The Financing of Genetic Technologies in the US Health Care System

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DR. McCABE: This afternoon we will continue with discussion of a variety of different topics. The first will be the financing of genetic technologies in the U.S. health care system, and the presenter will be Dr. Jack Rowe, who is Chair and CEO of Aetna HealthCare.

DR. ROWE: Well, thank you, Dr. McCabe, and thank you for including me. I'm delighted to be here representing Aetna and the health insurance industry. I must say also, as someone whose entire career has been in academic medicine up until three years ago, I'm delighted to be paired -- in fact, I even showed my wife that I was paired in the schedule here with Francis Collins and Claire Fraser, who, along with her partner, Craig Venter, have made such historic contributions to human biology and health. It's quite exciting for me.

I'd like to propose the proposition, at least, that the impact of the contributions of our colleagues in development of genetic tests is going to be influenced by the effectiveness of a partnership between three groups. One group is the producers of the tests and the biology behind it. A second group is the users or the consumers of the tests. The third group, whether one likes it or not, are people such as me who, in fact, decide whether to pay for the tests. I think that that's an important trio and that we have to work effectively together in order to realize the promise of genetics in enhancing the health status of individuals and populations.

I'm going to focus on genetic testing, although there are certainly other aspects of genetics that we could discuss here. Four of the usual and customary requirements for an effective screening test are here. The tests we're talking about are, of course, very sensitive and, in the main, very specific. So the question is are they cost effective and are they safe?

The cost effectiveness, from an insurance point of view for genetic testing, is determined by the degree of risk in the population that is tested. I think this is very important for us all to understand and agree upon. There are much data in the literature with respect to this, but let me just cite two examples of slightly different types. The first is a study by Eccles in the British Journal of Cancer, 1998, looking at the cost for detection of an abnormality in the BRCA1 gene, and looking at the cost if you were screening a general population, $170,000. If you screened only women who were under 40 years old, $1,700; and only women with a strong family history, less than $500. So obviously, the issue here is to apply these tests, if possible, to individuals who you can identify as being at risk.

Another way to look at the cost effectiveness of a genetic test is to look at its application once a test is conducted and the result is known. With respect to that, Vasen and colleagues in Cancer, 1998, reported this result in individuals who had the test and had a positive result for the familial form of colonic cancer. In that case, a group of 25 individuals were followed up routinely with passive clinical evaluations and no colonoscopies, and another group of individuals had frequent colonoscopies at one-year intervals in this case, although follow-up studies have been done every six months.

If you look at the cost of taking care of an average case of colon cancer that developed in these populations, you see that the individuals who were followed up more regularly, despite the extra cost of

the colonoscopies, actually resulted in 27 percent lower cost. So that is the business case for quality, if you will, in not only doing tests but following them up with aggressive monitoring of individuals.

I was very interested in this. This is something this audience may not be too used to thinking about, but this is a note from a sell-side analyst at Lehman Brothers on Wall Street. When we came up with our guidelines for the use of genetic testing, we thought we were going to get killed by Wall Street, and instead Mr. Raskin came out with this quote the next morning: "It becomes clear that as health plans become more proactive with respect to disease prevention, genetic testing will begin to assume a more central role from both a clinical and a cost-containment perspective," and I think that is very, very good news. I think that is, in fact, currently the prevalent view on Wall Street.

Now, is it safe? I'm sure you all feel that these tests are safe, but a lot of people don't think these tests are safe. They're safe from the point of view that doing the test doesn't hurt anybody. But the fact is that people fear these tests. They fear that if they have these tests, that they will be subjected to discrimination in the workplace and discrimination in trying to get insurance. There are a fair number of individuals who have, in fact, gone to health care providers anonymously or under aliases to have tests because they are concerned about the issue of privacy.

Fortunately, this is not the prevalent finding. In fact, I'll show you some results from a Harris poll indicating how people nationally feel about genetic tests, and then I'll look at some of the regulatory and legislative issues and the myths that are relevant to the issue of privacy and safety for individuals.

Harris did a poll last year of 1,100 adults nationally, and what they found was that over 80 percent felt that genetic testing was a good thing. They found that the more familiar people were with genetic testing, the more likely they were to say that they would have it. In fact -- and I don't know if this is good or bad -- half said that they'd be interested in having a test for a very serious disease even if there was no known treatment or way to prevent the disease, which is interesting.

So while there is a lot of concern from the privacy fundamentalists about safety issues and privacy issues, and those are important concerns and I'll address them in a minute, I think we should be aware that most people, in fact, are not in that camp. Forty percent of people said that they thought health insurers should have the information as well as their doctor, and we believe that to be the case, and I can give you an example of why.

