

Public Comments

DR. TUCKSON: So Amy Miller, you are with the Personalized Medicine Coalition you know --

MS. MILLER: Yes.

DR. TUCKSON: -- of the America's Health Information Community.

MS. MILLER: No. I'm from the Personalized Medicine Coalition.

DR. TUCKSON: Period.

MS. MILLER: Period. I'm the Public Policy Director there, and I'm starving. So I will keep my comments very brief. I also have submitted comments earlier. So they're available to the committee.

As you know maybe, the Personalized Medicine Coalition represents academic, industrial, patient, provider, and payer groups that seek to advance the understanding and adoption of personalized medicine for the benefit of patients.

And we thank the advisory committee for the opportunity to engage in this process.

My comments focus on the draft report on pharmacogenomics, and we thank the committee for all their hard work in putting together that report. My comments are going to focus on just some issues we'd like to bring some more attention to.

The first is the development of pharmacogenomic products. We feel that business incentives for pharmacogenomic products need to be developed. As the committee, we are developing a list of incentives that we think will help advance pharmacogenomics. We welcome the opportunity to share these ideas with this group or any other public policy group.

We also recognize the importance of public education and the lack of education in the world of genetics right now. The PMC is putting together a privately funded medical education program on pharmacogenomics, and so we thank the committee for pointing out this particular gap.

Public investment in pharmacogenomic development is also important. You're not exactly the right group to say it to, but we urge full funding of the Critical Path Initiative.

As far as reimbursement goes of pharmacogenetic products, obviously, the United States is the largest single payer of health care costs. The PMC has outlined lists of payer principles when it comes to genetic- and molecular-based products. They're more fully outlined in my comments in front of you. But one thing that the report pointed out and I'd like to stress is the prevention category as a Medicare benefit. The PMC thinks this is a fantastic idea and supports the development of new policies that promote prevention as part of health care.

Also, just to remind you of who we are, we do have the power to convene groups who can speak to these issues and others from all the different stakeholders in the field, and we thank you very much for allowing us to participate in this process.

Have a good afternoon.

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DR. TUCKSON: Amy, thank you very much.

Any quick questions to Amy?

DR. FITZGERALD: Just one quick question. Could you forward us that list that you have of incentives?

MS. MILLER: We will forward a list to you very soon.

DR. FITZGERALD: All right. Thank you.

MS. MILLER: You're welcome.

DR. TUCKSON: Ever the insightful question. Thank you so much, Amy. We appreciate your being here.

Christina Karas. Did I say it right? I finally learned to say Shobita, by the way. I did get that right now.

MR. COLWELL: I am standing in for Christina. I'm Chris Colwell with BIO, the Biotech Industry Organization.

DR. TUCKSON: Chris, how do you spell your name?

MR. COLWELL: C-o-l-w-e-l-l.

DR. TUCKSON: And you are literally standing. So go ahead.

MR. COLWELL: I am literally standing and you're literally hungry and nonviolent still, and I hope to keep it that way, so I'll be brief.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers. We have a broad membership. It deals with health care, environmental, agricultural, and industrial companies, but within that, we also have a large number of companies that are heavily invested in research and commercialization activities and pharmacogenomics research tools and molecular diagnostics. We are becoming increasingly engaged in the policy discussions around these technologies. I appreciate the opportunity to be here today and look forward to continuing dialogue with you.

Two points that I would make, two quick comments, one with regard to today's conversations and discussions. We again are appreciative of that. It's important to have these informed discussions on intellectual property issues. I'm sure you know intellectual property protection is essential to the success and, in some instances, the survival of biotechnology companies. Having spent hundreds of millions of dollars in many cases and decades to develop a product, it's these patents that can provide the needed insurance or assurance for investors to develop these processes.

Also, a couple of quick points on the draft report, "Realizing the Promise of Pharmacogenomics." Again, very briefly. We've submitted comments on this in more detail.

