FTS-NHGRI

Moderator: Sarah Harding
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Alan Guttmacher: Hello everyone, good afternoon or, I guess, for those of you farther out West good morning. I'm Alan Guttmacher, the Deputy Director of the National Human Genome Research Institute at the NIH, and I'm the moderator for today's Webinar.

On behalf of the (NHGRI) I'm extremely pleased to welcome you to the very first in what will be a series of Webinars about genome research and its application to health and to healthcare.

That we're kicking off the Webinar series now, and that its first subject is the Genetic Information Nondiscrimination Act, or GINA, is no accident. This is a historic piece of legislation that, as many of you know, took 13 years to fully gestate but was finally passed by both houses of the Congress and signed into law by the President -- and if the systems are working correctly you should be able to see that signing on your screens now -- on May the 21st of this year.

We could really think of no better subject to launch the NHR Webinar series with. We're going to hear today from two speakers who are not only experts

on GINA itself but, in fact, were intimately involved in its consideration and its eventual passage into law.

We'll hear first from M.K. Holohan, who's a Health Policy Analyst here at NHGRI, and then from Sharon Terry, who is the President and CEO of the Genetic Alliance.

Before we get started though, a few other logistical notes: if you have any technical problems at all - as you heard before, for instance, they were having trouble accessing the Web portion of the call, dial star zero and you can get the operator.

The format for the Webinar is that M.K. and Sharon will give brief presentations to start us off and then we're going to spend most of our time asking each other questions and answering to them.

We're going to take your questions over the Web. If you look on your computer screens you should be able to see a question box and submit the questions there.

You should feel free to submit questions during the presentation portion of the call. You don't need to wait until M.K. and Sharon are finished to start asking us questions. We'll keep track of the questions on this end and answer as many as we can after the opening presentation.

By the way, if you should get a message that says, "Message dismissed," don't be discouraged. That only means that we're keeping things organized on our end and we've moved the question out of the queue. We haven't actually dismissed it at all.

If you're having any difficulties submitting the question via the Web you can always email to Sarah Harding, on our staff here at NHGRI, who is really the person we have to thank for organizing this. And her email address is sharding@mail.nih.gov.

As you heard before, these are being recorded. Part of the reason why we're going to be recording this is that we hope to post the call online so that others can benefit from the conversation later.

Finally, before we get started, any of you who have any BlackBerries or cell phones near the phone if you could move them away we'd appreciate it since that can cause interference over the network.

And without any further ado, then on to our first speaker, M.K. Holohan.

M.K. Holohan: Thank you, Alan. Well thank you everyone for joining today. So we've all been talking about GINA for a number of years and the question now is, "What does it mean?"

So the Genetic Nondiscrimination Act is a piece of federal legislation which addresses employer and health insurer use of genetic information. And it regulates that use. So as Alan mentioned, this has been a 13 year effort.

Many of the states, I should comment now, have specific laws that are similar to GINA. Many fall far short of the protections that GINA provides. A few are - actually go further than the protections GINA provides and (unintelligible) I just want to make sure everyone's clear that those state laws remain in effect. The stronger state laws will - those protections will still remain in effect. GINA is - does not preempt those state laws.

So what does GINA does is provide a federal baseline that everyone in the United States is protected by. If you happen to live in a state that has stronger protections you still enjoy those stronger protections.

So why was this such a contentious process and why did it take so very long? There was really entrenched opposition by employer groups and, to a lesser extent, although that sort of varied over the years, from the insurance industry.

It sort of was perceived as more opportunities for lawsuits, as an unnecessary protection. There are really no instances of state laws, the state protection laws, being utilized for instances of discrimination. So those who opposed GINA pointed to that and said, “This is a remedy in search of a problem.”

That is certainly not the experiences that we heard relayed to us. It’s simply the process of the way laws are reported from the states. You really don’t know what incidents may have never made it to court, what things may have been settled at the trial court level.

If you don’t have appellate decisions it’s really difficult to track the impact of a state law. And also, many of these laws we knew were untested. So how the courts would treat the state laws was still very much an open question.

So GINA - this - in the 110th Congress GINA actually passed the House of Representatives on DNA day last year, April 25 by a vote of 420 to 3. And there was much celebration and we really thought we were looking for a fairly swift Senate passage.

But that was not to be the case. GINA was blocked in the Senate by - for almost a full year. And then it - there was a series of revisions. It was finally passed by the House on May 1 of 2008.

And you may wonder why it took a full year to - for GINA to get through the Senate. The Senate has a very different set of rules than the House does and a single Senator has the ability to (effectively) put a hold on a bill. Essentially this is a threat of a filibuster and it can create a real obstacle to moving a bill forward.

That all being said there was some negotiations that were ultimately successful and GINA finally passed the Senate, then passed the House again because it was a different version than passed April of ’07. It had to go back to the House. And then, as Alan pointed out, it was signed by the President on May 21.

