

***Congressional Efforts to Prevent Genetic Discrimination***  
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DR. McCABE: We're very pleased to have Kim Monk join us to present about the congressional efforts to prevent genetic discrimination. Kim is a senior health policy advisor for the U.S. Senate Committee on Health, Education, Labor, and Pensions, the HELP Committee. Her primary areas of responsibility for the Committee are in the private sector health benefits and insurance, ERISA, HIPAA, medical liability reform, the uninsured, genetic discrimination, medical records privacy, mental health parity, Patient's Bill of Rights, and long-term care. It appears that you're a generalist in this area.

Prior to joining the HELP Committee, Kim was senior health policy analyst with the U.S. Department of Labor's Pension and Welfare Benefits Administration, where she worked on policy and legislative analysis for the Department, Congress, and the employee benefit plan community. Kim was also manager of public policy for Washington Business Group on Health and worked for the health and welfare practice of William M. Mercer's Washington, D.C., consulting office.

Kim has a Master's degree in Health Services Management and Policy from George Washington University, and we're extremely pleased that you were willing to come and update this Committee on what's happening with the genetic discrimination legislation.

MS. MONK: Great. Thank you, and I apologize for being late. Unfortunately, that circle out there doesn't let you go all the way around the circle, so I found myself going north into traffic. How much time do I have?

DR. McCABE: You have half an hour.

MS. MONK: Well, what I'd like to do is describe for everyone the history of genetic nondiscrimination legislation as it's come through the Senate and the HELP Committee. We recently unanimously passed a bill out of the HELP Committee about three weeks ago, and we're very pleased about that, and I'd like to tell folks kind of how we got to that point and what's in the bill and where we might be going.

I've been on the Hill since 1999, but the genetic nondiscrimination bill actually predates me. I believe there were efforts made back in 1997 and bills drafted. Senator Daschle had a bill and Senator Snowe had a bill. Daschle's bill had both health and employment discrimination and the Snowe bill dealt only with health insurance, and those different approaches went on for a couple of years, and in the Senate, genetic nondiscrimination was included with Patient's Bill of Rights a couple of times and the Snowe bill was actually passed on the Senate floor three different times without the employment provision, but there were those who were repeatedly asking whether or not we didn't need to address the possibility of discrimination in the employment setting, and I used to work for Chairman Jeffords before he switched parties, and at that time, I think there was some concern and some questions about the degree to which the current statutes, like the Americans With Disabilities Act, already covered genetics issues, and so back when Jeffords was chairman, we had several hearings, began to explore the reach of the existing statutes, looking at some of the more recent case laws and interpretations, and then after Jeffords switched and Senator Kennedy became chairman, we all came together at that point, Senator Snowe, and based on the hearings and what we had learned while Jeffords was chairman, decided that there was indeed some gaps

or at least some questions about how the ADA could be interpreted or not be interpreted to include genetic discrimination.

So at that time, we went back and reworked the Snowe bill, updated some of the definitions, improved some of the provisions, redrafted the privacy provisions to reflect the comprehensive privacy regulation that had become final and come out of the Administration, and in addition, we added a whole new Title 2 which included discrimination in the employment setting which, I'll just point out for Republicans to draft a nondiscrimination bill for employment and allow employers to run the risk of being sued is a pretty big step. So it was not without risk on our side to come forward with that, but we did feel that there was a way to do it to address the gaps and a way to do it to not, if you will, open the floodgates so that you always are going to have a genetics suit every time you have any other kind of suit.

So we began down that path and while Kennedy was chairman, we got together with the Daschle-Kennedy camp and my boss was a sponsor of the Snowe bill to see if there was any way to iron out the differences in the two bills, if you will, kind of preconference them, within the Senate setting to see if we could merge them together for a single bill to bring that through the committee.

