Transcript of June 6, 2000 Meeting

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HEALTH CARE FINANCING ADMINISTRATION
Medicare Coverage Advisory Committee
Executive Committee Meeting

June 6, 2000

Baltimore Convention Center
One West Pratt Street
Baltimore, Maryland

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Panelists

Chairperson
Harold C. Sox, M.D.

Vice-Chairperson
Robert Brook, M.D.

Voting Members
Thomas V. Holohan, M.A., M.D., FACP
Leslie P. Francis, J.D., Ph.D.
John H. Ferguson, M.D.
Robert L. Murray, Ph.D.

Alan M. Garber, M.D., Ph.D.
Michael D. Maves, M.D., M.B.A.
Frank J. Papatheofanis, M.D., Ph.D.
Ronald M. Davis, M.D.
Daisy Alford-Smith, Ph.D.
Joe W. Johnson, D.C.

HCFA Liaison
Hugh F. Hill, III, M.D., J.D.

Consumer Representative
Linda A. Bergthold, Ph.D.

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Panelists (Continued)

Industry Representative
Randel E. Richner, M.P.H.

Executive Secretary
Constance Conrad, R.N.

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PANEL PROCEEDINGS

(The meeting was called to order at 8:35 a.m., Tuesday, June 6, 2000.

MS. CONRAD: Thank you, good morning. Welcome panel chairperson, members and guests. I am Constance Conrad, Executive Secretary of the Executive Committee of the Medicare Coverage Advisory Committee. The Committee is here today to discuss procedural aspects of future public meetings of the medical specialty panels of the MCAC and to hear reports from the Medical and Surgical Procedures Panel meeting of April 12th and 13th, during which biofeedback and pelvic floor electrical stimulation in the treatment of urinary incontinence were deliberated.

At the conclusion of the afternoon session today, if the Executive Committee ratifies the Medical and Surgical Procedures Panel recommendations, it will officially transmit that recommendation to HCFA. HCFA will develop a coverage policy within 60 days of the receipt of

that recommendation.
The following announcement addresses conflict of address issues associated with this meeting and is made a part of the record to

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preclude even the appearance of impropriety. To determine if any conflict existed, the Agency reviewed the submitted agenda and all financial interests reported by panel participants. The conflict of interest statute prohibits special government employees from participating in matters that could affect their or their employer's financial interests. The Agency has determined that all members may participate in the matters before the Committee today.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products or services they may wish to comment on.

And now I would like to turn the meeting over to Chairman Harold Sox, who will ask the Committee members to introduce themselves.

DR. SOX: Well, the Committee members are known to each other but they're not necessarily known to members of our audience, so I would like each person to identify themselves by name and also state where they're from and what they do very briefly, so that the audience will understand.

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Randel, would you like to start please?

MS. RICHNER: Randel Richner, Boston Scientific, vice president of reimbursement and outcomes planning.

DR. JOHNSON: Joe Johnson, chiropractor in private practice, Paxton, Florida.

DR. BERGTHOLD: I'm Linda Bergthold, and I'm a consultant and researcher, and I am the consumer representative to the Executive Committee.

DR. DAVIS: I'm Ron Davis. I'm a preventive medicine physician. I work at the Henry Ford Health System in Detroit, where I direct a center for health promotion and disease prevention.

DR. PAPATHEOFANIS: I'm Frank Papatheofanis. I'm an assistant professor of

radiology at the University of California in San Diego.

DR. MURRAY: Bob Murray. I'm an attorney and biochemist at Lutheran General Hospital in Park Ridge, Illinois, technical director of the clinical laboratory.

DR. BROOK: Robert Brook. I'm an internist and professor of medicine at UCLA, and head of Rand Health.

DR. ALFORD-SMITH: I am Daisy

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Alford-Smith. I am the director of the County Department of Human Services in Akron, Ohio.

DR. GARBER: I am Alan Garber. I'm a general internist at the Department of Veterans Affairs and a professor of medicine at Stanford.

DR. FERGUSON: John Ferguson, neurologist, former director of the consensus program at the NIH and now a private consultant.

DR. HOLOHAN: Tom Holohan, internist, hematologist oncologist, associate chief medical director at VA Headquarters, and chief of patient care services for the Veterans Administration.

DR. FRANCIS: Leslie Francis. I'm professor of philosophy and professor of law, and adjunct professor of medicine at the University of Utah.

DR. MAVES: I'm Mike Maves. I'm the president of the Consumer Healthcare Products Association and a practicing otolaryngologist at Georgetown.

DR. HILL: I am Hugh Hill, and as you heard, I'm the acting director of coverage and analysis, and I am the federal representative to the panel.

DR. SOX: I am Hal Sox. I am a general

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internist. I chair the department of medicine at Dartmouth-Hitchcock Medical Center.

Well, today's meeting basically has two parts to it. The first is to give the Executive Committee a chance to reflect on the responses that it has received regarding the interim Medicare Coverage Advisory guidelines that we ratified at our March meeting. We have both had a chance to get some written feedback from organizations and

individuals, as well as to use the guidelines in evaluating procedures for incontinence. So the first half of today's meeting gives us a chance to reflect on what we've done and to decide whether or not we need to make any significant modifications on the basis of this feedback and the single experience we have had in applying these guidelines to a real world task.

I think each committee member should be thinking about whether this is the right time to make fundamental changes in what we proposed or whether to make changes and to emphasize certain aspects of the procedure that may not have gotten full attention during the incontinence review by the Med-Surg panel. So the question is, do we make big changes on the basis of feedback plus one

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experience or do we make small changes that are aimed at trying to make the process fair and to give everybody a chance to hear from everybody who has an opinion about the process.

So, to get that process rolling, I am going to quote selectively from our, from the guidelines as much for the benefit of the audience as for the panel, who by now should have them pretty well memorized. Then we are going to be hearing from some of the leaders at HCFA about their take on the experiences of the past three months. Then we are going to hear from a number of people who signed up to give presentations for about an hour. And then after a break, we will have a chance to debate really, what we should do, if anything, at this point. That will bring us up to lunch and then in the afternoon we will discuss the recommendations of the Med-Surg panel regarding procedures for incontinence. So that is sort of a blueprint for what we're going to do today.

Let me quote sort of selectively from this document that we've developed and ratified on March 1st. The document has two purposes basically; one is to give some general guidelines, not rigid rules, but general guidelines about how

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to evaluate evidence, and it focuses first of all on whether the evidence is sufficiently strong to draw a conclusion about whether a potential

procedure in fact is effective in patients. And then secondly, if there is evidence, valid evidence that it's either effective or not effective, how big is the effect, is this a breakthrough technology, something that makes a small contribution at the margin, or something that in fact is less effective than currently covered procedures but has some benefits that might be advantageous to selected patients. The second part of the document deals with procedure, makes some suggestions about how the panels of MCAC can function most effectively.

So first on the evaluation of evidence, it states that the MCA panels should explore many sources of evidence in assembling the body of evidence to be used in their deliberations. The sources might include peer reviewed scientific literature, the recommendation of expert panels, and unpublished data used to secure FDA approval. The quality of evidence from these various sources will vary, and the panel should weigh that evidence according to its quality.

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So the first question is then, is the evidence adequate? The panels must determine whether the scientific evidence is adequate to draw conclusions about the effectiveness of the intervention in routine clinical use in the population of Medicare beneficiaries. There is a lot contained in that sentence. The assessment of the adequacy of evidence is a sine qua non of essentially all modern approaches to evaluation of medical technologies, and I want to underscore that. There are many efforts in many different venues for evaluating medical technology. They all have as a common feature assessing whether the evidence is adequate to draw conclusions about whether the technology is effective, so this panel is mainstream in adopting that approach rather than on the cutting edge.

Defining what constitutes adequate evidence is the critical step, and that includes both the validity of the evidence and its general applicability to the population of interest. And the question about validity turns principally on the question of whether the study systematically

underestimates or overestimates the effect of the intervention because of possible bias or other
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errors in assigning patients to the intervention and control groups.

Now, the best way to avoid systematic bias that leads to over or underestimating the effect of an intervention is to assign subjects randomly to the intervention or control group, and if the number of subjects is sufficiently large, the process of randomization essentially insures that any effect that's seen is due to the intervention rather than some other variable that might be causing differences between the two groups. Therefore, the randomized trial represents the easiest way to be sure that you're dealing with valid evidence.

There are other forms of evidence that may be considered in which controls are present, such as case control studies, cohort studies and the like. Because subjects are not randomly assigned to intervention and control group, there is always a possibility that some other variable causes people to either get the intervention or to be in the control group, and it is that variable rather than the intervention itself that affects the outcome. And so it raises the possibility of misinterpreting the evidence and assigning credit
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for the success of the intervention to the intervention when in fact it's some other variable that's at fault. And that's the reason why, insofar as possible, randomized trials make it easier on panels like this to make up their mind.

Although they do not have randomized controls, all well designed observational studies include some form of control. This is certainly a fundamental point. Controls may consist of an implicit or explicit control group. A body of evidence consisting solely of studies with no controls whatsoever, where they're based on anecdotal evidence, testimony or case series, is never adequate for making a decision about whether something is effective. That's a very strong statement and one that this panel has endorsed.

However, in many cases the panel will

determine that observational evidence is sufficient to draw conclusions about effectiveness. This panel would prefer to have randomized trial evidence but it has said to itself, you must consider other forms of evidence when randomized trial evidence is not available. But when these circumstances apply, the panel must describe possible sources of bias and explain why they felt

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they could draw a conclusion despite the potential for bias.

The second major point beside validity is external validity. Do the studies apply to the Medicare population? A study performed in 25 year olds, it may be a stretch to assume that that's going to apply to a group of 75 year olds. So external validity means, do the studies apply to the population in question. And the second major criterion for evaluating the evidence, is the size and direction of the health effect it demonstrates. Does the intervention improve health outcomes or does it make them worse, and by how much are health outcomes improved or made worse. And the Committee at its last meeting endorsed a way to categorize the size of the effect ranging from breakthrough technology in which the improvement is so large that the intervention becomes the standard of care, to noneffective, which means that it has no effect or even deleterious effects on health.

The second part of our report dealt with suggestions for panel operations, and I will just very briefly go over each of those in turn. The first had to do with the structure of the evidence

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provided to the panels. The panel, the Executive Committee asserted that panels should receive well organized high quality background information before beginning their deliberations. The evidence should be summarized in a report, not simply presented as a collection of data or primary studies. And we saw an example of that with the incontinence study, in which an evidence based practice center that is associated with Blue Cross/Blue Shield carried out the evidence report, which the panel considered in drawing its

conclusions.

The second major point about panel operations is that panel members should take an active role in preparing the evidence report, they shouldn't just be passive receivers of the report but in fact the panel chair should play an active role in framing the questions that the evidence report must address, and the panel must answer, and we'll hear about how that was done with the incontinence study. We assert that several panel members should participate actively in designing the evidence review and preparing the evidence report, so that there are few built-in experts on the panel who understand the evidence intimately.

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And finally, that the panel should assign two members to be sort of primary reviewers of the evidence and report, and to go over in depth, perhaps spending more time on it than every panel member would have time to do.

The third recommendation is that the evidence report should get external review by several experts in order to be sure it is complete and that it is free from bias, and that's a way of both protecting the panels against making mistakes, as well as protecting the advocates of the technology from a biased report that might be unfavorable to their interests.

Finally, explanation. A panel must explain its reasoning in coming to its conclusions and that explanation should be in writing. And in fact, we stated that prior to acting on a panel recommendation such as the Med-Surg panel recommendation on incontinence, that the Executive Committee, this group will have the following operational documents: First of all, a meeting transcript, which in this case I gather ran to 500 pages or 500 megabytes or something like that, and also a meeting summary prepared by HCFA staff and reviewed by the panel chair for approval, and the

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summary shall include the explanation of the panel's vote.

So that was our report, and again, the question before us during the first half of this meeting today is did we get it wrong, should we

make some changes, should me emphasize certain elements of the report that may not have been followed to everybody's satisfaction in the first report.

So, I guess before we proceed now to hear from folks who signed up to comment on this report, we're going to hear from the folks in HCFA and Hugh, do you want to lead?

DR. HILL: Yes, if I may. I just very briefly want to welcome and thank you all. In the interest of time, I will not respond or iterate all the comments that we received, that we collected for the Committee in the operations procedures mailing that you got. But on behalf of the Agency, the administrator, my boss, Dr. Jeffrey Kang, who may yet be able to join us briefly, I want to welcome you and thank you very much for participating, and especially to the panel for its hard and good work on this.

The summary statement I want to make is

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that HCFA remains strongly supportive of the MCAC and the Executive Committee and its work, strongly supportive and very appreciative. In addition to the comments that we received, a general theme that came up repeatedly was a question of whether we want the Medicare Coverage Advisory Committees to be telling us whether or not they think something should be covered. And our answer to that at the present time is that we are very interested in the MCAC telling us about its analysis of the scientific evidence. We hope that that analysis is informed by clinical and methodological expertise. Basically I'm reiterating Dr. Kang's letter to the Committee that was sent out, I believe in January.

And one other brief comment is we continue to get questions about whether or not the Medicare Coverage Advisory Committee and the Executive Committee is, in some people's terms, quote, setting the bar too high, closed quote, questions about whether or not the threshold that has to be crossed by technology in terms of evidentiary standards and proof is too great to be met. Let me reiterate what we've said before and what we've said consistently is that the threshold determination is a matter of our responsibility; we

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look to the MCAC for comments about the hierarchy of evidence, and analysis of comment of evidence at different levels within that hierarchy, but we have not abdicated our responsibility, nor have we tried to shrug it off for making the ultimate coverage decisions ourselves.

We will be talking about the urinary incontinence panel this afternoon, I will make no further comments about what happened there and what we, the way we structured the questions and that sort of thing. We are prepared to talk about that should that become necessary, but as a notice, just a heads up, I want to point out to the Committee something that I think most of the people in the audience already know, that we have published a notice of intent. Both the Committee and the public has expressed some of the same interests that we have in having guidelines for what we mean by reasonable and necessary as we try to continue to be increasingly open and consistent and fair in our coverage decision-making process. And this step is a major one; we hope it will lead to a notice of proposed rule making, which will define what we mean by reasonable and necessary, or give some criteria for that.

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We are not asking for a formal response from the Medicare Coverage Advisory Committee or even this learned Executive Committee about that notice of intent, but the comment period on it is being extended and your informed, given the wisdom you've shown in this, is especially important to us; statements and suggestions will be very much appreciated. And that's all I have right now.

MS. CONRAD: Thank you, Dr. Hill. Well, at this time, let us move ahead with public comments. And each, I have a list of speakers here and we have determined by the number of speakers and the amount of time available to us, each speaker may have six minutes. It's nine o'clock now. About -- excuse me. Yes, Bob?

DR. BROOK: Since we have a minute before nine, can I ask the HCFA representative one question?

MS. CONRAD: Please.

DR. BROOK: I am just wondering one question; if the purpose of the panels is only to provide evidence, to assess the evidence, can I ask a question about why, since another government agency, the Agency for Health Care Policy and Research, had already issued an evidence based

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report on urinary incontinence in 1996, were those two topics sent to MCAC? Was it because you felt that the report by the Agency was inadequate, out of date? I mean, there seems to be some confusion here about the roles of various agencies in the government.

DR. HILL: That's more than a one-minute answer. In the charter for this committee and its subpanels, we mention several criteria for when subjects would be sent to this committee. And one of those is impact on the program; we've talked about others, where something's controversial, there's a split of opinion among scientists in the area and that sort of thing. But in this case, tracing it back as far as I can tell, it was decided before I came on board because of its impact on the program. And we heard testimony at the UI panel about the significance of this to the Medicare population which reinforced our belief that it is important to the program.

DR. BROOK: I'm sure the Agency felt the same way. The question is, again, I come back: Was this -- it would be nice for this panel to know, because that's part of what we need to decide both for the morning and the afternoon, is there

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was presumably a first class evidence based report that had been released. Was it determined -- because that determines our role. If our role is only to look at evidence in the classical sense, then that report was already there and you could have just taken that report and used it, and made it your coverage decision. And that's what -- I'm trying really to understand the ground rules so I can listen to this public discussion before we go further, because this is what's confusing me.

DR. HILL: We have had discussions about whether or not questions that come before the panels should have technological assessments in

front of them, whether the panel should have TEC assessments to look at in their evaluation of the evidence. We are looking for obviously, more than what the TEC assessment gives us when something comes to the panel, and we're looking for your informed expertise beyond that. I think Alan had another response, based on his experience with the UI panel.

DR. GARBER: Well, Bob, I think it's a very fair question and it does deserve more than a minute, but I'm sure this is going to be one of the points of discussion this afternoon. If I could

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just briefly summarize, I was involved in the process of helping to refine the questions and wasn't participating in the initial formulation of this whole area as a topic. But my understanding is, first of all, the AHCPR report did not directly address the same questions, although it was in the same broad area, number one. And number two, there had been a fair number of publications since the AHCPR report was written. Now one could still question the wisdom of choosing to do this topic, but at least there was a rationale for why the AHCPR report might not be the last word at the current time for the questions that HCFA wished to consider.

DR. HILL: And I also point out that as ARCAS reminded us, this was not a full $500,000 18-month evidence report that we asked for as a supplement from them. This was a limited report on the randomized control trials that were available and a layer of evidence that was looked at in a more limited and briefer fashion, in part in the interest of time.

DR. SOX: Thank you for that question, Bob. I'm sure it's one we will return to, because it in part raises the question about a process

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that's intended to provide clinical guidance to physicians perhaps in the absence of good evidence on the one hand, and a process of making recommendations about that evidence on the other, and at least for now, our assignment is to make comments about the adequacy of the evidence, not really to give guidelines to physicians about how

to practice under circumstances where the evidence may not be full and complete. So with that brief exchange, why don't we move on here? Do you have the first speaker, Connie?

MS. CONRAD: I certainly do. The first scheduled speaker is Sandra Sherman, representing the American Medical Association. Following her will be Jerome Connolly.

MS. SHERMAN: Good morning. I believe you've already been provided with a copy of a letter that Dr. E. Ratcliffe Anderson, the AMA executive vice president and CEO, sent to HCFA on May 9th, offering comments on the interim recommendations. I just want to underscore a few of the key points in Dr. Anderson's letter.

First, we want to make clear our view that the interim recommendations have significantly improved the process for consideration of issues

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referred to the MCAC. The MCAC represents a major leap forward in the methods to be used by Medicare for the development of national coverage policies. We applaud the Committee's and HCFA's focus on evidence based decisions, and we were pleased by the significant level of participation in the April panel meeting by the national medical specialty societies.

The interim recommendations document focused on the question, is the evidence concerning effectiveness in the Medicare population adequate to draw conclusions about magnitude of effectiveness relative to other items and services. The Executive Committee indicated that the standard of excellence for evidence reports would include the best work in the private sector, e.g., Blue Cross/Blue Shield, by professional organizations, e.g., ACP, ASIM, and for other federally sponsored panels, e.g., the evidence based practice centers, technical support for the U.S. Preventative Services Task Force.

At the April panel meeting, however, it seemed as if the recommendations were being interpreted as stating that the only evidence worthy of consideration is that contained in peer

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reviewed scientific literature. The MCAC panel was

essentially asked to disregard clinical guidelines that had been developed by the Agency for Health Care Policy and Research, and expert opinions developed by national medical societies.

The second point addressed in our letter is that continued application of the Executive Committee recommendations in such a narrow fashion will prevent the MCAC deliberations from achieving the desired high standards of comprehensiveness and balance. The effectiveness of many procedures that are covered by Medicare today for aged and disabled beneficiaries has not been demonstrated in peer reviewed scientific literature. And even where the effectiveness of treatments has been demonstrated in a study population under study conditions, it is unlikely that effectiveness in routine clinical use in the Medicare population will have been demonstrated in scientific journals.

It is clearly important that MCAC panels focus on a critical evaluation of the available scientific literature on the effectiveness of procedures proposed for Medicare coverage. It is equally important, however, for the panels to critically evaluate other clinical information.

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Inclusion of a service within a clinical guideline that is accepted by the medical community as the standard of care is an important consideration. Omission of such clinical information from MCAC deliberations could lead to Medicare's failure to cover important and effective diagnostic and therapeutic options.

The issues that HCFA is most likely to refer to the MCAC are those that are controversial. If the questions surrounding these issues could be unequivocally answered by a technical assessment of published scientific evidence, HCFA would not need to refer them to the MCAC. What generally makes these issues controversial is that the published studies do not conclusively answer the question of effectiveness for Medicare beneficiaries.

Finally, our letter describes several suggested revisions to the document. In particular, within the section on adequacy of evidence, the AMA recommends that language be added

regarding how the panel should weigh and consider clinical guidelines, standard text books, review articles, and other clinical evidence that may be presented. Grading systems clearly give more

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weight to evidence from well designed clinical trials than what might be regarded as expert opinion. Nonetheless, when the data available from the scientific literature is insufficient to draw conclusions, expert opinion regarding the adequacy of available clinical information should be considered.

The AMA also recommends that several of the panel members be tasked with assessing the completeness and accuracy of the evidence report. If panel members know of studies, guidelines, consensus statements, or other information that should be but is not included, they should be encouraged to provide this information in time for the evidence report to be revised. Thank you.

MS. CONRAD: Thank you, Miss Sherman. Jerome Connolly, to be followed by Marshall Stanton.

MR. J. CONNOLLY: Members of the committee, good morning. My name is Jerome Connolly. I'm a physical therapist of 28 years, having graduated from the Mayo Clinic School of Physical Therapy in 1972. I currently serve as the senior vice president for health policy for the American Physical Therapy Association, and I have

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no current or past conflict of interest to be disclosed at this time.

I was told originally that I'd have between seven and ten minutes, so I only have six, so I'll speak a little more quickly than I probably ordinarily would. Plus the fact that I drove from Washington this morning in a driving rainstorm and I haven't had a chance to use a men's room yet, so I will probably only use six minutes, maybe only five and a half.

On behalf of APTA and its almost 69,000 members, I wish to thank you for the opportunity to address you today. APTA commends HCFA for its attempt to implement an open coverage process, a process that should allow the general public, the

health professions, and the health care industry to play an important role in the development of Medicare coverage decisions. Having participated in the Medicare Coverage Advisory Committee process relative to urinary incontinence in April, a participation which at times APTA found quite frustrating, APTA has several recommendations that it would like to offer in an effort to make the process and the experience more useful, more productive, and more credible. And these have been

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conveyed to you and to Dr. Hill in a letter that we have submitted.

First, we recommend that the catalogued information to be sent to the panel should be sent well in advance, to allow panelists a sufficient amount of time to request, to read, and to digest materials. Due to time constraints imposed on verbal testimony, it is difficult to provide extensive comment to the panel without the aid of written correspondence; however, written comments are only beneficial if the panel members read them prior to deliberation. APTA appreciates the fact that HCFA solicits written comments from the public. The process should provide assurance that the written comments submitted will be distributed to the panel, and will be done in a time -- and that distribution will be done so in a timely manner.

Secondly, when a technology assessment is done, and HCFA solicits written comments from the public, it is imperative that the public has access to the technology assessment for a reasonable period of time preceding the deadline for comments. In this case, the assessment was posted on the web almost a week after the deadline

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to comment had passed. This made it impossible for the public to address by written analysis issues raised in the technology assessment. To achieve an open public forum, HCFA must allow the public to be privy to, and provide written comment on relevant materials prior to the meeting. Otherwise, the public is disadvantaged and its efforts to provide meaningful comprehensive input are thwarted.

APTA's presenter, Cynthia Feldt, requested that

APTA's analysis, written analysis of the assessment, be distributed to the panel during her testimony, but that request was denied.

Third, in an effort to achieve an objective process, it is imperative also that the panel be sent, and not just have access to upon request, a variety of materials that reflect diverse opinions when such material is available. For example, the panel only received the Blue Cross/Blue Shield technology assessment, which expressed only one viewpoint. In addition to the assessment, it would have been beneficial for the panel to have received the AHCPR clinical practice guidelines, because they contained considerably different, yet valid, viewpoints. If HCFA is expecting the panel to make an impartial decision

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at the meeting's conclusion that day, more balanced materials and perspective should be provided to the panel well in advance of its deliberations.