First, we would recommend a more comprehensive discussion on the economic factors surrounding pharmacogenomics, particularly with some consideration or more robust

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consideration on appropriate reimbursement policies, which of course would be necessary for the incentives for investment and innovation.

Also, we believe that the report should indicate where enhanced congressional appropriations would be required to implement the recommended initiatives. We would particularly highlight that over the past four years funding for NIH has failed to keep pace with biomedical research inflation, and as a result, NIH has lost significant purchasing power needed to harness emerging scientific opportunities. To restore these resources, BIO and a number of other stakeholders are supporting an increase in NIH funding of up to \$30.8 billion for FY 2008 and we suggest that the draft report consider the need also for enhanced public funding opportunities for companies to develop innovative diagnostic and research tools technologies.

Thank you.

DR. TUCKSON: Terrific. Any questions, please?

DR. FITZGERALD: Same question. I'd be very happy to hear what you think are appropriate reimbursement policies because that's going to be the key thing.

MR. COLWELL: Absolutely. That's a key word, right.

DR. TUCKSON: So you will try to get back?

MR. COLWELL: We'll have a continuing dialogue with you.

DR. TUCKSON: I think that means you're going to get back?

MR. COLWELL: Yes.

DR. TUCKSON: This continuing dialogue business, I don't know. Thank you. I think, obviously, we respect what you all are doing and we really would like to get that kind of information. Thank you very much. Appreciate it. Good job.

You can pass that to Catherine Wicklund from the National Society of Genetic Counselors.

MS. WICKLUND: Hi. Good afternoon. I'll try too to keep this short. I've got the written testimony in front of you, so if you can read the whole thing, that's fine.

I'm Cathy Wicklund, President of NSGC. And as you're aware, NSGC represents over 2,000 genetic counselors, and we practice in a variety of medical specialties, academia, research, public policy, biotech, and we're the leading voice, authority, and advocate for the profession.

We want to thank you guys for taking into account our prior testimony and comments when you're developing policies and reports.

Today we're going to talk about two issues that impact the access of genetic testing and services. First, oversight of genetic testing and second is coverage and reimbursement of genetic tests and services.

Obviously, access to quality genetic tests and services is extremely important. Genetic counselors are often among the health care providers who explain the benefits and limitations of

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genetic testing, as well as provide results to patients. So when a genetic test fails or is inaccurate or is misinterpreted, we're often the health care professionals who are responsible for discussing these results. As such, we definitely applaud the committee's efforts to improve regulation that ensures the analytic and clinical validity of genetic tests. And we also support regulatory regimes that will increase quality while fostering innovation, but we don't want to significantly delay breakthroughs to consumers.

We do feel it's important, though, that there is pre- and post-test consumer education and counseling and it be provided by a properly qualified individual. Proper evaluation of the family history, ordering the appropriate and correct test, and the accurate interpretation of the genetic test are critical steps in the process. We don't want to promote that we're the only genetics professionals or that only genetics professionals can provide these services. We believe it's imperative that nongenetic health care professionals have a minimum level of genetics competence if they enter into this arena and encourage that they collaborate with genetic specialists when appropriate. They should also be aware that genetic counselors work in laboratories which provide the genetic tests and are really instrumental in ensuring that the correct test is being ordered.

We also think it's critical to assess and satisfy the consumers' needs for information that empowers them in making a personal decision. We understand that the Secretary is asking for guidelines on what should be discussed when offering a genetic test, and we'd be happy to collaborate with SACGHS to develop these guidelines.

We also applaud the committee for looking at the patent issue and any effects they have on accessing genetic tests. Obviously, it's unfortunate when individuals need genetic testing, they don't have access to it, or if there's a particular test a limited number of laboratories are performing. And coverage of tests with limited availability may also be an issue.

With the extraordinary impact of genetic information on our health and society, genetic service providers are in the position to impact the ability to deliver personalized medicine. However, without adequate coverage and reimbursement for genetic services, the full integration of these services may be difficult to attain.

