman during her pregnancy.

A common indication for prenatal diagnostic testing would be advanced maternal age. Testing is typically offered right off the bat for women who are 35 or older during the pregnancy. We don't even start with some of those more screening tests unless they don't want to go straight to amniocentesis or with one of the other diagnostic tests. Also, if we've done carrier screening and we know that both the woman and the father are carriers of a particular genetic condition, we know there are increased risks of having that baby affected with the condition, and we could test the pregnancy to see if indeed the pregnancy is affected.

Most of these results are available within two to three weeks, especially chromosome results. However, there are some genetic conditions that can be identified during pregnancy but where the testing takes a little bit longer for us to get the results. Options following the results are either to continue the pregnancy and to take that baby home once the baby's born, or to adopt that baby out once the baby's born, or to terminate an affected pregnancy.

I'm going to talk about two different diagnostic tests that are typically offered to women during their pregnancy. One of them is amniocentesis, which involves removing some of the fluid that surrounds the baby. It's done in the second trimester. We can look at the chromosomes and some of the cells that have slipped off the skin that are in that fluid, so we can look at chromosome abnormalities, and we can also look for particular genetic conditions if we're able to

during pregnancy. It also detects a large majority of spine abnormalities or neural tube defects during pregnancy. It does carry with it a risk of miscarriage, which we talk to the women about; the risk is about 0.5 percent. The test probably costs somewhere around $2,000, and that includes counseling for the amniocentesis and the cost of getting the actual carrier type of picture of the chromosomes.

Another test that's similar to amniocentesis but is done earlier in pregnancy is called chorionic villus sampling (CVS). It's done between the tenth and twelfth weeks, so it's done much earlier than amniocentesis and gives us information prior to the woman's actually feeling the baby move during the pregnancy. It involves removing some of the placental cells and gives us information about the chromosomes and genetic makeup, but we're not able to detect the possibility of spine abnormalities, because in that amniotic fluid we can measure alpha fetal protein to assess the risk for spine abnormalities, but we're not able to do that with CVS. It probably has a higher risk of miscarriage similar to amniocentesis, probably somewhere around 1 percent risk of miscarriage, and it's close to the same cost as an amniocentesis.

Newborn screening is typically state funded and managed. The conditions that it screens for vary widely, although most of them have to do with mental retardation and preventing mental retardation. If we diagnose and treat these conditions early, we can prevent those children from having mental retardation. Another example is phenylketonuria (PKU). People with PKU have a metabolic disorder where they can't process a certain protein, so we eliminate that protein from their diet, and it allows them to develop normally. One of the disadvantages is that we can potentially be labeling an infant with a condition when they may never present with symptoms. An example of this is a condition called MCAD (short for medium-chain acyl-CoA dehydrogenase) deficiency. I'm not going to go into details, but most people who have this condition don't even know that they have it and do not present with symptoms; but if we're identifying a child as having this condition, that could potentially leave them open for genetic discrimination later in life.

I'm going to jump on into pediatric diagnostic testing out of the prenatal area. Most of this just involves people who come in, bring their child with specific symptoms, and want to know if there could be a genetic cause. So we evaluate them and then do specific testing based on those symptoms. It often requires a genetic evaluation to determine what sort of tests we are going to test for and what tests we are going to start with. A lot of times, if we don't have a good idea of what's going on with that child, we may want to start with conditions that we know could be treated or easily treated earlier and could potentially prevent symptoms later on if treated at that point. It may require a geneticist or a genetic counselor to sit down and talk to the family about what this test is, what information we're going to get from the test, and also, when we get those test results, what does this mean for the child, and that includes negative and positive test results. Sometimes people will think if they don't have that genetic condition, then I'm in the clear, but that's not always necessarily true. Also we want to discuss positive test results with that particular family, because other family members could be also at risk for having

that same condition. The cost of pediatric diagnostic testing is extremely variable. I can't even give you a range. Some of them are very, very cheap to do, and some of them are more expensive if they're doing a specific genetic test.

I'm going to move on to adult onset disorders, which is one of my areas of interest, and I think is one of the areas that's going to expand and grow in the next few years. I'm going to again talk about diagnostic, presymptomatic and also predictive testing. So again, diagnostic testing is when we have someone coming in with symptoms, and we're diagnosing them with a specific genetic condition based upon the symptoms that they're presenting with, whereas presymptomatic or predictive testing is done with a person who is asymptomatic, they don't have any symptoms, but they may have a family history of that condition, or their family history is highly suggestive of that condition. The results of a predictive or adult onset disorder testing may increase the risk for other family members. It may require several counseling appointments prior to and after we get those test results. The cost for this is also extremely variable, and I'll talk a little bit about specific conditions.