So what does this law actually do? GINA will prevent health care insurers and employers from discriminating based on an individual’s genetic information.

And it is really our hope that this will allow Americans to take advantage of the benefits of genetic testing without being afraid that they’re going to subject themselves to risks of losing their health insurance, or their children or their other family members will, you know, be at risk of losing insurance, or that this will affect them in their employment: getting a job, keeping a job, being promoted.

So what GINA does specifically is prohibit health insurers from requesting or requiring genetic information of an individual, of their family members, or of using it for any decisions regarding coverage, rates, pre-existing conditions. They simple can’t use it for underwriting whatsoever.

It’s very important that the definition has been crafted in a way that is broad enough that this includes not only genetic test results but includes genetic

services; participation in a clinical research trial. And it also protects family history which is obviously, you know, a very important genetic indicator.

So, some of the core protections are for tests such as those that reveal a risk of a future disease like BRCA1 and 2 variant testing, testing for gene variances associated with Alzheimer's disease, for colon cancer, for Huntington's.

As I mentioned, it protects family history; would protect tests based on DNA or RNA based pharmacogenomics. Any test that measures human DNA or RNA, those are protected by GINA.

So as I mentioned, the genetic information is a pretty broad definition. It includes family history which is incredibly important. Many of the state definitions do not include family history.

And this was, really, I think a significant conceptual battle because health insurance companies' individual policies, which allow underwriting based on a specific application, specific health information, they always look to family history. It's a very important indicator for them and this is not something that - after GINA takes effect it's not going to be allowed to be used.

"For genetic services" means a genetic test, genetic counseling; genetic education. And this includes participating in any sort of research study that has genetic services of course.

What GINA does not cover: GINA is about the information, the genetic information. It is not about a genetic disease. So GINA would protect and preclude use of information about, for example, a woman who has BRCA 1 or 2 variant pre-disposing her to breast cancer. It would protect that information.

It does not protect a woman with breast cancer because that is manifest disease. That information can be used for underwriting purposes.

It does not protect the use of any genetic information in regard to life insurance, long-term care insurance, or disability insurance. It only protects relation to health insurance.

GINA also does not cover members of the military. It's something that sort of is conceptually difficult to accept. The military is an entirely different employment and health insurance system and GINA does not and cannot reach that.

So other limitations that are important to understand about GINA: because GINA uses definitions that are - it references other statutes, other employment statutes, it does not cover very small employers. So the definition of employer only relates to employers of 15 or more employees.

So for very small companies the protections of GINA do not extend. There is some argument as to whether smaller companies would still want to at least be aware of compliance with GINA and hopefully strive to not use information in this way but that's an open question.

And these are also companies who may be most at risk of, you know, increasing health care costs, health insurance costs. So there is a vulnerability there.

Also it's going to be difficult to prove violations of GINA, particularly in the employment context. So we are hopeful that we will get strong regulation which really will be critical to GINA having the impact that it's hoped for.

So what happens now? GINA was signed into law, as we said, May 21 so the agencies who are drafting regulations have 12 months to complete those regulations.

The insurance protections, which are Title I of GINA, go into effect May of 2009. The employment protections, which are Title II of GINA, those go into effect six months later in November of 2009.

So research implications: this is a question we've gotten from several different areas. You know, what does this mean about informed consent process for genetic research?

Many informed consents that - relating to studies that collect genetic information have one or two sentences that describe possible uses or abuses of genetic information.

At this point there's really nothing that can be communicated or should be communicated in the research context until the law takes effect which hasn't happened yet. Until the regulations are final it's not clear what the message should be.

The challenge at this point is to fairly describe the important protections that will be afforded by GINA but not to over spell in terms of: yes, someone will be protected and will have a remedy if there's a health insurance violation and misuse of this information. But that doesn't mean that if they apply for long-term care or disability insurance down the road that this information couldn't be used in that context.

So the primary concerns, really, have been about health insurance because I think for most people that seems to be a much more immediate concern. But

GINA does not address any other type of insurance product and that's important to understand.

So until the regulations are finalized the really - the true significance of GINA in terms of what we can communicate to patients and what we can communicate to research subjects will remain unclear.

So I just wanted to end with a little bit of information about the rule making process. So when we talk about regulations being issued, that's essentially - you can think of the law as, sort of, the skeleton and the regulations are, sort of, the flesh. It explains how a law will be implemented, and what it really means, and where someone would turn if they have - they think there's a violation of the law; what's the process.

So federal rule making is the next part. Congress passes a law that's designed to address some sort of social or economic need or problem, like the risk of genetic information - of the genetic information being used to discriminate. They pass a law like GINA.