At that point, I think that the Snowe bill probably had the votes to pass but we did not control the committee agenda, and I think there was a strong desire on Senator Snowe's part and others to see if we could work out the differences and have a single bill because at the end of the day, even if you can get the votes in the committee or on the floor, what have you, those things most likely to become law are those that are bipartisan agreements and that everybody's on board. So the end game, I think, from Day 1 was always to draft a bill that could become law, that would be signed, and back when President Bush came out and made a very strong statement about supporting legislation, I think it was probably like June two years ago that was a really strong sign that everybody at least wanted the same goal and that's kind of a rare thing with legislation.

I mean, different people draft legislation for different reasons and some people want to put a marker out and some people do it as a defensive measure, some people do it to get involved and some people actually do it with the goal of seeing something enacted. So we were in a good place to start off, and we spent throughout the Kennedy chairmanship, I'd say on a part-time basis, we spent time with the other side attempting to primarily work out the differences on the definitions.

I see Kathy Hudson in the back. We worked a lot with her. She helped us out on that and NIH helped us out.

But what we did is we had two very different approaches on the bill. We felt that the Daschle bill was too expansive in that it included nongenetic information and therefore would get into the area of regulating insurance practices, insurance underwriting practices around current health status which is very heavily regulated by the states now and is also very tricky because states that have gone too far or have tried community rating have seen their premiums shoot up and so it's a very sensitive marketplace. So we were concerned about going too far and Democrats are concerned that our definitions potentially had loopholes where if we had an exception, that the exception was too broad and swallowed the rule or once information fell into the exception, it was forever then unprotected as genetic information. So we kind of put aside both approaches and started literally back from square one and over the course of almost a year, I think, redrafted a whole new definition section, and we completed that many months ago actually and vetted with everybody in the outside world and got really good feedback, and so we kind of got that done, put it aside, and then towards the end of the legislative year, we got busy with other things and really didn't get the opportunity to finish because even though we had come together on definitions, we still had

some really big issues to sort out, such as privacy and remedies and things like that, and so there just wasn't time at the end of the year.

So we kind of put it aside for a few months, and then Republicans won the election and my boss, Senator Gregg, became chairman of the Committee, and at the beginning of the year, when we sat down to figure out the agenda and what the priorities were for the Committee, Senator Gregg, he made his rounds. He went to NIH. He met with Dr. Collins and Dr. Collins said, "Well, this is really important to do this legislation because we will never realize the promise of the Human Genome Project if we don't have these protections in place." My boss agreed with that and made a commitment at that time to move this legislation forward, and in his view, there's not really a huge problem today. We haven't seen a lot of abuses. There's been a couple of cases that are troubling.

From what we can gather, there's only been one or two cases in employment, and from what we can tell in the insurance side, there might be some insurers in the individual market who are using family history which we do count as genetic information, but for the most part, these tests aren't out there. The underwriting process is not that sophisticated. It's not really being used. So on the one hand, we're getting a little pressure. Well, why do you need to write a bill and expose industry to lawsuits if there's not a problem? But I think over time, we really were convinced that now is the ideal time before this information is in the mainstream, before there's huge opposition against doing legislation, and more importantly, as the science continues to move forward, we're hearing stories and it's pretty well documented that people are afraid to get genetic tests. Doctors advise their patients, well, I don't know what to tell you. You could get the test, but you might want to pay for it out of pocket because I'm not sure what's going to happen with the information.

So the lack of a clear federal standard protecting this information has been an issue in terms of really being able to move forward with the science and the clinical trials and really, I think, getting insurance companies to come forward and pay for these things, and so this really is kind of a threshold opportunity. So we put genetics really at the top of the list for the Committee agenda and scheduled it for markup which really put the pressure on the two groups to negotiate very hard to try to work out the differences, and we did have it scheduled for a couple of markups and had to bump it back, but since the beginning of the year, we have been negotiating very rigorously, before it had been on a part-time basis, we really stepped it up, to try to sort out the remaining differences on the employment title and the health title.