There are three adult onset conditions that I'm going to address here. One of them is familial hypercholesterolemia (FH), which is a condition in which people have high cholesterol. So a family comes in and has early heart disease in the family, or people in the family seem to be dying early of stroke or have quadruple or triple bypasses relatively early in life, between 30 and 50, then we may be concerned that there's a possibility that this family could have a high cholesterol problem. So what we would do is to do a lipid panel taking a look at the cholesterol. We would look to see if they have high LDL, the bad cholesterol, in addition to this family history. There is no genetic test currently to see if people have this specific change for FH, so mostly it's just looking at the lipid panel and basing the diagnosis on that and the family history, and the treatment for that is just putting them on lipid-lowering medications.

I'll talk a little bit more about Huntington disease, a neurodegenerative disorder, and also BRCA or breast cancer mutation, which is just one of many cancer susceptibility syndromes. Presymptomatic testing is testing done prior to presentation with symptoms, so there may be an identified condition or gene change in a particular family member, or the family is highly suggestive of that particular condition. A gene change in the gene that's related to that condition results in the development of that condition usually later in life or at a certain age. There are lots of concerns with presymptomatic testing because of the potential for genetic discrimination. Most of these are autosomal dominant inheritance such as Huntington disease, which is a progressive motor, cognitive and psychiatric disorder with the mean age of onset between 35 and 45 years old, and once they've presented with symptoms, it often is a quickly progressing course and results in death between 15 and 18 years from the onset of symptoms.

With those conditions, people often come in with a family history of particular

symptoms, or if they know that a family member has been diagnosed with Huntington disease, they're concerned about themselves developing symptoms. They want to know prior to developing symptoms whether they're at increased risk because they want to know whether they should have children or whether their children are at risk, or they would make lifestyle changes based on that result, and this often requires lots of counseling prior to having that test result, because there's no cure or treatment for that condition, and the age of onset and severity may be very dependent on the change that's seen in that gene. So with Huntington disease, it's actually an extension of a particular gene, so the larger that it has expanded, the greater the chance that you're going to have symptoms earlier and that it's going to take a more severe course. Testing is not recommended for children, so for people who are under 18 years of age, we're not doing presymptomatic testing, because even though parents really want to know this information, we want to make sure that individuals are making their own decisions about whether they want this information or not when they're ready as an adult. The cost is highly variable and dependent on the specific condition and the technique that is used to test for it. An example of this is Huntington's: gene testing is relatively inexpensive at about $200–400, but when you add in the cost of the genetic counseling, the psychologists, the neurologists to make sure they're not presenting with symptoms, the total can come to about $2,000. So it can get productively more expensive when you add in all the costs that go along with this testing.

Predictive testing is when we see a change in a gene and predict what the chance is for them to develop symptoms, a slight difference from presymptomatic testing. There may be increased risk for symptoms. An example of this would be screening for cancer. So if an individual with a family comes in, and many people in the family have been diagnosed with breast or ovarian cancer, we may be concerned about that individual's risk, and we may offer genetic testing to see if there's a particular gene change that has been identified that is associated with a significantly increased risk for those particular types of cancers. It does not determine or tell us yes or no this person is going to have symptoms or is going to develop cancer, but it does give us an idea if there's an increased chance for that. Testing is offered if a gene change has been identified in the family, or if a family member has had testing and a gene change has been identified, or again if the family history is highly suggestive of that disorder. And again there are concerns about potential genetic discrimination based on predictive testing, particularly for women who haven't had cancer yet, and they're coming to us with, for an example, a BRCA gene change. Maybe they come to us, they have a mother and a sister who have been diagnosed with breast cancer, and they want to know if they're at increased risk. Maybe upon getting some more family history we'll find out that her grandmother also had ovarian cancer. Now, we may be very concerned about her risk and offer genetic testing to her, but she may be concerned since she's never had cancer, if she's identified as a gene carrier, that there's potential for genetic discrimination in health insurance if she decides to go to another health insurance since she already has been identified as a carrier, and they may consider her at high risk, as you should consider her a high risk, because she is at a higher risk for developing those cancers. For changes

in the BRCA gene there's about a 50–85 percent chance of developing breast cancer over the lifetime.

For ovarian cancer, there's about a 10–45 percent chance of developing it, and that is kind of variable depending on the family history. Again, if the person is identified as a carrier of one of these changes, it does not mean that they will develop cancer. A good example of this is I had a woman who was 85 years of age. Her mother was diagnosed with ovarian cancer. She had a daughter as well with ovarian cancer and one with breast cancer. This woman was an obligate carrier of this gene change, which was identified in other family members, but she had never had cancer. In her whole life, she had never developed cancer, so it is possible that carriers will not develop cancer.