Specific agencies that have jurisdiction over areas relevant to this bill have to study it. They have to look at, sort of, the existing system and come up with regulations necessary to implement the law. And there has to be a period of public comment. So - and this is all laid out in a variety of formats and a federal law called the Administration and Procedures Act.

So regulations are - they're not the law itself but they have the force of law. And it's very, very important that these are done thoughtfully and with appropriate input.

So for GINA there's a few agencies drafting regulations. There's the Department of Health and Human Services, Office of Civil Rights. There's the Department of Labor, and there's the Equal Opportunity Employment Commission, the EEOC.

So some of the critical issues for the regs to consider are: what is genetic information? What are the definitions? What kind of examples are we going to use? What is manifest disease? When does a genetic condition with signs and symptoms but no clinical illness equate to manifest disease?

And so some of these don't have perfectly simple answers but they're important that we get them right. So for the public comment period there'll be a notice published in the federal register that will solicit comments.

We anticipate public comments to come from a variety of parties; from insurers and employers, certainly, possibly from pharmaceutical companies, from genetic testing companies, from privacy advocates, and from disease groups.

For GINA this process will be controversial as the whole process of getting the law passed was. And in this case there's also a complication because we're looking at a presidential election in November.

So the timeline involved is very likely to be that the career staffs who are making recommendations to the leadership of the agencies, who are working on these regs, will actually be submitting the final drafts to a new administration. So that just complicates things a little bit from their perspective.

So finally I'd just like to urge people who work in genetics and genetic testing, and work with patients and work in advocacy, to get involved. And it's very important to pay attention when the drafting of regs are released and to contribute comments in whatever way - whatever area your expertise is in and whatever the concerns are because it's really to the benefit of all of us to have really vigorous and broad public comments on GINA.

Thanks very much and I'll turn it over to Sharon Terry now.

Sharon Terry: Thanks very much, M.K., for giving us this great overview of where GINA stands. I thought I'd just say a word or two about the process. Not so much in the, kind of, history that M.K. just gave us but instead in terms of looking at how many groups were involved to get us this far and to go to M.K.'s last point that we really do want broad input as we go forward.

So I think as many of you know, from very different points of view since this audience is quite diverse, we have seen genetic discrimination in many forms and many ways.

And certainly the fear of discrimination has been overwhelming, especially in the realm of clinical trials and the research enterprise but also for a person. And so during the process of bringing this bill forward over these 13 years there's been a very good and active engagement from a very broad stakeholder community.

So certainly the Coalition for Genetic Fairness, with which many of you are familiar and in fact many of you are members, was very active in working with the organization's that M.K. mentioned: the Chamber of Commerce, the National Association of Manufacturers and then, more specifically, the various committees in the House that had difficulty with this bill.

And as our champions in the Congress are fond of saying, all of this work together created a better bill that was certainly more clear about many of these very controversial issues that M.K. pointed out at the end of her talk.

I think really significant for this process is that each of the stakeholder groups, be they providers, researchers, actual patients, patient groups, policy makers, has a stake in this endeavor.

And while it is thrilling and wonderful that we've come to a point where we can say the law has passed, the time that we're looking forward to ahead of us is important in a sense of both making sure that the regs are right as well making sure the community is educated.

And while the reg writing will happen with the groups - agencies that are federal that M.K. posted there, really what an important thing for all of us on the phone to understand is that our input is important.

And while, again, most of us will not be in those meetings and, sort of, dickering over the various points like: what's the definition of genetic information?" Or, exactly how far should a reg be pushed in order to afford the right protection? All of us in our various positions will have a say in it through the kind of active engagement that we've had with these agencies overall.

And so whether it's HHS, or whether it's EEOC or another agency, they certainly want to hear what you have to say and the practical questions that you're facing.

And I think the important thing going forward is what implication does this have on both the regular practice of medicine, as genetics gets integrated, as well as the broader issues around clinical trials and that sort of thing.

So what I think we will be looking for - so the Coalition for Genetic Fairness as well as, I'm sure, NHGRI will be looking for is input from stakeholders to say, "Here's the rub. Here's the things we're coming up with."

And we've certainly begun to get a lot of those questions. I know NHGRI's Web site offers you some answers to those kinds of questions. Genetics and Public Policy Center has a nice section in the Coalition Web site as well on so what does it mean practically?

And as M.K. said, we don't know what it means practically until the regs are written. We know what it means generally and our engagement as we go forward to understand exactly what this is going to mean. It's going to be important.

And meanwhile I think the stakeholder community communicating with one another through this process is going to be really important. And we look forward to, sort of, that continued discussion and continued refinement of what this will mean for those people that we know either haven't been tested, or have been tested anonymously, or have not entered into clinical trials because of their fear.

And I think I'll stop there because I think the most important thing for those of us who have looked at this Webinar is (hearing) the discussion and the questions that you have.

