Reaching Consensus on Final Draft Recommendations and Draft Report
Facilitators: Reed V. Tuckson, M.D. and Kevin T. FitzGerald, S.J., Ph.D., Ph.D.

DR. TUCKSON: Gurvaneet, you are not questioning.

Now, here is the deal. We are going to be okay in terms of time. We are going to quickly zip through the recommendations just so everybody can see them one more time. Be thinking about the totality of what we have done.

I would like for the members of the Committee who are ad hoc today and who cannot vote formally, which is all the new folk and some of the old folk. I have a list, don't I, somewhere of who can vote? Yes. Here are the people who can vote, just so you will know: Sylvia, Jim, Andrea, Kevin, Julio, Barbara, Joseph, Steve, this Tuckson fellow, and Marc. Those are the voting people.

We do want to make sure that all the rest of you [have input.] If you have any strong feelings, let us know through this last couple seconds here so that nobody feels like they are shut out and so you can feel like you are part of it even though you don't get to vote formally.

Kevin, why don't you zip us through just to look at them again one more time, and then we will get out of here by five. Nobody is going to mess us up with too much fooling around, but we will take some fooling around.

DR. FITZGERALD: Just to remind everyone, what you are going to see on the screen will be the only copy of our final versions right now. So nothing in your report, unless you wrote down all the changes yourself.

MS. GOODWIN: Just to add, I will be putting together a Word document with all of the final recommendations this evening, so you will have it tomorrow at your chairs.

DR. FITZGERALD: For those of you who have sight difficulties, I'm going to read each and every one as we go through quickly.

No. 1, "NIH should receive and put more resources into, 1) basic research on the biochemical pathways associated with drug metabolism and drug action, the genes and gene variations involved in these pathways, and the functions of those genes related to the safety and effectiveness of drug treatments and diagnostics; and 2) non-hypothesis-based approaches to the understanding of the relationship between genetic variation and individuals' responses to drugs." That was the first one.

Second, "As knowledge of the underlying biology accrues, further research will be needed to translate this knowledge into the development of clinically useful pharmacogenomics technologies and to assess their clinical validity and clinical utility. HHS agencies should facilitate the development of clinically useful pharmacogenomics technologies by investing more resources into all components of translational research, including the translation of basic research findings into clinical trials as well as the translation of clinical research findings into clinical and public health practice, insurance coverage, and policy."

No. 3A, "Where study results will be used to demonstrate safety and efficacy to support a pre-market review application, sponsors and researchers should be encouraged to consult with FDA and CMS early in the study design phases. This would help to ensure that these studies have

adequate clinical study design (e.g., sufficient statistical power) and quality controls in place should the research later be submitted for regulatory review."

No. 3B, "As appropriate, NIH should consider making FDA's existing quality of evidence standards a component of their assessments of the scientific merits of grant and contract submissions."

No. 3C, "In situations where pharmacogenomic diagnostics are essential to clinical drug use, HHS should require its grantees and contractors to participate in FDA's Voluntary Genomic Data Submission Program during the exploratory phase of drug development and/or the pre-IDE review process."

No. 3D, "To enable the investigation of biomarkers associated with drug response, HHS should encourage sponsors of federally funded clinical drug trials to obtain appropriate biological samples from research participants. HHS should develop guidance and standards on how these samples and other participant data will be collected, stored, shared, and used." We will reference the earlier SACGHS Large Population Studies report.

No. 4A, "FDA should develop and implement guidance on the codevelopment of pharmacogenomics drugs and diagnostics. FDA's guidance should clarify the review process for codeveloped pharmacogenomics products. It also should promote collaboration between drug and diagnostics developers."

No. 4B, "FDA's Office of Combination Products should coordinate FDA's review of pharmacogenomic tests and drugs to minimize delays in approvals of codeveloped pharmacogenomics products and to ensure timely access to such products."

No. 4C, "HHS should engage all stakeholders in identifying and providing incentives to encourage the development of pharmacogenomics drugs and diagnostics, especially for smaller patient populations and/or markets."

No. 5A, "HHS should identify and address evidence gaps in the analytic validity, clinical validity, clinical utility, cost effectiveness, and value of pharmacogenomics. Progress will require high-quality data resources; improved methodologies in the design, conduct, and analysis of observational studies; and empirical research on the evidence and standards necessary for making decisions for various purposes (e.g., coverage, clinical guidelines, performance metrics, value-driven health care) in different clinical contexts."

No. 5B, "HHS should initiate and facilitate collaborations between public (e.g., AHRQ, DVA, CDC, CMS, FDA, NIH, and NIST) and private entities (e.g., private health insurance plans, pharmacy benefits managers, healthcare facilities with electronic medical records, clinical research databases or genetic repositories) to advance the generation and sharing of knowledge on the analytic validity, clinical validity, clinical utility, cost effectiveness, and value of pharmacogenomics."