Fourth, the questions posed to the panel by HCFA should be broader than those used in April. These questions were very narrow in scope, and therefore only allowed consideration of a limited number of studies that carried out a very specific comparative analysis of treatment. APTA believes that the adoption of an evidence based standard for coverage should not preclude the consideration of either the expert clinical testimony presented at the meeting, panelists' own individual knowledge or clinical experience, or the personal experiences of consumers. Without allowing consideration of this input, panel members are essentially being told that the relevant clinical experience, even their own clinical experience, what has gone in this case, in April, for the past 50 years, is not noteworthy.

According to Sackett, et al., evidence based medicine means integrating clinical expertise with the best available external clinical evidence from systematic research. He goes on to say, EBM builds on and reinforces but never replaces

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clinical skills, clinical judgment and clinical experience.

Fifth, to insure the public of receiving

due process, it is essential that the panel members have more latitude when formulating their opinions on coverage issues. Amending the questions to be inclusive rather than exclusive would accomplish this goal. Therefore, APTA recommends that in addition to framing more broadly constructed questions, that the panel members be allowed to and specifically requested to call upon their individual clinical expertise and experience. An appropriate question to be posed to the panel would be worded as follows: Is the scientific evidence adequate, when combined with clinical evidence, clinical experience and consumer input, to allow a conclusion to be drawn that the intervention has a reasonable chance of benefitting the patient? In other words, we're talking about reasonable and necessary here. In other words, the basis for the panel's conclusion and recommendation should be evidence based, based on the preponderance of both scientific and clinical evidence. Preponderance of evidence, not beyond a reasonable doubt. Such an approach would be consistent --

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MS. CONRAD: Time please.

MR. J. CONNOLLY: -- With the writings of Sackett, et al., in evidence based medicine, how to practice and teach EBM, which is now in its fifth printing, which states, EBM is not restricted to randomized trials and meta-analysis.

So we would say in conclusion, that the process we participated in is not yet quite to the level that it needs to be, that it does contain some fundamental flaws, Dr. Sox, and in answering that question, there are some fundamental flaws, and the process can be and should be modified and improved before any decision reached by using this process is implemented. Thank you again for the opportunity to comment.

MS. CONRAD: Thank you, Mr. Connolly. Marshall Stanton, representing Medtronic Incorporated is next, followed by Alfred Chiplin please.

DR. STANTON: Thank you. Connie, have the panel members received copies.

MS. CONRAD: I'm not sure.

DR. SOX: We certainly received a letter

from you.

DR. STANTON: My name is Marshall Stanton, I am the industry representative the MCAC's Medical Surgical Procedures Panel. I am currently medical director and vice president of therapy development for the cardiac rhythm management division of Medtronic. Prior to this, I was a practicing cardiac electrophysiologist at Mayo Clinic in Rochester, Minnesota, holding an academic post there for ten years.

The MCAC Executive Committee has emphasized that its interim recommendations for evaluating the effectiveness of medical therapies and diagnostics will be a living document subject to modifications in substance and tone. I would like to take this opportunity to report on my observations from the first meeting of the Medical Surgical Panel, and suggest how the experience of this panel might improve the guidance document and the MCAC process.

I think we all agree that ideally, the MCAC process should be predictable, timely, accountable and consistent, while still maintaining the flexibility necessary to make the process of practical use. While a number of excellent points were raised at the recent Medical Surgical Panel meeting that considered biofeedback and pelvic floor stimulation for urinary incontinence, I believe that the panel's rigid interpretation of the guidance document led to deliberations and results that fell short of the Executive Committee's stated goals.

The Executive Committee has suggested that a variety of evidence, including recommendations from experts, could be considered adequate for a positive panel recommendation. However, the Medical Surgical Panel interpreted the guidance document to require conclusive scientific evidence from multiple large randomized control trials with consistent positive outcomes. The process virtually ignored other forms of evidence. The panel took no account of the views and recommendations of specialty societies, consumers or practitioners, and it ignored the results of

clinical practice in its determination that there was insufficient evidence.

In addition, the questions that were posed left the panel too constrained to be of any practical use. The purpose of an advisory committee, like the Medical Surgical Panel, should be to provide its clinical perspective on the value of a diagnostic or therapy. Instead, the exclusive

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focus of the panel on the adequacy of the scientific evidence and the Blue Cross/Blue Shield TEC reports left some panel members voting no, while stating they believed the therapy should be covered. Requiring the panel to vote on the question of adequacy of study design, consistency of results, applicability to the Medicare population, and applicability beyond the research setting before proceeding to an opinion on the potential benefit of the therapy, places a serious and in some cases insurmountable obstacle into the process, virtually excluding further rational discussion of evidence.

Many procedures and technologies that are widely accepted as standard of care will not meet the standard of conclusive scientific evidence from multiple randomized control trials. The notion that public health policy making will require rigorous scientific proof, will result in a disservice to beneficiaries. If we confine the panels decision making to evidence that satisfied the P less than .05 perspective, it will be an opportunity lost for Medicare beneficiaries.

Therefore, I believe the outcome of the Medical Surgical Panel meeting shows that the

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guidance document needs to be clarified to further strengthen the ability of the panels to give positive recommendations to therapies they believe are beneficial for certain patients, but may not be supported by conclusive scientific evidence. By definition, the standards established to judge adequacy of data in the guidance document seem to preclude uncontrolled observational evidence, including expert testimony and disease registries. The guidance document is not sufficiently explicit that various levels and forms of evidence are

acceptable, and this resulted in a panel meeting that merely rubber stamped a Blue Cross/Blue Shield TEC report.

We are naive if we believe that at a time when HCFA is emphasizing an evidence based coverage process, panel votes will not weigh very heavily in their final decision. A no vote that results in a noncoverage decision by HCFA may have significant impact on beneficiaries. Noncoverage decisions at the national level mean that no beneficiary will be able to access the therapy at any point in the treatment continuum, even as a therapy of last resort, and there is no practical right to appeal.

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As a physician, I want to emphasize that in clinical practice, treatment decisions for patients are made based upon an assessment of the literature, not on a meta-analysis requiring a significance level of P less than .05. If the latter were the case, few treatments would be initiated.

It was remarked that the standards used to make coverage decisions are entirely different from those used in the clinical setting. I understand the point that different levels of evidence may be required to make coverage decisions for large populations. However, I think we have to remember that the Medicare beneficiary population is made up of individual patients who together with their physicians, make decisions about appropriate treatments. If some of those treatments are not available, then it directly interferes with options available in the clinical setting. Coverage decisions and clinical practice are directly related in the real world.

It is worth noting some of the work of other organizations charged with evaluating evidence and making recommendations regarding the use of certain services in clinical practice. For

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example, it might be useful to look at the work of the American College of Cardiology and American Heart Association in developing practice guidelines. When developing pacemaker guidelines the committee emphasized that, quote, for certain

conditions for which no other therapy is available, the indications for device therapy are based on expert consensus and years of clinical experience, and are thus well supported even though the evidence was ranked at a level C. An analogous example is the use of penicillin in pneumococcal pneumonia, where there are no randomized trials and only clinical experience.

MS. CONRAD: Time please.

DR. STANTON: The Executive Committee should give highest priority to insuring that the Medicare coverage process will work for beneficiaries and the clinical community. This means developing a process that utilizes the expertise of the panel members to look beyond randomized control trials to other appropriate methods of evaluating evidence.

I will stop there, thank you.

MS. CONRAD: Thank you, Dr. Stanton. May we have Alfred Chiplin please, and following,

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Debra Jensen.

MR. CHIPLIN: Good morning, ladies and gentlemen. I am Alfred Chiplin, with the Center for Medicare Advocacy, and I represent several other beneficiary advocacy organizations whose names are listed in my testimony. I'd also say at the beginning that our organization, one of them I represented, the National Senior Citizens Law Center and the Center for Medical Advocacy, were involved in the initial litigation called Jameson versus Bowen, which began to open up at least through the settlement process in that lawsuit, open up a window to exploring and making more available to beneficiaries, information about the national coverage process.

Along those lines, we applaud the moves that have been made to continue to open up that process, but we do have some concerns. With the interim recommendations as they are designed, with the laudable goal of assisting the MCAC panel in evaluating the formal request for national coverage determinations, they also place an insurmountable burden on beneficiaries who are often asked to prove the safety and effectiveness of medical services, items and procedures. We ask you to

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reevaluate your recommendations for the following reasons:

Many services and items currently under review by HCFA have already received approval from the FDA and/or are already covered by other insurance carriers. The onerous evidentiary proof demanded by the interim recommendations ultimately hurts rather than helps Medicare beneficiaries by delaying access to services their own physicians found reasonable and necessary for their care. Beneficiaries often suffer negative legal consequences or die as a result of a lengthy coverage process, which often takes years to complete, while HCFA decides whether to cover the item, service or procedure prescribed by treating physicians. The requirements that outside experts be used in certain situations to further evaluate the evidence presented to the review panels of experts exacerbates the delay problem. Delays cause further disparities between Medicare and private insurance coverage. Together, the requirements exacerbate the disparity between what is covered by Medicare and what is covered under private insurance practices.

Finally, the interim recommendations

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inappropriately place the burden of proving effectiveness and reasonableness on those seeking coverage. This unfairness is magnified by the preference in the interim recommendations for clinical trials, the most time consuming and costly of scientific data collection. Reliance on clinical trials, especially where other clinical evidence is available to support coverage, increases the time and cost involved in making the coverage decision and discourages innovation. An efficient coverage determination process should recognize the range of clinical evidence to support the coverage of items and services, and recognize that for some items and services, clinical trials are not appropriate. It should allow Medicare beneficiaries to receive Medicare payment for services and procedures, devices and technologies, that have been approved by the FDA where appropriate, and found by the beneficiary's

physician to be reasonable and necessary for the treatment of that beneficiary's illness or condition. We thank you very much for the consideration of these very important points.

MS. CONRAD: Thank you so much. Debra Jensen, and the next will be Kevin Connolly.

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DR. JENSEN: Good morning. My name is Debra Jensen and I am the vice president of regulatory affairs, quality assurance and clinical research for EMPI. EMPI is a manufacturer and distributor of electric therapy and orthopedic rehabilitation products. Clinical studies conducted on EMPI's Innova pelvic floor electrical stimulation device for the treatment of incontinence were among those reviewed by the MCAC Medical and Surgical Procedures Panel in April. EMPI strongly supports and remains committed to HCFA's efforts to create a more open and predictable process for making Medicare coverage decisions. However, we have significant concerns about the panel and the Executive Committee operation in this time of transition.

Our discussions with other stakeholders have demonstrated that EMPI is not alone. Many organizations, clinicians and professional societies share our concerns regarding the evolving process, and echo our frustration with the deliberations and outcome of the April panel meeting. In an effort to improve this important process, we would like to offer the following observations and comments regarding the evidence

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standard, the duties of the Medicare Coverage Advisory Committee, and the role of public comments, especially those of professional medical societies.

The interim recommendations for evaluating effectiveness adopted by the MCAC Executive Committee were designed to provide a framework that would promote consistency within and between panels, and promote accountability to the public by providing a consistent framework for decision making. While the Executive Committee was well intentioned and should be applauded for their commitment to the principles of evidence based

medicine, we question whether this document was consistent with the mission defined for them in the MCAC charter and within the framework of the April 21st, 1999 Federal Register notice announcing HCFA's process for making coverage decisions.

According to these documents, the role of the MCAC is to provide the Agency with recommendations on whether a technology or service can be considered reasonable and necessary, and then to make recommendations on national coverage. MCAC referrals are made when the technology or service being considered is the subject of

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significant scientific or medical controversy. The recommendations ratified by the Executive Committee and utilized in the April Medical and Surgical Panel meeting appear to be in conflict with the MCAC charter, that provides for a process designed to review controversial technologies or services.

We believe that the process as originally envisioned and laid out in the charter in the Federal Register notice is a useful and appropriate method for reviewing controversial technologies. From our perspective, the outcome of the April meeting was diminished, however, because the questions and deliberations focused solely on the scientific rigor of the randomized control trials as reviewed by Blue Cross/Blue Shield while minimizing any discussion regarding other interpretations of the data and more importantly, the clinical experience.

It is our opinion that the coverage determination process can be approved if HCFA, this Committee, and the specialty panels, are refocused on the original goals defined for the MCAC. In order for the Executive Committee and the panels to be consistent with their charter and the processes defined by the Agency, we respectfully suggest the

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following for your consideration:

Refocus the Executive Committee and the panel on the goals that were originally defined in the charter and the coverage guideline published in the federal notice, that is, to provide coverage advice. Secondly, the interim recommendations for evaluating effectiveness may be useful in

determining if a technology needs to be referred to the MCAC. Once the technology is referred to the MCAC, these questions alone are not enough and should not be used as a no vote criteria for further discussion. HCFA makes a referral to the MCAC when an issue is either the subject of significant controversy in the medical or scientific community, has the potential to have a major impact on the Medicare program, or is the subject of fraud and public controversy. Given this, it is redundant to ask the panelists to reanswer a question pertaining solely to the adequacy of scientific literature if as was the case with PFS and biofeedback.

The reason the technology is being referred to the MCAC is because it was already determined that a controversy exists. Unfortunately, the panel members in the April

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meeting were not allowed to meld the scientific evidence, clinical experience and medical judgment, to make a recommendation regarding national coverage for either biofeedback or PFS.

Given the need to assess the controversy surrounding a given technology, the deliberations of a panel therefore, should be more global in nature, and allow for discussion and evaluation of the total body of evidence, including technology assessments, clinical guidelines, the testimony of clinical experts, professional medical societies, technical experts, and the scientific data obtained from nonrandomized trials. HCFA published a criteria for the evaluation clinical evidence, and specifically included expert consensus; it was not limited to peer reviewed literature. HCFA has not articulated a rational explanation for changing this policy for technologies that have been referred to the MCAC. Therefore, an MCAC recommendation that was based on analysis deviating from this criteria would be of little use to HCFA in developing a coverage determination consistent with its own regulations and policies.

The panel needs to be provided any and all comprehensive reviews of the scientific

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literature. Simply providing the HCFA contracted

Blue Cross/Blue Shield assessment and not providing other independent opposing assessments, such as the government funded AHCPR guidelines raises questions of bias and possible conflict of interest, and also compromises the quality of the panel's deliberations.

Finally, some words about the process. We must require as outlined on under backup regulations --

MS. CONRAD: Time please.

DR. JENSEN: -- that the public be given adequate time to review, comment and testify on issues relating to the technology assessments. It is our sincere hope that these suggestions are helpful to you as you refine your process. Thank you for your thoughtful consideration.

MS. CONRAD: Thank you, Dr. Jensen. Kevin Connolly please, and the next scheduled speaker is Nicolette Horbach.

MR. K. CONNOLLY: I am Kevin Connolly, CEO of SRS Medical Systems. We manufacture biofeedback and stimulation products. I want to thank the committee for giving me the opportunity to present today. Does the committee have the

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two-page written statement that I submitted?

When I was told that I would have the opportunity to address both sets of issues, I put together separate presentations, but they pretty much amplify points in those written statements.

As you can see, I'm pretty positive about this process in general, but I'm here because obviously I believe the process can be improved. Specifically, I think there were certain problems with the April meetings. In the interest of clarity, I'm going to limit my comments to biofeedback, also because biofeedback is a covered service and discontinuation of coverage would have a great deal more significance to most people.

My understanding is that the purpose of MCAC is to determine coverage in areas where the evidence is conflicting. In the case of biofeedback, however, I maintain that most of the evidence has been positive. And most significantly, HHS's own Clinical Practice guidelines established biofeedback as a standard of

care, but the April meetings hardly considered those guidelines. As you can see, the guidelines reached a very different conclusion than the Blue Cross TEC report regarding biofeedback
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effectiveness.

For a variety of reasons, it seems that the Blue Cross TEC report became effectively the only evidence considered. Now, I think the main reason was that it was the only substantive evidence that considered the question of comparative effectiveness. Now I know HCFA has decided to analyze most procedures this way and I think it's a very informative way to analyze them, but I do think you have to be very careful when you apply a comparative approach. If you compare two procedures with the use of different populations, you could end up comparing apples with oranges, even if both procedures have the same clinical purpose.

A number of the panel members were frustrated by the fact that the question to be voted, in their mind, changed several times, until it seemed that only a negative vote was possible, which rendered their clinical knowledge and expert opinion superfluous. Likewise, medical societies all wondered why they were invited, since what they said didn't seem to be part of the evidence that was considered.

Now I know this isn't a popularity
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contest, but there are two points about this slide worth making, the sheer number of expert opinions involved, and the unanimity of their opinion. I'm not sure you could get all these societies to agree about any other procedure. All the evidence listed here was theoretically included in the review process, but in fact, none of it was effectively considered. Incidentally, all of this evidence supports biofeedback effectiveness.

Now we come to the reason I was invited here for the morning. I have some suggestions. My main suggestion, following everybody from Dr. Sox on, is that the committee consider all appropriate evidence. In the case of biofeedback, there were some randomized control trials, although they were

used in part to limit other evidence. And one of the things I think that you're going to be faced with and one of the questions I think a lot of people in April were asking is why there weren't good studies.

I think the answer to that has some implications. First, if a procedure is regarded as a standard of care, like biofeedback, there haven't been any compelling reasons to run. Second, if the study is going to be run by private industry,

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someone has to benefit financially. Most of the companies in biofeedback are like SRS, very small. We don't have the facilities to run studies, and we wouldn't benefit financially even if we ran them, because there is no meaningful intellectual property left to be had; it's all prior art.

So, I think you should recognize that the only financial incentives are for doing exotic technologies like the Metronic Inner Stim, or for proprietary pharmaceuticals. So I recommend that the future panels consider the full range of relevant evidence, and that the role of the literature review be to simply organize information for the panel. I believe the panel, and not an analysis of literature should make determinations of effectiveness. Otherwise, frankly, what are they there for?

I know there are concerns as to how long the panels might take to make decisions this way, but I believe the process can be managed in a timely way if the literature review is crisp and inclusive and if subject matter experts are involved. I believe it's critical to include subject matter experts at all levels of the review process. Just by way of comparison, as far as I

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know, the Agency formerly known as AHCPR, all their guidelines were prepared by a panel of subject matter experts and as far as I know, their conclusions are uncontroversial.

Now, I don't pretend to know what specific factors HCFA should use to determine coverage. My suggestion here is simply that whatever those factors are, that you standardize them and you make their weighting public. That

way, everybody knows the basis for the decisions.
My slide shows one example. At the bottom right, though, is one thing I would like to point out, which is, I do think if a procedure has a history of coverage, that HCFA should analyze its own data with regard to outcomes. I remain very positive about this process. Thank you for allowing me to present; I hope this was helpful.
MS. CONRAD: Thank you, Mr. Connolly. Nicolette Horbach, followed by Tom Mesken.
MS. CHAPPELL: Nicolette is actually stuck on a detour, so I'm going to present her statement, read from it, and she will probably be walking in momentarily, and you may ask her questions about it. My name is Jodi Chappell. I'm manager of regulatory affairs at the American
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Urogynecologic Society.
I am pleased to provide the following comment on behalf of AUGS and eight other professional health care organizations. In the interest of time, I will not read the exact list; you have been provided the letter, and we have provided it today with the additional inclusions. These groups in coalition represent approximately 294,000 clinicians involved in the treatment for urinary incontinence. We as a coalition support and commend the efforts of HCFA and the MCAC Executive Committee to provide guidance for an open and consistent Medicare coverage decision process.
The procedures outlined in the interim recommendations released in March represent a positive step in the evolution and development of an open national coverage decision making process. We do have several concerns regarding the interpretation and use of these interim recommendations, based on the Medical and Surgical Procedures Panel hearings in April. During the hearing, narrow questions left the panel with no other possible answer than no, because there are few studies that make such an exact comparison.
The reason for such few studies is that
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pelvic muscle rehabilitation or for that matter, all rehabilitative techniques, must use some form of biofeedback in order to be delivered

effectively. All scientific groups and research efforts, such as the AHCPR guidelines, and HCFA's own technology assessment report, do accept that there is substantial scientific evidence that rehabilitative techniques are successful, and have a direct health impact in managing urinary incontinence.

Rather that asking the April panel to evaluate the adequacy of the evidence and the efficacy of the intervention, it seemed obvious that HCFA tailored the question to the panel in such a way that prohibited the members from answering yes to the effectiveness of the rehabilitative interventions for the Medicare population. The questions that were asked by HCFA were specific to a limited number of studies that met the certain criteria laid out by the technology assessment for evidence based practice.

We believe that the adoption of stringent standards for coverage should not preclude consideration of either the expert clinical testimony presented at the meeting, the

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panelists' own individual knowledge and clinical expertise, or the personal experiences of the consumers. Moreover, this seems inconsistent with the Executive Committee's procedures outlined in March. In limiting its focus to peer reviewed scientific literature only, the Medical and Surgical Procedures Panel was essentially asked to disregard clinical guidelines that had been developed by the AHCPR, and expert opinion developed by the national medical specialty societies. For the panels of the MCAC to make fair impartial decisions at the conclusion of these meetings, more balanced materials and perspectives should be provided to panels prior to deliberations.

In practice, when the evidence from analytic studies is poor or lacking, more relevance is given to observational and/or descriptive studies. The literature contains numerous observational and descriptive studies which demonstrate the efficacy and effectiveness of biofeedback and electrical stimulation in the treatment of pelvic floor disorders. The

effectiveness of the vast majority of procedures that are covered by Medicare today for its aged and
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disability beneficiary has not been demonstrated in peer reviewed randomized trials. However, such a level of scientific evidence is likely never to be available for every intervention. Because such evidences does not exist, HCFA questions the rationale for its reimbursement.

We agree that continued application of the Executive Committee's recommendations in such a narrow fashion will prevent the MCAC deliberations from achieving the desired high standards of comprehensiveness and balance. Omission of clinical evidence and clinical guidelines from the deliberations of the MCAC could lead to an adverse harmful coverage decision developed through an indefensible process, and to Medicare's failure to cover important and effective diagnostic and therapeutic options.

The consequences of developing a noncoverage policy for biofeedback and electrical stimulation will most likely result in the lack of appropriate conservative therapy interventions for needy patients, especially women and the elderly; a possible resurgence in the use of surgery and/or drug therapy, which are most costly measures, as the primary and initial modes of intervention;
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patients who lack access to effective therapeutics. The lack of poor coverage could result for useful and effective behavioral and/or rehabilitative intervention for Medicare patients suffering from urinary incontinence.

The issues that HCFA is most likely to refer to the MCAC are those that are the most controversial. Coverage decisions should not be based solely on the perspective of one faction within the medical community, but rather on the balance of scientific and clinical information and therefore, the input of both the scientific and clinical communities need to be considered and valued.

We understand that this process represents a learning experience for HCFA in determining the methods to be used to evaluate the

effectiveness of new medical products and services based on the adequacy of evidence and the magnitude of clinical benefit. Not only should the formal outcome of the Medical and Surgical Procedures Panel not be ratified, but more importantly, the flawed process must be corrected in order to eliminate the prospect and perception that the process was less than open and objective.

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Ultimately, elderly patients, mostly women, will suffer if needed services are not available to them or covered by Medicare because the bar for inclusion was set inordinately and unnecessarily high. Thank you for your time.

MS. CONRAD: Thank you, Miss Chappell. The next speaker is Tom Mesken, president of Medical Alley.

MR. MESKEN: Good morning, members of the Committee. My name is Tom Mesken, president of Medical Alley. Medical Alley is a 15 year old not for profit trade association, whose members are from all sectors of health care.

I wanted to follow up on your invitation from the last meeting to provide some suggestions on your interim recommendations document. We greatly appreciate the opportunity to be part of the discussion and dialogue on shaping the evolution of the Medicare coverage process. I'm not going to base my comments so much on the Medical and Surgical Procedures Panel meeting at all, quite frankly, and instead offer three specific suggestions on your document as it relates to the process.

The first item falls under the area of

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the document called evaluation of evidence, adequacy of evidence, and external validity. Our suggestions are the following: Number one, the Executive Committee or the document should define the terms typical practice setting and general practice setting. Secondly, a panel should be able to state whether the results of a study or studies validate receiving an intervention for the Medicare population or subgroups of that population in particular practice settings, and explain their reasoning.