Alan Guttmacher: Indeed, Sharon. Thank you very much for that and thank you M.K. as well. Just to remind folks, while we do have some questions already queued up, and I'll start in on those in just a minute, if you have other questions you want to submit go ahead and put them in the question box on your screen. Or if you're having problems with that remember you can email them to sharding@mail.nih.gov.

Because we probably won't be able to get to all the individual questions -- we have a couple hundred people on the line today -- we are going to group similar questions as much as we can and get to as many as time allows. So let's get started.

And this question I'll throw out to both of our speakers, "What were the changes that were made to the bill that allowed for Senate passage finally?"

M.K. Holohan: Sharon, do you want me to take that?

Sharon Terry: Sure.

M.K. Holohan: Well, the answer is it depends who you talk to. There were nuanced changes that really did not lessen the protections that were contained in the bill that passed the House.

There were some clarifications of language that made things a little bit more clear from the insurer perspective. For example: insurers are not allowed to request or require genetic tests.

However, if someone who has, for example, a BRCA variant wants to have prophylactic surgery to lessen their risk of developing breast cancer the

insurance company is allowed in that case to require the genetic test result for a coverage decision.

And so that was always the intent. It was never - the language of the earlier bill was never intended to preclude insurers from making reasonable requirements of medically necessary -- and coverage -- determinations.

But that was something specific that they wanted made very clear for their purposes. So I think the consensus was that was a reasonable thing to do and so that language was changed.

There was some clarification about under what circumstances manifest disease could be considered in a - manifest disease is for one person it is legitimate or it's open game. GINA doesn't preclude it from being used for underwriting.

However, if the manifest disease is of a family member who might be also an insured with the same company, possible on the same policy, that complicates things. Its one person's genetic information is another person's manifest disease information. One is fair game, one is not. So there was some language added to clarify that as well.

And then from the employer perspective a real sticking point for some time was this concept described as a firewall which would keep - in a nutshell would keep employers - limit employers' liability to only employer violations as opposed to insurance violations that - there are many employers are self insured so they wear both hats. They're health plan administrators as well as employers.

And so there was some, kind of, nuanced language agreed upon, albeit the eleventh hour, that gave some sense of comfort to people on both sides that - to limit the liability to instances of abuses of information and that tried to clarify situations where, you know, employers who are also health plan administrators could sort of delineate which hat they were wearing and which title they would be liable under.

Alan Guttmacher: Good, thank you. Sharon, anything you wanted to add to that?

Sharon Terry: No, I think that's fine.

Alan Guttmacher: Okay good. So Sharon this one I'll throw at you. And that is, "Is there any interest in Congress or in other communities in addressing discrimination based on genetic information and life insurance, disability, or long-term care insurance?"

Sharon Terry: The answer to that is yes. And we saw, even during the hearings for GINA, in various committees on the Hill, various members of Congress get quite excited by, for example, long-term care insurance which a lot - lot's of Americans are going to be facing.

And so they're - Anna Eshoo from California has said she will take up that issue. And certainly the Coalition for Genetic Fairness has not left those issues to the side. Neither has Genetic Alliance.

And we're just looking at how practical is it to consider those apart from healthcare reform generally and whether or not some integrated approach might be better.

Alan Guttmacher: And I might just add a number of people are particularly interested in this for a couple of reasons. One is that it is very rare that any states have laws having to do with genetic information and life insurance, disability, or long-term care insurance. Only a couple of states have approached that so there's no even floor there.

And also, of course, the nature of genetic information that's predictive is less likely, in fact, to be used against an (individuant) health insurance since most health insurers assume that they'll only be insuring a given individual for a few years. That is since our health insurance is employee - employer based, largely, in the United States.

Health insurers assume that any individual covered life will go to some other insurance company within a few years either because the individual changed jobs or the health insurer will stop covering that specific employer whereas, of course, life, long-term care, and disability insurers care very much about more predictive information.

They don't - health insurance tends to have a very short time horizon. Life, long-term care and disability insurers often care very much about: will somebody be well for ten years? Will they be well for 17 years? And that's where they really do their underwriting, etcetera. So that's a good question and will be a lively issue to keep attention to.

Okay and this one for M.K., "How would people know that an insurance company denied them on the basis of what GINA does cover? Wouldn't the insurance company try to hide that fact?"

M.K. Holohan: Well, I don't think they're going to be very honest about the reasons. So that is an inherent problem in any sort of legislation that would address something

like this because insurance companies are not, you know, they're not required to explain to you -- and you can't prove -- what the underwriting process was; what the decisions were based on.

I think the general thought on this is that an individual who has genetic information that may predispose them to a disease, they're going to be aware of it. They're going to be somewhat more hyper-vigilant about a process like applying for individual insurance and an underwriting process.

So if they suspect that they've been denied or if they've been, you know, rated at some incredibly high level of premiums, or the terms are somehow really not comparable to what they would have expected, or what other companies might have offered, I think the expectation is that those people would complain.