So the risk for symptoms is uncertain, and it completely varies. It is somewhat dependent on the specific gene change that we identify as well as the family history. If there's a stronger family history of ovarian cancer, we would be more concerned with an individual who's identified with a gene change for her risk for ovarian cancer than we potentially would be for breast cancer. It's management of symptoms only. We have no cure for a lot of these genetic conditions, so we're just going to manage the symptoms. We can offer increased or earlier surveillance, and a lot of times people will consider prophylactic surgery such as prophylactic mastectomy, removal of the breast, or a prophylactic removal of the ovaries to significantly reduce their risk for developing those cancers. Again, for predictive testing, testing is not recommended for children under 18 years of age, again because we want these individuals to make these decisions themselves, whether they want to have this information or not. Again, the cost is highly variable and dependent on the specific condition and the technique that is used. I give the example here of the BRCA gene DNA analysis. They sequence the whole gene, which is close to $3,000, and if you include genetic counseling and a psychologist's and other specialists' fees, if they want to talk to a surgeon about prophylactic surgery, it can add up to about $4,000 or more.

So where are we going with the future of genetic testing? As we identify more and more genetic conditions, at least it will increase the availability of testing, but a lot of times we may be able to do the testing, but we don't have any curative treatments, or maybe we will just do management of those symptoms associated with that condition. I think that one of the areas where we're going to learn more about genetic susceptibility is multifactorial conditions. An example would be diabetes. We know that people who have family histories of diabetes are at increased risk for developing diabetes themselves, not at a highly increased risk, but at increased risk. But maybe in the future we'll be able to identify certain genetic markers that we know place a person at a particularly increased risk.

Also, gene therapy may become more of a larger role of this process, so we may be able to cure these specific genetic conditions. We may be able to provide a specific treatment that essentially cures that condition. We're not there yet, and I

don't know if we're going to be there any time soon, but there are particular conditions for which people are looking into providing these cures.

MR. THOMAS F. WILDSMITH: I'm going to talk a little more from the public policy standpoint, and what I'd really like to focus on is the current debate about whether legislation is needed at the federal level to address the uses of genetic information by health insurers.

Now, I think it's very important to recognize that everybody involved in this debate is debating a future that we don't see yet. Clearly, the science is advancing very, very rapidly, and it seems very clear at this point that these new genetic technologies are going to be revolutionary. But we don't know what their ultimate power is going to be, and we really don't know yet what shape the future is going to take after the revolution. Everybody involved in the debate is concerned about this unknown future potential though, and the gut subconscious fear we have is that we're going to have this "Star Trek" medical power where, with a drop of blood and a $20 lab test, anyone who can get that drop of blood is going to know what your medical destiny is; and that's very frightening to people. It's also frightening to insurers if this knowledge of your medical destiny becomes as ubiquitous as our knowledge of our blood pressure or our cholesterol levels, because then individuals thinking about insurance are going to do so with the full knowledge of if and when they're going to get sick.

I also have to say that it's not a slam dunk that genetics is going to get us to that point. There are many things that affect us medically that are not purely genetic. Foremost on my mind are injuries. A couple months ago I had to have some knee surgery because I blew out the cartilage. Genetic technology is most likely not going to prevent that any time in the near future.

This is not a simple stand-alone issue. People see genetic information as particularly sensitive, but it's just a particular instance of some broader issues: privacy, who can see health information and what they can do with it, and the permissibility of underwriting in individual insurance markets. The current debate is focusing on medical expense insurance, and all of the legislation that's out there right now that has any political legs deals purely with medical expense insurance, but it's very important for us all to recognize that the core arguments used by advocates of legislation are not limited to medical expense insurance. There's nothing philosophical that would prevent those same arguments from being used in disability income or long-term care or life insurance.

What are the roots of the debate? Genetic information is seen as being particularly unique. There's a feeling that the genetic code in some way uniquely defines who and what we are, in a way that no other physical or medical measurement does. People have a very different sense of the genetic code than they would of a full body scan, for instance, or an X-ray of my entire skeleton. Medical expense insurance is rapidly becoming seen as a basic human right, and the leap there is that

basic health care—and you'd be surprised at what many people would include in basic health care—as a matter of basic humanity and compassion is viewed as a fundamental right of everyone.

More and more in our society we're seeing health insurance as a necessary prerequisite to getting medical care. Therefore, the health coverage is seen as fundamentally something that people are entitled to and need to have as a right. The expectations of how health insurance works are also shaped by employer-sponsored benefit plans in public programs. It's very understandable. Over 90 percent of us who have private health insurance have it through an employer-sponsored program. Virtually everyone who is a policy maker, everyone on Capitol Hill and Washington, is in the Federal Employee Health Benefit Plan, along with all their legislative assistants, everyone who's drafting the legislation, everyone who's analyzing it. Our instincts for how health insurance works are educated by our experiences with good coverage.