Our rationale for this is that the interim recommendations document states that the panels will need to explain their reasoning on whether an intervention is likely to apply in the general practice setting. This could be taken to say that the service must have studies which validate its use in the general practice setting. The questions may not even envision nor advocate using all studies to develop their studies accordingly. Given the Agency's capabilities to determine what is an appropriate setting, the panel should be empowered to discuss this aspect of external validity accordingly.

Our second suggestion under the item of

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panel operation is the structure of evidence provided to the panel. We suggest that the process of garnering the information for an evidence report should include the opportunity for an early discussion between the panel's information collectors and appropriate external advocates of the service. The rationale for that is that the Executive Committee calls for panel member involvement in the evidence report to insure that the evidence report covers a sufficient scope of studies, considers relevant alternative interventions, and can be useful to the panel in other respects.

In this same vein, the process of collecting information for the report can only be enhanced when there is an opportunity for those who are most familiar with the evidence which surrounds a service to share their materials and knowledge of relevant studies. We can certainly appreciate the Committee's interest in acquiring material that will allow for independent judgments. Yet, a conversation of this nature can also serve to facilitate better communications on the relevance and implications of the various pieces of evidence that has taken place under the public testimony

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portion of a panel meeting. Furthermore, such a conversation enhances the perception that the process is open, impartial and balanced.

Our final suggestion under suggestions for panel operations and a panel explaining its

conclusions in writing, our suggestion is that when a panel explains its conclusions in writing, it should explicitly address what role, if any, each of the following health outcomes played in its determinations: Mortality, morbidity, functional status, quality of life, and patient experience. We certainly agree with the Executive Committee that requiring the panel to explain its conclusions in writing will help insure the integrity of the MCAC procedures and judgments, and make the Committee's reasoning process more explicit and open, and provide internal and external accountability. We also agree that it is desirable that the panels specifically describe any additional research that would be required to strengthen that evidence.

That said, we believe that by asking the panels to explicitly address the role of each of these suggested outcome measures, the greater specificity that would become part of the

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explanation will only serve to enhance the benefits that the Executive Committee sees in calling for conclusions to be provided in writing.

The final comment I would like to make, and really it is not so much -- you have heard a number of comments today about the panel's ability to hear evidence, a variety of sources of evidence and to take action on that, based on the experience of the Medical and Surgical Procedures meeting. A lot of those comments have obviously been directed to this Committee, but quite frankly, it is our perspective that it is really the Agency's responsibility to cast those questions for you, so I will focus my comment to the federal representative of the Committee and suggest that we are very disappointed that the Agency has failed to signal to the MCAC Executive Committee that it wants the panels to be able to provide their clinical expertise and judgment on all ranges of evidence. Quite frankly, we think that the Agency is a fiddler here and it is they that should be setting the questions. Thank you very much.

MS. CONRAD: Thank you very much. At this time I would like to introduce Dr. Jeffrey Kang, director of the Office of Clinical Standards

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and Quality, who would like to say a few remarks.
DR. KANG: Good morning. I apologize, because I didn't have any prepared remarks, but I would like to take this opportunity to make a few comments. My hopes had been to stay here for the entire meeting, but I am actually involved in some testimony tomorrow which I have to prepare for.
I would like to say a couple of things. First, in the way of announcements, I understand Dick Coyne did announce the new director for the Coverage and Analysis Group, Dr. Sean Tunis, and he is here in the audience. He comes to us from Lewin, where at Lewin he was working on the development of clinical trials to inform coverage and reimbursement issues, but also has an extensive history at the Office of Technology Assessment, in looking at health care technologies.
I would like to take this opportunity to thank Hugh Hill for acting in the position. I think that given everything that we have been trying to accomplish in the last year, we have made remarkable progress. I understand from the testimony though, that we have a long ways to go, but I really thank Dr. Hugh Hill for his leadership here. I would like to point out that he actually
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will not be lost to the Agency though, as he is going to be the deputy director for our Program Integrity Group with Penny Thompson. I think that's very important, because as many of you know, our Program Integrity Group looks at fraud and abuse issues, but also runs our local contractors and is responsible for local coverage decisions. So I think having clinical input there is going to be very important in the future.
I understand Dr. Hill has already mentioned briefly about the notice of intent, and we are -- given the complexity of this issue, we did decide to add a third step to the process, a notice of intent would be to a proposed rule, which would lead to a final rule with regard to Medicare coverage. My only observation there is given kind of a lot of the interest there, we decided to extend the comment period for another 30 days until mid-July, and also are going to move towards a town

hall meeting to actually get public comments and obviously, I'm sure Dr. Hill has already mentioned this, we would love to get your all perspectives on what's in that notice.

I should say just by way of, I know the staff is going to work this afternoon to address

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many of the issues that have been raised this morning. I just want to say that at a larger level, I am aware of the interests in having the Medicare Coverage Advisory Committee and the panels actually talk or give us advice around the actual coverage decision and not be as limited to the narrow issue of the evidence. I think that is a place where we would like to go. Part of the problem has been, though, we've missed what the criteria are, and that these two things are very interactive. And one of the things that I would like to ask of not only the people in the public but also people here the on the advisory committee, if you can please bear with us, we are acutely aware of these issues, and just bear with us. We are trying to make all the efforts we can to make the coverage advisory committee work in the interest of Medicare beneficiaries and of science. And I just wanted to say that this will actually be one of the first issues that Dr. Tunis and I will be trying to tackle for future panels, and the Executive Committee.

So in some ways, I just want -- I appreciate your efforts here, I know that it's been rough going, but quite frankly, we are making this

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up as we go along, and I appreciate you all working with us on this. It's going to take some time. I do believe though, in the long run, this is the right thing to do, this sort of forum and these sort of meetings, and open discussion of the evidence, and trying to sort out what is adequate evidence and then what do you do in situations where there's insufficient evidence but a decision needs to be made, are issues that we're going to have to wrestle with together.

Thank you very much.

MS. CONRAD: Thank you, Dr. Kang. Let's take a short break. I want to see you back here at

10:15 please.
(Recess taken.)
MS. CONRAD: We have a quorum.
DR. SOX: The next part of the morning's agenda is entitled open committee deliberations, and what we're going to do during that time is talk about how the Committee will respond to, first of all, the comments that have come in about its process, and then also the prospect of our moving from a group that advises HCFA on evidence to a group that actually makes coverage recommendations. I have asked Dr. Kang to take the
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floor again to try to give us as clear an indication of what's going to happen over the next six to 18 months, so that we can plan as a group about how to respond to both the public comment as well as the prospect of broadening our responsibility somewhat. So Jeff, if you would?
DR. KANG: Thanks, Harold. I'm sorry, I may not have been completely clear. Because I think there's a short-term issue here and there's a long-term issue, and I think in the short run, that we have to -- what we have intact here at the Medicare Coverage Advisory Committee is a process to look at the evidence, and then advise HCFA on that and I also think just for the purposes of continuing our work, that that's really what we have to focus on.
The one thing I do want to assure you all and the public, is that when we, HCFA gets your advice on the evidence, we do not just look, quite frankly, at that, but we look at the entire record and that gets submitted. And those kinds of things, the entire record will really be forming whatever coverage decision that we make. And what has always been difficult here for us, quite frankly, is the lack of a rule like I referred to
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in my comments, of what the criteria are, and that really is our job, to wrestle with that.
I do think though, that in the long run, we should be moving towards this advisory committee as a forum for advice on actual coverage issues. And now with the publication of the notice of intent, I do think that we need to engage with you

all in beginning to think through how would we get that accomplished from a procedural standpoint. And part of the dilemma that I run into, that notice of intent and those criteria are not final. To the extent that it's a moving target, it gets really very difficult here also. So, one of the things that we had tried to do in the notice of intent was really actually make, hinge all the decision making points really on clinical issues, which really is I think in the purview of, the clinical judgment, which is in the purview of this advisory committee, leading to reimbursement judgments to us at HCFA.

At any rate, I think that the interactions and beginning to transition to this are going to be extraordinarily complicated, and my thought here is that when Dr. Tunis is on board, that I think we, HCFA will be willing to work with

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a small subgroup or work group of the Medicare Coverage Advisory Committee, to begin to think this through, and then obviously whatever document comes out of that, we would share to the public with, you know, appropriate notice and comment and discussion, et cetera. But I think that is, if you're willing, that's what I would suggest as a process to get from here to there in the long run.

But again, in the short run, I think because we are going to have coverage decisions that we have to deal with today and in the near future, that we kind of stick with what we have now with regard to your discussion of the evidence, and then we obviously will internalize that and make some sort of coverage decision.

DR. SOX: Thank you, Jeff. That's very helpful. What I would like to do for the remaining 40 minutes or so is to discuss two issues. Then we'll hear from public comment on our discussion and then we will make a decision, and then we will have lunch.

The two issues are, first of all, how do we prepare this committee for going beyond its current charge, which is simply to give HCFA advice about the quality of the evidence, to one in which

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we take into account the clinical evidence, a term

yet to be really carefully defined, and make recommendations about coverage. That's going to be a while before we start to do that, but we have to apply, if possible, the same methodologic, systematic methodology to evaluating what people have commented on as, quote, the clinical evidence, unquote, as we have for the scientific evidence. So that's the long-term issue, preparing for a transition, when we will actually be making coverage recommendations, that will take into account both clinical evidence as well as the scientific evidence.

We will talk about that first, perhaps hopefully briefly, and then we will go on to a discussion of a process by which we will, if necessary, modify our procedures, taking into account the comments that have pointed out opportunities for improvement in our evaluation of the scientific evidence. So, we've got to fix that, if need be, in the short run, while preparing in the long run for a broad role that will require us to be systematic and thoughtful and rigorous about evaluating what many folks at the podium here are calling clinical evidence.

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So, let's first of all talk about how we're going to prepare ourselves for this transition to a broader role in which we take into account both clinical evidence, as well as scientific evidence. And I guess I'm really thinking of the process, what are we going to do to get ready for this? So let's talk about that for about 20 minutes, and then we can talk about how we adjust, if necessary, our approach to evaluating the scientific evidence. So who would like to begin? John?

DR. FERGUSON: Is it appropriate here -- I think that part of the problem as I see it in many of these presentations was that the questions that HCFA posed to the panels were based on our interim report, and I, in my sense, there was a sort of built-in semantic hurdle, and I, in this interim report upon which these questions were based, and I would just like to make a few comments.

I really looked at this hard and it

bothered me, and it bothered me listening to the comments when I listened to this part of the incontinence thing, and the word was adequate. In my view, adequacy is in the eye of the beholder,

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sort of like beauty, and in looking in the dictionary, the dictionary always gives two definitions. Adequate is sufficient, but also, adequate is barely sufficient, mediocre, passable, okay, sort of like a C.

And basing -- I think that our interim document is wonderful, and I agree that evidence needs to be adequate and so on, and randomized trials are the gold standard and so on. But what it amounted to as I see it was that the questions were posed in a way to force a yes or no on the panel about adequacy, and that did not -- it was sort of like a hurdle, and they couldn't get to the discussion of the actual evidence.

Now I have some suggestive modifications of the interim report, it's a very mild one, if you want to hear it now.

DR. SOX: Why don't we wait, and either talk about that later, or you can provide that as written input to a group that might be working to improve the document. Let's talk now about a process for preparing ourselves for this broader charge we have just heard about from Jeff. Alan, do you want to comment.

DR. GARBER: I really have two sets of

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comments and I could reserve one of them. I think it is pertinent to discuss how the MCAC Executive Committee's recommendations were actually implemented by the Medical and Surgical Procedures Panel in moving forward, because I'm not sure that all of us have the same understanding of what occurred. Certainly, my understanding doesn't gibe perfectly with that of some of the public speakers today, and that might give us some perspective on how to go forward in terms of broadening the mission.

The second is really right on the topic of how to make this transition. I would propose, first of all, that we have used the term clinical evidence or clinical expertise, used in a myriad

ways, and I think it's safe to say that no two speakers have used it in the same way, nor has anybody been very precise about what that means. It has been used implicitly to mean anything from opinion or anecdote to evidence that wasn't obtained as part of a trial. But in fact, a coverage decision actually encompasses issues even broader than that, and I don't think in the next 20 minutes, we can take a big stab at taking into account all of the types of information that might

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be needed for a coverage decision.

And I think that HCFA was very wise in steering us away from making direct coverage recommendations at this point in time, even though it may be something we should be doing in six months or a year. They were wise in doing so, because they have not specified all the factors that should be considered in a coverage decision, nor I dare say, do most of us have the expertise necessary to do a credible job at that at this point in time.

So what I would like to propose is that we discuss a little bit about the types of information that are considered by the panels under the current recommendations, and I think that the current recommendations issued by Executive Committee are actually far broader and for more flexible than some of the speakers have implied.

DR. SOX: Randel?

DR. RICHNER: I would like to get this back on sort of a practical level here. I agree with what Alan is saying essentially, you know, that we have to have a robust criteria, et cetera, for making coverage recommendations. But it concerns me gravely that he's mentioning six months

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to a year before we ever get to that point. This process was started quite a while ago. In fact, in 1998 was when we began this whole process of thinking about how can we improve the coverage process to make it more transparent. And to think that we won't be able to make coverage recommendations for another year appalls me.

Even in England, with NICE, they can make a coverage decision in about four months,

which is clearly not what we have here. I have many issues about what has happened, but basically I want to say that it's important that we look at this in the spirit of what was intended, and that is to take all of us here and to give recommendations to HCFA that they will be able to use to make sensible recommendations for Medicare beneficiaries. And that means using, you know, an academic approach in a sense, looking at the objective criteria, et cetera, but we're here because we come from a lot of different perspectives, and we need to all bring that to the table to decide what is best for a Medicare beneficiary. We have forgotten that somehow, and it just concerns me.

We have to get back on track. We need

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to have the process clearly defined. There is ways to do that in a practical manner that we can all do it, and we need HCFA's leadership and guidance to do that. And so far, all I'm hearing are code words, and you know, and we've lost our intent. I'm passionate about this because it just seems that if you read all these letters that we have, everyone is concerned that we have lost what the focus is here.

DR. SOX: Thank you. Daisy?

DR. ALFORD-SMITH: Yes. I have some concern. I think my questions are still along the line of what is the role for HCFA, versus what is the role for this particular executive body, and I am almost coming to the conclusion that perhaps we need to really think as to whether we should be making recommendations to HCFA at all, but indeed, perhaps HCFA should come before us in some way to present their justifications and then have this body either review, approve or provide some input. But I think we're switching hats in some way in terms of who are the administrators and who are the policy makers, versus an advisory body. And I think until we resolve that, there is always going to be some level of conflict in terms of what we

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can really bring regarding our own areas of expertise, and ultimately with some type of recommendations to the official body, and that is

HCFA.
DR. SOX: Thank you. Yes, Bob.
DR. MURRAY: I would like to comment on Alan's question or Alan's proposal just a few moments ago, that we focus on what we mean by clinical. And I think that there's a bit of a problem in that clinical seems to be juxtaposed with scientific, as though scientific evidence were collected in a laboratory away from patients and clinical is what is done in a clinic, it's face to face with patients, hands-on evidence resulting from hands-on treatment. I don't see it that way.
I understood as these interim guidelines were being developed that the word scientific meant any evidence collected according to the scientific method. That is, it is objective, it is duplicative, it is capable of duplication, and I think that is really where I believe these guidelines are excellent, that they focus on the objective evidence. It can be clinical objective evidence; I don't if I'm erroneous in that assumption, but I would like to hear if others
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believe that the focus should be scientific method.
DR. SOX: Thank you. Alan, do you want to respond or if not, then Tom first.
DR. HOLOHAN: Thank you. I was waiting for somebody else to say that first so I wouldn't be viewed as the curmudgeon that I was at the first meeting.
It seems to me in both the presentations and the reading that the term clinical evidence has been applied to, and I'm quoting from some of the statements, both written and verbal, expert opinion, personal experience of consumers, the establishment of a standard of care, and where a standard of care exists, there is no necessity to do scientific study. The history of medicine is replete with examples of procedures, services, various interventions, that were provided not on the basis of evidence, but on the basis of so-called expert opinion, which have been shown ultimately to be of no benefit or to even be harmful.
The best most recent example is the

establishment of a standard of high dose chemotherapy in stem cell support for breast
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cancer. There is no question that the personal experience of some consumers supported that, people who believed that this treatment benefitted them. There is really no dispute that in many members of the medical community, this was believed to be so useful that it was unethical to do a randomized trial. We had 30,000 patients subjected to this treatment, only 1,000 were part of studies, and yet, when all of the prospective randomized control trials were in, excluding the one in which the data were found to be falsified, the evidence indicated that this was not beneficial to survival.

The various case series could be argued to be clinical evidence, and certainly the expert opinion of the bone marrow transplant community generally was in support of this. But the fact is, it didn't work. And I don't see that the simple expert opinion, if it's not based on evidence, whether we call it clinical evidence or scientific evidence, if expert opinion is not based on objective evidence, then one man's opinion is just as good as any other, and I would argue that something that's gratuitously affirmed can just as easily be gratuitously denied.

DR. SOX: So it's an important reminder
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that anecdote can lead to adoption of things that don't work, and potentially harm them.

DR. HOLOHAN: The plural of anecdote is not data.

DR. SOX: Alan?

DR. GARBER: Yeah. I think at this point it really would be relevant to say a few words about the role of clinical evidence in the Medical Surgical Panel's proceedings, and I want to clear up a couple of misconceptions along the way. No panel member that I heard ever said that they wanted data from multiple well designed randomized control clinical trials, not were they ever instructed to consider only those kinds of data. What they were instructed to do and what I believe they made a good faith effort to do, was to answer the questions that HCFA posed to the panel. And

they were free to consider all kinds of evidence and in fact, the evidence presented to them was not limited to randomized control clinical trials, it wasn't limited to good studies.

The evidence that was presented to them or distributed to them was selective, and the Executive Committee advised that the panel chair should assist HCFA in selecting materials to

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distribute, and I want to remind those of you who were at the last Executive Committee meeting and to tell the rest of you, that we discussed how much information should be presented.

The first two panels that met received voluminous amounts of material, and there was a general belief that panelists would not be able to assimilate that amount of information in any meaningful way, so there had to be some discretion. Does that mean that the evidence, that the literature distributed to the panel was the right set? No, of course we can't be sure it was right, and we're learning as we're going along. If I had it to do over again, I would have insisted that the AHCPR guidelines be distributed in the initial packet. But let me point out that, as was basically suggested by the Executive Committee, there were multiple opportunities for panel members to suggest that materials be added, including a conference call. And in fact, one of the people who complained that some material wasn't distributed was on the conference call and didn't mention it at the time.

So yes, there can always be questions about whether the correct set of literature was

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included. I believe we could have done a better job, knowing what I know now. I don't think that we could have done a better job knowing what I knew then. And to the extent that the public did not get adequate time to respond, that the report was not issued on schedule, that's a problem that should not be repeated, and we hope it won't happen again. But keep in mind that this is the first time through this process, so a certain amount of understanding and forbearance would probably be appropriate.

Now as I said, a variety of materials were distributed, and there was a large catalog of written materials. The evidence report provided by Blue Cross/Blue Shield considered a vast body of evidence, but focused, appropriately I believe, on better designed studies that were most directly relevant to answering the question that was put before the panel.

There was a third way in which other kinds of evidence could be presented, and that was during the public testimony and the documents that public commenters have presented to the panel. They were helpful, and the instructions that Connie Conrad actually gave to the public were to make

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sure that whatever you present is going to be pertinent to the question. She didn't say what type of information had to be provided, that it had to be clinical trials, it had to be published peer reviewed literature, nothing of the sort, just that it had to be directly relevant to the questions that the panels were posed with. And that was in the interest of keeping the discussion on track to address the questions we had.

So as a result, in fact, many kinds of evidence were presented. The public speakers for the most part, I thought did a terrific job in informing the panel. The panel didn't necessarily vote the way that they wanted them to, but I think it's interesting that the Executive Committee document was constructed to give the panels a great deal of discretion in deciding how much evidence is enough. It never said that randomized control trials had to be considered and as you will recall from our previous discussions, we wanted to make sure that there was a clear understanding that observational studies might be adequate, other kinds of information would be adequate, as long as the panel believed that they could draw conclusions about the questions from the data. If they

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believed that the information presented was from studies that were too poorly designed to draw conclusions, they might reject them.

What I saw happening at the Med-Surg panel meeting was that the panelists listened

carefully to all kinds of information, which was a wide variety of quality, at least from the point of view of answering the questions, and they did reject some kinds of data that public speakers, advocates had wanted them to consider. It's not that they ignored it, but my understanding is that the people who voted no on the questions, that is the questions regarding adequacy, had concluded that the data and the studies just weren't sufficient. So no one had told them it had to be randomized control trials; that was their judgment. And as an Executive Committee, we can give them detailed instructions about what kinds of information would be adequate to draw conclusions, or we can let them reach their own conclusions, and I believe they reached their own conclusions the way that we had intended them to draw their own conclusions. I'm not sure that everybody who was on the panel, or people who weren't on the panel had they served on the panel, would have voted the

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same way that all the panel members did, or the majority of the panel members did, but that's how this kind of process works. If you're dealing with a controversial area, not everybody will agree on the interpretation of the evidence, and you saw that in the discussion and the votes of the panel.

But the point is that I believe that the panelists did consider a wide variety of evidence, so-called clinical evidence, i.e., that falls short of randomized control clinical trials, yet in order to feel comfortable in answering the question, they seemed to be looking for a higher standard of evidence than was present in the literature.

DR. SOX: Before we go on here to more speakers, we only have about 15 more minutes, and sometime around half hour from now we've got to decide what we're going to do next. So with respect to -- I'm going to make a proposal that we can respond to if it seems worthy. I think we need to reconvene a methods working group, to meet and try to prepare this Committee with a series of procedures and guidelines about how to deal with the problem of making coverage decisions, which is going to include not only scientific evidence, but clinical evidence and other issues that Alan has

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alluded to, without identifying them at this time. So, I am basically proposing that we do have a methods committee to deal with this problem, that we give them roughly six months to try to solve the problem, that it's probably going to be a more intensive effort than the first one, because it is going to deal with standards of evidence that are perhaps less well established than those involved in evaluating controlled trials.

MS. RICHNER: Is there some reason that you have chosen six months?

DR. SOX: Beg your pardon?

MS. RICHNER: Why would you choose six months?

DR. SOX: Well, Randel, the reason for proposing that is, A, I think it's going to take a while, but secondly, Jeff has told us that the time table for us making coverage decisions, whether you like it or not, is not going to be in the next four months, it's going to be more like nine to 12 months, or even longer.

MS. RICHNER: So then what would happen then in the interim, to the panels?

DR. SOX: In the interim, we are going to do what HCFA has asked us to do for the urinary

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incontinence, which is to advise them about the quality of the evidence that bears on the question of coverage. So right now we have a fairly limited task, one that is going to change to a more comprehensive and responsible task in the future, and we need to get ready for that, but we're not going to do it right away. That's why I thought a reasonable amount of time was in order to get ready, but that could change if Jeff gives us orders that we're going to start making coverage decisions sooner than that. I think Mike was next and then Bob, and then we need to move on.

DR. MAVES: Actually, I appreciate that, and I rise to support that. As Alan's co-chair on the Med-Surg panel, I think the last panel, regardless of sort of your opinion of the outcome, was handled in a much better fashion, and I think the MCAC interim operating procedures helped us to put together a panel process that at least seems by

testimonial to have gone better than the first two panels. I wasn't at those panels so I can't directly compare.

I do think it's important, and I sort of view this as an evolutionary process, and I think probably, Harold, your comments are in the line of

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evolution rather than revolution, and I certainly would not be in favor of throwing out the document in its entirety. I do think it's important to have a couple points though.

One of the things that I sense that we need to make sure of, is that this is an open process with an element of due process. After all, this is the government and to a certain extent I think we need to make sure that, if you will, the minority opinion or if you will, the weakest voice is heard in this debate. And I actually think that at the panel that we had in April on urinary incontinence, I understand that we heard every speaker, every speaker was allowed a time to present. There may be some timing problems which didn't allow them to point there comments to us as appropriately as they should have. But again, I think these those kinds of problems can be addressed in an iterated situation, and certainly represent improvement in the process without throwing out the basic sort of framework of where we are.