It's going to be made very clear in the regs where they complain to. Do they go to HHS? Do they go to the state regulator? Is there a dual notification system where they would trigger some sort of evaluation of what the process was?

And in that case if the insurer couldn't point to something specific other than genetic information, which remember they're not supposed to possess - so first of all they need to have access to it. They need to have, I guess, gleaned it from a medical record or in some way gotten access to it and are - for example, family history might be in a medical record. They may request medical records.

Then there's going to be some review process. I assume that they'll probably have, like, a preliminary Q&A between a regulatory agency and an insurance

company if there is a suspected case of discrimination based on genetic information.

Alan Guttmacher: Very good, thanks. In answer to a question that several people have asked about accessing more information that the Webinar is based on, etcetera: for those of you who don't know it, there is an NHGRI Web page about the Webinar series that includes, for instance, the full text of HR493, some other articles about GINA, etcetera, an overview of the law's timeline, etcetera.

And you can get that either by going to - probably the best thing to do is to type into your search engine NHGRI Webinar and you'll come up with the page. But for those of you who are more obsessive than that it would be www.genome.gov/27527023.

Okay so here's a question, and I'll throw it out to either one of our speakers, "Would you recommend waiting until the regs are passed before getting genetic testing?"

Sharon Terry: (Well), I'll give the people answer and then M.K. can put - give a lawyer answer.

I think that one has to consider a number of things. And the example I gave the other day to someone, in fact, is, you know, a 68 year-old mother is diagnosed with breast cancer and is BRCA 1 positive.

Her 45 year-old daughter and 43 year-old daughter, whatever, might consider testing sooner than waiting the either 12 or 18 months before the law actually takes effect because of health concerns.

If somebody is much younger and has some time, perhaps, or has a condition for which there are either no treatment or less serious considerations then one might want to wait (until) one does have the protections afforded by this law.

M.K. Holohan: Yes, I agree with Sharon. I think the individual situation is what would make that determination. And, in particular, what the individual's insurance information is.

If someone is covered under a group health plan, and they're contemplating getting a genetic test for whatever, I think that, you know, if they feel they have a real health concern I would go ahead and get the test.

In terms of our concerns about the lack of protection for life, long-term care and disability insurance, I can just say that although we do see - we've just actually recently seen some data about individuals getting tested for genetic variance related to Alzheimer's disease and that, understandably, one consequence of learning that information is seeking out long-term care insurance. And I'm sure the long-term care insurance companies are paying attention to this fact.

It is my understanding that currently none of the application procedures for those insurance products or for the individual insurance market require genetic information - I mean genetic testing.

Many of them ask questions about family history. Typically not specifically about genetic diseases but, as I'm sure most of you know, really all diseases have some genetic component. Whether it's established at this point or not is a different matter.

But I think that if someone feels they have a pressing need for health information based on a genetic test they should proceed. And if you're undercovered - covered under a group health insurance plan your risk is very minimal.

Sharon Terry: I would just add as well that it is also probable -- and this is completely speculation on my part -- that, in fact, because we now have a heightened sensitivity around these issues, that employers and insurers will not be trying to tread in this area and there will be less potential for discrimination. Although that, again, that would be just speculative.

Alan Guttmacher: Okay now we have a series of questions that are about, maybe, sort of technical aspects along terms of, "What does this really mean; etcetera, etcetera?" So, maybe, M.K. you'll take the lead on these but, Sharon, you may want to play in.

The first is, "You mentioned that GINA does not cover members of the military. Does that limitation also extend to family members who are covered under the military policy; that is, the dependents of the military person?"

M.K. Holohan: As far as I understand, no. That does not extend to dependents who are getting care through their active duty family member. It is strictly about the service member.

Alan Guttmacher: Is that one of those things that the regs might define further?

M.K. Holohan: You know, I actually - I'm not sure. I doubt it because there is no trigger for that and because the employment agencies, Department of Labor and EEOC who are going to be drafting these regs, you know, their jurisdiction does not

extend to the military either. So I don't think they're going to be addressing that.

I think you should look, actually, for some work. I know that Genetics and Public Policy center has been actively engaged in this area for some time. And I think we'll be seeing some more exploration of these issues from that center. But I wouldn't expect that to be resolved in the regs. It's simply not implicated by the language of GINA.

Alan Guttmacher: Right. And here's a question: "Where's the enforcement mechanisms in GINA?

M.K. Holohan: So the specifics will be defined in the regs. The enforcement mechanisms in terms of the remedies available under Title I - really the remedies are equitable relief, which essentially means that if they were denied coverage wrongfully based on the law, you know, based on GINA then you would be covered. If your premiums were inflated, based on genetic information in violation of GINA, then your premiums would be adjusted to an appropriate level.