We should extrapolate and think about how people act in an a voluntary individual market and how that market's going to work. Why do I highlight that? Because the real issue for the use of genetic information in underwriting is in the individual medical expense market. The Health Insurance Portability and Accountability Act of 1996 prohibits the use of genetic information by group health plans for determining whether someone is eligible for enrollment. Federal law prohibits employer-sponsored health benefit plans from saying you can or cannot enroll based on genetic information, or in fact any other health status–related information, and it prohibits plans from charging one employee more than another based on genetic information or their health status. The real issue, therefore, is whether it genetic information can be used like any other form of health information in the voluntary individual market.

Something that's critical for understanding this debate is that, leaving genetics aside, people hate underwriting. They don't like it, they don't think it's fair. Even knowledgeable small business owners who understand the economics and can explain antiselection to you still, in their heart of hearts, feel that underwriting for medical expense insurance is fundamentally unfair, even though they're very comfortable with it, for instance, in auto insurance. That colors the entire debate over genetics.

Fundamentally, consumers don't want you to use personal health information against them, and there's a feeling that everybody has a right to coverage because it's so essential. We have to have it. People will say, "It's not fair to use this information against me because I have to have this," in a way that people don't feel they have to have life insurance or several other forms of coverage. There really is a strong ideological feeling that medical information should be used only to drive the delivery of health care. Now, academics will generally add one other allowable use, namely, research. Very few people outside the insurance industry are very comfortable with the idea of underwriting.

Insurers' concern is that in a voluntary individual market where no one is forced to buy health insurance—and it is critical to understand that no one in this country is forced to buy health insurance for themselves or for anyone else—that kind of market just won't work without some level of risk selection and risk classification, underwriting if you will, to make sure that the premiums each potential purchaser must pay are commensurate with the risk of future claims that they present to the insurance pool.

Now, the American Academy of Actuaries put together a work group that has studied this issue. I'm going to put on my Academy hat now, and for the benefit of the Academy staff in the room, once I get past this next bit, I'm not speaking for the Academy any more, so don't attribute anything else I say to the Academy. The work group worked very hard and has put together one monograph and three issue briefs—although a couple of them are more like issue "longs"—dealing with genetics. Two of them deal with medical expense insurance, two of them deal with long-term care and disability income insurance.

What did the Academy say? For medical expense insurance, first of all, the impact of genetic technology on health care is going to affect all forms of health insurance. Health insurance is uniquely affected because genetic information affects not just underwriting, but also the health plan, who gets to pay for the test and, we hope in the future, the treatment. So while for underwriting it's limited to the 10 percent of the market that's individual, the cost side is where the potential impact lies for all forms of health insurance, private and public.

Genetic information is also properly seen as part of the broader issue of personal health information. I think this isn't recognized enough. We tend to view genetic information as uniquely personal, and that's very understandable. That doesn't necessarily mean that confidentiality is any more important or it's any more sensitive.

Here is a simple example of that. What would be most sensitive for me: if I were found to have a genetic abnormality that put me at greater risk for prostrate cancer, or if I took a nongenetic test that would determine that I were HIV-positive? Odds are I might be more concerned about your learning about my HIV status than I would be about your learning about my genetic risk of future cancer.

I think there's a real danger when we focus in on the genetics that we can forget just how sensitive much of the health information is that we already see. There's also a danger that by segregating certain forms of medical information and putting special rules on them, you make the world a lot more complicated than it needs to be, and make it more difficult to provide the level of confidentiality you need across the board with medical information.

Again, the possible use of genetic information is only an issue in the individual

market. We already have federal law in place that addresses the group market and addresses the concerns of whether or not it is going to be used in underwriting. Anything you can do to provide mechanisms to ensure access to coverage to people with serious medical conditions can help solve that problem also. That would include the high-risk pools and other mechanisms to ensure people have access to coverage. Now I'm not representing the Academy anymore, just to make that clear.

We already have a boatload of laws on the books dealing with the privacy of health information. The regulations enforcing these and implementing them are just coming online now. So quite frankly, we haven't seen yet what the impact of the federal laws is going to be, because they're just now being implemented. But in the broader context, we are on the verge of having significant new privacy protections implemented for all forms of personal health information. Of course, the states have done things on both the privacy and the genetics fronts.

What's happening in Congress? Well, for genetics we have two Senate bills in play. S. 318, the Daschle proposal, is fundamentally the Democratic proposal; S. 382, the Snowe-Frist proposal, is the Republican one; and while a number of bills have been introduced, these are the two that have any kind of legislative momentum behind them. One of the key issues is "what is genetic." What is within the scope of proposed genetic legislation? The first thing we need to recognize is that statutory definitions have nothing to do with what the dictionary says. Once the definition is written in the statute, that's what it is for legal purposes, whether it comports with common understanding of what the words mean or not. There are two broad views. One is that genetic deals with information about a person's genetic code in some sense, dealing with chromosomal abnormalities or genetic abnormalities. A much more expansive view is that genetic information is, to paraphrase, any information about something that runs in families, anything that's inheritable.