I do think we need to approve some things, and I mentioned these to some HCFA staff at a meeting. We indicated that I believe when there

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is an AHCPR guideline, or AHRQ guideline now, that's appropriate and relevant, that ought to be included in the packet, and I think we have largely addressed that. I think it's important for the panelists to receive opposing viewpoints and document. One of the problems I had, we were sort of only given the con side of the argument, and we had to wait until the panel to get the pro side of the argument. It would have been better, I think, to have had documents, particularly I think from the medical societies.

As the person from the AMA has indicated, the societies put a great deal of time

and effort into looking at these, and I think they form a basis of expert opinion that again, may not rise to the same level or weight as a controlled randomized trial, but nonetheless represents a body of information I think is important in these deliberations. We need to find some mechanism, and I would applaud your decision to have a panel come together to look at how we recognize the information. I think the document actually allows that to be stratified and I think if the panelists at the meeting in April go away with the feeling that they were not heard, that is an incorrect

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perception. I think in point of fact, they were heard, and I can recall specific speakers that made very poignant comments, very pointed comments, but as Alan indicated, when you added those together in the weight of the evidence, they certainly were not as conclusive as some other evidence that we had at that time.

My last point was just simply, and it's sort of pleasing to see that Dr. Kang has agreed to allow us to look at the issue of coverage, because I think looking at the issue of coverage, although it may be more difficult, is an argument that is probably more to the heart of the real work I think that HCFA wants us to do, than just the science, and the comments that were given at the urinary incontinence panel seem to reflect that. The answer to the question was no, but as I think I indicated in my comments, if this were a family member had this problem, would you recommend it to the family member, then obviously the answer would have been far different. So I think the idea of proceeding with a panel, Dr. Sox, is one that's probably an appropriate thing to do at this time. But I would caution the Executive Committee not to sort of throw the baby out with the bath water. I

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think we've got a good process, it needs to be tweaked, it will be different in a year, and for those who are in this process, I think you have to be patient with us as we go through this process.

DR. SOX: Bob?

DR. BROOK: I agree that we need a methods working group, but I'm a little concerned

with what I have heard, and the last statement really makes me upset, that we're going to approve something where the evidence supports doing nothing, but we want our own family members to get it. That is so disturbing that I really believe it's almost unethical to do that, and I'll use really harsh words.

Now, there's definitely something wrong with the process that we're engaged upon. First of all, I want to go on the record as saying these two documents represent an analysis of the literature, mostly concentrated on trials with no synthesis. In the time I guess they had to do them, because they were pushed on the one side to be timely and on the one side to be complete. I can't judge whether they represent a good or bad product, but they represent that product.

My understanding of what this product

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would like if the panel had it, and the public had it, would be all of the evidence that's available. In the absence of randomized trials, I would have expected cohort studies, case control studies, simple follow-up studies, certainly guidelines, the kind of stuff you saw presented here ought to have been part of the document the panel got, and I would urge that be referred to the methods group for consideration. That's what we do when we do the appropriateness work at Rand. If there is basically randomized trials, there's no need to do all the other stuff, but the bottom line is it ought to have been part of that, so that's my issue.

Now, I have a second problem, and the second problem comes back to Daisy's problem of what the hell we're doing here, and I don't know what we're doing here anymore. If HCFA refers to us procedures where none of the literature here that I reviewed shows any harm, then if only somebody perceived they had benefit from it because they are satisfied in visiting their doctor and being stimulated, then it should be covered, because we have no right to deal with costs.

So if we are being -- the example of

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bone marrow transplant is judging a procedure that

has a hell of a lot of harm versus a whole lot of benefit, in trying to weigh big benefits and big harms, when they're big on both sides, to reach some judgment on coverage. Here we were faced with, or the panel was faced with something that there is no -- nobody has put forth a case that biofeedback or stimulation produces harm. It may waste time and cost money, it may produce poor inheritance to the children and less tax dollars to the federal government, but there's nothing in anything that we've gotten here that it produces harm.

I can't see how we can consider those procedures under the rulings of this Committee in the absence of considering cost, because I mean if we just get two patients coming here and saying they got better, and even if it's a Horthon effect, how are we going to judge this? And that's what I think this ethical dilemma is all about. Medicine has side effects, surgery has side effects, try it for six weeks and see if you get better, a simple question, and in the absence of cost you should cover everything. This would have covered vision rehabilitation, every kind of rehabilitative

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service, physical therapy, your knee hurts, you know, why not get a knee brace and try physical rehabilitation. I'm concerned with this problem, I'll state that categorically, and I think we have to deal with that issue.

Now, the second part of the problem is the fact that if it is indeed correct that it's in nobody's interest to produce information, if we vote no to ever produce new information about this procedure or these techniques that would benefit a large number of people, because there's no company's financial interest, then I don't think ethically we can deny coverage, in the absence of the federal government saying that we're going to use part of that $2 billion of extra money that went to the NIH to actually do the studies quickly to answer the question. Because we are now in a situation saying that we have an orphan technology that nobody will approve that people are using, and basically there is testimony it works, and we have no strategy to actually provide the knowledge that

this is going to work. So we need to force the government to make some consistent policy here if we are going to operate in a way that makes sense.

The FDA is in a very different

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circumstance relative to drugs, and we need to do something that makes some consistency here as we do this. So, those would be both my general and specific comments about what needs to be done.

DR. SOX: Thanks, Bob. Linda, I think you were next.

DR. BERGTHOLD: Yeah. I wanted to go back a little bit to Dr. Maves and Randel's comments. I sat on the very first panel, the multiple myeloma panel, and I don't know how many of you know that actually, I believe HCFA has issued some coverage determinations about that. It's on the web site. I don't even know if this Executive Committee knew that.

Our panel really struggled with the process and Tom can attest to that. I think we have improved the process a lot through the use of the interim guidelines, and I do see this as a work in progress and want to keep working on it. And while I am concerned about the public, the public is not the same as the industry manufacturers who make the products. The public is not the same as the advocacy groups who necessarily advocate for that particular product. And you know, I'm struggling, I think all of the consumer reps are

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struggling with our role on this, but I see my role as a very tough one, and that is sort of looking at the overall good for beneficiaries.

I would say that what happened with the multiple myeloma panel, as awkward and messy as it was, will result in better care for Medicare beneficiaries, because people will not be given painful very complex procedures that are really not going to extend their lives in the same way they were before our panel met. And to me, that's the bottom line, and the bottom line is we are deciding about things, and maybe the incontinence issue is just not at the same level of life or death, so it makes it more complicated to talk about it. But on the multiple myeloma issue, to be telling people

that they are not going to indeed live more than three more months with a procedure and it's going to be extremely painful and affect their quality of life, and the evidence shows that they're not going to survive this, that to me is an issue that these panels really need to be taking up, and hurrying it does nobody any good.

So I feel like we ought to -- I mean, I feel an urgency about it, Randel, but not enough of an urgency to do things that would be mistakes and

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that would harm patients in the long run. So I think we ought to keep working on this, and recognize that we're in a process that we are inventing this process as we go along, and we're going to have to accept that we're going to make some process errors.

DR. SOX: Thank you. We just have a couple minutes before we give a chance for public comment. I want to make sure that anybody who hasn't already had a chance to speak gets a chance to speak, however briefly that might be. Anybody else? Leslie?

DR. FRANCIS: I just want to be sure that we add to this, there are really two issues here. One is the substance of the panel recommendation and the other is the openness of the process, and I would hope that when you appoint a working group, you think about -- that group thinks about the second half of our guidelines as well as the first half, because I was not part of the research panel, but my sense is that a lot of the upset about it isn't the substantive criteria, it's whether stuff got out there fast enough for people to talk about, which actually goes against Randel's.

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DR. SOX: Okay. Well, before we enter into the period of public comment, I'm just going to summarize by saying that we're going to reconvene a methods subpanel or subcommittee, and it's going to have two charges. The first one, I think the most immediate one is to respond to issues that have been raised about the process for evaluating evidence; in other words, how we do our assignment as HCFA has asked us up until now. And

hopefully, we can fix some of the issues that came out in the incontinence panel procedure quickly so that subsequent panels that deal with advising HCFA on evidence can do so with benefit of learning from the lessons of the Med-Surg panel. That's number one.

And then the next step will be to tackle the big issue as I raised earlier, of how we make coverage decisions that are systematic, transparent, even handed, consistent from technology to technology. That will be a bigger issue, but one I think we need to take on only after we make a fix on the issues that have been raised about evaluating the evidence, which I think will be fairly straightforward.

So that's the proposals. I am going to

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ask you to think about it and hopefully affirm, after we have a period for public comment.

MS. RICHNER: I would like to say one more thing, is there time? I mean, certainly I'd like to defend my statement about the timing. Once again, it's related to process. I fully appreciate all of the issues associated with openness, careful evaluation of all of the evidence, I appreciate our time that we're going to be spending on developing the methodology and this subcommittee. That's not the point. The point is that we haven't had clear guidance from HCFA from the very beginning in terms of what our role is, and a lot of that has to do with coverage decisions.

And one more point that's very important. Dr. Hill in his opening statement when he was asked why was this particular technology, urinary incontinence, sent to this Committee, he said because of the impact on the program. I do have to say one thing. To me, that is very telling. Once again, that brings up what Bob Brook just said. What that is, using coverage to control volume to me sort of defeats what we're all about here. There's lots of way that HCFA can control volume beyond using the coverage process for that.

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Thank you.

DR. BROOK: I would just like to go on record that I don't agree with that. The most

effective way to control volume is coverage, and the most effective way -- and somebody eventually down the road, and that's why I'm sure that HCFA didn't deal with this up front -- when there are a large number of people that can use labor intensive services over a long period of time, that have extraordinarily small benefits, somebody is going to have to step up to the plate and say this is not covered, you can get it outside the system but it's not covered. So I don't agree with you, Randel, about what the issue is. I do agree that we are confused at this moment, and because of our role here in what we're doing and therefore, this confuses the whole process, even to the whole question of what the evidence is.

DR. SOX: Okay. Before we move in to a chance for public comment, maybe I could ask Jeff or Hugh to comment on this discussion and give us some guidance about whether we're going in the right direction here, from your perspective as the Agency that we are trying to advise.

DR. HILL: Well, I will take the first

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stab at that and then Jeff, maybe you can clarify. I am not confused at all. We in the charter said quite clearly that we wanted the Executive Committee and the MCACs to comment on the scientific evidence. The charter also says that the committees may be asked about other things, but it says they will be asked about the scientific evidence. And Dr. Kang has indicated to us a future direction, but for now we're asking for clarifications on the evidence, and I appreciate the committee's willingness to go forward with us, and look forward to where we're going in the future, and I hope that you will set up a subcommittee and a working group that will work towards that.

DR. SOX: Jeff, do you have anything to add?

DR. KANG: Yeah. This has been very helpful for me to hear the conversation here. First of all, just in answer to Randel's question, coverage is not all about controlling volume. What coverage is about is whether or not the benefits should be available; that's the threshold

question. Then once the benefit is available to Medicare beneficiaries, then there are whole

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subsequent issues about trying to control volume. But I think the threshold question, and this is in the notice of intent, and maybe what might be useful in some future MCAC meeting is for us to come and present that notice of intent, because it begins to flesh out the questions that both Dr. Alford and Dr. Brook is wrestling with, what is the role. But I think coverage really is about the threshold question as to whether the benefit should be available, and then there are subsequent questions about volumes and appropriateness on an individual case by case basis.

I agree with Dr. Hill that short term, your charge is very explicit. We want you to focus on the evidence. This largely has been because of the lack of criteria, and part of our dilemma, and I understand Bob's impatience with us, but part of our dilemma is we have not been clear about the criteria, and we're working on that.

The only thought, Harold, for your work group is in listening to discussions, I actually wanted to follow up with what Dr. Murray and I think it was Tom actually, Dr. Holohan was saying, I think there is some confusion about scientific evidence versus clinical evidence, and I think we

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would really appreciate your advice on that issue. Are we, from an evidentiary state, is it about the scientific methodology, or in fact is this the gray area of kind of consensus and expert opinion and recommendations, so that, I think would be very helpful also. I don't know if you were referring to that in terms of when you say the process itself, but I think it's a different question in the process, a very substantive question about what's good evidence.

DR. SOX: Thank you. Well, the podium is now open. We have about 10 minutes or so for anybody in the audience who wishes to comment on whether we're heading in the right direction or veering dangerously off the path.

Anybody who wants to speak, please get up behind the mike, and that will give a chance for

me to gauge how many people want to talk, so that we can allot the time fairly.

DR. STANTON: Marshall Stanton. I want to start by complimenting Dr. Garber on his chairing of the Med-Surg Panel. I think that he allowed a lot of open discussion that was very useful for everybody that was there, both concerning the urinary incontinence question, and

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also, he allowed us to discuss some of the process and some of the frustration.

I will differ a little bit with Dr. Garber in at least not letting people here leave with the impression that everybody was satisfied with the process. And I don't want to put words in his mouth but I want to make sure that people realize there was a lot of frustration with the process, and I would encourage those who are interested to look at the transcript at the end of the first day and the beginning of the second day particularly.

Dr. Garber also made comments about the conference call where people were given the opportunity to request additional information if wanted. Now I for one, being a cardiologist at that time, and participating in that conference call, did not understand enough about the urinary incontinence area to be able to know which pieces of evidence I would want to request. I certainly, from my academic upbringing and scientific background, know how to look at evidence when it's presented, but I'm dependent on the other experts on the panel and on HCFA to present a balanced view of the literature that's out there, and the

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opinions that are out there, and not just provide the Blue Cross/Blue Shield TEC report.

Regarding Dr. Sox's formation of the methods subcommittee, I think that's a very good idea, but considering listening to everybody's opinions, how diverse this group is, I would encourage that subgroup to be diverse as well, and I think it would be important to have industry representation on that group.

And lastly, I just want to make a quick comment on Dr. Holoran's rejection of expert

opinion. I found that interesting but a bit bothersome. I think many people certainly respect the opinions of experts when conclusive data are absent, and I find it interesting that I think this Executive Committee as well as the panels are panels of experts that were brought together to render expert opinion.

DR. SOX: Thank you very much. Center mike please?

MS. WOOLNER: My name is Barbara Woolner, and I am a clinician, I am not a scientist. I would like to make two points only.

Number one, I would like to reiterate what Dr. Stanton has just commented on, and urge

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you to look at the dissatisfaction of the panel members, particularly on the second day. The first hour of the entire meeting was spent on their dissatisfaction and frustration with the process.

I would like to make one other comment about the AHCPR comments that were omitted and point out that earlier, I believe Dr. Hill or Dr. Garber were asked this morning why they enlisted the Blue Cross/Blue Shield Technology Evaluation Center to issue a report, and their reason was that they wanted to look at the new evidence when in fact, the six studies that were looked at were done in 1993, 1993, 1996, 1996, 1986, and 1983. Certainly, there was not a lot of new evidence. Thank you.

DR. SOX: Left mike, two minutes.

MS. SHERMAN: Sandra Sherman again, from the AMA. I just want to underscore what Dr. Kang was talking about in terms of the importance of the criteria that HCFA is going to establish for making Medicare coverage policy and the interaction of the criteria that are going to be used with the evidence that this Committee is going to consider. Certainly we want the basic effectiveness of procedures that are proposed for coverage to be

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demonstrated through scientific methods and available in scientific literature. But when the panels have to extract from that science to determine how effective would this procedure be in the Medicare population, in our aged and disabled

beneficiaries, when we look at criteria that HCFA is proposing in its notice of what is the impact, not just on mortality and morbidity, but on quality of life.

Is a certain procedure that's proposed for coverage more convenient for patients, does it improve compliance with prescribed therapies? These kind of questions are going to require you to have some expert opinion. They are not going to be demonstrated, I don't believe, in the scientific literature. Basic effectiveness, yes, but these other questions, you're going to need to take a broader look at what's available.

DR. SOX: Next, left mike.

MR. MESKEN: Tom Mesken, Medical Alley. There seems to be some question among the Committee about what its role is, and I'm sure everybody can cite different things from the charter, and the preamble to the interim recommendation, but in the charter it explicit says that panels may be asked

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to develop recommendations about specific issues of Medicare coverage and/or to review and comment upon proposed or existing Medicare coverage policies. And in the discussion paper, in its preamble, the Agency says that HCFA views the materials being developed as helping to insure that MCAC panels have complete discussion around the questions posed to them by HCFA.

And I appreciate that you want to set up a methods subcommittee to address these issues of both the process and the larger coverage issue, but I think whether it's the leadership of this Committee or otherwise, they should put strong pressure on the Agency to get explicit instruction to address this so-called gray area, as Dr. Kang suggests. Your ability to do that comes from the Agency, and for them to put it back on you and say, well, help us think about what gray area is, does get to the point of can you address gray area or not. And I think that you need to put strong pressure on the Agency to do that. To do otherwise is to wait for criteria regulation, which will probably never see the light of day. Thank you.

DR. SOX: Thank you. Next?

MR. J. CONNOLLY: Jerome Connolly, with

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APTA. Just very briefly, Dr. Kang has indicated that there is some confusion and acknowledged that there is some confusion over what is scientific versus what is clinical, and I think if you review the transcript, that there was confusion on the panel members' behalf, that in fact they could not use clinical evidence, they could not use clinical expertise, their own clinical judgments. They did not feel the capability or latitude to call upon that clinical experience in making the judgment and answering the very narrow questions.

There was a primer provided by Dr. Zarin prior to their discussion that indicated what scientific evidence and how it was developed, and that was the background and framework by which this panel operated. The panel was not familiar with the AHCPR clinical practice guidelines before they came in here. Many of them acknowledged during the meeting that this was the first time they had heard about them. So in a few hours in the course of a day, to try to become familiar with clinical practice guidelines that members of the scientific and medical community have reviewed and said have good clinical applicability and utility, and to not be familiar with those in order to make a decision

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is not really fundamentally correct.

Dr. Garber has indicated that the correct set of information was not distributed. He acknowledged that if he had it to do over again, I think he would do it differently and I believe that he would, and said he has.

The questions were too narrow. Everybody has said that. The question was changed the morning of the meeting, the first meeting on biofeedback, and in fact, the technology assessment was not posted on the web site allowing written comment until after the written comment period had expired. These are not small refinement issues. These are not issues to tweak. These are fundamental issues that need to be brought up and need to be changed, and any decision that you make or you allow to go forward, allow to be ratified on the basis of a process that is fundamentally flawed will be a fundamentally flawed decision. Thank

you.
DR. SOX: Last speaker?
MR. GEIGLE: Thank you. My name is Ron Geigle. I'm a writer on technology issues, and I'm representing only myself. And I think I have a philosophical point. I've attended almost all MCAC
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meetings, including almost -- I missed one panel meeting. And the issue obviously comes down to adequacy of evidence, and the philosophical issue that troubles me as a consumer is, and I think this especially applies to the methods panel Dr. Sox is talking about is, what is the answer when we consistently conclude that the evidence is inadequate? Do we always say no?
Because I think a lot of, as I listen to clinicians speak, and have done a lot of research over the years, randomized control clinical trials are generally not available because if they are available, there is going to be obviously continuing disagreement in many cases. Then as I listen to the panels, it's not just randomized control clinical trials, it's extensive randomized control clinical trials; it's randomized control clinical trials that have consistent findings where there is no potential for bias, and the potential for bias was a critical element in the urological panel.
So therefore, I ask you to think about as part of the methods, the issue of when the evidence is quote-unquote inadequate, is the answer no, or does the federal government allow what Dr.
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Brook was saying, have some responsibility to jump into this and try to help resolve this, whether it's NIH or elsewhere? Many of the people on the urological panel said, why isn't there more randomized control clinical trials, where is the evidence, why isn't is being done? What do we do when we run into that?
And one final point is, this is not just an issue for MCAC. The first, in a decision tree on the NOI on coverage, the first question relates to advocacy of evidence. If no, we stop. What do we do about that?
DR. SOX: Thank you. Before we move

back into the deliberation of the panel, I would like to call upon anybody in the office who wishes to help us define clinical evidence and distinguish it from scientific evidence, to write to us and help us, because that's going to be one of the tasks that the methods work group undertakes, if this Committee decides to go that route. So this is an open invitation to help this Committee try to define what's meant by clinical evidence.

Well, what I would like now is to here a motion from the Committee about proposed procedures for going forth to deal first of all, with

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improving our procedures for evaluating evidence, but then also moving on to the larger issue of procedures for actually making coverage decisions.

MS. CONRAD: Before you proceed with that, I am obligated to read something for the record, as follows: For today's committee meeting, voting members present are Robert Brook, Thomas Holohan, Leslie Francis, John Ferguson, Robert Murray, Alan Garber, Michael Maves, Frank Papatheofanis, Ronald Davis, Daisy Alford-Smith, Joe Johnson. A quorum is present. No one has been recused because of conflicts of interest. You may continue, Dr. Sox.

DR. SOX: Thank you. I have to remind the nonvoting members of the panel that they are not eligible to engage in the discussion of the motion that we will discuss, but hopefully they have had adequate opportunity to give us their input before the discussion.

So I would like to hear a motion that we can discuss and hopefully act upon. Ron, you're one of our star motion makers. Do you want to give it a shot?

DR. DAVIS: Well, I would move that we form a methods subcommittee to address the issues

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that you just mentioned a few moments ago, as our court reporter could read back to us.

DR. MURRAY: Second.

DR. SOX: Okay. So we have a motion to form, or reform a methods subcommittee, to deal with both short term issues of improving our ability to evaluate the evidence and then as a

second assignment, to prepare us with procedures and approaches to evaluate clinical evidence and other issues that may bear on our responsibility to make coverage decisions, something that is still a ways off, but for which we need to be prepared.

So, time for discussion of that motion. Anybody have discussion? Frank, then Bob.

DR. PAPATHEOFANIS: I wanted a clarification on one of the potential responsibilities of this working group, and that goes back to the framing of questions that each of the panels are asked to address. I remember from one of our initial meetings, that my understanding was that HCFA would provide us as panels with questions, but we would be able to provide some feedback to HCFA until we finally came to some consensus. And there seems to have been a little bit of an imbalance, or at least a perception of

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imbalance in the types of questions that we're asked, to the point where a lot of the letters seemed to suggest from the public that the questions were setting up a no answer.

And so, a question I have is, is part of this working group going to be charged with the responsibility of working with HCFA in refining the questions and selecting appropriate ones?

DR. SOX: I perceive that this committee is going to read every single letter that's come in commenting on our methods, both generally as well as in respect to the Med-Surg Panel, and is going to consider each one of them and whether to adopt it or not. So -- and certainly, that's among the issues that were raised by those who wrote to us. Bob?

DR. MURRAY: First, I would like to say that I support the motion and intend to vote for its passage. But secondly, I would just like to comment that many of the comments that we have heard this morning urge that the Executive Committee develop guidelines that are more open and allow consideration of a wide variety of opinions as well as evidence. I would like to comment that the reason we have the interim guidelines is that

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the first two panels that considered questions did

so with no guidance, and as a result, the Executive Committee refused to ratify, or decided not to ratify the votes or the recommendations of the panels.

I believe that the guidelines need to be prescriptive, and I would urge that the working group keep that in mind, and that they be clear so that the process remains predictable and consistent.

DR. SOX: Thank you. Leslie?

DR. FRANCIS: I just want to comment that I hope that the working group will be balanced in the folks who are on it, and that there will be opportunity for going back and forth between the working group and the Executive Committee as this process continues.

DR. SOX: Yeah. I envision first a representative committee, and I would point out for everybody that both the consumer representative and the industry representative were on the previous working group, so there was balance. But I envision one group that's small enough to get something done, but getting feedback on a continuing basis from the whole committee. Other

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questions or comments? Bob?

DR. BROOK: I wanted just a clarification. Alan, in the report of the two subcommittees, if I remember and I don't have the document in front of me, it said something like the evidence was inadequate to support doing procedure X or Y. It wasn't a question of this is the level of evidence that's available, it was that it's inadequate, just inadequate. So was that, the reason you responded that way because HCFA demanded an adequate or inadequate response, as opposed what the preventive task force has done, and other panels have done with A, B, C, D, E, and 1, 2, 3, 4 and 5?