There's not punitive damages available under Title I however, in Title II there actually are damages for an employer who acts illegally in using genetic information in terms of hiring, firing, promotion, et cetera. There are monetary penalties which follow the - a typical structure from other employment statutes.

It's consistent with other employment statutes that are determined on the size of the employer. So the largest sized employer, I think, can be $300,000 or $350,000 for employers of, I think, 500 or more. So there are actual monetary remedies.

But even though for the health insurance context you don't have the same type of remedy, health insurers are not going to want the bad publicity that will come from being identified as intentionally violating people's civil rights under GINA by using their genetic information to screen them out, to drop them from insurance, to raise their rates. So there's sort of a more powerful disincentive than that simple equitable relief may suggest.

Alan Guttmacher: All right. Thank you. A couple of questions about: to what degree is the law retroactive? That is, for instance, someone asks, "Is there a timeframe as to when the law takes effect on an individual basis? For example, BRCA results from someone who had testing in 2006, are they covered? Or is it only if the testing is done after the law goes into effect that they're covered?"

M.K. Holohan: So the law does not provide for retroactive applications and I don't think there's actually any language that addresses timing of the test. The standard, sort of, legal interpretation would be: it would be timing of the illegal act; the timing of the violation under GINA.

So it really wouldn't matter when you obtained the genetic information. What would matter is: when was the illegal action by the insurer or the employer? And it wouldn't actually be an illegal action if it occurred prior to the law taking effect which, as I mentioned, was May '09 for the health insurance and November '09 for the employment protections. So that would be, really, the start.

Alan Guttmacher: Right. So just underline that. Even if this information was somehow known to the insurance company prior to May of 2009, let us say, but they took no act upon it, but then in 2010 did something which was discriminating and based on that information, even though they had prior access to that information

which was legal, they're now use of that information in a way that is illegal would subject them to the law.

M.K. Holohan: Right, right; exactly. I mean, they can't be held liable for something that wasn't illegal when they, you know, obtained that information and filed it away. It's their actions after the law takes effect that they would be liable for.

Alan Guttmacher: Another, sort of, technical question: what are the - can you go over again the differences in coverage of the law between group health and individual insurance policies?

M.K. Holohan: Okay so GINA relates to all health insurance policies; all types of health insurance policies. But in actuality its major effect will be to protect people who are covered under individual health insurance policies.

That's because HIPAA, which went into effect in the 90s, already protected these type of actions of underwriting and pre-exing (sic) conditions and, you know, excluding people based on several types of information one of which is genetic information.

So for those of us who were under group health insurance plans we already had some measure of protection against discrimination based on our genetic information under HIPAA. But HIPAA did not and does not cover individual insurance plans. So this was really a very important gap to be filled.

And GINA also amends HIPAA to sort of broaden and clarify some of the protections to make those consistent with what will be available for people in the individual health insurance market who weren't covered at all.

Alan Guttmacher: Thanks. And now a question for, maybe, both of you about - several questions that have to do with this idea of the rule making process. And folks are asking, first of all, during the public comment period of the rule making process, will there be any particular efforts for - to create strategies for getting a broader representation of the general public involved in the discussion beyond the stakeholders?

And then perhaps related to that, there's a question whether genetics professionals will be involved in any way in the rule writing process?

Sharon Terry: So I certainly can answer the first part and comment on the second part and comment on the second part. And yes, we will still play a very active role as we did throughout the crafting of the bill itself.

So the Coalition for Genetic Fairness which, again, is a now 500 organizations - and they span the whole spectrum of health care providers. And that includes genetic specialists as well as the more general practitioner groups and the medical specialties, the research community, the stakeholder community in terms of the various disease organizations, and then individuals within those organizations; hospitals, universities, etcetera.

So we will undertake a process whereby when the public comment period opens we'll be both doing webinars, putting things on our Web site, etcetera, to help prepare people to make comments as well as sharing our comments so that if people want to sign onto those that can happen.

And then the comment I'd make on whether or not genetic specialists will be involved: I believe they are already involved because HHS itself, of course, has some of those specialists in the various agencies under HHS and they have

been involved in definitions and in the kind of finer points of the actual genetics.

And then certainly the American Society of Human Genetics, American College of Medical Genetics, the National Society of Genetic Counselors, all have been very active in the Coalition and in the various discussions that have happened so far. And they will continue to be so.

M.K. Holohan: Yes, I would agree with all of that. And certainly we at NHGRI are - have been and continue to be available to our sister agencies and their work here. And our own department is working on these and we're in close contact with them. We are providing technical information wherever and whenever appropriate.

And in terms of the solicitations that will go out for public comment, those are open to any party. So they sort of organize that so that the Coalition, you know, that Sharon will be working on, is really fantastic because these are going to be, you know, kind of involved and lengthy documents.