No. 5C, "HHS should encourage and facilitate studies on the clinical validity and clinical utility of pharmacogenomics and the dissemination of study findings, including negative findings, through publications, meetings, and information clearinghouses."

No. 5D, "HHS should provide mechanisms that promote interactions among basic translational, clinical, and outcomes researchers for the identification of endpoints and data elements to be

measured. The goal of these interactions would be to maximize the value and utility of basic and translational research data for downstream assessment of the clinical validity and clinical utility of pharmacogenomics tests."

No. 6A, "HHS should encourage private sector entities, including academic institutions, to share proprietary data voluntarily to advance the development and codevelopment of pharmacogenomics products. Manufacturers should be encouraged to make their data publicly available to allow others to conduct research and publish such studies."

No. 6B, "HHS should work with the private sector to identify obstacles to data sharing and develop solutions to overcome these obstacles (for example, legal and data confidentiality assurances, intellectual property protections, funding of databases and health information technology)."

No. 6C, "HHS should work with other relevant departments (for example, DVA, DOD, and NIST) and the private sector to improve data sharing and interoperability among databases. Specifically, HHS should work with existing organizations to create uniform genomic data standards, explore ways to harmonize data analysis methodologies, and develop an infrastructure to enable data exchange. Data sharing and interoperability of research, regulatory, medical record, and claims databases will facilitate the study of the molecular pathogenesis of disease, the identification of targets for drug development, validation of pharmacogenomic technologies, assessment of health outcomes associated with the use of pharmacogenomic technologies, and determination of the cost effectiveness and economic impact of using these technologies."

No. 6D, "FDA should identify, initiate, and facilitate research opportunities and public-private partnerships to encourage the development and codevelopment of PGx products (for example, the Critical Path Initiative and Biomarkers Consortium)."

No. 7, "Stronger data security measures will be needed as more pharmacogenomics researchers access patient data. HHS, through mechanisms such as AHIC's Confidentiality, Privacy, and Security Workgroup, should develop guidance on how to balance the protection, privacy, and confidentiality of personal data with access to these data for pharmacogenomics research."

No. 8A, "FDA should develop guidance that encourages the collection and analysis of genetic and other biological factors that may be better biological predictors of individual differences in drug response than broad categories such as race, ethnicity, and gender."

No. 8B, "When drugs are shown to be more effective in certain racial and ethnic subpopulations, FDA should encourage manufacturers to conduct additional post-market studies to identify genetic and other biological, social, behavioral, and environmental markers that may underlie the differential drug effects."

No. 9A, "CMS should develop a guidance document detailing current Medicare, Medicaid, and SCHIP coverage and reimbursement of pharmacogenomics. CMS also should survey public and private health plans about their decision-making processes and coverage policies to help inform its future pharmacogenomics coverage and reimbursement decisions."

No. 9B, "As the issues identified in the SACGHS Coverage and Reimbursement Report are still current, SACGHS urges HHS to act on the report's recommendations."

No. 10A, "HHS should assist state and other federal agencies and private sector organizations in the development, cataloguing, and dissemination of case studies and practice models relating to the use of pharmacogenomics technologies."

No. 10B, "HHS should assist professional organizations in their efforts to help their members achieve competencies on the appropriate use of pharmacogenomic technologies. HHS should also encourage and facilitate collaborations between the organizations and the federal government around these activities."

No. 10C, "As evidence of clinical validity and clinical utility for pharmacogenomics technology accrues, HHS should support the conduct of systematic reviews and technology assessments to summarize the evidence base. These systematic reviews and technology assessments should be disseminated to facilitate the development of clinical practice guidelines."

No. 10D, "HHS should facilitate the development of evidence-based clinical practice guidelines and dosing guidelines by supporting consensus-building efforts among guideline developers. These consensus-building efforts should include development of standards that define the minimal level of evidence required to support guideline decisions. These standards should take into account the clinical context (for example, prevention, diagnosis, treatment) in which pharmacogenomics tests may be offered."

No. 10E, "To inform the development of pharmacogenomic tests and dosing guidelines, HHS should fund clinical studies that provide evidence on whether pharmacogenomics information is clinically useful."

No. 10F, "The Secretary should encourage organizations to submit clinical practice guidelines that they develop for pharmacogenomic testing to AHRQ's National Guideline Clearinghouse to facilitate dissemination and encourage their implementation and use."

No. 10G, "FDA should work with manufacturers to ensure that all relevant pharmacogenomics information is included in drug labels in a timely manner. When a pharmacogenomics test is mentioned in a drug label, information should be included about the test's analytic validity, clinical validity, clinical utility, dosing, adverse events, and/or drug selection for clinicians to use when making treatment decisions based on pharmacogenomic test results. FDA should provide guidance on the standards of evidence that must be met for pharmacogenomics information to be included in the label."

