
Public Comments

DR. TUCKSON: For the record, I need to make two comments. One, the vote that we took right before the lunch break was unanimous, and I'm supposed to let somebody know for the record that the vote was unanimous. So I've done that. So whoever needs to know that the vote was unanimous, please know that the vote was unanimous. It was unanimous. That meant everybody agreed.

Secondly, some people asked about the DVD. Apparently, until and unless we outsell Amazon's site, it is actually available for the public to get a copy. Debra put hers on eBay and it sold well, she said. But you can get a copy. Now, the question is how do they do it.

MS. CARR: Actually, we're going to explore the possibility of posting it in our website so that people can download it or at least look at it from there.

DR. TUCKSON: If the committee members wanted one, what would they do?

MS. CARR: If the committee members would like another copy, we can send you another DVD. We do have extras. If the demand is that great, we can always make more copies, too.

DR. TUCKSON: Great. All right. So with that, that's terrific.

Now it's time for the public comment portion of the meeting. One of our critical functions is to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies, so we greatly value the input we receive from the public.

We set aside time each day of our meetings to hear from the public, and we welcome and appreciate the views that they share with us. We have also received a number of written comments that can be found in your table folders. We, again, appreciate the effort that people have made to make those available to us and the staff for duplicating those. So I would urge you to pay attention to those.

As always, in the interest of our full schedule, we do ask the commentators to please keep their remarks to five minutes and submit the rest for the record. Today we'll be hearing from first Greg Rabb representing Advamed. Is Greg here? Thank you. Please come right to this table right there.

MR. RABB: Thank you.

DR. TUCKSON: Thank you.

MR. RABB: Thank you. My name is Greg Rabb, and I'm an independent consultant here on behalf of Advamed, the Advanced Medical Technology Association, a technology association representing the medical device industry.

It has more than 1,200 manufacturers of all sizes, and it has in its membership many, many in vitro diagnostics firms. Advamed has followed the work of this advisory committee closely, especially your work surrounding the coverage and reimbursement of genetic tests.

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We submitted comments on your June, 2004 staff draft dealing with this matter, as well as the April, 2005 draft. We hope that you and your staff have viewed our comments favorably.

Advamed would like you to know that in the next week or two, we'll be releasing a report on the value of in vitro diagnostic tests. This report prepared by the Lewin Group will address factors associated with innovation, adoption, and diffusion of diagnostic tests.

Advamed commissioned the report to serve as a source document to both inform various audiences about the diagnostics industry, and to identify and describe barriers that exist, hindering innovation and patient access.

As you might expect, the current coverage and payment system is addressed and found wanting. There will be a number of recommendations for reform so that new tests, like the genetic tests that are your concern, are properly handled.

We think that you might find this report valuable as you continue your work, and we will provide copies to you and your staff if you'd like.

I'd like to conclude my remarks by reading a sentence or two from an Institute of Medicine report on the Medicare Laboratory Payment Policy that was published five years ago.

The report, which called for a series of fundamental reforms in Medicare's clinical laboratory fee schedule, most of which have gone unaddressed, concluded by saying that we have, "The opportunity to fix the current payment system for clinical laboratory services, averting the possibility of a crisis in the future. Payments for some individual tests likely do not reflect the cost of providing services. Anticipated advances in laboratory technology will exacerbate the flaws in the current system. Problems with the outdated payment system could threaten beneficiary access to care and the use of enhanced testing methodologies in the future. While Advamed believes that the current Medicare payment system for tests is a poor foundation for new tests, including genetic tests, the anticipated advances referenced in the IOM report are here today and both device innovation and patient access are threatened if we do not correct the way new tests are valued and priced. We encourage the advisory committee to make this point as it moves forward."

Thank you.

DR. TUCKSON: Thank you very much. We appreciate that. Thank you for making the supplementary material available and taking the time.

We will next year from Sharon Terry from the Coalition for Genetic Fairness. Always appreciate your coming by and sharing thoughts with us.

MS. TERRY: Thank you. I appreciate the opportunity.

Today I represent both the Genetic Alliance and the Coalition for Genetic Fairness. The Alliance has over 600 organizational members, largely genetic disease advocacy organizations and community-based organizations that are underserved. The Coalition for Genetic Fairness is composed of the Genetic Alliance and over 100 other organizations and companies dedicated to the enactment of substantial genetic nondiscrimination legislation. This coalition includes an executive committee that is comprised of nonprofit consumer organizations, industry partners, and health professional societies, and is guided by Robert Mells of Affymetrix, Joann Boughman

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of the American Society of Human Genetics, Marla Gilson of HADASA, Brian Monroe of Millennium, Jill Fonda Allan of the National Society of Genetic Counselors, Jeremy Gruber of the National Work Rights Foundation, and myself.

We are at your service, and we invite your comments and your questions. We are also welcoming departing committee members to our effort.