How does the Daschle proposal work? It's got a broad definition of protected genetic information that includes fundamentally any inherited characteristic. It's a pretty broad definition of what they're going to protect. Now, there is a safe harbor provision, an exception clause, if you will, that accepts certain types of information, including in that routine chemical, blood and urine analyses. The safe harbor exception is overridden if those routine chemical, blood and urine analyses are genetic tests, which is a circular reference back up to the original definition that the safe harbor is an exception to. The bottom line is HIAA's lawyers aren't sure what it means, but it surely doesn't appear that you can rely on that safe harbor.

If you think about how this language developed, I wasn't in the room when it was drafted, but you can almost see the layers. You say, What do we want to protect? Well, we want strong protections about anything that could be genetic. So they write the first layer. Then people say, Well, you know, what about blood type, O positive, is that genetic; cholesterol levels, iron count, is that genetic? Well, not that routine stuff isn't. But what if someone used that exception to slip in a genetic test?

Well, you go in and draft it. The concern that the insurance industry has is that this definition is so broad that when it goes into court, it could sweep in anything that's inheritable.

The Snowe-Frist proposal also has a very broad-based definition, and I think you should be sensing something here, that the people who are writing these definitions tend to see genetics much more broadly than we do, much more broadly in fact than many in the scientific community do. Again, there's a safe harbor exception. The critical difference in this legislation is the safe harbor appears to be clean. There's no circularity going back, and it seems like the safe harbor would hold.

Now, why are the definitions important? This would be, as best we can tell, the first statutory definition in federal law of what genetics is, genetic information and genetic tests. It's going to be a critically important precedent, and the way laws are written, they always plagiarize, if you will, prior legislative statutes. So this definition is most likely to be the base for any future legislation dealing with these issues.

It's very important that if legislation is going to be passed, it create a framework that's going to work in the future. These newly emerging technologies are unquestionably powerful, and a lot of stuff is going to be coming out in the future, but not all future medical advances are going to be genetic. There's going to be an imaging technology. I don't know what it's going to be, but something that's going to supercede the MRI and the CAT scan. Just because it's new doesn't mean it's genetic, and just because they can diagnose some things that may run in a family doesn't necessarily mean it's genetic. If Marcus Welby M.D. could have done it for you 30 years ago, it's probably not genetic in the way most lay people think about it, but it could be swept into some of this legislation.

It's also critically important that we not short circuit very important policy debates. Part of the reason these proposals are written as broadly as they are is that fundamentally people don't like the use of medical information by health insurers in the underwriting process. So offices such as Senator Kennedy's, when they're working on drafting this legislation when it's in front of committees, are going to lean toward sweeping in more medical information rather than less. That affects the way the definitions are drafted.

From a insurer perspective, genetic privacy rules need to be consistent with rules for other health information. Unfortunately we're looking at 50 sets of state privacy rules, plus a federal level on top of that that gets stirred in some ways. We don't need another 50 plus one federal set of genetic privacy rules. It's just going to make life way too complicated and make the administration more difficult than it already is. Fundamentally we believe that the definition should be narrowly focused. What the public, I really believe, is most concerned about are the newly emerging technologies that are coming out of science like the Human Genome Project. We need a safe harbor that's defining what's not genetic, particularly given the sweeping nature of the definitions that are being used now. Fundamentally what

most individual medical expense insurers want is continued access to the routine, nongenetic information that they've been using for decades. Now I'm putting on the trade association hat, so you know who I am.

There's good third-party research out there. Professor Mark Hall from Wake Forest University has done a couple of studies showing that insurers are not in fact abusing genetic information. No one is requiring applicants to take genetic tests when they apply for health insurance. They're not using blood and urine samples and running genetic tests on them. They're not asking specifically have you ever had a genetic test. Now they are asking for routine medical information, getting the files from the primary care physician. If there were genetic information in there, it would show up. Dr. Hall's research shows that there are few enough of us as adults who have taken a genetic test that genetic information almost never shows up, but as it stands now, health insurers are not using genetic information in the underwriting process.

There are some significant legal protections already in place. Clearly in the group market there are significant privacy protections, confidentiality protections for all of the health insurance market, and so we think that a lot has already been done. The technology is evolving very rapidly, and if there's any sense that I want to give to you, it's my conviction that everyone who is involved in the debate is arguing over their vision of a future that we really haven't seen yet. We're not arguing over the use today of tests that you and I are having on a routine basis. We're arguing over what rules we want to have in place five years out, eight years out, 10 years out, because we see this technology advancing so rapidly.

