Overview of Legal Analysis
Peter S. Gray, J.D.

DR. TUCKSON: As Peter gets ready, let me introduce him. Peter is from the Equal Employment Opportunity Commission. He, as you heard, will review the legal analysis that we commissioned.

Now, understand and I remind you all that there was a very important point that Agnes made. That is that we have had some pretty intense discussions with all of the stakeholders who care about this issue. One of the elements that really kept popping out from some constituencies was do you really need new legislation? Why doesn't the existing legislation solve the problem? Why reinvent all of this?

I want you as a committee also to understand. Not only did you see this video here which we are doing, but we are an advisory committee, but we are an active advisory committee. We are engaged. So the conversations that we have had with different stakeholders in all of this have been to elicit and elucidate positions, but also quite frankly they have been trying very hard to try to see if there was common ground, and to see where that common ground is.

I want to be very clear to the committee. We are not sort of sitting back on this. We are really trying to find common ground. Out of that need, we're trying to determine common ground comes this idea of well, is current legislation adequate. So that's the context for this analysis, which was prepared by Mr. Robert Lanman, a consultant to NIH Office of Biotechnology Activities. Mr. Lanman has subsequently retired from HHS after three decades of service. So he is not able to be here today, but we are really glad that Peter consented to present the analysis on his behalf.

Let me also acknowledge the agencies with jurisdiction over the laws that were analyzed, namely EOC, DOJ, Department of Labor, and HHS, CMS, and the Office of Civil Rights also reviewed this analysis for technical accuracy. So we thank all of you around the table who had a role in that also.

Thank you, Peter.

MR. GRAY: Good morning. Let me just start right at the outset with just a couple of little caveats. As Reed mentioned, I was asked to present the report that Mr. Lanman had prepared because he was unable to be here.

What I know about the health insurance part of this, what I know about health insurance is that I have some.

(Laughter.)

MR. GRAY: Beyond that, I really don't know that much, but there are folks here who can provide you with some assistance if you have questions following my presentation.

Second, let me note that neither the contents of the report, nor my participation or my presentation of it, especially the sections concerning employment discrimination should be in any way seen as the EEOC's endorsement of the report conclusions.

During the question and answer, I can explain it. Actually, during the course of the presentation, the report does reflect the Commission's views on the legislation. I will reflect those at that time.

The report begins by noting that the bill that passed the Senate and is pending in the House cited gaps in the protection for persons in the area of health insurance and employment. These gaps have become especially significant over the past several years because of the advances in the science of genetics and the potential that these advances present in the area of medical progress.

The bill notes specifically that deciphering of the human genome opened new opportunities for medical progress. The report also reflects concern among the public that the fear regarding the loss of privacy with respect to genetic information and the effect that that fear is having. Of course the DVD we just saw sort of I think drives home that point.

In this regard, I would note that some of you may have seen a couple of weeks ago, there was a new study printed in the May/June 2005 issue of Genetics in Medicine, reporting that 40 percent of almost 87,000 study participants in this particular study raised concern about genetic testing and the potential loss or inability to obtain health insurance as a key concern.

The report itself if you look at it, contains discreet sections addressing federal law and health insurance, privacy of medical information, state law, federal employment nondiscrimination law, constitutional protections, and protections geared for federal employees contained in Executive Order 13145 that President Clinton signed in February of 2000.

The section on health insurance covers HIPAA, the Social Security Act, and Title III of the ADA. The section on federal employment law covers Title I of the ADA, as well as Title VII of the Civil Rights Act of 1964.

We're going to first move into the health insurance part of this. One of the interesting facts noted in that recent Genetics in Medicine study regarding the concerns of the public relative to genetic information in health insurance is that the fear of discrimination is lower among persons in the U.S. over 65 and among Canadians generally. One segment of the study included a large number of Canadians.