(Laughter.)

MS. TERRY: The Coalition for Genetic Fairness has been here advocating for this legislation both literally and figuratively before. Earlier today you heard all the major arguments supporting genetic information, nondiscrimination legislation, and you saw a video of very powerful testimony of some of our fellow Americans whose lives have been negatively impacted by genetic discrimination, or the fear thereof.

As such, I'm not going to rehash the major points you heard today. Instead, I'm going to ask you as a committee advising the Secretary to continue to articulate the urgency of this issue. Americans need to be protected from discrimination in insurance and employment, and they need this protection now.

Yes, we've been here before standing with a Senate that has unanimously passed legislation, and with a President who has issued a statement of administrative policy again this year in favor of this legislation. However, this year the House of Representatives, a body that in the past has not been able to move this, is very much engaged.

Our coalition has been and is currently working with the House, particularly with Congresswoman Biggert and her staff to move H.R. 1227 as evidence of this fact. As noted this morning, the major opposition to this legislation is the business community, particularly the Chamber of Commerce and the National Association of Manufacturers.

We do not believe that the House, and ultimately Congress as a whole, will choose to allow the interests of business groups to override the basic rights of individuals to manage their own health care in the most appropriate manner, which is to make use of genetic tests and emerging technologies.

Additionally, we do not believe that this Congress would not seize this opportunity to leverage the amazing investments that they've made in the human genome and in the sequence of the human genome as raw material to be developed into tools, tests, and technologies that should be integrated into medicine today.

However, now research has been impacted. In fact, it has experienced a significant chill. In my mind, a deep freeze by fear of genetic discrimination. As we learned from the Genetics in Medicine article, increasing numbers of individuals shy away from clinical research because of the very real fear of discrimination.

Remarkably, it is we, those who are impacted by genetics that have to take up this gauntlet, and are working to prove to Congress that this legislation will not hurt employers as it protects ordinary people. The Coalition for Genetic Fairness is working hard to rally Republicans in all states. We continue to mobilize our grass roots members, over 14 million of them, encouraging them to speak with the congressional members in their districts. We have met multiple times

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with those that oversee the business community working with them to limit liability, and to make them more comfortable with this legislation.

At the end of the day, we believe that Congress will make the right choice, making it possible for individuals to use their genetic information for health purposes for which it was elucidated. None of us have any choice over our gender, our ancestry, our disabilities, or our genetic makeup. However, as a nation, we do have a choice about how we treat that information.

Support for this legislation is support for improved health care for all Americans. We are confident that Congress will make the right choice in this regard. Finally, we would like to thank the committee for all your work. We ask you to make sure the Secretary and all relevant parties receive the information you have compiled, along with your careful and insightful analysis.

In this manner, the millions of individuals who carry genetic mutations they did not choose are asking us to do what is necessary to alleviate the burden of discrimination and the fear of discrimination on our nation.

Thank you.

DR. TUCKSON: Thank you, and I see you've provoked a couple of questions. Let's start with Ed.

DR. McCABE: Thank you, Sharon.

I'm sure you're already doing this, but in terms of trying to enlist other Republican members with I'm sure you're using the members of the Alliance to go out and bang on some doors.

MS. TERRY: Yes. We've used the members of the Alliance, as well as the biotech and pharma industry have been both involved with us a great deal. They have gone also to their Republican members.

We've also really focused on Republicans who last year did cosign and haven't cosigned yet. I think as Jaimie said, it's really a combination of some people not having this on the radar screen with all the other things like Medicare on their plates, as well as the Chamber less so and NAM more so this year has raised more red flags that have made it difficult for some Republicans to sign on.

DR. TUCKSON: Yes?

DR. McCABE: In follow-up, do you have anyone in any of your groups who have an affiliation with the Chamber? That run small businesses that have been impacted by genetic discrimination, or with manufacturers groups?

MS. TERRY: So we do, and they have been less inclined to comment. It has been this chicken and egg thing. They say if the Chamber and NAM will back off, then we'll be more vocal.

The Chamber and NAM tell us we'll be more vocal and back off, back off and be less vocal, if these groups will come forward more overtly. So it's very hard. What we have been trying to appeal to is to the biotech and pharma companies that have lots of employees and are major employers that in fact them joining our coalition and supporting this would give the right signal to those trade associations.

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DR. TUCKSON: Agnes?

MS. MASNY: Mine is just a comment actually to commend you and to thank you for all the work that you're doing for the Coalition for Genetic Fairness. The task force on the antigenetic discrimination legislation has really been well aware of the work that you've been doing, and we feel that we have a wonderful partner in the trenches. So thank you.

MS. TERRY: And the feeling is quite mutual. We're very happy that you see this as such a serious issue. Thank you.

DR. TUCKSON: Great. Thank you again very much.