
Public Comments

DR. TUCKSON: We have two things. We wanted to hear, before we vote, public comment. As we invite to come up to the microphone Amy Miller of the Personalized Medicine Coalition, who has a public comment germane to our discussion, let me read you an Email that has come in.

"I have been listening with interest to today's webcast of the meeting on the draft pharmacogenomics report. I'm sorry I'm unable to attend in person. Please accept this Email as my public comment for the meeting.

"During the report recommendation overview, Dr. FitzGerald questioned whether sufficient evidence of a genuine pharmacogenetics-based effect in drug development has been demonstrated yet. In the area of HIV drug research, the answer is yes. Just this month, a peer-reviewed study was published describing ways to reduce CNS effects associated with administration of Sustiva based on genetic differences in the patient population.

"In my earlier written comments dated May 17th of '07, I also described the important genetic test component necessary in the prescribing of other HIV drugs. These examples illustrate the importance of this form of personalized medicine. They also demonstrate the importance of facilitating codevelopment of diagnostics and drug development for the benefit of patient care for serious life-threatening illnesses. I have copied the journal references below.

"Thank you. Robert Reinhard from San Francisco."

Anyway, a very reasoned and appropriate response. Robert, if you are still out there, thank you very much, and anyone else, for taking the time to inform the Committee's deliberations.

With that, do we have Amy?

DR. A. MILLER: Yes, I'm right here.

DR. TUCKSON: Amy, go for it.

DR. A. MILLER: Thank you. My name is Amy Miller and I am public policy director for the Personalized Medicine Coalition, a federation of over 100 organizations representing a broad spectrum of academic, industrial, patient, provider, and payer communities that seek to advance the understanding and adoption of personalized medicine concepts and products for the benefits of patients.

During the last SACGHS meeting, the PMC made public comments on the draft report that we have been discussing today and we also mentioned our work in developing business incentives for personalized medicine. We are pleased that many of our ideas were contained in the conversation that we had today, but I want to reiterate those incentives, which we believe will advance personalized medicine.

One, federal funds should be appropriated to expand and accelerate genetic and genomic research through research and development grants.

Two, FDA should put in place an accelerated approval process for personalized therapeutics and diagnostics developed together or developed separately but designed to work together. This reiterates the comment just made by the person watching over the Web.

Three, reimbursement practices governing new technologies have a profound impact on both patient access and also the incentives of industry to develop new technologies. Therefore, we urge you to suggest new policies that expand payer coverage and reimbursement of personalized medicine products and services focused on disease prevention and those that improve the efficiency and value of our healthcare system.

In that vein, PMC is developing ideas on reimbursement models that will promote personalized medicine and pharmacogenomics. We expect to articulate these ideas through white papers, workgroups, and public meetings, and look forward to sharing the results of these efforts with you.

DR. TUCKSON: Hold on. Before you go, in Tab 6 of your books you will see a letter from Amy to the Committee as well that defines some of these things.

Amy, did you feel like -- I'm sorry to be overly familiar. I know Ms. Miller.

DR. A. MILLER: Doctor, but you can call me Amy.

DR. TUCKSON: I can call you Amy, MR. MILLER. I will call you MR. MILLER.

DR. A. MILLER: The recommendations that we have discussed this morning, and I know you have been attentive in the back there, do they speak to the issues that you have raised?

DR. A. MILLER: I think they speak quite well to the federal funds issue. I think it is appropriate the way you have instructed the Secretary to get it done and leave it open to the Secretary and director of NIH as to how to get that done.

DR. TUCKSON: Great. Thank you. Is there anybody on the Committee who would like to query MR. MILLER?

MS. ASPINALL: On the federal funds issue, I understand your answer. We had a lot of discussion on the reimbursement issue. Does it deal with the issues that you are talking about in terms of creatively thinking about new approaches?

DR. A. MILLER: One specific recommendation by this group is that prevention be covered by CMS, and I think that would go a long way to getting to the reimbursement issue. But I think it is a beginning and one step. I'm not sure the recommendations fully articulate the reimbursement issue, which is partly why PMC is going to be dedicating a considerable amount of time and effort to more fully articulate ways that reimbursement can drive the adoption of personalized medicine.

DR. TUCKSON: Thank you very much for your public comment and the letter that you wrote.

DR. A. MILLER: Thank you for your time.

DR. TUCKSON: Is there any other public comment that wants to be heard prior to our taking this vote?

[No response.]