DR. GARBER: We were certainly trying to answer the questions, so the narrow answer to your question is yeah, we were guided by what the question was that HCFA proposed. But at the same time, as I understood the panelists' thinking on the matter as they publicly expressed, it was that they thought they couldn't draw conclusions, in

part because -- there were randomized trials by the way, and we will be talking about this more this afternoon I presume -- but there were issues of conflicting results and also questions about

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various kinds of biases like ascertainment bias, which might have made it impossible to determine whether the treatment was really effective. So I think the individual panelists didn't go through study by study to say their reasons.

DR. BROOK: I want to come back to the general concept, because I am trying to figure out what has to be done with this working group motion, and that's why I'm asking you this question. Virtually every other expert group that's looked at evidence, when they have rated evidence, has graded the level; they've never come up with evidence is adequate or inadequate, they've graded the level of evidence, so that the evidence might be that this is only supported by clinical opinion or behavior, or this is not supported even by that. But you just said that the statement as read in the minutes of this meeting, is the evidence is inadequate. And I wondered, because I'm just wondering how that came out as opposed to a gradation statement.

DR. GARBER: That's the way it was posed. Let me say that not every expert group uses that scoring system that the preventive services task force uses. And a difficulty in applying that scoring system is it gets a little confusing when

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you have studies that are randomized but have various kinds of biases, because it's a very approximate rating system and when you have conflicting results, although that's usually a strength of evidence issue. But, I personally think it would be worth exploring from the methods group, I think it's worth exploring doing formal grading or not, don't forget that if they had concluded that the evidence was adequate, there would have been a second exercise of assigning it to one of the seven categories. And I thought that the reasoning in doing it this way was primarily that it wasn't necessary to go into the gradation steps if the panelists felt they couldn't draw conclusions about effectiveness. But it would have

helped to specify the reasons for it, I agree, if they had been grading it.

DR. SOX: So at present we have a system for grading effect size. It sounds like we should put on the table the issue of a system for grading the adequacy of the evidence, to make a conclusion about whether something works or not, and that's another task for this work group.

DR. GARBER: But I think that if you were to say you must put the adequacy of the

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evidence into, say, U.S. preventive Services Task Force categories, there would have been fairly straightforward, I believe, if I understand the categories correctly, because there were multiple randomized trials on both of these. There were flaws in things like blinding and outcome measurement that at least were critiqued during the meeting, and then they have mixed results on effectiveness. And you might alter the balance by saying you excluded or included different subsets of studies, but it wouldn't be that hard to go back and come up with it.

DR. SOX: Well, anything we could do to improve the transparency of our deliberations, I think is a plus.

DR. GARBER: Right. But let me just add to Bob's suggestion that this Committee should think of all the ways that they can improve transparency, and I think the grading scheme is one set, but the other is that we could have something that's more specific about where the critical areas are, where we would need more information so we know if a particular new study is likely to resolve the problem, or to give some guidance as to what kind of study would need to be done. And I think

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we could do a good job of that if we made that an explicit part of the process.

DR. SOX: Bob, do you want to respond to what Alan said?

DR. BROOK: I would just wanted to, based on this, I would like this working group to do two things then, and I don't know how your motion quotes that: One is to actually help prepare for HCFA, because under the current rules,

it sounds like we're helping make the coverage decision. I'm going to interpret this in the near term that way. So we want to produce the best written document that would help people at HCFA understand the evidence so that they can make a decision about whether to cover or not cover a procedure. So we want that document to be fair, unbiased, open, all of the things that we talked about. We ought to reexamine what we did to do that.

I would urge that we take a second step. We would also like to develop a guidance to the panels to say that in the case that the evidence is inadequate, not because there are substantial negative trials or negative results but that it's just inadequate, that the panel must

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discharge its responsibility by suggesting who needs to do what or what needs to be done to produce an evidence base that this process then could be revisited and this topic decided again or examined again, with a time frame and a specific work plan. I would like to move us to a point where we don't discharge our responsibilities by saying, hey, we haven't studied this enough. I don't know if that's in the scope of what we're supposed to do or not, Hal, but that would be an interesting document that should go to HCFA in terms of the second part of this.

DR. SOX: I think all of us would like to have a better evidence base for medical practice and that suggestion would hopefully put some pressure on somebody to provide that evidence base. Yes, John?

DR. FERGUSON: Is it my understanding that this methods subgroup will address possible changes to the interim document in trying to come to grips with the evidence and the coverage issues, this methods group will consider modifications of this to enhance the process?

DR. SOX: That's right. I think everybody agrees that the present document is a

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good beginning and it needs to be tweaked, for lack of a better term, to make it better in helping us to advise HCFA about the quality of the evidence.

And then it probably needs some fairly major changes as we prepare for our broader assignment from HCFA, which is to make coverage recommendations.

DR. FERGUSON: I want to be sure that my comment is related to making sure that this is enhanced to help this document. The second thing is, the questions that HCFA poses to the panels, I think I would like to recommend or suggest if it's not already implied, that this methods group also consider these questions, and to work with HCFA on the kinds of questions.

I say this with some, I won't say emotion or experience, but because in the consensus program at the NIH, the questions were paramount. We spent the majority of planning trying to arrive at what questions would bring out the best discussion of the evidence, and so I think that's a very important part of this methods group.

DR. SOX: Yes, Bob?

DR. MURRAY: I have heard nothing in the motion that would rescind any of the current

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guidelines, so I just wanted to clarify. It's my understanding that any panels that meet between now and the time when the new guidelines are approved, will still operate under the current guidelines; is that correct?

DR. SOX: That's correct, and I think that the working group, methods working group, ought to have a pretty tight time line.

DR. BROOK: I don't believe that.

DR. SOX: What?

DR. BROOK: I disagree with that and I was just wondering, to beat the process, that this document, the next document that looks like this, ought to include the kinds of pieces of information -- this is just a list of the randomized trials that were done, or the exclusion of the randomized trials. That's what was given to the panel in terms of background information. I think that's inadequate in terms of -- unless it's a field that has had multiple randomized trials, that's all that's in this document, and it's inadequate, from the perspective of the testimony we heard today, and I would urge that -- I don't know where the

stage is for the next document or the next meeting, that this document needs to be a broader document
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that goes to the panel before the panel meets, period. It's not state of the art. If the randomized trials were there, we wouldn't be in business. So I disagree. I mean, I basically heard that we have an inadequate written process here and for that reason, either this document gets expanded for the next panel rapidly, or we delay the next panel. Sorry about that.

DR. SOX: Thank you, Bob. I'd like to see if there's any more comments, and then we can take a vote. Tom, did you want to comment?

DR. HOLOHAN: Just a comment to Dr. Brooks. Virtually all of the evidence, save one piece of published information, given to the myeloma panel, was not randomized trial.

DR. BROOK: But that evidence wasn't synthesized any way that anyone can understand it. So the question is, can we produce a synthesis that people can understand that contains all of the evidence, that labels the evidence for what it is. I mean, I'm not arguing that the panel ought to make -- by the way, I'm not disagreeing, I'm not saying how the panel ought to make its decision about the adequacy of the evidence, I think our guidance is perfect on that. What I would like to
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know is that no matter if you're the person, the consumer, the manufacturer or the panelist, when somebody reads a synthesis of the information, that they will say that this is something that I have faith that has been done in an open complete process, period. And not to have the guidelines, not to have the endorsements, not to have all this material synthesized in some way as part of the package.

That is evidence, and it's even included under our interim guidelines that that's evidence. That is a mistake. And I think that's how we got into trouble. I did not expect to see a randomized, a list of descriptive literature from randomized trials when I read this document after -- you know, my documents came after the panel met, so I did not expect to see that document,

based on our interim document. It didn't correlate with what we had said.

DR. SOX: Well, number one, this committee is going to start meeting quickly and hopefully come to conclusions that will affect subsequent operations of the MCAC panels in a timely fashion. And secondly, you Bob, will have an opportunity to decide whether we've done an

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adequate job when we bring the revised document to a vote, which hopefully will be soon.

Any other comments before we vote?

MS. CONRAD: Okay. Let me repeat the motion as I understand it. You're going to vote on establishing a methods subcommittee which is a working group to deal with the current Medicare Coverage Advisory Committee process. As an aside, that includes modifying the interim procedures, the interim recommendations guideline, and to help establish formation of the questions that HCFA addresses to you.

DR. SOX: So far, so good, but also moving on to discuss and develop procedures for the broader issues that are raised by an expanded assignment of our MCAC to give coverage advice to HCFA.

MS. CONRAD: All in favor? Those in favor please, a show of hands?

(All members with the exception of Dr. Brook voted in the affirmative.)

MS. CONRAD: Opposed?

(No opposed votes.)

MS. CONRAD: Abstain?

(Dr. Brook abstained.)

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DR. SOX: Do we have a requirement to ask for people to explain their votes.

MS. CONRAD: We do for the panels, but I don't think it's necessary here.

DR. SOX: Good. Yes, Ron.

DR. DAVIS: Would it be appropriate for me to quickly raise a related issue? It's kind of a generic issue about process and really doesn't fit as neatly in the afternoon discussion. The title of our Committee suggests that we have a fairly broad remit, Medicare Coverage Advisory

Committee, and this subcommittee that is going to be formed is going to be exploring the issue of our remit being expanded and getting more into the coverage recommendations. And I feel that to properly discharge our responsibilities, it's important that we are generally aware of all the important decisions and documents and activities on Medicare coverage that are occurring at HCFA, and I feel that in some cases we've fallen short of that. For example, I wasn't aware of the notice of intent that apparently was published by HCFA a month or so ago, or maybe it was earlier than that. And maybe we were notified and I just missed it, but I was also not aware that any action had

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been taken as a follow up to the multiple myeloma issue that we spent a half day or so considering in the Executive Committee. And I suspect that there are other important activities and decisions and documents being made about Medicare coverage more broadly. And even if there are activities going on behind the scenes that don't directly relate to our formal responsibilities, I think it would behoove us to be well educated and well informed about what's going on.

So if other people on the Executive Committee share my concern, the suggestion that I would offer is that we would request that HCFA staff keep us informed on a proactive basis on various documents that are put out for public comment, various decisions that are made, especially decisions that follow up on actions that have been on our table for consideration. And this could be done by mailing us material, by e-mailing us notices, by letting us know where on the web site these things may appear. I personally don't have time to be checking the HCFA web site on a daily or weekly basis, so that's my comment.

DR. SOX: Do you want to respond?

DR. HILL: Yes. Your chairman has

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already indicated the need for that, so I'll offer you a three-part response, in view of the time. You're right, we hear you, and we're working on it.

DR. SOX: So basically, when you get to where you want to be, we will kind of understand

the broader context of HCFA decision making.
DR. HILL: As best we are able to articulate it.
DR. SOX: Okay. Is there anything you want to say about logistics of lunch?
MS. CONRAD: I am informed that I neglected to read the results of the last vote into the record, and I must do so at this time. We had all affirmative, all for votes except for one abstention, so the vote, the motion is carried.
DR. SOX: We are going to reconvene in precisely one hour.
(Luncheon recess taken at 11:44.)
MS. CONRAD: We have a quorum; let's go.
DR. SOX: This afternoon is going to be a discussion of the Med-Surg recommendations about incontinence, and just for the information of the committee, what I'm aiming at is a motion that will basically, a blanket motion to approve the

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recommendations of the Med-Surg panel with the possibility that if an individual member of the committee feels strongly, we can pull out different of the subquestions that the committee considered for individual discussion, but I'm hoping we can deal with what the committee did with one motion. So for those of you who have some particular bone to pick with some aspect of it, be ready to identify that aspect of it for special consideration.
The first part of the session will begin with a presentation by HCFA staff, and who is going to do that?
MS. CONRAD: Dr. John Whyte, please.
DR. WHYTE: Thank you, Connie, and thank you, Dr. Sox, for the time address the panel. What I'm going to do over the next 15 minutes is to talk about how we came to the overall topic of urinary incontinence, how we narrowed it to these two topics, the process we used relating to the technology assessment, the formulation of the assessment questions, and discuss a little about the AHCPR guidelines. I'm going to talk about how we disposed of materials, and how we came to the panel with questions.

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So to start with how we came to the overall topic of urinary incontinence, and as you all know, it's a significant source of morbidity for the Medicare population, and the diagnostic and therapeutic options have not been definitively studied and researched. So originally, when someone asked this morning, why did we decide to even tackle the topic of biofeedback, as well as the topic of pelvic floor electrical stimulation, the reality is that we really wanted to look at the overall topic of urinary incontinence; how do you treat it, what are the various therapeutic options, are there a continuum of options, and where do they all fit. And this would include pharmacologic agents, surgery, bulking agents, biofeedback, sacral stimulator, pelvic floor electrical stimulators, as well as other behavioral modifications, which as you can imagine, was quite an ambitious undertaking.

But what we learned from the first two panel meetings was that we needed to limit the number of topics that could be addressed in the two-day meeting. So what we decided at a staff level was to limit the first incontinence panel meeting to two topics. We chose the issue of
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biofeedback primarily because there was a difference in coverage policies. If you look at our April 1999 Federal Register notice, we say that when the service is subject to inconsistent local coverage policies, we may take on that issue for national coverage determination. Biofeedback is one of those issues where there is local carrier discretion.

We also decided at that time to look at pelvic floor electrical stimulation, since there had been several requests over numerous years to readdress the issue of noncoverage. As opposed to biofeedback, pelvic floor electrical stimulation was essentially noncovered. And finally, we have decided there are other areas of urinary incontinence left to address, and that actually will be addressed at the next Medical Surgical Procedures Panel. So in answer to questions on urinary incontinence and biofeedback, it was a

broad issue of incontinence that we wanted to look at, because we realized it has a significant morbidity issue for beneficiaries and if it could improve the quality of life, we would be interested in doing so.

Can everyone hear me? How's this?

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Better?

So let's spend a few minutes discussing the process relating to the technology assessment. Based on the interim recommendations of the MCAC Executive Committee, we decided to order a technology assessment, and our policy for external assessments is to go through the AHRQ, the Agency for Health Research and Quality, formerly known as AHCPR, which has 12 evidence based practice centers throughout the country.

Now based on the comments that we received in the mail as well as what we heard at the previous panel meeting and this morning, there appears to be some confusion as to what the Blue Cross/Blue Shield TEC, technology evaluation center, is, and why it was chosen to do this assessment. TEC is one of 12 evidence based practice centers, TEC was founded in 1989 by the Blue Cross/Blue Shield Association, and since then has produced over 400 technology assessments.

Now when people hear TEC is part of the Blue Cross/Blue Shield Association, they often feel there is an inherent bias towards a negative assessment. It's important to note that the staff persons are noninsurance executives but rather are

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primarily physicians and other health services researchers with advanced degrees in statistics, whose stated mission, I'll just read from it, is to produce rigorous high quality scientific assessments of medical effectiveness. The goal at TEC is to provide plans and subscribers, which includes Kaiser, with the best available evidence. And again, it's important to note that TEC does not consider costs, nor does it make coverage recommendations.

Now HCFA in some consultations with the AHRQ, but primarily HCFA determined that TEC would be the most appropriate center to develop the

evidence report, primarily because TEC had previously done assessments on these modalities. It is a common practice for AHRQ to select an EPC that has conducted the initial assessment when a new evaluation is requested. And I really want to emphasize that a previous assessment, despite what people have said, does not predict nor does it prejudice the outcome of a subsequent assessment. We made it abundantly clear throughout the process that this was to be a de novo assessment.

Now some critics have argued that there should have been a group of experts on incontinence

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who did the technology assessment. We would disagree with this premise. Technology assessments, as you all know, are based on systematic reviews of literature. The experts in methodology and health services research should do these type of reviews. Unbiased researchers are often the best individuals to perform these roles, so it's really unfair to criticize the TEC assessment. So it's really unfair to criticize the TEC assessment as a biased assessment.

Now critical to the assessment is the formulation of the assessment questions, and I want to spend a significant amount of time on this particular issue. Again, the assessment questions were determined by the HCFA staff with consultation of the TEC staff, and for biofeedback, the assessment question was: For urinary incontinence patients, does adding biofeedback to pelvic muscle exercises result in greater improvement in health outcomes than the use of pelvic muscle exercise alone?

Now you can ask, why did we choose this question, and that's a reasonable question to ask about our question. We know that biofeedback and pelvic muscle exercises work compared to nothing,

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and we know that pelvic muscle exercises alone work compared to nothing, but we do not know the effectiveness of biofeedback and pelvic muscle exercise works in comparison to pelvic muscle exercises alone, in other words, what is the added benefit of the biofeedback component. And that's really what it has come down to, and I am going to

talk in a few minutes about how the AHCPR guidelines relates to that question.

So again, we know that biofeedback and pelvic muscle exercises works compared to nothing, and that's what the AHCPR report addressed. We know that pelvic muscle exercises alone works. So it's not an unreasonable question to ask, what is the added benefit of biofeedback to pelvic muscle exercises.

Now it's also important that we clarify as to what we mean by biofeedback, because there are different definitions out there, and it may not be a single unifying definition, but let me tell you the definition that we used, because that relates to the assessment, because throughout the day, to be honest, people are sometimes having different conversations or are talking different things, and we're not always in disagreement. So

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hopefully, through this talk, we can really focus on what the assessment is about and what the questions have been.

So for biofeedback, the definition that we chose which relates to the assessment is a therapy that uses either an electronic or mechanical device that relays visual and/or auditory evidence of pelvic floor muscle tone. This is done in an effort to improve the awareness of pelvic floor musculature and to assist patients in pelvic muscle exercises.

Now, the selection of the assessment question that I just discussed, as well as the definition of biofeedback, have been a stimulus for continued discussion. Now we would assert that biofeedback, remember, always involves pelvic muscle exercises. You can't have biofeedback without pelvic muscle exercise. Now some persons have suggested that pelvic muscle exercises always involves biofeedback and we do not support this premise, primarily because of how we define biofeedback for this meeting.

There are other types of biofeedback which do not use an actual mechanical device, such as verbal feedback, digital probe, and actually the

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AHCPR guidelines state on page 36 of their report

that pelvic muscle exercises can be done with or without biofeedback, and I'll quote from it: Pelvic muscle exercises may be used alone or augmented with bladder inhibition, biofeedback therapy, or vaginal retraining.

For pelvic floor electrical stimulation, there were three questions. Compared to placebo, is treatment with pelvic floor electrical stimulation efficacious in reducing incontinence? What is the efficacy of pelvic floor electrical stimulation as compared to pelvic floor muscle exercises or alternative nonsurgical treatment? Does the addition of pelvic floor electrical stimulation to pelvic floor muscle exercises result in improved outcomes above that obtained with pelvic muscle exercises alone?

So there were different questions for there. Pelvic floor electrical stimulation wasn't being just viewed as adjunctive therapy but also as a primary therapy, so they are questions that we are different questions that we were interested in for each modality.

Now let me address the AHCPR guidelines, because they have been discussed throughout this

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morning's meeting as well as at the previous meetings. Now the first report was issued in 1992 and updated in 1996, and I'm going to discuss really what are the guidelines and what they said.

First, they are guidelines, they are not the same type of systematic review of literature that was done in this assessment, and that's an important point to emphasize.

Second, the guidelines, as I mentioned earlier, focused on the use of biofeedback and pelvic muscle exercises compared to nothing, so when the guideline said that biofeedback assisted pelvic muscle exercises are effective, they were saying that biofeedback assisted pelvic muscle exercises are effective as opposed to nothing. They did not actually address in any great detail the contribution of biofeedback to biofeedback and pelvic muscle exercise, which was the focus of this meeting.

And I'll quote from page 38, because you don't have to believe me. On page 38 it says:

Further controlled trials are needed to assess the conditions in which biofeedback provides an added benefit to pelvic muscle exercises alone.

Now contrary to what some people have

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said, we do not disagree with the AHCPR guidelines. If we had asked the panel if biofeedback and pelvic muscle exercises are effective compared to nothing, the answer would most likely have been yes, but we did not ask that question. Rather, we asked again, is biofeedback and pelvic muscle exercises more effective than pelvic muscle exercises alone? We wanted to determine how much of the benefit is due to pelvic muscle exercises alone and how much is due to the addition of biofeedback to pelvic muscle exercises.

And again, for pelvic floor electrical stimulation, our questions were more numerous than the AHCPR guidelines since we looked at the effectiveness of pelvic floor electrical stimulation compared to placebo, compared to pelvic muscle exercises or alternative nonsurgical therapies, as well as compared to pelvic muscle exercises alone in combination with pelvic muscle exercises.

As someone else mentioned this morning, it's also important to note that their has been an enhanced body of literature since these guidelines initially came out. So not only are there different questions, but there's also different

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literature.

I just wanted to discuss the exclusion articles which have sometimes been overlooked. In an effort to be fair and comprehensive, we prepared a table of exclusion articles, and by exclusion articles, I mean we abstracted several articles that were included in the assessment since they were primarily studies that involved historical controls or pre-post designs. We also included several articles that were typically quoted and cited, and these were extracted in the exact same manner that was used for the assessment.

I want to address the assertion by several members this morning that we only considered randomized clinical trials, and that is

very inaccurate. For those of you who have the assessment in front of you, there are grids that are set up and if you have it, I ask that you refer to it, because what you will see on the one grid, they talk about group allocation and you will see it will say randomized, nonrandomized, randomized, single blinded trial, K series, K series, K series, questionnaire, cohort study. So, the point is that there was an entire body of literature that was looked at. To say that we only allowed randomized

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clinical trials to be examined is a fallacy.

In the previous discussions of the Executive Committee, you all talked about a hierarchy of evidence, and it's important to keep that focus, that there is a hierarchy. That does not mean that other information, clinical expertise, anecdotal experience, is ignored. It is considered and it was encouraged to be considered; that does not mean it was weighted in an equivalent type of point scale as other types of studies. So I really want to emphasize that point, and I challenge these people that say that we only looked at randomized clinical trials to actually look at the assessment, because that assessment is a synthesis of the body of literature to answer the question that we formulated at the beginning of the assessment.

Now we mailed the technology assessment, the exclusion tables, and articles that were extracted, to the members of the panel as well as the two guests that we invited to participate on the panel. And we did indeed receive a significant amount of materials from various persons, some at our request, often the specialty societies. We asked for their input. And at a staff level, we

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have reviewed and catalogued all of these materials, and did make every item available on the catalog to every member of the panel, and we did discuss the catalog in a conference call prior to the meeting, as well as described it in a cover letter that went out to the panel. All the panel had to do was ask for an item and we would send it to them, and indeed, we did send several items to several members of the panel.

We made the decision at a staff level based on the Executive Committee interim recommendations in consultation with the panel chair, that the catalog was the most fair way to handle the information that was sent. We were sent a very large volume of information from people; we felt it would overwhelm the panel if we sent all of that information, especially based on discussions of the first two panels. We felt that the most fair way was to catalog it; we did not want to be the arbitrator and decide what we would send and what we would not send, because in that way, we would never please anyone, you know, why didn't we send this report?

So what we did was say we will catalog everything and then to say if you need something,

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you let us know. And the reason why we may not have pointed out specific items on the catalog during the conference call, it would not be fair to say, well, this is more important, you might want to request this, and not look at other items.

Now, the issue about the time frame and how the report got on the web, this was all done in a compressed time frame and we are trying to do better, but it really is consistent with the time frame of other federal agencies as well as other federal advisory panels, roughly a two-week time period to receive information is a reasonable period of time.

Now along with materials I just mentioned, we also sent questions for the panel to address. These questions were largely based on the interim recommendations of the Executive Committee, again, in consultation with the chair of the panel, and I'll just read you what the questions were very briefly.

For biofeedback, is the scientific evidence adequate to draw conclusions about the effectiveness of biofeedback as an adjunctive therapy to pelvic muscle exercises in routine clinical use in the Medicare population, for the

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following three indications? We had broken it down to stress incontinence, urge incontinence and post-prostatectomy incontinence.

Then for pelvic floor electrical stimulation, we asked them: Is the scientific evidence adequate to draw conclusions about the effectiveness of pelvic floor electrical stimulation compared to placebo, compared to pelvic muscle exercises or alternative nonsurgical therapies, and then a combination of pelvic floor electrical stimulation and pelvic muscle exercises, compared to pelvic muscle exercises alone.