No. 10H, "NIH and FDA should continue expanding the Internet-based DailyMed project, which provides up-to-date, real-time prescription drug label package insert information to people with Internet access. To ensure that all sectors of the public have access to this information, FDA and NIH should develop other ways to disseminate this information."

No. 11A, "To inform the public about the availability, benefits, risks, and limitations of pharmacogenomics technologies, HHS should ensure that credible education resources are widely available through federal websites and other media."

No. 11B, "HHS should use existing public consultation mechanisms to dialogue on the potential benefits, risks, and limitations of pharmacogenomics technologies. This dialogue should include an assessment of their perceptions and of receptiveness to pharmacogenomics and their willingness to use these technologies and participate in studies."
Wait a minute. That doesn't sound [right.] Assessment of whose perceptions; the public? Okay.

"The Office of the National Coordinator for Health Information Technology, through the activities of the American Health Information Community, should study how clinically validated pharmacogenomic test results are being incorporated into electronic health records. HHS, in consultation with DVA and DOD, also should take steps to ensure the necessary infrastructure is in place to support the representation of pharmacogenomics data in electronic health records for use in decision support systems and tools. HHS should explore development of pilot studies that examine the impact of clinical decision support systems for pharmacogenomics technologies on clinical practice at the point of care to maximize evidence-based best practices."

There is no 12B and No. 13 is gone, so this will be No. 13 now, I presume.

"HHS should support policies that afford access to pharmacogenomic technologies in ways that reduce health and healthcare disparities, improve quality of health care, and prevent genetic discrimination. To this end, HHS should continue to encourage and fund research in support of this goal."

No. 15, "The Secretary is requested to take all necessary steps to review and prioritize these recommendations, assess whether and how to implement them, monitor HHS's progress, and report back to SACGHS."

DR. TUCKSON: A quick scorecard of what we are saying, and this is just giving some broad categories. You have two categories where you are saying spend outright bucks. There were two outright expenditures.

You have 24 recommendations that said either develop, facilitate, engage, coordinate, encourage, urge. So you did a lot of developing, facilitating, engaging, coordinating, urging, and considering.

You have three where you require or ensure that the Secretary do something, and you have five where you said identify and address or study something.

So again, that is not a bad actual mix when you think about it. Two finances; 24 develop, facilitate, engage, coordinate, encourage, urge, and consider; three require and ensures; and five identify/address studies.

DR. FITZGERALD: Yes, Marc.

DR. WILLIAMS: I'm sorry. Could you go back to No. 9B for just a second? I think we may have missed a concept that would be kind of important. I think as opposed to "still current," I would say "are relevant to recommendations in this report." We don't have to have the "still."

MS. ASPINALL: Can I ask a question? It was an awkward moment before, but for us new people, if we haven't identified which report this is, can you highlight the key points of what that said? We are telling the Secretary to go back to it.

DR. WILLIAMS: There is a series of 10 or 12 recommendations that basically look at barriers to reimbursement and coverage and lays out, I think in a very reasonable way, what the issues are and how they might be able to be addressed.

Some of the issues relate to genetic testing, and so essentially I think what this recommendation is saying is that this needs to expand and include pharmacogenetic testing and that some of these

recommendations have not as yet been acted on. So it is a reinforcement of previous recommendations.

There is, in fact, an ongoing dialogue that is going to be taking place in the next month to specifically address some of those issues and get a progress report, so this is not outside of the context of the work of the Committee.

DR. FITZGERALD: Mara, do you want more information or is that sufficient? I can read you what is in it.

MS. ASPINALL: I was trying to understand it, because my concern is on reimbursement. Without this we are not taking a stand. We are just saying explain what happens today. So I wanted to understand what stand this took.

DR. FITZGERALD: "Recommendations cover a range of topics, including evidence-based coverage decision-making, Medicare coverage of preventive services, the adequacy of current procedural terminology (CPT codes) for genetic tests and services, billing by non-physician genetic counseling providers, and genetics education of health providers." Those were the topics that were addressed.

Then, in July, CMS sent feedback back on these recommendations, and then a small group, led by Marc, has been reviewing the comments by CMS. There will be a meeting with Barry in December.

MS. ASPINALL: Let me just ask one specific question on the CPT code piece. Was the recommendation that it was adequate or it was not adequate?

DR. WILLIAMS: Heck no.

MS. ASPINALL: I'm with you, then. I got the list. I now know what it does, but I don't know if you went "thumbs up" or "thumbs down." That is what I'm trying to understand because that is kind of important. I got it.

DR. TUCKSON: We are going to make sure that everybody is comfortable. Did we accept the change and the augmentation just now?