To have people who are very familiar with some of the underlying issues helping to understand what the main points are, that need comment, are very helpful but anyone separate from those organized groups can make their own comments. And I think that's actually a really important part of the rule making process and one that shouldn't be overlooked.

Alan Guttmacher: Thanks. Now a couple of questions that get at the same kind of essential issue and that is, "Once GINA becomes fully effective will it be permissible for employers to use genetic information in the workplace to protect workers from exposure to agents that might result in work related illness?"

M.K. Holohan: So, again, the absolute specifics will be clarified in the regs. From what I understand from my colleagues at the EEOC, the only circumstances under which an employer can require genetic testing from an individual is in the framework of there's a necessity that we know this information because you'll be at risk for working in this, you know -- the example that was given was someone working in a chemical plant -- is if they give them notice they want them to test - to be tested for x or y variant related to a sensitivity, if they ask for their informed consent, if they make it clear the testing is voluntary, and only if the employee agrees to be tested can an employer do the testing.

So they're not able to require it as a term of employment. And I expect that this will receive a very intricate regulation, and a very specific regulation, with examples of what, perhaps, was permitted in the past that will no longer be permitted regardless of the circumstances.

Alan Guttmacher: Good. Thanks. Here's one about, again, the sort of technical aspects. "What will the penalties be for violation of GINA?"

M.K. Holohan: So they're different for Title I and Title II. There are monetary penalties and there are equitable relief, which are really remedies for the person aggrieved.

For insurance it would be what's called equitable relief which would be restoring coverage if it was denied, adjusting rates to the appropriate level if they were inflated based on this information.

There's also penalties for the administrators of the health care plans for intentional violations of GINA. And for employers there's monetary penalties.

And one thing that really can't be underestimated here is that if a pattern or a specific intentional violations of GINA are brought to light the actual

publicity of that is going to be something insurers are not going to want to be tainted with and certainly employers wouldn't either.

But the regs are going to spell out very specifically what the remedies/penalties are for both Title I and Title II.

Alan Guttmacher: Okay thanks. "Are there states that currently have on their books regulations or laws about genetic discrimination that are stronger than GINA's?"

M.K. Holohan: Yes. And those will remain intact. GINA provides a baseline protection. It does not preempt states that go further than GINA does. For example, there are some, very few, but some states that include protection for life insurance, long-term care and disability. GINA does not.

Alan Guttmacher: Very good. Thanks. "What about GINA's affect on Medicaid and Medicare coverage? Will it have any?

M.K. Holohan: Not to my knowledge. But I think the HHS portion of the regulations will spell that out.

Alan Guttmacher: All right.

M.K. Holohan: So in terms of coverage, GINA doesn't affect coverage of any health insurance plan. It doesn't mandate coverage for genetic tests. It doesn't mandate coverage for treatment of genetic disorders. There's not a real coverage - the only coverage issue is a person cannot be denied for health insurance policy based on their genetic information.

So I know that part of the Medigap's program is implicated by GINA but that's simply a result of where different statutes are amended to enact GINA. But that will be clarified in the HHS regs.

Alan Guttmacher: Thanks. "Will GINA have any impact on medical records release?"

M.K. Holohan: I don't think GINA will have any impact on any otherwise authorized medical records release. However, I think the specifics - I mean, I don't even actually know whether there'll be ancillary sections to regulations.

I think that's a legitimate question for someone during the comment period to pose to HHS, to ask about that. But I don't see anything in the language of GINA that would change any preexisting law.

So I think my understanding is whatever was authorized before in terms of release of medical information is unchanged by GINA.

Alan Guttmacher: Okay. "What about an individual who has some -- we hear it described as variant disease -- but something that's picked up in newborn screening but which is completely asymptomatic?" So in other words, it's a biochemical abnormality but no symptom at the time that the newborn testing is done. Technically are - would they be somehow subject to GINA, this information?"

M.K. Holohan: Well if it's - if the screening picked up a genetic variant then - and it was testing human DNA or RNA then it's genetic information so it's protected under GINA.

Now, when and if that person were to develop a manifest disease related to that genetic variant, that disease information would be fair game but the genetic information never would be fair game.

So the fact they had a disease -- if they develop a disease -- that would be something that could be used for underwriting or anything otherwise allowed by law.

But the fact of the genetic variant would be protected, you know, not only up until the time they got the disease. It would be protected thereafter as well.

Alan Guttmacher: This is where this question of manifest disease will get very interesting because one can think of various kinds of examples where the question is: "At what stage, exactly, in the process does the disease become 'manifest'?"

M.K. Holohan: And the best - it's going to be a very sticky issue and I think one that was really - of all of the things that were explored ad nauseam during the many years it took to pass GINA this was one that I think is yet to really be explored in the depths to which it's going to need to be for the regs to make sense and be useful.

Alan Guttmacher: Sharon, did you have something to add there?