HIAA's view is that the legislation, given the fact that the information is not being used now, is premature, and that we need to wait to actually see a problem before we try to fix it. Having said that, if you're going to write legislation, it's critical to get the definitions right, and you need to do it in a way that doesn't cause the individual market to melt down. As you know, in the states that have tried to reform the individual market, given the fact that no one's forced to buy the insurance, it's very difficult to strike that balance and to accomplish some of the access goals that people want when they move into a reform effort without causing the market to melt down, or at least to shrink and increase premiums.

Now to some of the future issues. How pervasive is this testing going to become? We really don't know. I think that the fear is that it will become as ubiquitous as blood pressure or cholesterol level tests. Most of us in the room who are over 35 years old can tell you whether or not they have high blood pressure or a cholesterol problem, because it's part of the annual physical, it's what our doctors are looking at, it's common knowledge. How predictive will it be? Are we going to reach a point where we've got people who are genetically blessed and genetically cursed, or are we going to find that we're all cursed, it's just a different personalized curse for each of us? Are there going to be parallel cures; you know, finding the genetic abnormality may not be a big deal if you can fix it.

One concern though is that the diagnosis is going too far and is going to come a lot faster than the cure. So even if ultimately we reach this nirvana where we can catch a lot of stuff and fix it, there may be a long time where we're catching a lot of stuff and don't know what to do with it, and that's going to be an issue. More broadly, if you do more than medical expense insurance, you need to ask yourself if other forms of insurance are going to be swept in, once whatever is done for medical expense insurance is done, because there's this fundamental feeling that personal information about this code that defines me shouldn't be used against me, because I can't help it, I can't change it, I didn't ask for it, I was born with it, you shouldn't use it to hurt me. There's no codicil to that feeling that says you shouldn't use it against me for medical expense insurance only. That same feeling is going to be there for life insurance, for disability insurance, for long-term-care insurance. If you look carefully at the Academy briefs, because the disability and the long-term-care insurance tend to be longer-term risks, where issues such as Alzheimer's and some of these later in lifetime onset diseases become very important, the debate potentially would be much more affected by a ban on the use of genetic information than medical expense insurance would be.

MR. KIPP: Yes, we've already seen the can of worms being opened, and we talked a bit about genetic information, and I'll show you a little bit that I think is kind of interesting. One state has defined "genetic information" as follows: "The information about an individual or family obtained from a genetic test or an individual's DNA sample." You can see how very broad and general the states' definitions are if you don't have sufficient drill-down on some of these terms like the term "genetic test" itself. Without more information, you really don't have a good basis to make a judgment about what genetic test really means. Some people would argue that broad definitions are dangerous. We might not all agree. Maybe Tom would say that. It depends on your perspective, I guess.

The underwriting issues that surround all this are really where I want to head here. The fear in all this from the industry point of view is what a purchaser would do if they happen to know something about their health status that the insurance company didn't know. If they are permitted to keep that information private, they might buy insurance at the most opportune time (from their perspective), thus causing adverse selection. On the positive side, the individuals would upon discovery of a genetic illness seek treatment in advance of the disease's onset and before that disease progresses to any great extent. Certainly that's what you'd hope people would try to do once they had obtained that information.

The legal measures Tom has covered quite well. I won't go through any of that, and I guess there's an angle on disease management that we haven't really explored very much. Stephanie gave some indications of how this might work. Payer programs that have disease management aspects to them might employ genetics information to help identify people for enrollment into disease management programs to help them with their treatments. It's being done today

on a limited basis.

Hundreds of thousands of people are, in fact, at risk for diseases for which tests currently exist. Some of the books I was looking at, some of the research I was doing, dated back to 1999, and you've all seen some of the major advances that have happened just in the last couple of years. Back in 1999 there were about 450 genetic diseases that tests had been developed for. Stephanie's gone through how those diseases are caused and the various ways, you know, one copy of the dominant gene and so forth, the recessive gene combinations and some multi-gene-related diseases. The question, of course, is whether or not you're talking about something that's a predisposition for a particular future problem or whether there's a direct link, and therefore, once you observe it, there is, in fact, a disease present, and that's something that the underwriters would, of course, be very interested in. At this time, there were alterations in genes responsible for about 5,000 clearly hereditary diseases, and I'm sure that number will grow substantially.

I've used the Milliman underwriting guidelines to come up with point values for individual diseases, values that an underwriter might assign a case when evaluating an application. Unless you put them into some perspective, you really wouldn't be able to say whether any given disease is an expensive thing or not. If underwriters see cystic fibrosis on an application, the point level for that, I think, was 300 to 500 points, something along those lines. The average points in the middle of the range give you a sense of what percentage of the population might fall into the point category (300–500) that would have that sort of cost level associated with it. This begins to give you the sense that some of these diseases are fairly important from an underwriting prospective, and knowledge of them would certainly be interesting information for an underwriter to have if they were trying to set a price for a particular product for an individual.