Now, as far as the states are concerned, all but two states, Idaho and North Dakota, have passed some form of genetic non-discrimination testing legislation. The Partnership for Prevention has just put out a very nice pamphlet that you may all have seen about state programs in genetic testing, and I would recommend that to you. Perhaps, Sarah, the Committee would appreciate getting copies of that. It's a very useful, well-done piece from a good organization.

So all but two states have passed laws. The laws impact individual and/or group insurance and specify broadly that health plans may not do one or more of the following things. Don't establish rules for eligibility based on genetic information; don't require genetic tests; use genetic information for risk selection or risk classification purposes; and don't disclose information without informed consent.

Now, it's interesting that most of the regulators that we contacted didn't know why the laws were passed. In other words, they knew that the laws were passed but they couldn't exactly tell us what the problem was that the law was designed to correct. There was concern about privacy and a fear about it, but there hadn't been examples in the states of some behaviors, egregious or otherwise, that the law was in response to. In fact, I'll show you some data on this in a minute, but I think this is a situation where the lawmakers

are ahead of the law breakers. In fact, there's been an epidemic of these laws, and that's fine, except it creates a problem for insurance companies because if you're an insurance company like Aetna, we sell insurance and serve members in 50 states, and now we have to comply with 48 different laws, soon to be 50. No two of them are exactly the same.

So we would be much better off with a national standard so that people in the same company who happened to work in different factories in different states were being dealt with the same way. So we're looking to a national standard, and there are two bills in Congress. The first is from Congresswoman Louise Slaughter, who I think is in Rochester, New York, and she's offered H.R. 1910, which prohibits the same things that the state laws generally do and does allow a private right of action, which would mean that there would be an uncapped potential liability for insurance companies, and individuals could go to the courts if they had a dispute.

On the other side, in the Senate, there is a Snowe/Jeffords/Gregg bill, which I guess qualifies as a tripartisan bill --

(Laughter.)

DR. ROWE: -- which has been passed. It passed out of the Health, Employment, Labor, and Pensions Committee on May 20th. We support this bill strongly, and it has the same prohibitions but it basically gives people relief out of ERISA rather than on individual state court levels, and it's a very similar discussion as to the current medical malpractice discussion that is ongoing around the country. We would hope that this bill might get --

DR. LANDER: Could you just elaborate on relief through ERISA?

DR. ROWE: Yes. ERISA is a national -- it's the Employment, Retirement, Income Security Act, or something like that, and what it does is it basically preempts state regulations. So you're forced to go to a federal court, not an individual state court where there's a lot of variability, and there are some limits, I believe, to the awards that could be given, equitable relief, et cetera, instead of permitting the private right of action for an individual to go to an individual state court. That's my understanding. I'm not an attorney, but many insurance issues are covered under ERISA rather than under individual state mandates. States are preempted by ERISA for many insurance issues. So I think that's the distinction, and this would give a national standard dealt with in state court -- in federal court, not in state court.

DR. LANDER: So this would remove any private rights of action currently available under state laws?

DR. ROWE: Well, I'm not an attorney, so I'm not prepared to provide an opinion with respect to that, but informally I might think that would be the case.

DR. LANDER: That would be interesting to find out.

DR. ROWE: Yes. This is the same provision that's in many of the medical malpractice so-called reform bills that are discussed as well.

DR. McCABE: We will have a presentation by Congressional staff tomorrow, so we can get that clarified at that time.
DR. ROWE: Okay, great. Thank you.

MR. MILLER: If I may just jump in, there is a private right of action in the Snowe bill, and enforcement through --

DR. ROWE: Through ERISA rather than at the state level, I guess. What it does is it permits a private right of action but not at the state level, at the federal level.

MR. MILLER: In federal court.

DR. ROWE: Right.

MS. BERRY: I could be wrong, and we'll find out more tomorrow, but I think that the compromise that was reached between Senator Gregg and Senator Kennedy might have removed the private right of action provision that was initially in the Snowe bill, but the Snowe bill was how it started out. I may be wrong, but we'll get clarification tomorrow. That's my understanding.

DR. COLLINS: I just want to point out the bill is in the briefing book, and if you turn to the second page, there's a summary of what happened under enforcement that goes through the penalties and the remedies in enough detail that I think you can figure out what the compromise was. I don't think we should spend a lot of time on it now because we'll talk about it more tomorrow, but it is right there if you want to go and look at it.

DR. McCABE: Is there a comment from someone in the audience? Please come to the microphone.

DR. BARASH: It's my understanding that one of the issues in regards to this legislation is that ERISA exempts self-insured employers, and there are quite a lot of self-insured employers.

DR. McCABE: Please identify yourself, please, for the record.

DR. BARASH: For the record, Carol Barash, Genetics/Ethics Policy Consulting in Boston, Massachusetts.

DR. McCABE: Thank you.

DR. ROWE: I have a number of comments about this which you'll all be happy to hear I'm not going to offer at this point.

(Laughter.)