I'm a health care person. So I don't really work on the employment title. My colleague David Thompson was the lead on that, but they had several big issues on that side to work out. One of the issues was what we call the "watercooler problem." Because family history is genetic information and can come up in casual conversation, oh, you know, sorry, I'm going to be late tomorrow. My mother's in the hospital. She has breast cancer. Well, that's a revelation of genetic information, and if you tell your immediate supervisor, that's a disclosure to the employer, and it might not be that the employer is acting on that, but we certainly had restrictions in the legislation not just for acting in a discriminatory manner but also for wrongful disclosure. So our concern on the disclosure front is somebody could read an obituary and, oh, don't send flowers, send a contribution to the American Cancer Society or something like that.

I mean, there's many opportunities to inadvertently acquire genetic information, particularly if you define it broadly to include family history. So we had the watercooler problem that we had to sort out which we eventually did by focusing in on, I think, key terms like "collect," "purchase," kind of steering away from the nebulous "acquire" term, and then we put a provision in there that specifically kind of creates the safe harbor for the inadvertent collection or acquisition of information like reading an obituary.

Another issue is the entire Title 2 is basically modeled after the Civil Rights Act and it kind of parallels ADA but it's the structure of the Civil Rights Act. So if you have a claim, you file it through the EEOC and they make an initial determination and weed out frivolous cases and then the rights and remedies that would flow for a genetic discrimination would be the same as those under the Civil Rights Act, and under the Americans With Disabilities Act, there's something called disparate impact which is even if an employer doesn't intentionally or on its face act in a discriminatory manner, if the effect of their employment practice is to discriminate against a group or a class of people, then that would be discrimination, but the ADA includes sort of a protection for that, saying that if it's part of normal business practices, then that's a defense against a disparate impact claim. So it really gets into the details of really liabilities and lawsuits, but that was a big question as to whether or not we ought to have a disparate impact claim for genetics, and we really racked our brains trying to think about if there's some sort of fitness-for-duty test or requirement that might have some disparate impact on folks with a particular kind of gene, and I think right now, we couldn't identify anything but we were very aware that who knows what the future may hold.

So there are choices where to include disparate impact, have a business defense, include disparate impact but not have a business defense which I can tell you my boss was not comfortable with at all, or to not include it at all, and where we ended up was not including it at all but realizing that this is an area that could develop with the science. So we established a commission to study the issue to see if there was a need or a possibility for that type of protection in the law and those were the issues on the employment side.

On the health side, as I said before, it's really confidentiality or privacy and the rights and remedies, and as I said before, when we redrafted Senator Snowe's bill, all the bills were originally drafted before there were even draft privacy regulations, and since then, the Clinton Administration issued privacy regulations. The Bush Administration revised some elements and reissued final privacy regulations.

So we took a very careful look at the privacy regulations and they address the use and disclosure of all medical information, including genetic information, and we even had some hearings to see, well, do the privacy regulations adequately address genetic information, and our feeling was that, after studying the regulations and consulting with experts, was really did cover genetic information, except there was one place that we ran into a problem and that is, under the privacy rules, it allows for the use and disclosure of information, including genetic information, for purposes of treatment, payment and health care operations, and under health care operations, there's this one thing called underwriting, reinsurance, placing a policy with somebody, which, in insurance terminology, means basically discriminating. You're looking at somebody's medical information and deciding how much of a premium you're going to charge them and what have you and that's a practice right now that really only occurs in the individual market because HIPAA actually bans it for the group market and has since 1996. Then there's also reinsurance which isn't underwriting on the individual but is on the ground as a whole.