And then we asked them to consider when they looked at the data, the adequacy of the study design and the consistency of the results, the applicability to the Medicare population, and applicability beyond the research setting. What we were trying to do is to develop consistent questions that we would ask for every panel, so that's the reason why these questions were phrased that way.

The second point deals with the issue of the health effect that some of you talked about earlier. If the evidence is adequate to draw conclusions, because remember, the first question

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is, is the evidence even adequate to draw conclusions? So if the answer is no, then you can't go on to the second question. If the answer is yes, you then say, if the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect? And then there's various categories on the seven point scale that all of you know from having helped us devise those seven points.

Now I want to point out some issues about the assertion that somehow we changed the question or made it more narrow. And I really need to point out that there was never a change in the intent of the question. There was a clarification based on some confusion as to what we meant by biofeedback and originally the question read, if I can get it for you --

MS. WOOLNER: Do you want a copy?

DR. WHYTE: No, I have it. Thank you, Barbara. Is the scientific evidence adequate to draw conclusions about the evidence of biofeedback in routine clinical use in the Medicare population, et cetera. The difference that, between the two

questions, was the addition of three words, or four words, as an adjunctive therapy. And the reason

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why we made that clarification, because as phrased it became apparent to us that some people assumed or wished that we meant biofeedback and pelvic muscle exercises compared to nothing, but as you know from this discussion, this is not what we intended, by adding those words, as an adjunctive therapy, to clarify it.

For pelvic floor electrical stimulation, we had broken it down into three categories, the pelvic floor electrical stimulation compared to placebo, compared to pelvic muscle exercises, and then in combination.

And again, there's been an intimation that we narrowed the question to focus a no vote, and that's simply not the case. These modifications were not meant to be more restrictive but rather, more clarifying. And it's also important to note that these questions are consistent with the technology assessment questions. I read to you early on what the technology assessment question was, the issue as an adjunctive therapy.

Dr. Simon, who made opening HCFA remarks at the presentation at the biofeedback panel, clearly point out that it's viewed as an adjunctive

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therapy, so to point out that somehow we only meant biofeedback and pelvic muscle exercises compared to nothing, really is inconsistent with what we have said all along.

Those really are the points that I wanted to bring all of you up to date on. At this point in time I am going to defer to Dr. Garber to actually discuss the content that was discussed at the meeting, and after Dr. Garber, if that's allowable by the chair, myself or others would be happy to answer any questions you have, or I could answer them now, however you want to handle it.

DR. SOX: Does the panel have any questions for John before we proceed to Alan's report of the committee? Alan, why don't you go ahead?

DR. GARBER: Well, I understand that my

task is to give a concise statement that explains everything about the panel's reasoning even though the panel never really had a chance to individually explain all aspects of their reasoning. It may be a little ironic in that I could not and did not vote on any of the questions, so I cannot be said to be speaking for myself about reasoning, but I will try to reconstruct what I think was going on.

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Let me just make a couple of background statements that I think are relevant to the members of the Executive Committee who will at some point presumably this year also be in the chair's role on their committees, because a very important aspect of this process is the chair's input and other panel members' input into areas like formulation of the question and selection of the literature for distribution. We've already spoken about selection of the literature, I've already said my mea culpas about that, and I'll leave it at that.

But about the formulation of the question, I was consulted about the questions and I asked myself a few things in trying to evaluate whether this was a reasonable question to put before the panel. One of them was, is this a reasonable question to answer in coverage, for the purpose of coverage decision making, that is, could an answer to this question be helpful to HCFA, and I decided that I am not really the right person to judge, that's HCFA's question and one should give them a lot of leeway. But I did ask, is this a separable service, is there some reason why you might want to ask this question, and though I'm not an expert, it seemed to me that was plausible and I

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deferred to their greater expertise about that issue, and feel that I should question that very hard.

The second aspect, is it a reasonable question to ask of the literature? And if you knew before you started that there wouldn't be any reasonable literature on this, that is, studies that address this question, that strikes me as not something that is worthy of the panel's time even if it is a reasonable coverage question. And in this case, there was a substantial literature,

including randomized trials and many other kinds of studies addressing the question, at least in biofeedback -- actually all aspects of the questions, but in the case of biofeedback, was it effective as an adjunct to pelvic muscle exercises? So indeed, there was a literature, so it was feasible.

And then there are questions, is the question that's being posed to the panel clear and consistent with the instructions from the Executive Committee, and I thought here that was quite true with the proviso that it did need to be changed as John described, to make it a little clearer what was meant by biofeedback, because one thing that

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became very clear in the public testimony is that there are many different forms of biofeedback, and a manual examination where the provider feels a muscle contracting can be one form of biofeedback, but what HCFA had in mind was more mechanical and electrical assistance as part of the process. So that all seemed reasonable.

Now there is also a question, did HCFA and me as panel chair consult widely enough early enough about the formulation of the question, and I think there is probably substantial room for improvement. It would have been nice to get a lot of the input that we had received during the panel meeting at an earlier stage of the process so that the questions could have been refined if suitable. But I actually thought that the questions were clear and appropriate, at least in broad terms.

The second issue is about expertise on the panel. It's important to point out, and John mentioned this, that although the panelists come from a wide variety of backgrounds, it was clear there was a need for expertise in the continence area on the panel. A panelist from another standing MCAC panel, Lisa Landy, who is a urogynecologist, was brought on to the panel for

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this meeting. She apparently uses these techniques, has a lot of hands-on familiarity. Another regular member of our panel is a gynecologist who has experience with them. HCFA also brought in a nonvoting continence specialist

to be a member of the panel, and I dare say that she and Lisa Landy spoke more than anybody else, each one of them spoke more than anyone else by a substantial amount, and they were heard. I think people took what they said very seriously. So don't get the idea that content expertise was ignored or overlooked, although it certainly was the case that not all the panelists voted the way that the clinical experts in the field might have preferred.

There is a second operational issue and that is the review of both the evidence review and the panel's deliberations as a whole. Hugh Hill had mentioned beforehand that it would not be possible to fully implement the external review previsions that the MCAC Executive Committee had recommended and still stay within the time frame that we had set as goals, and so that part was not done, but we had the two designated members of the panel to review this material in detail, Lisa Landy

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and Les Zendel, who I believe is trained as a geriatrician and has substantial experience with the treatment of incontinence. So they were sort of the panel's designated experts who reviewed the material.

John described what the questions were and to give you an idea, every comparison was subdivided into three clinical indications, urge incontinence, stress incontinence, and post-prostatectomy incontinence, and then we have this rather complex day on the pelvic floor stimulation, where there were a variety of comparisons, comparisons to placebo -- well, you've heard it all, but what that meant is on the second day we were asked the questions for basically nine different pairs of indications and which treatments were being compared.

Let me add, by the way, that one of the reasons I thought the question on biofeedback was reasonable is it seemed to correspond directly to what the Executive Committee had laid out among the comparative effectiveness criteria, that is, to compare it to other treatments in making the determination, at least as part of the process.

So, what happened in terms of the

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committee deliberations? As John said, the evidence review that was conducted by the Blue Cross/Blue Shield Association TEC center did incorporate both nonrandomized and randomized trials. And I should say in passing that I have participated in authoring an evidence based practice center report, I'm part of the UCSF-Stanford evidence based practice center, and I have served as a formal reviewer for other EPC reports, and I would say that this report was very much of the same quality as all the other EPC reports. There was nothing particularly to distinguish it, except it was done on a shorter time frame and it was shorter, it was a briefer document.

And in contrast to Bob Brook's impression of the report, I felt it was very carefully done and in fact many of the people who spoke publicly and criticized aspects of the report actually commended it on its thoroughness and completeness, and indeed it was a synthesis. The one thing that Bob mentioned that it didn't have, and it really didn't have, was a review of the guidelines. I looked in vain for anything in the Executive Committee report that said the evidence
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report should include a summary of guidelines; I didn't see that there.

I actually think it adhered closely to what we asked for, and I don't mean to imply it was a perfect document, but it was reviewed very extensively by a number of people, and I would urge the Executive Committee to look at that very carefully and where you see flaws, omissions, things that were not done properly, to send back comments to HCFA staff and to the rest of the Executive Committee, because we need to know what needs to go into these evidence reports. But as I said, I thought it was every bit the typical evidence based practice center report, and did not see any obvious omissions. Now that's not to say, by the way, that I have enough expertise to know if studies were overlooked or to know about highly specific details of the studies that formed the foundation for this report, but I thought in format

and general content, it was roughly what we were working for.

Now the panel, the voting members of the panel, turned out to be nearly unanimous on all the questions that were posed with a couple of exceptions. The first day on biofeedback, Lisa

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Landy and a nonvoting member and another voting member strongly disagreed with the claim that the evidence was inadequate. And I think that what Lisa's main point was, and I mention her because she had the most complete explanation and I thought she put it very well, was that clinically the distinction between pelvic muscle exercises plus biofeedback and pelvic muscle exercises alone was not meaningful, and she did not think that's what the question should have been. And I believe that the other people who voted that the evidence was adequate or expressed opinions to that effect agreed with that.

I did not hear among the panelists any claims that the literature was very compelling. And the reason I think that's true is that there was a large catalog of flaws in the studies and the panel had to consider whether these flaws were serious enough to call into question the conclusions of the studies. And the second reason is that many studies were negative and some were positive, and the panelists had to weigh that.

They heard very informative presentations from public speakers, including some from authors or participants in some of the

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studies, which helped clarify the study designs. For example, one study that I in particular found relatively compelling was on the pelvic floor stimulation, one by Sand, and from the published version of the study it was unclear whether there was a flaw in follow-up and how patients were assigned when they were lost to follow-up, and that was clarified by the author himself at the meeting, and the study turned out to be stronger than it appeared to be from the published form.

But I believe that the panelists concluded that in total on both days, and for each indication, the evidence was not adequate. There

was more support for biofeedback than for the pelvic floor stimulation, and that really very clearly reflects the volume of the literature and I think to some extent the quality of the studies that were done.

And of the indications, if I can generalize, and this may not be completely accurate, I think -- well no, this part is true, that post-prostatectomy incontinence was very poorly studied and panelists made a point of saying that of all of the indications, and this is for both biofeedback and pelvic floor stimulation, of

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all the indications, the evidence was virtually nonexistent for effectiveness in treating post-prostatectomy incontinence. There was more discussion on the other indications.

And furthermore, aside from Lisa Landy's yes vote on the first indication for pelvic floor stimulation, there were no affirmative votes about adequacy of evidence for any of the indications on pelvic floor stimulation. And I believe that the discussion of biofeedback, or the voting on biofeedback, was a little more mixed and the discussion was more heated on biofeedback, because there was this concern about the phrasing of the question and in addition there were more studies that lend some support, even though the panelists seemed to feel that the total evidence did not enable them to draw conclusions.

Let me reiterate, and this is somewhat my own inference rather than based on direct statements, it's not that they felt that there had to be multiple randomized trials, but they seemed to believe that in this area, it was important to have a fairly rigorous study design because of the number of outcomes in urinary incontinence and so on. If you had biased ascertainment, for example,

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there wasn't a strict criterion for deciding when events occurred, how you measured outcomes, it would be very easy to be misled by placebo effects and any other number of confounders, so I believe that that was their reasoning.

So I think that there was a lot of sympathy for one issue that did come up in

discussion, and that is the difficulty in finding the funding to do adequate studies. And although much has been made of the statements that some people said that they would have voted to cover even though they didn't think there was enough evidence, on my review of the transcript, I think only two people said anything like that, that is, if they had considered the clinical evidence, they would have voted to cover. But they didn't explain what they meant by clinical evidence and frankly, I'm not sure if we had time to probe it, if it really would have supported the statement that they made for those two people. So I think that there is a very interesting issue there about why they said that, and maybe this goes back to what we call clinical evidence and how it should be used, but the panelists who voted that the evidence was not adequate seemed to be quite confident in their

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conclusion.

Can I turn it over to Michael, because he may have some additional perspectives on that?

DR. SOX: Here you are.

DR. MAVES: You know, Alan, I basically agree with your report and as I indicated before, I thought it was a much improved process at least from the historical perspective of where we had learned a little bit about the first two panels, and I really want to commend Alan for I think really trying to make this as fair and open a process as is possible.

I would agree with him, I think much has been made over the phrasing of the questions and the fact that the question was altered slightly. I don't think that had a substantive effect on the end result of the deliberation, and I think hopefully we can learn a little bit from this and perhaps make the process better in the end. I do think as I indicated before, that it is important to have a roundness of information and not just controlled randomized clinical trials, but to obviously listen to what's going on in the medical practice community, listen to what's going on with clinicians, and we had some people in that

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audience, and particularly those from the specialty

societies, they were extremely distinguished individuals. I think that they were heard, I don't want to make that misstatement that they weren't, but I think the process and I think what Dr. Sox has outlined hopefully will allow us to more formally integrate that into the deliberative process of the panels.

DR. SOX: I would like to give an opportunity for members of the panel to ask questions of fact to Alan or Michael, not to express opinions, just clarification questions, and then we will move on to the open comment. Any questions of fact? Ron?

DR. DAVIS: In looking through the minutes of the meeting, I notice there was a question posed where the vote wasn't indicated, and this is on the minutes on the meeting for biofeedback, it's page 4, middle of the page, and just above the bolded heading. The question is listed and there is no vote indicated, so that has to be indicated. I presume it's like --

DR. GARBER: Ron, are you talking about the post-prostatectomy indication there, just above panel comments on their votes?

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DR. DAVIS: Yes.

DR. GARBER: That was unanimous negative, and I'm sorry that we didn't catch that.

DR. SOX: Any other questions or points of fact? Yes, Bob?

DR. MURRAY: In the TEC summary on page 20, I note the pages aren't numbered, but it's the last paragraph under the section Review of Section, Stress Incontinence, the sentence reads: In summary, and these are the words of the author, it is not possible to draw conclusions from this body of evidence on whether the addition of biofeedback to PME results in improved outcomes as compared to PME alone.

My question to you, Alan, is: Do you feel that the members of the panel did an independent assessment of the studies that were presented, or were they simply ratifying or agreeing with his statement? And I will tell you the reason that I ask that question. I found some of the evidence rather persuasive that there is no

benefit. The best studies found no benefit, the weaker studies were equivocal, so on balance I found the evidence persuasive against, yet the author says it's not possible to draw conclusions.

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What was the feeling on the panel?

DR. GARBER: That's an excellent question, and I'm trying to remember. I think I did hear one or two statements similar to yours, Bob, that the evidence went the other way, but there was a lot of discussion about positive evidence too. And you know, I hate to speculate about how much people read and absorbed of this, but judging from the questions the panelists asked, I felt confident that at least a number of them did very detailed readings of at least the key studies and did not rely solely on the evidence report. And let me also say though, that it was clear that the evidence report had a great deal of credibility and received a great deal of weight among the panelists, and that's one reason why it was so important to insure that it be comprehensive and fair.

DR. SOX: Anything else?

DR. BROOK: Can I ask a question of Alan?

DR. SOX: Please, Bob.

DR. BROOK: Alan, since this report has come out and all the comments, have you received anything indicating there were significant pieces

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of good studies that were not included in this report?

DR. GARBER: Well, there have been some claims like that. Let me just tell you that the issue that's more of an issue in my mind than overlooked studies is really knowing what was going on in the studies that were reviewed. On a lot of these studies, you know, many of us have reviewed papers before, and I guess I was surprised that there were probably correct things that were done in these studies that did not appear in the published versions. And anyone who has gone through the literature, in some fields anyway, would be surprised to see how often that occurs.

DR. BROOK: Let me go back to the first

question. As far as you know as chair of this committee, there is no specialty society or nobody that has come forward with a paper that meets the methodologic criteria of this TEC assessment that was overlooked?

DR. GARBER: Not to my knowledge.

DR. BROOK: That's a statement of fact, to your knowledge and to any of the committee members that were on the committee, that's the case?

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DR. GARBER: Yeah. Now there are people who would make the claim that there were. I'm saying that there is none that I have seen that would.

MS. RICHNER: I think I read in one of the reports that there was an article published in March of 2000, either biofeedback or whatever, that was significant for this process. I don't have it in front of me.

DR. GARBER: Well, yeah. As I said, there have been claims. The ones that were brought to us that were not included that I saw did have flaws. That doesn't mean that there isn't some study out there that is just recently published or will be published to meet the criteria. Bob's question was about to my knowledge, were there things? I'm not saying that -- that doesn't mean something out there exists.

DR. BROOK: Let me ask the second question. Somebody pointed out that there are, I went back and looked at it, and I missed the fact that there were one or two of these studies that were nonrandomized in one of the tables. This report is about a few number of studies, something like 11 to 15 total is what it looks to me in these

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tables. As far as you knew as chair, the summary of the TEC report, the questions that were asked, you believe that the assessment of those studies were fair, complete, unbiased, and as far as you know, nobody has come forward, the authors, or nobody has come forward to say you guys misrepresented what we did? In other words, you haven't gotten anything -- there is nothing in all these letters that we got.

DR. GARBER: There are undoubtedly members of the audience who will tell you that.
DR. BROOK: No, no. We have gotten no specific -- to be honest, I have seen zero specific -- I have read all the letters -- zero specific comments that the abstraction of the study, the way it was described, the limitations that were described, the positive features of any of these studies, there's no specific detail that I've read, and I just wondered if there is any body of evidence anywhere floating around that would indicate that people were concerned over how these studies were described.
DR. GARBER: I wouldn't go that far. I think people would dispute how the studies were described. I think the panelists felt comfortable
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with how the studies were described. And as anyone who has been involved in the process of abstracting studies, summarizing them, pulling them knows, there are aspects of this process that are judgment calls. Like what criteria you use to decide which studies to include and exclude, how far you go using information that's not available in the published studies and about how they were designed. And the way I would characterize this is I have not heard major defects that aren't matters of judgment calls, as opposed to things that are clearly done wrong in the report.
DR. BROOK: And when you've heard these comments of defects, have they been sort of on both sides equally in terms of you, this was really more positive and this was really more negative?
DR. GARBER: No. The vast majority of comments that we have received have come from people who disagree with the conclusions of the panel.
DR. BROOK: I'm not talking about the panel.
DR. GARBER: But that's the people who have expressed substantive concerns about what's in this report.
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MS. CONRAD: I wonder if we could hear from our public commenters.
DR. SOX: It's time for the public

comment. And would you like to announce the first person please?

MS. CONRAD: The first speaker is Barbara Woolner, followed by Debra Jensen please.

DR. SOX: As much as possible, I hope that those who stand to comment will try to address the issues that were raised by both Dr. Whyte and Dr. Garber, so as much as possible -- we know we've had a lot of written comment, what we want is stuff that's kind of on this discussion. Thank you.

MS. WOOLNER: My name is Barbara Woolner, and I am a clinician. I am certified in biofeedback incontinence care. I have been practicing this for 12 years. I stand today before you as representative of the Continence Coalition, a group of urologic nurses and wound ostomy incontinence nurses who have banded together for the benefit of patients suffering from incontinence.

I did present before the Medical Surgical Panel last month, actually in April, and I actually made three points. I'm not going to go

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through -- you got my testimony that's written here today right before lunch. Don't look at it, because what I'm going to say is not there, most of it at any rate.

I would like to some of the things that Dr. Whyte and Dr. Garber have said, not all together disagreeing, but maybe enhancing a little bit. There was a question by Ms. Richner about the study that's floating around out there that might have to do and that might have been relevant to this whole issue had it been available for the TEC report. That is a very well designed study, and I say that because my colleagues, my scientific colleagues tell me so, by Carolyn Samselle, who is a nurse researcher, and it was published in March of 2000 and it was regarding pelvic muscle exercise alone, and pelvic muscle exercise alone, done with her very rigid criteria, and I actually know this lady.

She got a 27 percent improvement in patient symptoms, which is not terribly good, because if you look back at the studies that were included in the TEC report, they give you overall

biofeedback, 61 percent, 89 percent, 91 percent, 54 percent, and 76 percent. And I know for a fact

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because I know two of the people that produced a couple of these studies, particularly Patricia Burns in 1993. She had a nonsignificant effect in her pelvic muscle exercise group versus her biofeedback group alone. I know for a fact that the pelvic muscle exercise group, though not reported in her outcome, was a group of patients that did get a very very specific muscle testing with a very skilled nurse practitioner. The biofeedback they received, however, was done by a person who was not trained in biofeedback, who was merely a technician, so I really think there was a lot of fault with this study.

Pat Burns herself will tell you that she did use biofeedback EMG to evaluate the patients in her pelvic muscle exercise group alone and as a clinician I will tell you that once a patient sees a screen and sees what's happening, they learn very quickly, sometimes in a manner of seconds. So you can't say that that was a pelvic muscle exercise alone group.

In terms of other things that support what I'm saying, Bump in 1993 reported on 27 women, and I'm pulling this from my head, not my paper. He found that 50 percent of the women that he asked

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to perform a pelvic muscle contraction could not do so on verbal instruction alone. And in fact, the majority of instruction in this country is from a physician who hands a patient a piece of paper and says go home and do this while you're sitting at stop signs, or you're sitting on the toilet, and there is in fact no good instruction to pelvic muscle exercise.

In a study that I reported on at the last panel because I was thinking that they would pay some attention to really good clinical work, we found in over 200 patients that 65 percent of the patients that we evaluated both manually and with EMG had either abandoned or had failed pelvic muscle exercise alone. I thought that was very significant, and I still do.

Actually, getting back to the Blue

Cross/Blue Shield TEC report, I think one of the things that we have all overlooked is that report did say that there was some efficacy to biofeedback. They didn't say it wasn't efficacious. However, I think that we need to look at the fact that while HCFA has really avoided mentioning this fact, that it was efficacious, and while all the professional organizations have been

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looking at problems with the process, we have all forgotten what happens with the patient.

I would like to just bring this point up and have you be a little forward thinking about what's going to happen if you choose to ratify this vote from the last panel. This is a very expensive proposition. This data was developed by Tai Wei Yu in 1995, it was reported in '98, and according to him, the expenditure for incontinence in persons over the age of 65 was approximately $27.8 billion per year, and almost half of that was due to consequences of untreated incontinence. Consequences. These are UTIs, these are falls, these are skin irritations, prolonged hospital stays, and additional skilled nursing facility admissions. Of that $13.5 billion, 92 percent of that money was spent on these adverse consequences, 92 percent.

Of the other 8 percent, it was broken down in this manner: Surgery got the majority in the red, I don't have a pointer, but the large block there of the pie is surgical treatment. Evaluation got the next largest part of the pie. Pharmacological and behavioral treatments got less than 0.1 percent of the treatment that was paid out

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to treat incontinence.

If you hear nothing of what I've said today, please hear this. Do not let these technologies fall victim to a process that is in evolution. The Continence Coalition joins its professional colleagues, consumer groups, and other concerned individuals in asking you to withhold ratification of this vote by a panel which was forced to judgment on a comparative question that cannot at this time be answered purely in a scientific way. Thank you.

MS. CONRAD: Thank you very much.
MS. WOOLNER: Oh, one point. I still had a green light.
Let me just say that be ratifying this vote, we are actually giving HCFA permission to withdraw coverage, and I would like you to know that there are a number of states that have reasonable coverage for biofeedback. So, I ask you, can you just take it away? Is there not a process by which you have to review the information and the safety of a treatment or a technology from all of these states: Alabama, Alaska, Arizona, California, Connecticut, Georgia, Hawaii, Idaho, Indiana, Kansas, Maine, Massachusetts, Maryland,

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Michigan, Missouri, Mississippi, New Hampshire, New Jersey, North Dakota, North Carolina, Nevada, Oklahoma, Oregon, Pennsylvania, Utah, South Dakota, South Carolina, Tennessee, Utah, Virginia, Washington and Wisconsin. Thank you.
MS. CONRAD: Debra Jensen please; the next speaker will be Kevin Connolly.
DR. JENSEN: Good afternoon. My name is Debra Jensen and I represent EMPI as their vice president of regulatory affairs and clinical research. EMPI is a manufacturer of biofeedback and pelvic floor stimulation devices.
Once again, we appreciate the dedication of the panel, the Agency and their staff for their efforts to develop a fair and equitable coverage process. But as we have previously communicated, we were deeply disappointed in the outcome of the April meeting of the Medical and Surgical Procedures Panel on urinary incontinence. Despite working with the Agency for the past six years on the issue of coverage for our pelvic floor electrical stimulation devices, we are no closer to resolution of this issue than when we started our discussions with the Agency.
While we can appreciate the difficulties

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in implementing a new process such as the MCAC, quite frankly, we are tired of being a guinea pig. We are concerned that fair coverage policies for this technology and also biofeedback will be further delayed while you make this up as you go

along and continue to refine your work in progress. It is obvious from this morning's discussion that much work remains in order to make the process work for the benefit of Medicare beneficiaries. Thus, you as members of the Executive Committee are in a difficult position regarding what conclusions should be drawn about the recommendations made by the Medical and Surgical Procedures Panel concerning the adequacy of the scientific evidence supporting these technologies.