DR. ROWE: But that is correct. If you're a self-insured employer, and that of course makes a huge difference to large employers who are self-insured because there are some states in which there are many mandates, and the self-insured employer is not currently subject to those state mandates, whereas a small company that can't afford to be self-insured and is fully insured is subject to the mandates which we think increases the cost of insurance, which makes it worse just for those employers who can least afford it. So this is the issue about state mandates and ERISA.

You should also be aware that 62 percent of my customers are self-insured, and 65 percent of UnitedHealth Group's customers are self-insured, where Dr. Tuckson works. Is that right, roughly? I think 60 percent of CIGNA's customers are self-insured. So self-insured is a really big part of the commercial health insurance business in the United States, and therefore these ERISA preemptions of state mandates are very, very significant issues, whichever side of the issue you're on.

Moving along with respect to the fear factor, in addition to the issues about the legislation, I think it's worth talking with you a little bit about the myth versus reality in the genetics of health insurance. I mentioned to you that the lawmakers are ahead of the lawbreakers, which is ideal. There was a study by two folks at Wake Forrest, Hall and Rich, that was published in 2000, and they evaluated the history to see whether they could collect examples of group insurance cases where individuals were discriminated against based on genetic testing. They were unable to find one case.

There have been, to my knowledge, no published cases of group insurance where individuals have been discriminated against. For those of us in the insurance industry, this makes perfect sense for a number of reasons. Number one is most of our customers are self-insured, as I said. Number two, the average age of our customers is 32, at least at Aetna. We have our customers for an average of two to four years, and then they leave and go to someone else. Ninety percent of our customers are gone within seven to ten years. The near-term expenses are the dominant focus. It feels like it's the next quarter or the next week, but it's never more than the next year. The major determinants of expense are demographic ones and not really related to issues of genetic tests.

Now, another myth is that health insurance coverage decisions are arbitrary, and I can tell you what we do. Dr. Tuckson can tell you what they do at United, which is a leading company in our industry. My guess is that there are more similarities than differences about the approach. But we have what we think is a comprehensive process for making these decisions. It's based upon current peer-reviewed literature. It's based upon recommendations, standards and guidelines of the relevant professional colleges.

So we start with professional sources, whether it's the IOM or the published literature or the American College of whatever, Obstetrics and Gynecology, Genetics, whatever the relevant group is; and then we go to a national expert review group and we pull together people such as some of them in this room, and we ask them what they think we should do. Then we go to participant providers in our network who, in fact, see Aetna members and are paid by Aetna, and we develop a policy with their assistance and disseminate the guidelines.

If you go to the Aetna website and you go to the Coverage Policy Bulletins, which are on the Aetna websites, there are hundreds of these, and for each test -- hemochromatosis, familial colonic polyposis, whatever it is -- it will tell you what our policy is, it will give you the references, and it will tell you why we made this policy, and when. This is available to the public and you can access these coverage policy bulletins. So we try to have as much transparency as possible.

Now, our coverage policy principles with regard to genetics basically indicate that we want to pay for these tests for individuals who are at risk, back to the breast cancer example. We want to pay for tests in which there is information that affects the course of treatment, and this is often very difficult. If somebody says "I want to be tested for Alzheimer's disease," and they have no symptoms, and we are not aware of any treatment that has been generally agreed upon to be effective in the preclinical phase of Alzheimer's disease, and there may be a study showing that people with Apo E4 may respond to this or that but there's not enough literature to meet the test of generally accepted at this point in our minds, then we would say no.

That person might say, well, for family planning reasons, financial planning reasons, professional planning reasons, life planning reasons, I want to know whether I have the likelihood of getting this, and we would say those are all valid reasons, but we don't think your health insurance should pay for that test. We think you should pay for that test if this is a legal or family planning or financial planning issue rather

than a health issue, per se. Obviously, you get those kinds of things in other diseases for which there's no treatment.

Huntington's, on the other hand, as somebody said, I'm going to decide whether to have a baby and I want to know if I have Huntington's disease, then that's a different story. That would change something clinically and something different would be done clinically, and therefore we would pay for that kind of test.
We also are interested in care services and treatment for our members, rather than people who are not our members but who are related to our members, such as siblings, twins, et cetera.

So several months ago we offered a set of guidelines. We didn't offer this so much as groundbreaking but we saw confusion, all of these different state regulations. There was a lot of sense that insurance companies didn't want to pay for genetic tests. We didn't think that was the case. We think most of us are paying for these tests. So we offered some guidelines, and I'll give you Aetna's guidelines. I'm happy to tell you that since we offered these, these have been discussed and, in fact, a set of guidelines have been adopted by the American Association of Health Plans which are very similar to these. They're not identical but they're very similar. So the industry has now followed with a set of guidelines.
I'll show you ours, and I have copies if anyone wants copies of the Aetna guidelines. We feel that there are things that health insurers should do and things that they should not do. All the state laws are pretty much the things you should not do, thou must not. So we have thou shall as well as thou shall not.