So we did realize that that was a problem in the privacy rules and attempted to address it in the Snowe draft but still didn't get it quite right. So throughout our negotiations, we refined that provision and we also had some in-depth discussions. The Daschle-Kennedy sponsors felt that the privacy regulations had an additional gap in that they only dealt with use and disclosure and they didn't deal with how an entity gets information up front. We never really came to any kind of agreement about that issue because I think that the privacy regulations do deal with that because in the use and disclosure, the regulations do lay out this consent process and an authorization process which really does get to how an entity gets information, and even if they get it and if they can't use or disclose it, our feeling was that there wasn't a gap. But there were still some who were concerned about ever letting an insurer even acquire that information and we were likewise concerned that, well, you know, there are bad uses of genetic information and good uses,

and we want insurers to pay for genetic tests and genetic services, and if we create a whole different regime and set of rules around genetic information, that will be a disincentive. They'll never do it. We also want them to be able to continue with their disease management activities and health care improvement activities and genetic information can be a key part of that.

So we had to be very careful in our privacy provisions, and where we ended up, I'll just describe to you the privacy provisions, is we basically said the privacy rules apply to genetic information. That's kind of stating the obvious, but when it comes to use and disclosure of genetic information, the privacy rules govern, except that there is no allowance for underwriting because that's inherently contradictory to the nondiscrimination bills. So we created an exception to say basically you can never use or disclose genetic information for purposes of underwriting and then we take it a step further and we say you can never even -- insurance companies are what we're talking about. Insurance company can never even collect genetic information for purposes of underwriting.

So we do have an upfront ban that they don't have with the privacy rules because there's a feeling if they couldn't use it or disclose it for underwriting, why do they ever need to even collect it? We also put an additional ban on insurers collecting genetic information prior to somebody being in their plan. So in other words, an insurance company can't go out and just make a database and collect information and solicit information for the purpose of having a database in case you're ever in their plan and then we have that information.

The marketplace is really changing. You're seeing a lot of Internet-based technologies and insurers like ehealthinsurance.com, where you get online and you do a bid. You may not sign up for insurance but it's an opportunity for somebody to collect information on you.

So we made it clear that there's no collecting of information, of genetic information, before somebody's actually in your plan, and then once they're in your plan, the privacy rules govern with respect to how they can get information and when they need to get authorization and then they can get it for treatment and payment and health care operations, except underwriting, so they can do things. Obviously they can protect themselves against fraud. They can conduct wellness programs, disease management programs and what have you. So that's what we did on the privacy side.

There are kind of two elements to this bill. There's the governing of the flow of information which I'm calling privacy, use, disclosure, collection, but then there's also the straight-up insurance ban on discriminating for underwriting, and what that does is say for group health plans and insurers in the individual market -- well, for group health plans. An insurance company can't set the premium or eligibility on the group as a whole based on any individual members of that group's genetic information.

That's kind of going beyond current law and HIPAA. HIPAA doesn't currently address premiums on the group as a whole, only addresses discrimination against an individual in the group, and then we further said because the HIPAA 1996 included discrimination provisions for group health plans, the individuals in group health plans with regard to premium rates and eligibility, you can't discriminate based on health status, current health status, including genetic information.

What we did was further flesh that out in terms of defining genetic information, making the rules a little more clear, breaking out the genetic piece and kind of clarifying some of the remedies around that, and the remedies are as follows. We really built on the framework of current law. So HIPAA's a really big statute and people talk about sometimes they mean privacy and sometimes they mean portability, but there are different pieces in HIPAA.

So Title 1 of HIPAA really addresses the traditional insurance things, portability, nondiscrimination. So for the nondiscrimination provisions of our ban, we just really build those into Title 1 of HIPAA which already addresses those issues, and then we do some additional things there. We say with respect to genetic information, we clarify that if somebody's in a group health plan and they're denied coverage and they think it's because of some genetic information or because they got a genetic test or something, we make it clear that if they're going through the appeals process and that's taking forever and in the meantime, their child needs to get well-baby care or somebody breaks their leg or what have you and there's health insurance claims, we make it clear that the person can kind of opt out of that administrative process and go to court and get injunctive relief and go to court and the court can say guess what, you're wrong, you have to let this person into your plan.