In recognition of the importance of clinical evidence, I would like to present a brief summary of the relevant evidence presented to the Med Surgical Panel about pelvic floor stimulation. Pelvic floor electrical stimulation was presented as a technology that has been studied extensively in a clinical setting and was found by the AHCPR guidelines to have the same level of evidence as other incontinence treatments such as surgery and

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collagen implants, both of which are covered Medicare benefits.

PFS was presented as a technology that is already the standard of care, as evidenced by the unanimous support of all of the medical societies that presented at the April panel meeting and were involved in the treatment of urinary incontinence. PFS was presented as a technology that has been recognized by over 300 private insurance carriers as a covered benefit.

The point was also made in the April meeting that Blue Cross/Blue Shield in conducting their technology assessment did not appreciate the subtle differences in the various stimulation devices when they wrote their report. Dr. Sand, the author of the randomized placebo control trial that Dr. Garber mentioned earlier very adequately explained how these differences in technology were a factor in the outcome.

In light of the difficulties acknowledged this morning and the clinical evidence presented at the April meeting, we encourage this Committee and HCFA to look at recent past coverage decisions made by the Agency to guide the ultimate coverage policy determination for pelvic floor

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electrical stimulation. For instance, a review of recent coverage decisions shows that the Agency has acted without ratification by the MCAC panels. In the case of external contrapulsation therapy, the Agency felt that there was a lack of evidence and requested additional studies by the manufacturer. Industry complied by conducting one study of less than 150 patients, and a positive national coverage decision was granted.

In the case of augmentative and assisted communication devices there was evidence to the issue was left to carrier discretion. No noncoverage decision was issued. In fact, the Agency plans to issue new national coverage guidelines soon for these guidelines, according to a recent article in Inside HCFA. Unlike augmentative and assisted communication devices, pelvic floor stimulation does have evidence to support its efficacy. Based on this, it appears that the Agency's policy with regard to durable medical equipment is inconsistent in both the application of the standard of evidence as well as their guidelines for MCAC referral and ultimately for coverage decisions.

We believe that we have demonstrated

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that PFS is a safe and effective treatment and that a positive national coverage decision is warranted. Without evidence that our technology is unsafe or that it offers no benefit for anyone, the national noncoverage policy implemented in 1994 is inappropriate and should be lifted. Based on the information that is provided to the Agency, or that has been provided to the Agency over the past six years and the testimony before the MCAC relative to the scientific evidence, the technology's clinical utility, and the support of the professional societies, we believe there is adequate evidence that PFS is a reasonable and necessary service for Medicare beneficiaries.

It seems that everyone this morning agreed that the process used to review PFS and biofeedback was problematic. Therefore, in the interests of fairness, we respectfully request that the panel not ratify the results of the Med-Surg

panel. Thank you.
MS. CONRAD: Thank you, Dr. Jensen. Kevin Connolly. The next speaker will be Francie Bernier.
MR. K. CONNOLLY: I am Kevin Connolly, and am still CEO of SRS, at least for the moment,

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and we manufacture biofeedback and stimulation products, and I want to thank the committee for allowing me to make a second presentation.

Since Dr. Sox has asked us to address Dr. Whyte's and Dr. Garber's comments, I'm going to start with a slide that didn't make it into my presentation otherwise, which is, Dr. Whyte spent a lot of time talking about the definition of biofeedback, but the really key thing here in these studies, this slide was put together to show that basically the use of randomized control studies as a methodology does not in itself guarantee a well-constructed study.

But the key point that I'm making here is that the definition of PME that's used in these studies versus what's used in the real world is vastly different. The Samselle study that you quoted is much more typical of how PME is used in real clinical practice. Companies like Kimberley-Clark prepare a little sheet saying here's how you do these exercises; you give that to the patient, that's PME. So the idea of this intensive coaching, you know, vaginal exams, EMG exams, that's rolling downhill with the wind to its back on a sunny day. Arguably, the benefit of

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biofeedback is that it offers a simple standardized way of getting people to do these exercises well, that obviates the need for all of those things.

Now, hopefully, I will still have time to do my presentation. I'm going to skip through a lot of this stuff but I will just touch on it quickly. The evidence listed here was theoretically included in the review process, but in fact, none of it was effectively considered. And one of the other issues that has come up repeatedly is the use or the role of subject matter experts. Now, since part of what we are here to do is make recommendations, my recommendation is a

multidisciplinary panel at this level is very effective, but subject matter experts, I think are required for the analysis, because only they can look deep enough into the studies that are cited, only they can look at the premise of the study to see whether it's valid in terms of being consistent with clinical practice.

And I think that you have to understand the role of the clinical practice guidelines. In the real world, they define the standard of care. And where you have a multidisciplinary group that doesn't have the background in the subject area,

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they are not necessarily going to know to ask for this. And I think one of them said that. And I think it's disingenuous to say it was on the list of materials. As far as the clinicians are concerned, if you want to put together an authoritative evaluation, you have to start there and diverge from it, but --.

We have already covered the fact that the guidelines found a very different conclusion but as Dr. Whyte acknowledged, nobody's really disputing the fact that biofeedback is effective. The question really comes down to a comparative one. This is the study that I wish had been in there, and was excluded on the basis of the comparative effectiveness issue. And the reason I have this up here is not just because its conclusion is so definitive, but because one of the authors who was cited in the TEC report has declared that this is the best constructed study that's ever been done in this area.

And obviously we covered this this morning, but as you can see, panel members were a bit frustrated, and I don't think that content expertise was overlooked, but if you ask Lisa Landy, it was just outvoted.

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I'm running out of time. Can I have a little more time? Dr. Whyte and Dr. Garber had a lengthy time to be able to make their case. Can I just have a few more?

MS. CONRAD: You want two more minutes?

MR. K. CONNOLLY: Okay. I'm going to just skip to the most important part of this thing,

which is, I think a lot of the issues came down to this question, the question of the question, as we phrased it, so I would like to examine whether this was an appropriate question. As I said this morning, in actual clinical practice, these are sequential, they are not competitive procedures. And HCFA's own experience at a regional level in covering them, there are explicit exclusion criteria. Patients have to have failed with more conventional treatments, including PME.

Now, there is some amount of plasticity to the staging of this, but I don't think too many UI experts would disagree with this basically. Now, the real action for HCFA is on the side, because that's where you start paying out dollars, after patients have failed on the left side.

And just very quickly to go over what biofeedback is and what its clinical function is

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for UI, the key point is it's only used when it's needed. This is where it's needed, not for the folks on the left, but for the patients on the right. The Bump study that another one of the presenters referred to, found with urodynamic studies that not only do half the people not do pelvic floor exercises correctly on the basis of verbal instruction, but half of them do it in a way that's clinically counterproductive, i.e., doing things that are likely to increase an incontinence problem.

In light of this, in light of the fact that biofeedback is not a first line intervention, and explicit exclusion criteria exists, and in light of the fact that that's actually how it's used, I think that the panel should have been asked a question more like this: Does the evidence support a sizable health effect from the use of biofeedback for those UI patients who have failed to respond to PME alone?

MS. CONRAD: Time please. Thank you.

MR. K. CONNOLLY: I'm sorry I can't get to my next point, because it's really one of the most important ones.

DR. SOX: The committee always has the

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option of asking you later on during discussion.

MR. K. CONNOLLY: All right, thanks.
MS. CONRAD: Francie Bernier please.
MS. BERNIER: I am Francie Bernier. I am a clinical consultant and on staff at Rose Medical Center in Denver. I've had a large continence program in Denver for the past eight years.

In 1948, Dr. Arnold Kegel described the use of pelvic floor exercises to treat urinary incontinence and other pelvic floor dysfunction. His research provided the beginning for nonsurgical rehabilitation programs to treat incontinence. Over the last 50 years, Kegel exercises have been prescribed and offered as the first line treatment for incontinence. Although the medical profession understands the usefulness of this therapy, physicians have never been taught how to do adequate pelvic floor muscle contractions. As clinicians offering continence care know, just handing an exercise instruction sheet to a patient or telling a patient to just squeeze the Kegel muscle, has never provided adequate instruction.

You are faced with the challenge of deciding the fate of biofeedback and the probes for

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electrical stimulation used in the treatment of incontinence. The decision was based on the TEC report, which claims there is a lack of scientific evidence to support utilization of this therapy. During the meeting, during the previous meeting, the question posed to the panel was changed three times, demonstrating a lack of understanding of what was to be decided. Additionally, most of the panel members were not familiar with the supportive scientific literature or therapeutic value of a continence program. The panel agreed with the TEC report and therefore decided there was a lack of randomized double blind placebo controlled studies. The incomplete and damaging information the TEC report provided has put the coverage of this therapy in jeopardy.

The U.S. Department of Health and Human Services created the Agency for Health Care Policy and Research, AHCPR. AHCPR was established in 1989 under Public Law 101-239 to enhance quality, appropriateness, effectiveness of health care

services and access to these services. AHCPR carries out its mission by conducting and supporting the general health services research, including medical effectiveness research findings

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and guidelines, and dissemination research findings and guidelines to health care providers, policy makers, and the public.

The TEC report clearly ignores the AHCPR guidelines, which reviews all of the literature and reports its findings on strength of evidence. For the sake of time, I'm not going to go into all of the strength of the evidence. However, just to mention that the strength of evidence for biofeedback, pelvic muscle exercise, and bladder inhibition augmented by biofeedback, was given a strength of evidence of A, and pelvic floor electrical stimulation was given the strength of evidence of B.

Another concern voiced by our clinician was the lack of review of very appropriate studies by the TEC report. With so many clinical studies demonstrating usefulness of this therapy, it seems amazing the studies reviewed by this group eliminated those which the expert field reports is statistically significant information to support the use of biofeedback and electrical stimulation for the treatment of incontinence.

Additionally at the previous meeting, one panel member chose not to vote. He reported he

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was not provided the information to make an informed decision. He claimed he was not even aware the AHCPR guidelines were available. He appeared obviously angered, confused and disappointed, and frustrated with the situation. It appeared that other panel members felt the same way.

Interestingly, one statement was made on behalf of the panel. Without question, we all agree, we would have this therapy in our office. Looking at the lack of randomized studies on biofeedback directed pelvic floor exercises, it makes the clinicians wonder how a study like this can be done. The TEC report excluded the observational studies that report the outcomes of

the continence programs. They excluded very strong and thorough studies on pelvic floor rehabilitation as compared to drug therapy. There have been randomized double blinded placebo controlled studies on electrical stimulation, reported by Dr. Pearcy and at the April meeting.

Over 20 million Americans are calculated to be experiencing urine loss today. These people are over the age of 65 for the most part. Treatment options are limited to medication,

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surgery and behavioral therapy. The use of the medications carry a risk of severe side effects affecting daily life. Patients report such significant side effects as intense dry mouth, inhibiting their ability to speak. Other side effects are constipation, which is known to hospitalize patients in some instances, dry mucous membranes which contribute to vision problems and general malaise. Most patients abandon the use of the medications to the due to the side effects of the drugs.

Additionally, these medications are very costly. Most of the elderly population are Medicare subscribers. For those on a fixed income, the cost of Ditrepam XL for a one-month supply is over $200, or $2400 per year. Drug therapy is cost prohibitive. With no side effects from biofeedback and electrical stimulation, why is this not offered as a first line therapy for patients? The cost of therapy is generally half the cost of Ditrepam XL. Surgery is even more expensive. The complication rate, morbidity and mortality rate is very high in the elderly.

Finally, consider the 1993 report from the Alliance for Aging, which reported that $22.5

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billion could be saved by the year 2000, if the incidents of incontinence were reduced by 20 percent. This report also described how $80 million could be saved annually if surgical patients also appropriate for behavioral therapies were treated with behavioral interventions.

The April meeting demonstrated a bias and predetermined outcome of biofeedback and electrical stimulation. I and the hundreds of

patients my colleagues and I have successfully treated hope you will thoroughly take a look at the major concerns we voice today. Take into account the many medical, nursing, physical therapy organizations which support the therapy, and please keep these codes and treatments available for patients who suffer from urinary incontinence. Thank you.

MS. CONRAD: Thank you.

DR. SOX: Thank you very much. I was asked to say that Dr. LeFevre, who did the TEC report, is actually on the telephone someplace and if we have questions for him, we can ask them and he will be able to respond in a way that we can all hear.

Dr. Hill wanted to make a brief remark

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regarding the assertion about the effect of our decision on coverage.

DR. HILL: Thank you, Chairman Sox. I wanted to make sure that it was understood that the effect of ratification by the Executive Committee of the panel's recommendations functions as advice to HCFA. It will inform our coverage decision. We will have to weigh that recommendation with all the other information. It doesn't result in an automatic taking away of coverage. I won't prejudice by speculation what the outcome would be, but we could decide to cover, noncover, local discretion, we can leave it up to local discretion, we can cover with limitations, we have a number of options open to us, and this will be a piece of advice that we consistently said fits into the matrix that we have to use to make the decision that is ultimately our responsibility. Thank you.

DR. SOX: Thank you. We now come down to the point of having a proposal to discuss, and perhaps I could take a minute to lay out what I thing are the options.

The first is that we could approve the recommendations of the panel, either separately for biofeedback and for pelvic floor stimulation, or do

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them together. And if we were to vote that way, we would say that the process was good, it was close to or as close to as we can get for our first time

around, to the process that we outlined as an Executive Committee, and that the committee made a correct interpretation, that is to say that the evidence really is inadequate to make a statement about whether these technologies are effective or not in the way that the question is framed.

The second thing that we could do would be to disapprove the recommendation of the panel, which I think means that we felt that the process they used was a reasonable process that covered the evidence, but that they simply made the wrong call, that in fact there is adequate evidence to make a decision about whether this works or not.

The third option would be to send the thing back to the panel, which I would suggest would be because the process was flawed in important ways that if corrected, would lead to a high probability of a changed recommendation if it came back to us.

So in a way, I think we first of all have to address the question, was the process a good process and one that would allow a decision

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about whether the evidence is adequate or not, and if we decide that the process is a good process then we have to decide whether the committee in fact made the right call in stating that the evidence is inadequate to make a decision about whether it works or not. Alan or Mike, do you want to comment on that formulation, whether that makes sense to you, and how you might suggest that we proceed here?

DR. GARBER: Yeah, Hal, if I understand how the way that you defined it, it does come down to breaking it up between whether the process was good and whether the panel followed the process, and I think that's perfectly fine.

DR. SOX: Michael?

DR. MAVES: I feel that is the appropriate way to look at it, and I would concur.

DR. SOX: Well perhaps then, unless somebody else has a serious objection, why don't he we talk for a little while about whether the process as outlined by Alan and Mike was a reasonable process and one that in fact would allow them to make an informed decision up or down about

whether the evidence is adequate. So let's concentrate now on the question about process for a
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while, and just see whether we have a consensus on whether the process was adequate or not. Ron?
DR. DAVIS: Just a question that picks up on your question. We had a nice explanation from Dr. Whyte about the reasons why the questions were framed the way they were. I'm wondering whether that explanation was provided to the panel so they had an equal understanding of that?
DR. SOX: Alan, can you respond?
DR. GARBER: That's a good question, and the way I would answer it, we had a conference call before the panel meeting, and I had a pretty clear idea of that. It was not said in so many words all at one time the way John Whyte did it today, but the pieces were there at least for the panel members. I'm not as certain that that was done for the general public, but we got it from the conference call.
DR. DAVIS: So procedurally, I would suggest that we take care to explain why the questions are worded the way they are for both the panel members and any members of the public who are involved in the process or in attendance.
DR. SOX: Are you satisfied with Alan's explanation or do you think the committee didn't
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understand the question and was kind of off base to start with, based on what you've heard so far?
DR. DAVIS: With all that we've heard today, I'm reasonably satisfied that the process was a good one, not a perfect one, not without some flaws that can be improved upon in the future, but I think overall, they did a very good job and good enough in my mind that we can move forward in making a decision.
DR. SOX: Randel?
MS. RICHNER: I think when I reread the transcript, including I think Dr. Epstein's discussion, was very relevant to this discussion, and I think beyond the point of whether the questions were understood was once again, getting back to what their purpose was in terms of whether it was a coverage decision or evaluating that very

narrow question of medical evidence. Because I mean, when I read Dr. Epstein's note, it's very very relevant to this discussion, and I think everyone needs to think about, once again, what is important for the Medicare beneficiary and whether or not that was achieved in that first panel.

For instance, when Arnie said one is, you know, the whole idea about making coverage

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decisions. One is, we're going to cover procedures where there is clear scientific evidence indicating the procedure is effective or efficacious, and you would like both. The second runs orthogonal to that; it says in the face of broad consensus from medical experts that a procedure is effective, we'll cover it absent evidence that it's not effective, so long as the clinical down sides are minimal. What's making everyone uncomfortable is that the scientific question that is designed to lead to the former approach, as opposed to the latter approach. We should have asked two questions: Is the scientific evidence adequate to show that the procedure works? The answer was no. Is the scientific evidence adequate to show that the procedure doesn't work? The answer was no.

And that's pretty relevant to this, and I hope the essence of what you have just proposed brings in that flavor as well.

DR. SOX: As you noted, some people raise the question about whether the scientific evidence was adequate enough to say it doesn't work or doesn't add anything.

Well, I'm eager to sort of cut to the chase, so I guess I'd like anybody who really feels

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as if the process was seriously flawed and would have made it difficult for the panel to reach an appropriate decision about the adequacy of the evidence to speak up, so that we can kind of cut to the chase in this discussion. John?

DR. FERGUSON: This is kind of hard to explain, perhaps, but I don't think that the process is flawed in the larger sense, in that we have an interim report which is sort of a blueprint, and we have an evidence gathering that was done and presented and given to the panel, and

we have a series of questions asked by HCFA to the panel.

However, semantically, I think what happened makes the process in this particular case flawed, and the reason or reasons that I think so are this: By asking the question, is the evidence adequate, it sort of assumed, adequate for a positive answer is implied, and forced the panel new a yes or no vote. In my view, that seemed to obstruct rational discussion and deliberation of the evidence. And in that sense, in my view, the process was flawed.

I would like to mention that it seems to me that both the evidence reports for biofeedback

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and for pelvic floor stimulation, actually did reach conclusions, in which there were conclusions stated, yet the panel was not really allowed or because of the semantics and the way the question was asked, to reach conclusions, they were forced to go yes or no on the adequacy. So I feel that that was a snarl in the process, which I mean on paper in the large sense, is a good process and I believe, I am very much a believer in evidence based medicine and the necessity to have good studies. But in this case the way the questions were phrased and basing it on this interim report, to me led on a process that did not allow the panel to debate the evidence, and that I think is not proper.

DR. SOX: Alan, you and Michael were there. Do you want to comment on John's assertion?

DR. GARBER: I don't agree with the position that the interim recommendations in any way limited debate on the questions that John raised. And there are many ways to approach this, and I thought about this a great deal too, and I'm sympathetic with John's point. One approach we could have taken as a panel that wasn't quite

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allowed by the interim guidelines, would have been to say what we thought the effect was, and I think this is what John was alluding to, even if we thought the evidence was inadequate. But the more I thought about it, the more meaningless I thought

that any such statement would be, simply because if you don't think you can draw conclusions because the scientific evidence, either the studies have tremendous biases, and I'm not referring to this specific topic now but thinking in terms of general recommendations for how the panels should operate, if you really think the evidence base isn't adequate, what is the meaning of saying there is a slight benefit, that's our point estimate, and the confidence regions include some horrible detriment and some greatly large benefit. So, I'm struggling with the same issue as John. I think this is something that we will have to revisit again, but I actually think that the interim recommendations worked well in this context, and I don't think that had we chosen a different approach that the panel would have reached a different conclusion. And again, that's surmise based on what I heard the panelists say. Mike?

DR. MAVES: I would agree. I think that

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the answers to the questions would have been the same. I do think it was interesting and part of the discussion really revolved around what was the effect of the intervention, and a number of the medical specialty societies gave opinions, and I think the range was somewhere in the four to five range on our seven point scale. We never actually got there as a committee in deliberation. And I think that, again, would be something that the Committee looking at the process might want to wrestle with a little bit, is there some advantage perhaps to integrating that. But as Alan has indicated, with the body of evidence that was reviewed, and I think for a lot of us looking at those studies and going over that material, it was certainly not as clear as one like to see. I think the answer would end up being the same even if you had gone around the other way.

But I do think as a matter of process in the future, perhaps looking a little bit at what is the effect of this, if you back off a little bit and say, just give me an estimate of the treatment effect, you know, without a yes or no answer on scientific evidence, might help the process a little bit and again, might give a roundness and

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some idea. I think someone mentioned earlier, should we let the individuals know what kind of work needs to be done in the future to jump this hurdle. That might be very very helpful to those that are trying to get this technology accepted and covered by HCFA.

DR. SOX: Bob?

DR. BROOK: Well, one, the process is much better than it was for the last panel. Two, I'm a little sad that the evidence based report is not more readable in terms of an executive summary so the public can really understand what the evidence shows. I don't think that this report is readable, so it's going to be hard for HCFA to use it in any positive way. It could have gone through a process of summarizing, like evidence based medicine does for different diseases, and it could have been a chapter on urinary incontinence, these kind of issues and that kind of a format, and I think that would have been easier to understand at the end.

We've heard about problems in the process, timeliness and whatever, but I've been really dismayed that after 50 years of introducing all this technology, the level of science is so
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poor, and it's being used so poorly by the people that have come before us. That really is what has dismayed me more than anything else. I mean, if this is a sequential procedure, fine, but if you have a randomized trial at the beginning and you know that half are going to fail, you still will pick up that difference if you power it enough. So, these are not insurmountable questions, and it's not like assigning people to randomized cardiac surgery.

So, I've been impressed that no matter how much I have tried to pull out of any of these letters or testimony, I don't think see any evidence that comes to me to argue that the process did not identify the evidence, that it did not deal with this. So, in that regard, I think the process is fine.

I am a little bit sad, however, that it almost appears like a setup, and let me give you

the example. If indeed, pelvic floor exercises, for instance, are being dealt with by handing out a piece of education, and if indeed there are lots of clinicians who know that women who get this fail, that's true, and you've got a lot of testimony for that. And if you know that you can then apply

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biofeedback, for instance, to that group, and you'd get a lot of people that succeed, but you also know, these are also facts, then the question is, how is the material that we produce here going to be used? That's the real problem and that's the dilemma, and I think we need to caution HCFA in terms of either saying, it's your responsibility or somebody's responsibility to answer the real world question of, does pelvic floor exercises for example, used in the way it's used in the community, versus that with biofeedback used in the way it's used in the community, make a difference? I see no evidence that there has been any studies to answer that question.

And the scariness of all this is that I don't see any evidence that when we finish our deliberations, anybody will do this in the next decade, and that to me is the dilemma. And I at least, if we approve this report, and I don't see how we cannot, with basically the testimony we have heard today, we would basically want to add some caveat that there has to be some responsibility here to quickly and definitely address some of these questions, and in order to discharge our responsibilities socially and in a responsible way,

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because I think Tom is right.

I believe that if somebody had any one of these conditions, with so little of a benefit risk to the patient, no risk, that people would want to try everything they possibly could to get rid of this problem before they went to drugs or surgery, a large number of people would want that, and that there's probably some added benefit to this, but unfortunately, nobody has shown it. That's the sad part of this, that unfortunately, it just ain't there. And you coming up and showing slides and all this other kind of stuff, I'm sorry, you didn't make -- to me, the public did not, the

advocates of this procedure did not meet the case of the evidence, that there's evidence there to do this, from the standards of evidence that one uses in this field.