Sharon Terry: I was just going to add that I recall, and I'm sure that M.K. will know the detail better than I, the issues around newborns are a little different in that newborns have no pre-existing condition even if they're born with something, obviously - well, maybe not so obviously, and that insurance companies treat the newborns and their information somewhat differently than someone who comes into a plan later on.

M.K. Holohan: Well that's a good point, actually, in terms of coverage. So the information would be, as I said, you know, as that person went through their life that genetic information would certainly be protected under GINA.

However, I think what Sharon is referring to is that fact that all 50 states have laws that prohibit an insurance company - you know, they can't deny coverage to a newborn. They can't pre - you know, impose preexisting condition restrictions on a newborn born with a genetic disorder or any other kind of disorder. So this is not - there's sort of a special legal treatment of that area.

Alan Guttmacher: Right. The question: "Do - is there any concern that insurers will raise rates based on genetic information now in order to avoid being prosecuted once the law does take full effect?"

M.K. Holohan: I think that's very unlikely. You know, if there's a - there would be a legal argument to be made after the law takes effect that the continued imposition of this higher rate, which was justified by, perhaps," It's legal to do that today," if they continue to charge that rate in May or, you know, June of 2009 after Title I of GINA takes effect that that continued imposition of that rate was a violation because the law changed.

And certainly in this case you could argue the insurer knew the law was changing - I mean, it would not look very good for that to be the strategy employed.

Alan Guttmacher: A question about the state coverage, it's not about GINA per se, but the state laws that cover genetic information: "For such state legislation does jurisdiction fall under the person's place of residence or the company's place of business?"

M.K. Holohan: Well, if a company - so I'm not an expert on this area. My general legal sense here is that if a company is doing business in your state, and you live in the state, and they're insuring people - so wherever Aetna is headquartered, if they're doing business in Maryland and insuring people in Maryland, they're subject to the laws of Maryland for those insureds.

So it doesn't make sense that it - if an insurer didn't want to do business in the state of New York because they felt their insurance laws were too restrictive they could decide to do that.

A large insurance company probably wouldn't but it would be where they were - you're supposed to be protected by the laws of the state in which you reside. So if a company is reaching into your state and doing business there I suspect they would be covered by the laws of that state.

Alan Guttmacher: That's my - at least I think it may also - could depend somewhat in the way the state law is crafted but my experience, at least in a couple of the states that I was well aware of, was very much what you described.

And since health insurances in different states governed by different state agencies, etcetera, most of them define these things. But, in fact, as long as you're offering your product in the state it comes under that law. So it really does sort of follow the residence of the individual.

M.K. Holohan: Yes.

Alan Guttmacher: Another question: probably will have to be our next-to-last one, "Does GINA cover genetic information of fetuses; that is before delivery?

M.K. Holohan: Yes, it does.

Alan Guttmacher: And is that explicit in the law or is that simply because it covers the mothers or how does that happen?

M.K. Holohan: It was actually made explicit in the law based on some concerns that Senator Coburn had during the - when it was passing the House. And language was added during the Energy and Commerce hearing to clarify - this was - and really - this was thought to be implicit in the bill that if the mother was protected that the - an embryo or fetus would be protected. The language actually extends to an embryo or a fetus.

Because GINA relates to employment or insurance information and fetuses and embryos, you know, don't have their own insurance and don't have their own jobs, it was thought to be implicit.

But the agreement was that the language would - we thought, you know, I think as an observer working with the Coalition my sense was that the advocates thought well, you know, there was - this was fine to agree to because it just clarified something we believed was already implicit and that Senator Coburn had expressed some concerns in this area, this did not ameliorate his concerns overall about the bill. But that language was added specifically for that purpose in spring of '07.

Alan Guttmacher: Thanks. Well unfortunately the hour has passed; didn't even get time to get to that one more question I'd hoped to get to. There were a number we didn't get to, unfortunately, but our time is up.

On behalf of NHGRI I'd like to thank all of you for participating in the Webinar. We certainly enjoyed hearing your questions; reading your questions.

And my thanks to the NHR staff, particularly Sarah Harding, for organizing the Webinar, and certainly to both of our expert speakers, M.K. Holohan and Sharon Terry.

We will be holding the second of these Webinars in two months on September the 11 at 1:00pm Eastern time. The title of the Webinar is “Family History: The Next Generation.” Please do join us to hear about what’s going on in the field of family history, and upcoming NIH State of the Science Meeting on Family History, and how your own organization or group might get involved in the Family History Day on Thanksgiving Day, 2008.

You’ll be receiving more information from Sarah Harding as we get closer to that date, but again feel free to join us and thanks a lot for participating in this. If you have any comments or questions about the way this worked we’d like to hear those so please mail them to Sarah Harding at sharding@mail.nih.gov.

And we look forward to talking with many of you again in two months. Bye-bye.

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