Then we think that's probably current law but it's not explicit in the statute, and so it's a bit of a gamble as to whether or not the courts would actually give you the right. They might say oh, you haven't exhausted your administrative remedies. Go back and go through external review and all that. In the meantime, months could pass and you could be incurring pretty significant health care costs, and we've also clarified that if that should happen and you have to go to court and it turns out, you know, it took you three months, you were fighting with your health plan, turned out that the health plan was wrong, they should have let you in the plan, they were discriminating based on some genetic factor, and we make it clear that your coverage should be restored retroactively to that point where they actually denied you coverage.

Again, that's probably current law and these things usually get sorted out before somebody has to go to court, but we wanted to make it clear that if there was some gap in time and somebody didn't have coverage when they should have, that that individual is not on the hook then for paying for any health care costs that really should have been covered by the health plan. So we also clarify that.

We largely followed the remedy structure for the nondiscriminations that exist now under Title 1 of HIPAA, but we do make some, I think, important changes in terms of enforceability and also in terms of being a little more consumer-friendly than what's out there with HIPAA. The way HIPAA works now under Title 1 is kind of messy. It's three agencies are involved. States enforce for the individual market and if states fail to enforce, then HHS is the fallback enforcer. DOL enforces against the group market, in other words, employers who sponsor health plans, and then if there's any kind of violation that DOL finds, they don't have the ability to levy a penalty. They have to go to the IRS and bring them in to levy which is actually an excise tax under current law. So it's a lot of people involved, and as you can imagine, it's rather difficult to enforce that the way it is.

So we took it away from the Internal Revenue Code, the penalty here, and made it no longer a tax and we gave it to the Department of Labor, Secretary of Labor, and made the penalties civil penalties, civil monetary penalties. So now, when DOL goes and does plan audits, are you HIPAA compliant, they can also look at are you HIPAA genetic compliant, and if they find something wrong, they have the ability to go ahead and levy a penalty right then and there.

This is sort of the Secretary enforcing against the plan. The penalties would be the same as they are now for HIPAA Title 1, which is \$100 a day per person per violation. So usually the way it works is if a plan is messing up, they're usually doing it on a planwide basis, so if you have 20,000 people in your plan, it's however many people you're treating this way times per day, and then they go up for more than de minimis violations. It goes up to \$1,500, then to \$2,500, and then for a really bad planwide violation, it's the lesser of \$500,000 or two times whatever your total claims payments are, which could be a lot more than half a million dollars if it's like a General Motors plan where they have hundreds of thousands of people in their plan. So that's the change that we made to HIPAA.

We made one additional change which was a big concession on our part and made us somewhat uncomfortable but was really important for, I think, Senator Daschle to really give the consumers some ability or some leverage against the plans, because under ERISA now, you have a private right of action. We've also said in addition to the Secretary's ability to enforce a plan, the individual, if they are discriminated against and they end up suing and we give the court the discretion to award the HIPAA penalty to the individual -- so that \$100 a day per violation and \$1,500, \$2,500, more than de minimis -- the court then would have the discretion to reward that to the individual.

So if I work for XYZ Corporation and I sign up for the plan and they don't let me in and there's no reason, except that I have a family history of breast cancer, and then I go and I sue and it turns out that they should have let me in, by the time I sue, say that's six months later and the court rules in my favor, that's \$100 a day and they can direct it towards the individual.

I will say there are folks that feel like that's kind of opening a Pandora's box because it's giving sort of like damages to the participant when heretofore most of the remedies have been on a planwide basis with the Secretarial enforcement, but there is also some precedent for it now in ERISA in a couple of places. Under COBRA, if your plan administrator fails to give you your adequate COBRA notice, you can go to court and the court has the discretion to actually award the COBRA penalty to the individual, and there's also something in ERISA now that says if you request plan documents from your plan administrator and they fail to provide them within 30 days, then the plan administrator's on the hook for I think it's \$1,000 penalty, and again the court has the discretion to award it to the individual rather than back into the health plan or to the general treasury.