Genetic information and how you might use that information we've talked about a bit. Certainly, diagnosis, prognosis, prevention and treatment would be the main and typical uses for this, and it varies from disease to disease quite a bit. There's a Web site that I would direct you to that has quite a bit of interesting information on it, http://www.genome.gov. It's a National Institutes of Health Web site that has a great deal of interesting information that's come from the Humane Genome Project. This flow chart lays out how they think of the progression and use of genetic information in the management of diseases. You start with a disease that has a genetic component, and you identify those genes. Then you understand the underlying biology, and you may have some drug therapy that applies. There may be some diagnostics that give you some way of preventing symptoms from developing. There may be some new form of genomic solutions to some of those kinds of problems. And lastly, the gene therapy that Tom was alluding to at the end of his presentation—that is certainly all very seductive thinking that we'll have these gene therapy solutions for some of these problems; that is what all of our hopes would be.

There's genetic disease management being done today, and I think going from what Stephanie said, that it's true that it's used in various ways for diseases like Tay-Sachs where you're testing to prevent passing a gene or Down Syndrome where you're preparing for a birth with parental education and helping the child once the child's born. These may be viewed as types of disease management that are currently taking place today, and there are other examples as well.

One thing that kind of fascinates me is there's really not been a lot done, or at least not that I can find in doing the research for this or that has been published anyway, with regard to the cost benefit of genetic testing. What I was able to find in doing some research was a report that was put together under a government grant. I'll give you the reference for that, but it was for cystic fibrosis in particular, and Stephanie's already given you some of these stats. One in 3,000 newborns per year in the U.S. is born with cystic fibrosis; there are 30,000 individuals in the U.S. today with the disease; one in 25 carries the recessive gene, at least in Caucasians. Typical life span is on the order of 28–30 years. It used to be that it was only eight years. Average annual treatment costs are fairly substantial and can vary quite a bit. There is quite a variation in the severity of the disease from year to year and for various individuals, but on average it's somewhere in the order of $10,000–15,000 a year to treat.

Also, this Office of Technology assessment study that I mentioned modeled the costs. They weren't able to go to an administrative claims database for their data, so they created a treatment and created an analysis from that kind of data. So in creating this model, they've made a variety of assumptions. They used an example of 100,000 couples and then go through various scenarios of how and when those couples would be tested and in what order of succession, and I think their sort of primary scenario was a situation where the women would be tested first. This is an autosomal recessive problem, so you need the pairing of the two genes, one from the father, one from the mother, to cause the cystic fibrotic child, so you've got the testing of the woman first to establish whether she's a carrier or not, and then if found to be a carrier, you test the husband to see whether or not there's the possibility of that 25 percent chance of a sick child resulting. Then they model the number of people that would actually avoid becoming pregnant based on that knowledge: those people who already had become pregnant and how many of those would probably abort. Then they go through a scenario of what the test costs versus what the avoided direct medical costs would be and what the other support costs would be for supporting the care of the cystic fibrotic children, which is a lot more involved than just inpatient care and so forth. There's a lot of outpatient home care where nurses come out and help with the relief of some of the symptoms.

The primary scenario actually showed a savings in 1990 dollars of a couple million dollars on this base of 100,000 couples, which, of course, would translate into something different if you spread it over like a typical insured population, because that's only a segment of what would be an insured population.

Anyway, I think these kinds of studies and the thought process that is revealed by looking at this study are something that we should all become aware of. Those of us who are interested in these problems as we go forward will need to think in terms of including them in coverage, and if you include them in coverage, consider if there is any possibility that there may be some savings downstream from having included them in coverage. These are going to be questions that our chief financial officers and chief medical officers are going to be asking us to try to research.

The report I was referring to was published by the Office of Technology Assessment, Report DA 532, in August 1992, *Cystic Fibrosis and DNA Tests: Implications of Carrier Screening.* It was a very thoughtful piece, a 300-page document. There was a chapter, chapter 19, I think, that really dug into the cost benefit analysis aspect of it, but it's preceded by a lot of background and an approach to thinking about how you would even structure a cost benefit analysis for a genetic test. I think for that it's probably very valuable to take a peek at.

One other thing that was noted in some of the research that I went through as I was pulling this information together was, at least in the year 2000, that fewer than 16 percent of carriers covered genetic testing for the screening for cystic fibrosis. I don't know that that's changed a great deal over the last couple of years. So currently the insurance industry is not typically covering this sort of thing. And additionally there was a story that I happened to see that dealt with gene therapy for cystic fibrosis, and I was amazed to see what the cost of that was. Now, of course, this is presale to public. You're talking about a clinical trial–type situation, but the cost for what amounts to a three-month relief of the symptoms was $80,000. Now, people who go through current treatment are talking in terms of $10,000 a year for a life span of about 30 years, so you can see what the kind of average lifetime cost might be for an individual who has those problems. If you're going to talk in terms of $80,000 for the 90-day periods of relief, you're talking about substantially more money. Of course, once made available, the price for this would probably go down substantially, and I'm sure these types of things will be pursued in spite of high potential costs, because at some point you're talking about potential cures down the line.