With respect to thou shall, we believe that we should cover genetic testing in individuals shown to be at risk where the results may affect the course of treatment of the insured. That's critical and central to our position. Second, we should cover genetic testing for a family member where the family member is not otherwise insured and results may affect the course of treatment of an at-risk insured. So if there is a mother who is not an Aetna customer but knowing her genotype with respect to a certain situation will be important to how we treat a child who is an Aetna member, we would pay for that test.

Three, we would cover consultation with qualified counselors and physicians and facilitate the appropriate interpretation of genetic testing results. I think this is one of the most important things we've had to say. No genetic testing without genetic counseling. In fact, we believe that often the genetic counseling should occur before the test. In fact, sometimes the right thing is not to have the test, and we think it's very important for insurance companies to pay for counseling as well as pay for testing.

We support physician education in the appropriate interpretation and use of genetic tests, including guidance in the selection of medications -- i.e., pharmacogenetics. This, I think, is really important too. This a lot of people think is a throwaway. "Of course, physician education. They always say that." But the fact is if there were one thing the federal government could do, it would be to really get a push behind physician education in the appropriate use of genetic tests and genetic counseling, and we are strongly in support of that and looking to work with foundations and others to try to help in that regard. And we believe that we should work with physicians to promote confidentiality and to use the information for the maximum benefit of the member.

I mentioned, I think, that we should have the data as well as the doctors. Let me tell you for a second why I think that is. We have a lot of disease management programs, and we enroll people at risk for disease or at risk for complications of a present disease, such as diabetes or chronic heart failure, in these management programs. There are cases in which we can't enroll people unless we know the results of the test.

For instance, let's say that you have the gene for colonic carcinoma. You should probably have a colonoscopy every six months, let's say. I'm making that up, but I've heard that recommendation. Now, we wouldn't ordinarily pay for that. We would only pay for X number of years depending on your age, or not at all depending on your age. But how do we know that we should pay for it unless we know that you have the gene? So we have to have the result.

Now, it's true, we don't have a lot of people asking to have six-month colonoscopies, so there's not a lot of abuse here.

(Laughter.)

DR. ROWE: But nonetheless, you get the idea that if we have the information, we can identify people. Then if information comes up about treatment or preclinical stages of diseases and we have the information, we can contact the 400,000 doctors in the Aetna network and say we know that you have a patient in your practice who has this, and are you aware of this treatment? Because, in fact, early treatment is a good thing. It's good medicine, it's good business. So we believe it's important for us to have access to this information.

Thou shalt not.

DR. WILLARD: Let me jump in before you move on.

DR. ROWE: Yes, please.

DR. WILLARD: What do you mean by "at risk"? Is it two-fold elevated over the population? Is it greater than 25 percent?

DR. ROWE: I think it depends on the cost of the treatment, probably. If the test is $1 million, you don't want to do a lot of people. If it's very inexpensive -- I think it sort of depends on the effectiveness of the treatment or the change that would be available. I don't think there's a simple rule. If you're an obstetrician and a patient comes in and you go through the usual sort of software package that obstetricians have, which you may even be for all I know, and you calculate did your mother have it, and your sister, and your twin sister, and your grandmother, and you get a probability, and if it's more than 30 percent likelihood that you have the BRCA gene, the recommendation is that you're at risk and should have the test.

Well, somebody made up 30 percent. I mean, they just picked it out of the sky, some group of experts. It could have been 50 percent. It could have been 10 percent. So we generally go by what the profession says. If the American College of whatever says they think people with X percent, then that's what we would use. We're not trying to set our own limit, and Reed can tell you how he thinks it's approached at United at this point. But it does vary from group to group. Thank you.

DR. WILLARD: Thank you.

DR. ROWE: These are the things you should not do, and these are basically the same things as are in the state laws. Establish rules for eligibility; require that tests use the test results for risk selection or risk classification; and disclose the results without authorization.

Let me end with a little commercial. This is actually our award-winning website. There are awards for websites. This one won a Webbie. I have trouble keeping Tonys and Emmys straight, and now we have

Webbies. This is available to the public. We own a website called IntelliHealth, which is populated and edited by colleagues at Harvard Medical School, and there's a genetic testing set here of several pages, 10,000 words -- Do I need a genetic test? What is genetic testing? -- and we have different modules for different diseases that we're putting on this, so one or two at a time, and it's going well, so everybody who has used it is very enthusiastic about it. I think this is helpful to physicians as well as informing lay individuals.

Again, thank you very, very much for inviting me to participate in this. I think it's an exceptionally important group and I think you have a lot to offer.

DR. McCABE: Thank you very much, Dr. Rowe.

(Applause.)