The authors of the study suggest that this may be because of Medicare for U.S. seniors and national health insurance for Canadians where coverage is not at issue. For most of the rest of us, as the report and this slide note, health insurance is employment based. The report notes about 60 percent of the U.S. population is covered by employer-provided health insurance. Of those who are insured by employers, most of these plans are covered by ERISA, and by the Health Insurance Portability and Accountability Act.

The report notes that one basic purpose of HIPAA was to ensure that in some circumstances, individuals who change employers, and thus health coverage, should not have new coverage denied or restricted because of a preexisting condition. In other circumstances, the report continues, an employer would be permitted to impose limited restrictions on coverage, limited in terms of time based on preexisting conditions that fell within certain noted parameters.
The report further makes plain that under HIPAA, group health plans and group health insurance issuers cannot impose a preexisting condition exclusion on the basis of genetic information unless there is an actual diagnosis of the condition related to the information.

In the example noted in the report, an individual who tests positive for the mutation in the gene linked to breast cancer would not be deemed to have a preexisting condition in the absence of a diagnosis of breast cancer. As this slide notes, the report includes a reference to the HIPAA rule limiting covered plans from establishing eligibility requirements for individuals or charging specific individuals more based on genetic information, though nothing bars establishment of a group rate based on or in part on genetic information.

The report states that the HIPAA provision in the small group market prohibit an employer from refusing to renew a policy based on genetic information about an enrollee or potential enrollee, but it would not restrict an issuer from taking genetic information into account when determining the employer's overall premium.

The report states that an insurer could require that an individual take a genetic test as a condition of coverage, not to deny coverage to any individual, but for the purpose of determining the premium to charge the group and its members.

In the individual market, HIPAA guarantees that certain individuals who have lost group coverage have the opportunity to purchase individual coverage without an exclusion based on genetic information. As I noted before with regard to the individual market, the report indicates that although the issuer can't deny or refuse to issue a policy, it can set the premium based on whatever genetic information it obtains.

Some of what HIPAA does now, the report focuses on gaps in HIPAA coverage, or protection. First, as noted here, HIPAA doesn't prevent a group health plan from requesting, purchasing, or otherwise obtaining genetic information about an individual, or requiring an individual to submit to a genetic test as a condition of coverage.

On the basis of genetic information, the information obtained, charging all members of the group higher premiums. The report states that charging higher premiums could make health insurance too costly for small employers, and thus have the same effect as denying coverage.

Other gaps noted according to the report. HIPAA protections do not apply to small groups. From what the report notes, these are plans with fewer than two participants who were current employees on the first day of the plan year. Nor does HIPAA apply to plans that cover retirees only, or to plans that elect under HIPAA to be exempt from the nondiscrimination requirement. I'm going to leave it to others to explain later if you need or want an explanation of what plans may make this election to be exempt from these particular requirements.

The report identifies as a significant gap the fact that HIPAA nondiscrimination provisions do not apply to individual health insurance policies. Even though 10 to 15 percent of those covered have such policies, and even though the number of Americans seeking insurance outside of employment is likely to increase rather than decrease in the future.

HIPAA does, of course, guarantee that certain individuals who lose group health coverage have the opportunity to purchase individual coverage without any preexisting condition exclusion, which I mentioned earlier. But of course as I also mentioned, it doesn't prohibit issuers from taking health factors, including genetic information, into account when setting premiums.
The report looks at the Social Security Act and notes that federal law sets national standards for Medicare, supplemental, or Medigap policies which are health insurance policies that cover out of pocket costs under Medicare such as coinsurance and deductibles, as well as specific costs not covered by Medicare.

The report states that Medigap issuers are prohibited from conditioning the issuance or effectiveness of a Medicare supplemental policy or discriminating in the pricing of the policy because of health status claims experience receipt of health care or medical condition of the applicant. But the report notes that unlike HIPAA which expressly includes genetic information within the coverage of the term "health information," that is not the case here.

The report suggests that there is some ambiguity with respect to whether, and if so, to what extent a Medigap policy might limit access to and use of genetic information.