But the problem is that since this is not a billion dollar drug market, where comes the incentive to get those things done quickly so that we don't really harm people by getting rid of a therapy which if you really tested it out in real world circumstances well, you would show a marginal benefit that's worth funding? That's the problem I'm faced with.

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But the process is, I think -- I have seen no evidence to support, even though I was very critical this morning, I see no evidence to support, from both this afternoon and morning session, that there is anything here that would indicate that we should overturn the panel's deliberations.

DR. SOX: Well, you could make a case, Bob, that the fact that this panel exists, that we have a transparent process for evaluating the literature is the key point of departure for improving the situation that you're decrying, and that we all recognize as a big problem, but that's kind of a side point.

DR. BROOK: Well, I'll just make one last point. It happens for most services that involve functioning, rehabilitation, these kinds of things, it happens over and over again, and there's no constituency to study them, and there's no funding from the government to study them. It would almost be really nice for this Committee to say to HCFA, we ought to cover it because the government is being irresponsible to fund the studies to do this, and as long as we have these things, there is no evidence to support funding it,

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but it ought to be funded anyway because the government is socially irresponsible.

DR. SOX: I want to try to keep the conversation on point, if I can. Again, I'm looking for somebody to speak up and say this is a seriously flawed process, it's so flawed that if we send it back to the committee, that there is a

fairly high probability they would come to a different conclusion, if those flaws were fixed. And I'm not hearing anybody so far who's willing to say that. And if they are not, then I think we ought to move on to the point of making a formal motion to decided whether or not the evidence is adequate based on the process, which we seem to be implicitly if not explicitly endorsing. Leslie?

DR. FRANCIS: I want to ask a couple of questions about that, but before I do that I want to say that I think we all understand that one question about the process is, was it limited in ways that later processes might not be, and that's part of what the working group is going to be doing, it's going to be opening things up more.

The questions that I have about whether it was flawed in its own terms, given the kind of process it was and that we set up for you to do, is

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first of all, in the report, the AHCPR report that didn't get to people, was there evidence of the kind you would have considered that people didn't have, and was there an adequate amount of time for a variety of commentators and so on to try to bring that evidence to the committee? Because it does seem to me that if there was evidence out there that you didn't get for some reason, that would mean the process was flawed on its own terms. And I just want reassurance on the answers to those questions.

DR. GARBER: Leslie, there are flaws and there are flaws, and I already said, I think it didn't work that well; if I had to do it over again, I would have made sure that the panel received a copy of the report. Did that flaw in the process affect the outcome? I don't believe it did so at all. I think that it would have been good background material; I don't think any primary matter data were missing by the lack of the availability of the AHCPR report. And it's been pointed out repeatedly, that was addressing a slightly different topic. So the AHCPR report might have had different significance if the question had been biofeedback plus exercise

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compared to placebo, or nothing. So no, I don't

think that affected the outcome, even though I believe that the process was flawed in a minor way.

DR. FRANCIS: Thank you, you answered the question.

DR. SOX: John.

DR. FERGUSON: Just a comment. I think that the panel could have come to the conclusion of inconclusiveness, that the data was inconclusive, or they could have come to a conclusion that the data was, did not point in the direction of positivity, or that it was suggestive but not good enough, but they weren't able to do that because of what I think is sort of a false barrier of voting on adequacy. Now maybe I'm all wet, but it seemed to me that the evidence was adequate upon which to base a conclusion, and the conclusion could have been it's not very good evidence. And they weren't allowed to do that, and that to me -- or at least it didn't seem to me that they -- and I'm not blaming you, I think it was a combination of the way the questions were structured, plus this blueprint which I think needs a little bit of tweaking. So I think that that is not quite proper, that they weren't allowed, or weren't -- it

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wasn't structured in such a way that they could evaluate the evidence and say the evidence is poor or the evidence is good.

DR. SOX: Alan, do you want to comment?

DR. GARBER: Like I said before, I think John has a point, and we'll have to struggle with how to deal with these kinds of situations. In terms of the bottom line, I don't think this had any effect, but we have to be sensitive to this issue about where the evidence is so-so, we might be very confident, if I could rephrase part of what John said, or paraphrase him perhaps, we might have been confident that there was no significantly large effect. That's -- and I'm not saying that's the case here, but that's the kind of conclusion me might reach, the evidence is murky, we're quite confident there's no large effect, and it could be detrimental. That's the kind of situation we might want to handle with a different procedure than we used here, and I think we should be aware of that. I don't think that rises to the level of a

fundamental flaw in the process, as it applied in this case.

DR. BROOK: But I do think, I mean, it does raise the question, I think we are all groping

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with this, why does the government choose to fund a $100 million study of carotid enterectomy and not a $500,000 study of urinary incontinence? And it does raise the question, and I think to discharge our responsibility in the area where Alan at least has described the studies as being flawed, difficult, not realistic, in general poor, that we ought to make some statement that this is something from the clinical testimony that they heard that by our action, we do not mean to suggest that this therapy ought to be relegated to leeches, that it looks like there's something here, and we think the government ought to pursue this vigorously to try to see if there is ways of producing the evidence quickly to either refute or substantiate that claim.

There's enough solid clinicians who really are reputable human beings, that argue that we missed the effect, and just to drop this with this statement would do a hell of a lot of damage to the field. That's what I'm really sad about in terms of where we are at, and I will predict that that's what, if there's any impact at all of what we will do, it will be that, and it may be the wrong impact.

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DR. SOX: Well, we're certainly learning that the playing field is not level and that certain technologies, because they're produced by relatively poorly capitalized operations have a recurrent system of not as good a chance of having an adequate test as those that are produced by well capitalized organizations. Hugh, did you want to say something?

DR. HILL: Some of my plastic surgical colleagues tell me that for a narrow defined population in certain situations, leeches are still quite useful.

DR. BROOK: That's true by the way, especially fingers.

DR. HILL: I just want to say, it looks

like you're heading towards a vote or some conclusion about the process itself, and pardon me for being legalistic, I think that's my role here though. You're not going to vote on the process? Okay, well that ends that.

But let me just say this briefly about the ratification. The panel is asked in the charter to review and ratify panel reports, and submit the report to HCFA. And so, I would hope that you would decide whether or not to ratify

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based on whether given the questions and the process and the vote of the subpanel as a closed system, was it internally acceptable? You could refuse to ratify as some form of protest about the questions we asked or whatever, ratify is well defined at this point, or you could ratify with comments that would indicate your feeling as a panel about us and about the result in your advice to us separately from that.

But I also wanted to point out that on the presentation of any new evidence, if this does happen to stimulate new evidence or if it's coming in anyway, requestors can request reconsideration the day after we issue a decision on the basis of new evidence, and we'll have to look at it again.

DR. SOX: Okay. Well, I'm really eager to move on, so if there is anybody else who wants to make the case that the process was flawed in a way that would lead to a different decision if it was to be reconsidered, now is the chance to speak up, because what I'm hearing is general consensus that it was an adequate process and that we need to move on to a decision about whether or not to endorse the committee's recommendations. Randel?

MS. RICHNER: I just want to make sure

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that it's on record that I think that the process was flawed, and I think that it's important to note that I think that the whole issue of what our mandate is as a committee needs to be clarified and needs to go on record. I think that the coverage criteria is critical. I think HCFA needs to give guidance as to what kinds of questions we need to answer, and it's much broader than just looking at the adequacy of the scientific evidence. And I

think that in a sense you did what you were supposed to do in a narrowly defined way for that particular panel meeting on April 12th and 13th, but it didn't do service to, or justify or help the overall mandate on our mission of what we were supposed to do.

I am still absolutely surprised that all of these different associations all agree to support this. In my clinical experience and my industry experience, you rarely see that, and there has to be some kind of weight put on that kind of endorsement.

DR. SOX: Well, let's move on then. Alan, actually I'd like your advice and Mike's advice about whether we should have a motion for biofeedback as an adjunct to pelvic muscle

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exercises, and a separate one on electrical floor stimulation, or whether to do them both together. Do you have an opinion?

DR. GARBER: I have a procedural suggestion, which is to take it as a whole and if the panelists in the discussion indicate that they feel there's some reason to distinguish them at that point, to separate them. But I think it's unlikely that the Executive Committee would vote to ratify one and not the other.

DR. SOX: In that case I would like to call for a motion.

DR. BERGTHOLD: Can I ask a question of process? I notice that we have open public comments before we take --

DR. SOX: Yeah. The plan will be to have a motion, to have discussion, then we'll have public comment and then come back to brief discussion and vote. But I want to get something on the table so we can have a conversation. Ron?

DR. DAVIS: I would like to make a two-part motion, if I could. One would be just to get the issue out on the table and to facilitate action, that the Executive Committee ratify the recommendations of the panel.

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DR. SOX: Okay, there is a motion. Is there a second?

DR. HOLOHAN: Second.

DR. DAVIS: Can I mention the other part of the motion, or a second motion?

DR. SOX: Please do.

DR. DAVIS: Picking up on Bob Brook's suggestion that the Executive Committee encourage HCFA to open a dialogue with appropriate funding agencies to discuss the need for good research on the treatment of incontinence, that would help inform future decisions and actions on Medicare coverage.

DR. SOX: I think we should treat those as two separate motions. Is there a second to the second motion?

DR. BROOK: Second.

DR. SOX: Let's not talk about the second motion, let's just talk about the first motion for a while, because my sense is the second one, probably everybody's going to think that's a good idea, so let's focus on the first motion, which is to ratify the panel's recommendation.

One question I guess we ought to address right away is whether we should pull any particular

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element of their actions out of this blanket motion, because the evidence for it looks like it might be treated differently than the rest of the evidence. Anybody want to pull a piece of this out for separate consideration? Good. Okay.

Let's talk about the motion, which is basically to endorse the committee's conclusion that the evidence is inadequate to draw a conclusion about the effectiveness of these procedures. Yes, Bob?

DR. MURRAY: Will we have an opportunity to explain our vote after the vote is taken, so we can put comments new the record? If so, I'll withhold my comments until then.

DR. SOX: Not only opportunity, but I think requirement.

DR. MURRAY: I'll save my comments then.

DR. SOX: Well, hearing no discussion, I think it's now probably time for us to go into public session and hear from folks who are here who would like to make comments before we actually take a vote. So anybody who would like to make a comment on the discussions so far, please step to

the microphones.

MS. CHRISTIAN: Hi. My name is Martha Christian. I am a health policy and clinical outcomes panelist for EMPI. I just have a couple of concerns in evaluating the process. One of the things I spent a lot of time with doing is looking at the MCAC charter and the federal guidelines for the whole MCAC process. One of things that those documents are very clear on is that the role of this Committee is to make advice on coverage. In fact, the vote that it actually specifies in those guidance documents, that the panels are supposed to make vote on national coverage. From that perspective, the Committee failed in its duties as defined by HCFA to vote on coverage, so you didn't vote on the right question, and part of that is because HCFA didn't give you guys the right question to answer. So I would have to object to that, and feel the process is fatally flawed because of that.

Secondly, I'm also very concerned following this morning's decision to have a subcommittee. I think that's a wonderful idea; this is a great process, it has great opportunity to make sure that the process is inclusive and open and we can get some good advice and input into the coverage decision making process. However, to subject PFS and biofeedback, and to make a decision based out of this process that has been determined that, one, we didn't do it quite right, that there were some problems, it's a work in process, we're sort of inventing the process as we go along, it's really unfair to our technologies to make decisions based on a process that isn't as good as it could be, and future technologies are going to have the benefit of a better process, and that would concern me greatly both as a representative of a technology but also as someone who has parents who are Medicare beneficiaries.

As a person who's a geriatric former long-term care administrator, I see the effect of these policies every day in my career and I'm very concerned that Medicare beneficiaries are going to be harmed greatly by the fact that this technology

isn't going to get a fair hearing that's consistent with what's going to happen down the road. Keep up the good work, keep working on your process, but don't penalize these technologies because we aren't quite where we should be. And, I guess I would encourage you not to ratify this, or at least say that the process was screwed up. Thank you.

DR. SOX: Thank you. Middle mike, please.

MS. CHAPPELL: My name is Jodi Chappell, I'm manager of regulatory affairs for AUGS, and we would agree with the process that you are, it is in evolution and we support that, and we want to continue our work, to work with HCFA and work with the MCAC committees and panels to insure that a clinician's point of view is represented.

I wanted to also commend Randel for paying close attention to the transcripts, especially the end of the first day and the beginning of the second day, there was a lot of verbal communication back and forth among the panelists, and this might -- I have not reviewed the minutes of the meeting, I have not seen that, and I understand they were posted, but I have not found those yet. But the review of the minutes by some panelists were concerned that those comments and dialogue were not reflected, so I would just urge you to read that dialogue.

In addition, the questioning, the concerns that Dr. Whyte was talking about, the question that was posed, I would like to reiterate a comment by panelist Dr. Lisa Landy regarding her feedback on the questioning. The original question posed to the panel in advance of the proceedings was, is the scientific evidence adequate to draw conclusions about the effectiveness of biofeedback? This is what I base my primary review on, and she served as a primary reviewer. As the presentations proceeded the morning of the first day, I realized the question had been changed to be of a more narrow scope. The question was altered to, is the scientific evidence adequate to draw conclusions about the effectiveness of biofeedback as an adjunct to pelvic muscle exercises?

This may seem like an insignificant alteration, but actually changed the entire course of the panel proceedings. This precluded discussion of the efficacy of biofeedback assisted pelvic muscle exercise as an intervention. The focus was redirected to analysis of adequacy of scientific evidence, comparing two types of intervention, as opposed to clinical efficacy. The scientific literature clearly supports the efficacy of biofeedback.

Due to the panel being unaware of this change until the day of, or if they were, they weren't totally. I understand Dr. Garber understood it and maybe -- and I appreciated your

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comments about being told about it -- but I would hope that all the panelists would clearly understand the question. Due to these flaws, and I support the definition that we need to come up with some standardized terminology and we support those efforts, and anything we can do to support HCFA and the MCAC on that standardizing the terminology, clinical evidence, adequacy, even biofeedback itself, we would be supportive of. Thank you for your time.

DR. SOX: Thank you very much. Left mike?

MR. J. CONNOLLY: Jerome Connolly, American Physical Therapy Association. There has been some concern suggested that, or some concern indicated why there aren't more studies, and I think this goes right to the heart of the issue again, of the narrowness of the question. And there's so little at stake here relative to the Medicare dollar that I'm wondering why this is an issue that is requiring this much time and this much effort, because I am not sure that a whole lot of dollars are going out of the Medicare coffers to pay for biofeedback enhanced pelvic muscle exercise to warrant this kind of attention.

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Yet there are a few studies relative to this specific narrow question of comparative analysis, a head-to-head study, that was asked. And I think it goes right back to the question that Jodi just reiterated that Dr. Landy had mentioned

in her letter. And the changes that were made to the question, they seemed insignificant, but it was a significant alteration. And Dr. Ferguson picked up on that, in that it changed the entire course of the proceeding in terms of the discussion. And I think that that really needs to be weighed heavily, because if you're talking about going forward on a process that isn't necessarily fundamentally fair or inclusive, or thorough, and in fact the primary reviewer indicates that the discussion was changed considerably by the nature of the question, then I think you really need to consider where you are in this process.

So it would seem to me that given this from a primary reviewer, that you may want to consider a remand, because if in fact the primary reviewer were here today, I wonder if she would be wondering if she was in the same meeting that we're talking about on April 12th and 13th. Because it seems to me if the primary reviewer is confused or

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indicates the discussion was altered, that perhaps there could be, there could be a substantial chance, maybe even a likelihood upon remand, that further discussion and different kind of discussion, and the panelists would utilize the clinical experience, the expertise, and the opinion of clinical experts that they were not and did not feel allowed to use during that proceeding on April 12th and 13th.

DR. SOX: Thank you. If there is no more comment from the floor, we are now discussing a motion. Are there any comments before we go to a vote? Alan?

DR. GARBER: Well, I think that if there had been a major substantive change in the question at the last minute, that would indeed call into question the validity of the process. And I believe that that quote from Dr. Landy is correct, but I have to point out that the changes in wording were as far as I could tell solely of a clarifying nature. The evidence report, which Dr. Landy had well before the meeting, and which she was charged with reviewing, was very clearly structured toward the question of the additional effect of biofeedback to pelvic muscle exercise. I found her

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comment very thoughtful and helpful, but it was difficult to believe that one could have thought the comparison was primarily against no treatment at all, that it had ever been conceived as that, recognizing of course that the language was not perfectly clear at the outset, and there was room for ambiguity.

And let me just reiterate, this is why I think that formulating the questions should be done early and with broad consultation with a lot of people. But I don't think that was the reason that she voted one way and the rest of the panel voted another way on the majority of the questions. And by the way, none of what she said applied to the pelvic floor stimulation component of the assessment.

DR. SOX: Other comments before we vote? Hearing none, I'll turn to Connie to make sure we do this right.

MS. CONRAD: Okay. There is a motion that the Executive Committee ratify the Medical Surgical Procedures Panel recommendation from April 12th and 13th. Do we have a vote? In favor? Hands?

(Dr. Brook left the meeting before the
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vote was taken.)

(All remaining panelists voted affirmative, except Dr. Ferguson and Dr. Johnson.)

MS. CONRAD: Against?

(Dr. Ferguson and Dr. Johnson voted in the negative.)

DR. SOX: Let's move on now to --

DR. FERGUSON: Can I be sure -- oh, that's right.

DR. SOX: If you have an explanation of dissenting votes, it's an opportunity; I don't know if it's a requirement, but it's certainly an opportunity.

DR. FERGUSON: I am not noted for my curmudgeonness, but I'll reiterate my main concern, was that the questions were worded in such a way, to some extent based on the way our interim report was, that in it in effect blocked the panels from evaluating evidence and forming their own

conclusions, because they were forced to vote yes or no on adequacy.

I think in the biofeedback portion, the questions were narrower than they could have been and perhaps should have been, but my understanding from what I have been able to talk with the people,

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the word PME alone is kind of an oxymoron in the sense that biofeedback is often used to inform and allow people to use PME.

And what applies to both the areas from what I can see, conclusions were drawn on the TEC reports for both of these, stimulation and biofeedback, and how did they do that if the evidence wasn't adequate. And I think that in the biofeedback portion, not apprising the panel of the AHCPR report was a mistake. But basically it was the formulation which did not allow the panel to address what I would consider necessary to debate the evidence.

DR. SOX: Thank you. Joe, do you wish the say something about your vote?

DR. JOHNSON: Yes. The vote against ratifying, on page 4 of the minutes, it says under panel comments on their votes, and I quote: Panelists expressed views that if the question had been posed to suggest a decision based on the belief from clinical experience rather than scientific evidence, the results of the voting may have been different. Several panelists offered the feeling that if this were a coverage decision, their votes would have been different as well,

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because biofeedback does prevent or deliver effective treatment and is efficacious. And I think that vote would be consistent with Dr. Landy's, Dr. Bradley's, as well as the numerous professional organizations and public testimony that brought forth comments.

DR. SOX: Thank you. Well, let's move on to the second motion. Ron, perhaps you could restate it just to remind us.

DR. DAVIS: I tried to clean it up a little bit, it's still a bit long, but here it is: That the Executive Committee encourage HCFA to open a dialogue with appropriate funding agencies to

discuss the need for good research on treatments for incontinence to better inform future decisions by HCFA on Medicare coverage of those treatments.

DR. SOX: That motion has a second, so we can discuss it. Alan?

DR. GARBER: I just want to suggest a friendly amendment. In the beginning where he said about the research, support for research, can you insert support for?

DR. DAVIS: That's fine.

DR. SOX: Any other comments?

DR. FRANCIS: I want to make a comment

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that is in part an explanation of a positive vote on the prior motion, which is that I certainly understood the vote for ratification as being a vote about the panel's judgment about the adequacy of the evidence, and not at all about a coverage recommendation to HCFA. And so it seems to me in that spirit, that the second motion is particularly important.

DR. SOX: Thank you. Well, if there are no further comments, why don't you restate the motion as amended?

DR. DAVIS: That the Executive Committee encourage HCFA to open a dialogue with appropriate funding agencies to discuss the need for support for good research on treatments for incontinence, to better inform future decisions by HCFA on Medicare coverage of those treatments.

DR. SOX: I think we're ready for a vote. Connie, will you do that?

MS. CONRAD: Sure. Could I see a show of hands for those for the motion?

(All members present voted affirmatively.)

MS. CONRAD: Unanimous? Thank you. The motion carries.

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DR. SOX: Well, it's then time to move on. The last item on the agenda is HCFA announcements and information.

DR. MURRAY: Dr. Sox, I thought that we were going to have an opportunity to make comments on the vote that was made before.

DR. SOX: I'm sorry.

DR. MURRAY: I will keep this very very brief. I think that as the conversation, as the discussion has gone forward, I see an analogy to the area of practice with which I'm much more familiar, and that's laboratory testing, and we have struggled through negotiated rule making to develop NCDs for many laboratory tests. And basically what we're talking about here is a service that's analogous to a test, or has some parallel. And that is that there are diagnoses which justify, which provide medical justification for the use of that test, and there are diagnoses which do not provide medical justification. And I think all that we said today is that the diagnosis of urinary incontinence is not in and of itself justification for the use of this service; we're not saying that the service does not have a place, we're not saying that the service is of no value;

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all we're saying is that urinary incontinence in and of itself is not adequate medical justification.

If there is and ICD-9 code or if there is a diagnosis of urinary incontinence following failure of PME, that is a totally different question, and one which would probably elicit a different answer, and I would expect that the proponents of this therapy would bring this to HCFA and say, well, if urinary incontinence in and of itself, you know, initial urinary incontinence is not adequate medical justification, then failure of PME, failure of other therapies, and they would ask for acceptance of that diagnosis as medical justification, and my expectation is that they would get a favorable hearing at HCFA.

DR. SOX: Hugh?

DR. HILL: Just real briefly. I had planned at this point to give you some of the feedback that Ron had pointed out, that we have been remiss in not giving you along the way, and simply point out that the multiple myeloma decision had been issued based on the TEC assessment that we got rather than sending it back to the panel as you had instructed.

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And the other panel finding in December

that you asked to go back to panel, refusing to ratify it, was the human tumor assay for cancer chemotherapeutic sensitivity. All of the requestors joined in asking us to please withdraw that request from the decision making process. At least one of the requestors has indicated his intention to resubmit separately a request for a decision on that, so it may come up again.

The only panel that we currently have planned subjects for, and the date is not yet firm for and the subjects are not yet firm, is another meeting of the same panel whose report you were reviewing today, on sacral nerve stimulation for urinary incontinence, I know you're looking forward to reviewing that again, and electrical stimulation for wound healing.

And since this is my last meeting with you, I want to take advantage of the opportunity to very briefly thank you very much for your service on this. I've enjoyed wrestling with some of you and strolling with others, and I very much appreciate your public service in this regard. Thank you.

DR. SOX: Well, Hugh, you have a very

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distinguished place in the history of what many people think is a very important effort on the part of HCFA, and as you go on to your other assignments in HCFA, you know, you'll leave back a lot of fond memories about your leadership and understanding.

DR. HILL: Thank you.

(Applause.)

MS. CONRAD: Thank you. Could I have a motion that the meeting be adjourned? No. Linda?

DR. BERGTHOLD: I would just like to ask HCFA to consider convening the Executive Committee at some point in the fall to have an open public discussion about many of the issues that we've talked about today, absent a panel decision. I think we all feel that we don't have enough time to substantively talk about issues, about sort of issues about what is clinical evidence, about a lot of this work. And perhaps it will follow on some of this subcommittee work, but you know, we feel a need for more training, and I don't think I need to make a motion about it. I think several of us

agreed at lunch that --
DR. HILL: Without a motion, we are already working on that, and we can't promise you in the fall, but we're working on it.

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DR. BERGTHOLD: For the public's sake, I would just like to say that while this is a messy process, it's an open messy process, and to remember that it used to be a closed messy process.
MS. CONRAD: Do I have a motion to adjourn?
DR. GARBER: So move.
MS. CONRAD: Do I have a second?
ALL PANELISTS: Second.
DR. SOX: We are adjourned.
(The Executive Committee meeting adjourned at 3:08 p.m.)