MR. DAVID BAHN: I have just a couple of comments on the underwriting aspects. I can see it going either way. If I look back 30 or 40 years, race was generally considered an acceptable factor for underwriting; but society said no, that's not right, so now underwriting typically does not include race as a rating factor or an underwriting factor. The other frightening thing though potentially is, let's see, whether I'm a boy or a girl depends on chromosomes, X and Y, that kind of stuff. Well, chromosomes are genetic factors, so we cannot include gender in rating, because those are genetic factors.

MR. WILDSMITH: You know, that's a good point. We all recognize that society makes decisions about which risk classification factors are legitimate and which are

not, and we have a very clear legal, professional and moral obligations to abide by those legal decisions. I think the concern is that there are states that have made the decision such as New York, Washington and Kentucky at one point, where it's impermissible to use any health information, and we would argue that the results on the market in those states has been very bad. It's clearly increased the cost of coverage and reduced the number of people who have insurance. The fear is that if there is expansion of the technology and broad definitions, if most of what you have in a person's medical file 10 years from now is deemed genetic and we can't use it, then de facto you've gotten to community rating, and we would argue that state experience shows that that would harm the market.

MR. BAHN: I agree with you in terms of that. I think those states that use community rating probably are trying to solve one problem by spreading it and in the process of creating other problems. I have another comment related to the testing, etc., and this perhaps goes back toward the BRAC genes that are markers, if you will, for breast cancer. Now, you said that it's not a sure thing that you will get breast cancer; you may get breast cancer at some point in the future. We as actuaries could probably run off the probabilities of year by year getting breast cancer, and if it does occur in year 8, it would cost $20,000 or something like that, assuming ongoing early detection, mammograms, whatever. Then we come back down, and we put that into our pricing programs, and we really say, well, let's see, is this individual who's applying now who has that marker, what is that individual going to add to my total claim cost in my risk pool for individual insurance. They might not even be covered by me in eight years with 25 percent average annual lapse rates on individual medical insurance. You know, what's the possibility that this person will still be here in eight years, and you run that in, you run into the costs, perhaps other illnesses along the way, nongenetic if you will. Are those really worth it? Are they really going to add to the total premium income or total premiums that we have to charge? I'm not sure yet. There are probably some genetic tests that are predictors of more immediate medical costs, if you will, and some that are predictors or markers toward the possibility of future costs.

MR. KIPP: I'm not sure, David, exactly where the question lies in that last part, but I think the one thing that I can say is it's not often the case that the BRCA test is covered for its screening use, so that already we're not paying the $2,500 or $3,000, or I guess up to $4,000 if you include all the counseling and so forth that might go along with it, for that particular test. Now, I guess if you had access to that and you wanted to build some models and try to take the result of something that wasn't covered and try to make some projection about your pool's future experience, that would be an interesting exercise. I'm not sure we can even guess today what the result of that would be.

MR. BAHN: Suppose we have an individual who applies for insurance and presents genetic information that they do have the BRCA marker. What is that individual going to add to the total medical costs for my insurance pool over the years versus if we have covered that individual for two to three years, and that individual at that

time becomes concerned enough for whatever reason to apply to have the genetic test; should we pay for the genetic test? That gets to be, I think, a different kind of question. What do we do with that genetic information once we get it for an applicant, and then what tests do we pay for?

MR. WILDSMITH: If I may, my impression is that there are few enough adults who have had the genetic test, and in many cases they're not predictive enough, that what most insurers are interested in is not being able to use the genetic test. The reason I focused so much on the safe harbor language is that the primary concern is that, under the rubric of outlawing the use of genetic tests, they don't take away the blood pressure, the cholesterol, the sugar in the urine for diabetes, all this stuff we've been using since 1950, because we really do depend on it. So at this point I think what the industry's most concerned about is protecting the information we've used for decades rather than gaining access to this new stuff.

MR. KIPP: If I could add just for a point on that. The underwriters are currently using a rate-up, a point assignment for family history of individuals that might have cancer, so they're already making a judgment about some probability of an individual having cancer based on some far less refined information, I guess you might say, when compared to the genetic test; but you can only imagine that, if underwriters had access to that additional test information, it would go into their thinking about what they would assign for the cost of that policy, and that's the thing that people are afraid of, that extra revelation might cost them some additional money. In the case of cancer, I'm not sure that it's going to cost them any more than it might already, just to know that they have a history of cancer.