Title III of the Americans With Disabilities Act provides that no individual shall be discriminated against on the basis of disability and the full enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any public accommodation by any person who owns, leases, or leases to or operates a place of public accommodation.

Places of public accommodation include insurance offices. But according to the report, the real issue is not Title VII coverage of the physical location where insurance is written, but rather the content of insurance policies, what is covered by the policies.

Although there are federal court cases and some comments by legal scholars arguing that Title III requires equal access not only to insurance offices, but also the terms included insurance policies, prevailing sense is that ADA does not cover insurance policies.

As the slide notes, most of the federal appellate courts addressing this issue have ruled against coverage. Specifically, these include decisions from the 3rd, 5th, 6th, 7th, 9th and 10th circuits. Only the 1st and 2nd have ruled the other way. Apparently the 4th, 11th, and the D.C. Circuit have not yet ruled. But the trend clearly is against coverage.

The report notes that even if coverage might be included within Title III's protection, there is a separate provision in the ADA called the safe harbor provision which arguably would limit the reach of the ADA. According to the report, the safe harbor provision means that Titles I through IV of the ADA are not to be construed to prohibit or restrict an issuer from underwriting risks, classifying risks, or administering risks that are based on or consistent with state law.

A key requirement of the safe harbor provision is that the terms at issue not be deemed a subterfuge to evade the purposes of the ADA. Most courts deciding cases under the safe harbor provision have taken a broad view of what the safe harbor provision means. Some courts have even allowed issuers of insurance provisions that even lack actuarial justification.

The argument is that so long as the provision in the insurance policy was adopted before passage of the ADA, one can't argue that the use of that particular provision constitutes a subterfuge to evade the purposes of the Act. On the flip side, the contrary argument is that the current use of a provision that does in fact evade the purposes of the Act should be deemed violated because of the present use of that provision. But that argument has not gained currency with the courts.

The report looks at the HIPAA privacy rule. It is a relatively new rule. Final regulations were issued just a couple of years ago. The rule establishes the minimum national standard for protecting the privacy of protected health information. The definition of health information under the rule is quite broad, covering all individually identifiable health information, which encompasses genetic information, including family history.

A covered entity is defined as including a health plan, a health care clearing house, health care providers, and whoever transmits any health information in electronic form with a transaction covered by the HIPAA regulations.

The report suggests that there are some gaps, though, in the coverage of the HIPAA privacy rule. Basically the privacy rule does not bar the use of any medical information, including genetic information. Rather it merely sets the standards for getting access to the information.

So that in this regard, the report notes that health information which could include genetic information is available for use in underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits.

The report also notes that the privacy rule does not limit employer access to health information or genetic information. Under the privacy rule, once protected health information is lawfully provided to an employer, that information becomes an employment record and is no longer considered to be protected health information.

The report looks at state law. It notes that there are many different state laws providing all sorts of differing levels of protection. The report identifies 47 states and the District of Columbia that restrict or limit the use of genetic information to determine health insurance rates or eligibility in group or individual insurance plans.

These laws vary in scope, and they vary in how they define genetic information. Some states, for example, exclude family medical history from their definition of genetic information. According to the report, the three states without specific health insurance protection are Mississippi, Pennsylvania, and Washington.

The report also notes that some states have enacted widely varying laws dealing with genetic information generally. Of these laws, the report notes that they treat genetic information differently, or most of these laws treat genetic information differently from other medical records. They focus on the information rather than on user or use. They rely on various measures to safeguard genetic information at different stages of its acquisition and retention, and they provide for greater individual control over personal genetic information through varying means such as consent requirements, rights of access, civil remedies, and property rights.

But the bottom line -- oh, and before I get to the bottom line. One other point to remember with respect to these state laws is as I discussed with respect to the laws affecting insurance is that they also contain different definitions of what constitutes genetic information. Again, most of these laws include genetic tests and will not include family medical history.