In terms of coverage and access of these services, NSGC is pursuing recommendations outlined in your report of February 2006. Addressing barriers to genetic services by improving consumers' access to genetic counselors has been a top priority. As you may know, we've been successful enacting licensure bills in several states. They're listed here, most recently in Tennessee. And genetic counselors in Utah, because of this licensing, has undergone an increase in their numbers as well as coverage of their services. We're also working with policymakers in Congress to add genetic counselors as recognized CMS providers under Medicare, and we believe these are critical steps in improving access to quality genetic services.

So just in summary, we appreciate all the hard work of the committee and we hope that you'll make formal recommendations that will define regulatory regimes that ensure analytic and clinical validity of genetic tests while fostering the innovation of new tests; recognize, through support of licensure and federal legislation, nonphysician providers with expertise in genetics, as demonstrated by certification by a national credentialing organization; and support the funding of further studies to assess the value and effectiveness of genetic counseling services provided by nonphysicians.

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I'd like to thank you. Our technology has progressed at an unbelievable pace, but we've definitely fallen behind, and we welcome the opportunity to continue working with you.

DR. TUCKSON: So this is terrific.

So for the committee members, you have on your table somewhere this response from CMS on our coverage and reimbursement policy thing. So recommendation 7 you should look at in the three seconds you get to eat lunch. Marc is going to take us through that. So this is like the 99th time that we've had a respected, reasoned genetic counselor, association president/leader come before us and make these points. So you've kind of got to draft of where CMS is on this, and I'll just tell you, as you fast forward reading it, it ain't the answer yet. So we're going to have to figure out how, with the scope of work that we've got, to move this forward the next time.

So we will be back in touch with you. You've done a great job of bringing this back again. You've been just as eloquent, as all of your predecessors, on the point. I feel like it's almost like water torture. Every single time you guys are going to be in here saying -- but remember this. You've got to go back and look at the notes. We asked you all for some stuff and we were pretty clear that we needed you all to come together and get everybody together and say what's the credentialing organization, what's the -- you know, everybody, all the nursing organizations need to get together and come together and work it out also. So we've got to go back and reproduce all that work. So you have been eloquent, got our attention.

Marc, pressure on you.

But I also urge again every one of the genetic counselor organizations to come together and not have the differences of opinion, because you all weren't on the same page. Who's qualified, whose board do you follow, who gets to be in charge of what, who gets paid for what, how many people get to get paid every time. You can't just keep bringing it back to us (*Tape flip, 3B to 4A) coming back in here. So I've got to keep putting the pressure back.

MS. WICKLUND: And I agree, and we've definitely been working closely with our other organizations, and we've definitely taken strides towards, again, introducing a bill to Congress and being more specific about what we need and not relying on others.

DR. TUCKSON: But you've been great, but you all are deflecting. I'm a heat shield.

(Laughter.)

DR. TUCKSON: Thank you very much.

MS. WICKLUND: Thank you.

DR. TUCKSON: By the way, Shobita is back, and I just wanted Shobita to know that I did get this figured out.

Sharon? Jonathan? Jonathan is next? Jonathan Cohen? But everything is crossed out here.

MS. CARR: No, no, not Jonathan's name.

DR. TUCKSON: But who is he talking for?

MS. CARR: He's speaking on his own behalf.

DR. TUCKSON: Jonathan Cohen, unaffiliated. He's so unaffiliated, he's not here. We'll get Jonathan later.

Now it is Sharon Terry. My God, are we glad to see Sharon, the Coalition for 21st Century Medicine this time.

MS. TERRY: Thank you for this opportunity to present brief comments on behalf of the Coalition for 21st Century Medicine, which is a coalition of innovative diagnostic companies, clinical laboratories, policymakers, researchers, physicians, venture capitalists, and more than 30 patient advocacy groups, including Genetic Alliance. We believe that access to advanced diagnostic products and services is vital to the future quality and affordability of personalized health care. We also believe that innovation and quality patient care are the keys to 21st Century medicine and that timely access to new information by physicians and patients is critical to improving the quality of care and providing more personalized medicine.