So that's the framework, and I'm sorry it's so complicated, because it really does build in many ways on what's already out there and then there's some variations on what's out there, but that's the enforcement on the insurance discrimination provisions, and then on the privacy pieces, we kind of made a pretty big decision during our negotiations to split that out. The way we had originally drafted the Snowe bill is, it was all under that Title 1 framework, but the way the privacy regulations work now is very different from the rest of HIPAA. You don't have the multiagency enforcement. It is a federal standard. Unlike HIPAA Title 1 where states enforce against individual insurers and DOL enforces against group, with the privacy standard, it's a federal standard and that is the rule and states have the ability to do something more protective, but it's a federal standard that is enforced through the federal government, the HHS Office of Civil Rights, and we felt that HHS is going to be in the process of developing an incredible amount of expertise on privacy. They actually wrote the rules. They will build up their Office of Civil Rights and we didn't think it made sense to have pieces of privacy related to genetics enforced by DOL and IRS and kind of spread all over because they obviously do need to coordinate with the rest of the privacy rule.

So what we did for the enforcement of the privacy provisions is put it under the privacy enforcement framework under Title 2 of HIPAA, and the way that works is, it's a federal standard. It's enforced by the Office of Civil Rights, which we thought was important because we do feel it's a civil rights statute, and the remedies there are -- I apologize if I don't get this right off the top of my head. This is where I should have brought my summary information. But the penalties are similar to Title 1 but they're also a little bit heftier. It's \$100 a day, but they graduate up for should have known, didn't know, should have known, knew but acted really badly, and it goes up to half a million dollars and also including criminal penalties for somebody who knowingly violates.

So that is the enforcement provision for the privacy pieces of genetics, and it seems kind of strange when we're describing the bill -- why did you split it up, it's hard to follow -- but I think from a consumer standpoint, actually it will make a lot more sense.

You know that all your privacy protections fall under the same kind of rules. You know you call the Office of Civil Rights and here are the remedies, and there's no interagency -- there's no question of, well, is it the state law or federal law or is it IRS or DOL or HHS? So we think that probably makes a lot more sense, and there's already on the nondiscrimination pieces, there's already nondiscrimination rules out there. So building on that framework makes sense because it doesn't make sense to have a discrimination rule for current health status under one framework and then a slightly different framework for genetic discrimination. So there is actually a rationale for how we ended up the way we did.

That is a lot of detail but that's the bill that we approved as a manager substitute in Committee, and I think everybody's very pleased. It was a unanimous agreement, and I think there's a very strong desire on both sides to move it forward quickly. We do have to report it out of Committee, which means we are going to draft a Committee report. We think it will help to have an English language explanation for some of these things, and our goal is to get that done as soon as possible and bring it to the floor, hopefully on a UC basis and not spend a lot of time having to do a floor debate, but as you all know, the beauty of the Senate is one person can object and then you do have to have a debate and schedule time. So we're hoping, given the amazing cast of characters who support this bill, from Kennedy and Gregg to Daschle and Frist and Snowe, that that kind of lineup really covers the political spectrum, that it would be really tough for anybody to object, but you never know in the Senate.

So our goal is to probably after the 4th of July recess because we're going to be turning to Medicare and that'll probably take up two weeks maybe -- I think there's a question about that -- bring it to the floor, and hopefully pass it and then hopefully get your help and start working on the House.

DR. McCABE: Thank you very much.

I would point to everyone's attention to the last subsection under Tab 4 which is the summary of the bipartisan agreement that was prepared by staff. The bill is also there. I'm not sure how it's changed perhaps since.

MS. MONK: No, that's it.

DR. McCABE: Okay. So this is the way it is.

MS. MONK: That's what the Committee approved.

DR. McCABE: And I'd also point out that there is a letter, dated May 20th, from Secretary Thompson to Senator Gregg supporting this bill.

I think it's also important to recognize what was stated, and that is that everyone has anticipated that the real contest will be on the House side with this bill because things have come together so well on the Senate side and that's an area that we need to consider also as a group.