So the bottom line is that different laws provide different scopes of coverage and protection and allow for different enforcement methods. So we could have 20 state laws and 20 different ways of enforcing 20 different levels of protection and 20 different ways of enforcing the law.

I'm going to move into the area of genetic discrimination and employment. I'll repeat my earlier caveat that I'm merely the presenter and not speaking as if I could, officially as an employee of the Equal Employment Opportunity Commission.

The report notes that as of August of 2004, 32 states have enacted laws restricting the use of genetic information in the workplace, and that nine states were considering such legislation. Most of these state laws establish greater protection for genetic information than for medical information generally. But again, as I have said now a couple of times, while these statutes do offer some protections in the workplace, there remains the problem that they again have very widely differing scopes of protection and definitions. Many of these laws also do not encompass family medical history within the definition of genetic information.

As the report notes, and as we've heard earlier, there is no specific one federal law that directly prohibits or protects against genetic discrimination and employment. The main federal law that addresses issues relating to genetic discrimination is the Americans With Disabilities Act, specifically Title I of that act.

This slide sets forth the basic coverage of the statute, the three prongs of coverage. Prong one covers a person who has an actual disability, someone who is substantially limited in major life activity. Prong two is somebody who has a record of a disability. Prong three is an individual who is regarded as disabled.

Now, the report notes, and the slide notes, that the Commission, the EEOC, has interpreted the ADA as protecting against genetic discrimination. In this regard, the report cites to a 1995 EEOC compliance manual chapter in which the Commission elaborated on the definition of the term "disability."

In the compliance manual, we included an example regarded as discrimination that include the following facts. An individual applied for and was conditionally offered a job, and was then given a medical examination, at which time a genetic profile revealed an increased susceptibility to colon cancer.

The individual currently was asymptomatic. The employer, seeing this medical report, then withdrew the job offer based on concerns about productivity, insurance costs, and attendance. The compliance manual notes that this would be considered a violation under the ADA under the "regarded as" prong of the statute. In the Commission's view, the employer was regarding this person as disabled.

The report also notes that the Commission settled its first case addressing genetic discrimination in 2002. This is in reference to a case that started in 2001 involving the Burlington Northern Railroad. I'm going to assume that most of you are aware of this case, and not discuss it here in any detail. Suffice it to say that it involved an employer secretly testing employees to determine whether they had a genetic predisposition to carpal tunnel syndrome.

As it turned out, the test that the employer was using only determined whether an individual had a rare genetic condition affecting 1 in 20,000 to 50,000 persons called hereditary neuropathy with liability to pressure palsy, HNPP. Apparently, carpal tunnel syndrome and one form of HNPP share certain characteristics.

It was the Commission's position that this test was not job related or consistent with business necessity, the standard that is required to be used when conducting a medical exam of a current employee. As the slide notes, the EEOC and Burlington Northern eventually settled this case, so no court was required to look at, or to address the Commission's view with regard to the ADA's coverage.

Limitations. This slide discusses some of the limitations. Specifically it notes that the scope of the ADA has been narrowed since 1995, and particularly beginning in 1999 with respect to how the term "disability" has been defined.

In particular, the report notes three cases, one decided in '99, and one case decided in 2002 in which the court said that courts need to pay very special or careful attention to the person at the moment an employer makes an employment decision. Specifically it noted that the ADA uses the present tense to determine whether an individual is impaired, and if so, whether that person's impairment rises to the level of a substantial limit on a major life activity.

The key is that the language defining disability should be read as requiring that a person presently, not potentially or hypothetically, be substantially limited in order to demonstrate a disability.

The report suggests that the upshot of these cases makes it unlikely that the Supreme Court would find that a mere genetic predisposition to disease or disorder would constitute a disability. A person who was asymptomatic would be unable to establish disability under prong one actual or prong two record, and in fact it might be hard for the person to further establish a prong three violation of regarded as.

As an employer would certainly argue, that they were taking actions against a non-disabled individual who might develop a future impairment, but they had no misconception with regard to his current status.