The coalition shares HHS' focus on personalized medicine and the Congress and FDA's goals of assuring that treating physicians and their patients have access to safe, accurate and reliable information to assist in decision making. In light of that, we support Congress and the various agencies striking an important balance between regulation and innovation.

The coalition looks forward to FDA reissuing draft guidances for IVD MIAs and ASRs to allow all interested stakeholders an opportunity to review and comment on these documents again. We have met privately with FDA leadership in December and May. We've given comments and given the comments of us and other agencies and organizations. We believe that there's clear concern in the community regarding the draft guidance that they put out the first time. We and others expressed concern that if implemented in their current form, the draft guidances for both IVD MIAs and ASRs may result in adverse, unintended consequences. There are ambiguities in the current guidance and laboratorians will require considerably more clarity moving forward. We urge the FDA and the Department to consider the comments of the patients, providers and innovators.

There's a very real chance of Congressional action and the resulting novel or substantially modified statutory authority may ultimately supersede the draft guidances in important ways. It is important that the Department is clear in its intentions and that all entities are working toward the same end. In that regard, because of the IVD MIA and ASR, policies are inherently linked to policies on genetic testing and personalized medicine and may be appropriate for the Department to merge plans to finalize the IVD MIA and ASR guidances with plans to develop oversight policies for genetic tests and personalized medicine based on the recommendations of this committee. In the interim, the coalition will continue to educate key stakeholders about the importance of innovative diagnostics and their role in health care.

With regard to CMS, the coalition will continue to emphasize the importance of the Clinical Laboratory Improvement Amendments of 1988, CLIA, in assuring that patients and physicians have timely access to accurate, reliable and safe advanced diagnostic medicine. The coalition believes that enhancing and strengthening existing requirements under CLIA by issuing a genetic testing specialty may address some of the recent concerns about accuracy, reliability and safety of genetic tests and laboratory-developed tests in general, particularly the genetic specialty for which a notice of intent was issued. CMS indicated in letters and in the DHHS regulatory agenda

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that it would proceed with a Notice of Proposed Rulemaking, but this was subsequently dropped without adequate public rationale or explanation.

The coalition also believes that any regulation of LDTs, including genetic tests, should be risk-based rather than technology-based.

We also believe that the Genetic Information Nondiscrimination Act is a critical component of personalized medicine. The bill passed the House on April 25, as you said, 20 to 3, an overwhelming bipartisan majority the likes of which has not been seen in some time on an issue of substance. Though initially it seemed stalled in the Senate, it is important to note that that chamber passed it unanimously in two previous Congresses. We respectfully ask that the SACGHS recommend that the Secretary express his strong support for the Act and encourage the Senate to vote on it as soon as possible.

We look forward to working with you and all parties on these matters of vital interest to the public health, patient safety and personalized medicine. Thank you.

DR. TUCKSON: Thank you very much.

Any questions?

(No response.)

DR. TUCKSON: As always, thank you.

Now we finally get to eat, so the deal is this. What we're going to do is at 1:45 we were scheduled and are scheduled and will have a comparison of the patent system of the U.S. and select countries, and Joe Straus has been warned to go get something to eat right away. So Joe is ready, I understand. Where is Joe? He's out eating.

(Laughter.)

DR. TUCKSON: So he took the advice.

The one thing about the food that we have is it's not noisy.

(Laughter.)

DR. TUCKSON: So you're not noisy people, and because you're intellectuals, you can eat and listen at the same time. So you're going to eat and listen at 1:45. Food is served. Our guests will run and get something. There's no line, I understand. Lunch is outside. So your lunch committee is right out there.

See you at 1:45.

(Whereupon, at 1:30 p.m., the meeting was recessed for lunch, to reconvene at 1:45 p.m.)