DR. FITZGERALD: Yes. Is everybody all right with the change that Marc just put in?

DR. TUCKSON: Are we good? All right. Now we are going to vote on this package. We are not going to go one-by-one. We are just going to vote on the package. No line-item vetoes.

I want to make sure, again, we are not rushing through this. So even the members who can't vote, I assume that we have kind of gotten a consensus here and that everybody is feeling comfortable about this very important report. So I'm looking around. Paul?

DR. BILLINGS: Reed, as a de novo, newbie, rookie, whatever you called me earlier, first of all, I want to at least express my gratitude. Being part of this discussion today was really quite an amazing tour de force by the Committee members.

There are a couple of issues that, again, may be buried in the deliberations of the Committee which, I guess for the record more than anything else, I would like to address.

It seems to me that what we have learned from the provision of pharmacogenomics so far -- for instance on the issue of point-of-care testing versus lab-based testing, or on the role of proteomic-based testing versus genotype-based testing, or on the question of whether pharmacogenetic tests should become a gate for access to certain drugs for that matter -- there is data already present in the healthcare system for these things.

The report is relatively silent on that. I wonder whether the report is going to suffer because of that. So I just raise those issues. Again, I mentioned it at the beginning and I raise it now.

DR. TUCKSON: I think it is very appropriate to raise it again. I know that Suzanne will ensure that the narrative, as she has already committed to do earlier, will reflect this very important though. So the narrative needs to remind all of us that we are not starting with a blank piece of paper here, that there is a history. I think that is a very important comment, and you might want to work with her on that.

I'm looking around the table.

[No response.]

DR. TUCKSON: So the formal people, for the record, whose hands will raise or not will be Sylvia, Jim, Andrea, Kevin, Julio, Barbara, Joseph, Steve, Tuckson, and Marc. With that, all in favor of the recommendations as summarized in the last iteration, please say "aye."

[There was a chorus of "ayes."]

DR. TUCKSON: All opposed?

[No response.]

DR. TUCKSON: All those abstaining?

[No response.]

DR. TUCKSON: So moved. You all have done a hard day's work today. Wait till we get to Andrea tomorrow.

I will let Kevin do whatever kudos he needs, but once again, Kevin, you have done just terrifically and just wonderfully.

DR. FITZGERALD: Thank you, thank you.

[Applause.]

DR. FITZGERALD: It is just my continual effort to live up to you, Reed, or "Red."

DR. TUCKSON: Suzanne as well.

DR. FITZGERALD: That's right. Before we do end this, I would like, again, to take an opportunity to thank some people. We did some of that at the beginning, but there were some people that we didn't have the time at the beginning to specify.

First of all, again, I would like to thank everybody on the taskforce. Obviously this is a group effort, and that is what makes it so rich and I think what makes it so substantive. Again, thank all of you. Thanks in particular Suzanne.

[Applause.]

DR. FITZGERALD: Her fingers have lost several centimeters in length being crammed on a keyboard.

Then I would also like to thank Sandra Howard. Is Sandra here? And Theresa Lawrence. Thank you very much.

[Applause.]

DR. FITZGERALD: As I mentioned before, the Lewin Group, but they should get some specific recognition. Cliff Goodman, Christel Villarivera, Erin Karnes, Lindsey Wu, Charlene Chen, Laura Peterson, Eric Faulkner, and Amanda Thomas out there in the audience. Thank you again.

[Applause.]

DR. FITZGERALD: Finally, thank you to the public commentators. We really did listen to what you had to say and it was very important in our understanding of how to go ahead.

And always, thank you, Reed, for your leadership.

DR. TUCKSON: Thank you. Now, as we close off, Robert is still out there, by the way. He sent us another Email.

[Laughter.]

DR. TUCKSON: So Robert, who hung in there until the end.

Also, I want to thank our transcriber, who is working diligently over there despite the fact that we keep forgetting to push these buttons.

I also want to knowledge the translators who are working so hard over there to try to make all this make sense, as well as our colleague from Gallaudet, who has set through this. We are pleased that you have come to do this.

[Applause.]

DR. TUCKSON: Also, finally, we want to thank the folk who are manning the cameras to make sure that this gets on the Internet. You guys are terrific back there.

[Applause.]

DR. TUCKSON: With that, we go to dinner tonight.

I always thank Abbe. I haven't gotten there yet. I'm telling you about dinner. They don't think I'm going to thank Abbe.

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Abbe, if you can hear me out there. I know you can because you never come in here when we talk about you. Abbe has us going to the Old Ebbit Grille. We are to meet, according to Abbe's instructions, at 6:15 in the lobby of the J.W. Marriott and then it is just a short walk.

Now, tomorrow, no fooling around. You know we are going to start at 8:30, so woe befall anyone who is late. Thanks, everybody, again.