Other limitations. The ADA does not prevent an employer from gaining access to your genetic information. Specifically, and in this context, an employer is permitted when in the hiring process to get information. Once an employer makes a conditional offer of employment to an individual, the employer is permitted to conduct a medical examination of that employee. There is no limit at that point on the information the employer is allowed to obtain. No limit. So if an employer wants to spend lots of money, he can get every genetic test available.

There is a limit presently with respect to what an employer can do with that information. Under the statute, an employer is limited with respect to making employment decisions based on medical information conducted in the post-offer phase of employment. But I will note this. Again, that where an employer withdraws a job offer to somebody who is asymptomatic based on the genetic predisposition, it is at least questionable, according to the report, whether the individual would be able to argue that he or she, or whether the employer considered that person, regarded that person as disabled when withdrawing the offer based on fear of future impairment.

As for current employees, the standard that exists to conduct a medical exam is that the exam has to be job-related and consistent with business necessity. Although it may be less likely that an employer would be able to meet this standard with respect to ordering a genetic test, it is not outside the realm of the possible. For example, during discussions that led to the adoption of the federal executive order for federal workers, some agencies argued that they should be allowed to conduct a genetic test of current employees if they plan to assign an employee to a remote location.

For example, to do a BRCA1 test, even of an asymptomatic employee before assigning her to a place where it would be hard for her to get medical care. This situation could arise in a situation where in the post employment scenario, an employer gets genetic information and then based on that genetic information before it assigns somebody else where the employer could argue that it wanted to do a follow up exam. It might be hard to argue that that would be not job related.

The report addresses some of the more traditional defenses that are available to employers in ADA cases which are reflected on this slide. The report also notes that the EEOC has expressed support for legislation addressing genetic discrimination. Even though the Commission has and continues to argue that the ADA offers protections against genetic discrimination, Cari Dominguez, who sends her regrets and is unable to be here today, testified before the Senate HELP Committee in 2002, noting that the application of the ADA to genetic information is less than clear. Because it is less than clear, both individuals and employers need understandable rules so that they can be guided in the future with respect to how they handle and use such information.

The report looks at Title VII of the Civil Rights Act of '64 which prohibits discrimination as noted on the slide. The report notes that if an employer discriminates on the basis of a genetic condition that affects a discreet, protected group. Here, for example, people of Eastern European Jewish Ethnic background. This use of genetic information would violate Title VII.

Similarly, the report notes that if the employer were to selected a specific protected group for genetic testing, say women only for BRCA testing, this would also violate Title VII. Title VII doesn't bar use of genetic information or testing. It just prohibits treating discreet groups differently with respect to that testing.

This slide on constitutional protection references a case that is discussed in your materials called Bledsoe v. the Lawrence Berkeley Lab. It's on page 20. In that case, they talked about federal constitutional protections. Again, you should note that federal constitutional protections are limited, in that it only applies to governmental action, and that there is a weighing that goes on between individual rights against the public health or other interests of the government in taking action. So it is quite limited.

Protection for federal employees, I referenced earlier. Executive Order 13145. It applies to federal sector workers. But enforcement of the Executive Order requires use of the Rehabilitation Act, in that there is no remedy for a violation of the Executive Order itself. So unless the conduct also is deemed to violate the Rehabilitation Act, the protections included in the Executive Order are not enforceable in a court.

In the report's conclusions, the report notes that there is no one federal law addressing access to and use of genetic information, that the laws that are out there that may be used have significant weaknesses and gaps in their coverage. In the absence of a federal law, we may enter a period of litigation using these different and divergent federal and state laws, thus spending a lot of money and a lot of time trying to figure out what kinds of protections these laws offer, and at the end of the day finding out that for all these costs and all this time, that there is little that protects against the use or abuse of genetic information.

I believe that after the next presentation there will be an opportunity for public comment, or for committee comment and discussion of the report.

Thank you.

DR. TUCKSON: Thank you very much for a very excellent presentation, and for a significant body of very great work.